Comments on the ACD Received from the Public Through the NICE Website

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I have concerns regarding the above, in particular the recommendation that infliximab and adalimumab will not be recommended for maintenance treatment and instead we will be expected to use them episodically. I am sure many patients will suffer as a result, rather than remaining well and symptom free over a longer period. This policy may well result in increased hospital attendances/admissions, which must be counter-productive for all concerned.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	08/10/2008 08:19

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is shown to be effective and supported by the patient?s consultants.
Section 2 (clinical need and practice)	I believe Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4	You need to consider the full opportunity cost .If adalumimab is

(Evidence and interpretation)	effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date
Date	07/10/2008 23:19

Name	[redacted]
Role	Patient
Other role	NHS DOCTOR
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (clinical need and practice)	By definition in 1.2, I had severe active Crohns until put on Infliximab in April 2008. I was diagnosed 17 years ago at 10 years old, and have tried dietary, corticosteroids, azathioprine, mesalazine, and have also needed some minor operations. Since diagnosis, despite different treatment combinations, I remained symptomatic, on a daily basis. I have never been as well as I am currently, on maintenance Infliximab. I am totally symptom-free, enabling me to continue with and really enjoy my job, family, friends and social life.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The health of patients eligible for Infliximab by definition, is poor. Unwell, uncontrolled patients to this degree may need: -Regular attendance to GPs -Regular attendance to hospital clinics (nurses, admin staff, doctors) -Regular input by specialist nurses -Regular admission to hospital -Dietician input -Regular prescriptions of other medications (multiple) -Regular blood tests if unwell -Medical certificates to excuse from employment while unwell -Sickness benefits claimed by patients -Management of other conditions related to their Crohns disease eg. conditions requiring surgical management, mental health issues such as depression For every patient, these costs may be present, and accumulate.

Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	6.5 - Quality of life with active Crohns Disease can be extremely poor. The severity and range of symptoms affect literally every part of the daily routine, from waking in the night to use the toilet, to poor appetite and nausea, therefore less oral intake, therefore increased tiredness. Increased, loose bowel opening leads to less absorption of what little nutrients are eaten, and so the cycle continues. Tasks which are usually easy such as walking up stairs become difficult, and trying to hold down a job (of any sort) or to continue family life becomes almost impossible. I am not talking about enjoying - simply trying to continue on with multiple pains and symptoms on an almost incessant basis. When a treatment finally relieves those symptoms, with the hope that it will not be just a few weeks or months of relief, but possibly years, it is indescribable. Life returns to normal - or better than you ever remember it being. By changing this treatment to episodic, it will likely lead to an increased number of flares in a set period of time, causing the pain and upset more often in any one patients life.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 21:39

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7	

(related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 20:37

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	1.1 Infliximab and adalimumab are effective in mod to severe CD. 1.4 infliximab is not of value for episodic treatment as the perianal external fistula may have healed but not the internal opening. This inevitable leads to disease recurrence. Instead infliximab or adalimimab should be continued until there is evidence of fistula healing on MRI 1.6 The duration of therapy should be determined by the healthcare porfessional as stated in 1.3. If the healthcare professional can determine choice then she/he should be able to determine duration depending on the clinical presentation and in discussion with patients.
Section 2 (clinical need and practice)	
Section 3 (The technology)	Many units are now infusing over one hour without adverse effects.
Section 4 (Evidence and interpretation)	The clinical effectiveness is clear and undebatable. The cost effectiveness analysis considers it is more cost effective to treat a relapse than to prevent with scheduled therapy. This analysis does does not factor in the implications of antibody formation. The risks to patients are twofold 1) a higher risk of loss response with episodic therapy 2) higher risk of allergic reactions. These have serious clinical implications not included in the cost effectiveness analysis. Moreover there is a lack of evidence from clinical trials with regards episodic adalimumab. The other point is the cost effectiveness of treating children because of their lower weight. Will childrens continued therapy be decided on body weight or age? At what body weight would NICE consider recommending stopping scheduled therapy in children.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	

Date	07/10/2008 19:20

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Dear Sir/Madame I am astonished that the committee considers that maitenance infliximab should not be reccomended! I understand this is based on a cost benefit analysis. Such analyses are notoriously difficult to construct accurately. What we are talking about here is preventing an operation at which time patients may have a sizeable piece of their gut cut out with a possible stoma etc etc Ie. it is not simply related to cost it is to do with Quality of life has this been analysed too?! We have several patient in our unit already established on maintenance therapy-what is to happen to them? Is their treatment to be withdrawn? We also have paediatric patients on maintenance (i gather agreed by NICE) who are comming into the adult service-what about them? Compare this with rheumatoid arthritis where maintenance tharapy with biologicals has been long agreed- i really cant see the difference between Rheumatoid arthritis and Crohns in this context. I strongly urge the committee to reconsider their decision on the matter of maintenance therapy of infliximab for Crohns. Yours faithfully, Dr Richard Pollok Consultant Gastroeneterologist, St Georges Hospital SW1
Section 2 (clinical need and practice)	See above there is a significant clinical need for maintenance IFX. we have around 10 patients (catchment 0.5-1 million popullation)who have been on maintenance greater than a year. Our initiation of treatment is based on the strict NICE guidelines. Practise in Europe and USA is moving toward top down therapy ie starting biologicals early on as we do in RA. In the UK we are moving strongly against the trend in the rest of the developed world.
Section 3 (The technology)	IFX and its associated side effects and complications are well established. Adalulimab is likely to be more cost effective since it can be adminstered by the patient without the need for day case admission.
Section 4 (Evidence and interpretation)	It seems the committee would rather believe their own analysis than one published in a peer reviewed journal.

Section 5 (implementation)	no comment
Section 6 (proposed recommendations for further research)	re 6.4 a trial has been published in the Lancet this year comparing top up versus top down therapy in Crohns has this been considered? 6.5 Quality of Life data was collected as part of the ACCENT trial and other trials-i suggest that you approach these trialists. i would also suggest you engage with National Association of Crohns and Colitis (NACC) on issues relating to quality of life.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	suggest an earlier review-this field is moving rapidly
Date	07/10/2008 19:14

Name	[redacted]
Role	other
Other role	Friend & taxpayer
Location	England
Conflict	no
Notes	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patient?s consultants
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Having commenced useage of the drug it is totally immoral to cease supplying
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	No account of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services. No account of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	An absolute disgrace to any reasonable and responsible person
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	07/10/2008 19:13

Name	[redacted]

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision. I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patient?s consultants. I believe these drugs should be given on either an episodic or maintenance basis, as recommended by the patient?s consultant
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	No account of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 17:29

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on either an episodic or maintenance basis, as recommended by the patients consultant.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed	

recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 17:06

Name	[redacted]
Role	NHS Professional
Other role	paed gastro clinical expert for this appraisal
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Some paediatric patients may not have ?severe? disease according to CDAI (ie will not fulfil criterion 1.2) but will need this therapy eg those with disfiguring refractory orofacial Crohn?s disease, complex perianal disease, or those who have disease-related growth and pubertal delay. Provision must be made to include such patients.
Section 2 (clinical need and practice)	
Section 3 (The technology)	Paediatric gastroenterologists in the UK are pleased there is marketing authorisation for maintenance treatment for children and adolescents (section 3.5)
Section 4 (Evidence and interpretation)	4.1.11 - maintenance treatment showed better results in paediatric patients given 8 rather than 12wkly infusions. 4.3.13 - Infliximab is cost effective treatment for paediatric patients. Liquid diet therapy (LTD) is standard care in paediatric Crohn?s to avoid steroid therapy. It is used to establish remission and for any subsequent relapses. Cost of LTD is similar to biologic tharapies (6 week course of LDT with polymeric feed costs Â£400 with elemental feed it costs Â£700). On this basis, a cost analysis including LTD in the standard care arm would be even more favourable towards Infliximab. Paediatric gastroenterologists worry about lack of specific guidance for episodic versus maintenance therapy for paediatric patients implying it is at the discretion of the clinicians. We welcome the latter but feel concerned that primary care trusts (PCTs) may use this lack of clarity as a reason not to approve funding for maintenance therapy. We ask that the recommendation for maintenance in paediatric patients is more clearly stated.
Section 5 (implementation)	In view of potential toxicity of biologics all paediatric patients receiving this therapy should be registered on a national register. Written material outlining benefits and risks of biological therapy with written informed consent should be obtained. This will provide the best protection for children and teenagers, their families, prescribing paediatric gastroenterologists and for the manufacturing companies.
Section 6 (proposed recommendations for	

further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 16:58

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients where their consultant supports this decision.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti-TNF it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-TNF drugs are used on a maintenance basis in other countries, I would ask for an earlier review date.
Date	07/10/2008 16:31

Name	[redacted]
Role	Private Sector Professional
Other role	
Location	US
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Based on my experience with patients (whom I refer for Crohns treatment) their favorable response warrants continuation of therapy. It would be clinically unwise and unethical to withdraw this therapy when a good clinical response is observed. These drugs should be given either acutely or for maintenance as deemed appropriate by the clinician.
Section 2 (clinical need and practice)	Where patients have been symptomatic for an extended period, but respond to TNF, it would be unwise clinically and unethical

	to withdraw this treatment. While there is legitimate concern for long-term effects, the long-term morbidity of Crohns is a compelling reason for using all available treatment modalities. This can reduce the need for surgical intervention as well.
Section 3 (The technology)	This treatment incurs no hospital costs furthermore, the benefits include improved quality of life with the economic benefits to society of gainful employment, ability to pay taxes, and less dependence on social support services.
Section 4 (Evidence and interpretation)	The potential benefits include reduction of long-term sequelae, including fistulae, which are debilitating and often require surgical intervention.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Based on the successful experience using anti-Tnf drugs in other countries, and the recommendations of consultants to use these drugs on a maintenance basis, I would respectfully request an earlier review date.
Date	07/10/2008 16:29

Name	[redacted]
Role	other
Other role	Friend of patient
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I think the drugs should be given on a maintenance basis when the drug has been effective on a patient and improved their quality of life and its use is supported by the patients consultants.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 16:09

Name	[redacted]
Role	other
Other role	Parent of patient
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unreasonable to withdraw the treatment
Section 3 (The technology)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	07/10/2008 16:01

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients who are already taking it and where consultants support the decision.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	There is no account of giving Adalimumab to patients because it will enable him/her to support themselves and not need additional support from health and social services.
Section 5 (implementation)	
Section 6	

(proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti Tnf drugs are used on a maintenance basis in other countries, I would request an earlier review date.
Date	07/10/2008 15:49

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe that these drugs should be given on a maintenance basis to patients, where their consultants support this decision. I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants. I believe these drugs should be given on either an episodic or maintenance basis, as recommended by the patients consultant.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment. No account is taken of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-TNF drugs are used on a maintenance basis in other countries, and as consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	07/10/2008 15:17

Name	[redacted]
Role	other
Other role	Friend of patient affected
Location	England
Conflict	no

Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	It is surely unethical to discontinue these drugs to someone who has been receiving them on a maintenance basis, where the drug is effective and supported by the patient?s consultants.
Section 2 (clinical need and practice)	Where someone responds to anti TNF, and where nothing else has worked, it seems unethical and frankly cruel to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If the drug is effective, patients are able to work, live relatively normal lives and pay taxes, incurring virtually no other costs for the health service and they will not need to attend hospital for further treatment - freeing up NHS time and government money.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I think an earlier review date would be more appropriate.
Date	07/10/2008 15:15

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti-TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	In cases where adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	

Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	07/10/2008 15:02

Name	[redacted]
Role	NHS Professional
Other role	head of GI medicine Northumbria healthcare trust
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am concerned that we have to wait for relapse before retreating patients with severe Crohns with biologicals. This guidance goes against expert advice in USA and Europe and is counterintuitive if the disease process is understood Episodic treatment puts patients at risk of antibody formation and reduced response. Adalimumab works as a slow start but sustained remission on maintenance thus a few treatments will not have the effect required The patients I treat have failed 2 disease modifying agents and biologicals offer them the chance of good health, allows them to hold down a job and pay taxes and reduces their demands on the health services. If I have to wait for them to relapse then they are likely to loose jobs and be a burden on the tax payer. There is good evidence that mucosal healing lessens relapse rates and hospitalisation and surgery This appears to be a decision made on financial grounds and is against expert advice I would urge NICE to reconsider
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	I would urge the committee to reconsider the use of maintenance biological therapy for patients with Crohns. The improvemnt in well being and quality of life cannot be underestimated and the committees provisional decision to not allow maintenance therapy goes against world experts in the field. The cost effectiveness study has over-reliance on data taken from Silversteins paper, published in 1999, which was based on analysis of a well controlled relatively mild group of patients in Olmstead County, Minnesota and not the severe group that we treat. Thus the cost benefit is greater for our severe patients and needs to be recalculated. The last patient I treated spent 60 days in hospital despite treatment with Methotrexate and steroids and had lost his job Since transfer to Infliximab he is in remission has remained out of hospital, gained employment and married. When we tried discontinuing it he relapsed- thus he needs maintenance therapy. The price of 60 days in hospital, medical treatment, invalidity benefit is more than his Infliximab cost. He is not an isolated case
Section 5 (implementation)	

Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	If the committee does not allow maintenance therapy I would expect them to reconsider their decision within 2 years as it will become apparent very soon that they are not correct and the data will be overwhelming
Date	07/10/2008 14:54

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Dear NICE, In Crohns disease, I have always tried to practice preventative medicine rather than wait for a disease flare and then treating the patient. I feel this offers the patients the best quality of life and there is evidence that this approach prevents long term complications such as hospitalisations and surgery. Furthermore, the majority of Crohns patients are young adults and the economic costs of a chronically sick and unemployable young person is immeasurable and has not been factored into the cost per QALY, not even accounting for the psychological effects of a chronic poorly controlled disease. Furthermore it will place further pressures on clinicians to review sick relapsing patients with regard to the need for further episodic treatments with anti-TNFs. This has not been taken into account either. Therefore for those reasons I think the argument for giving anti-TNFs as episodic treatment only is flawed as it should be given regularly, as directed by the clinician.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 14:36

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	These drugs should not be removed from patients who are receiving it for maintenance when their consultant supports the decision to continue treatment. Whether for individual episodes or maintenance, full support and supply should be given when recommended by the patients consultant. It is unethical to remove such treatment from patients who have previously been given the drug to control the effects on a longer term basis
Section 2 (clinical need and practice)	Even if patients have had no remission for a long period but respond to anti TNF, treatment should be maintained for as long as recommended by the consultant. It is unethical to withdraw treatment which has such a profound effect on the patient
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Maintenance is a preventative measure and, as such, little or no cost is incurred in addition the basic drug cost since further treatment or hospitalisation is minimised. No account is taken of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	07/10/2008 14:32

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants
Section 2	Where patients have had no remission for a long period, but

(clinical need and practice)	respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	No account of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier re view date.
Date	07/10/2008 14:31

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	As a consultant gastroenterologist looking after adolescent patients the removal of the option for maintenance therapy makes management difficult - many of these patients are growing and controlling their inflammatory load is vital for ongoing growth (a high proportion of patients with CD have permanent growth retardation). This will be difficult if we require them to relapse before treating again as there is a limited time window in puberty for optimal growth. In addition many of those with colonic disease may end up requiring stomas - these are physically and psychologically very unsatisfactory for adolescents and young people to cope with.
Section 2 (clinical need and practice)	
Section 3 (The technology)	Immunomodulator and dietary therapy are the mainstays of managing young people with Crohns but steroids should not be given their side effect profile - including limiting growth in young patients therefore corticosteroids will always be relatively contra-indicated in these patients excepting perhaps the 1 st treatment.
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed	I have no issues with further research/close monitoring of treated patients to optimise drug use.

recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 14:25

Name	[redacted]
Role	Public
Other role	Taxpayer
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on either an episodic or maintenance basis, as recommended by the patients consultant.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to antiTNF, I believe it would be unethical to withdraw the treatment
Section 3 (The technology)	I am not qualified to comment
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment. The evaluation also needs to take account of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	No comment
Section 6 (proposed recommendations for further research)	These recommendations do make sense.
Section 7 (related NICE guidance)	No comment
Section 8 (proposed date of review of guidance)	Anti-Tnf drugs are used on a maintenance basis in other countries. I would ask for an earlier review date as consultants already support the use of anti-TNF drugs on a maintenance basis.
Date	07/10/2008 14:19

Name	[redacted]
Role	Local government professional
Other role	
Location	England
Conflict	no
Notes	I was informed that the patient Charlie Croft is in danger of having his treatment for Crohn?s disease withdrawn. Charlie is currently at university and doing very well under his current

	drug regime. If this was to be withdrawn, it is likely that the boy would be unable to continue university and would very likely require hospitalization at which point he would probably be put back on the drugs. All of this would require more of the NHSs funds than if he continued on the treatment in the first place. The NHS was set up to provide medical treatment to everyone, free of charge. I see no reason why politics and/or funding has to interfere with this. If the patient has a chronic disease which needs to be controlled than he should receive the medicine. Thank you, [redacted]
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 13:53

Name	[redacted]
Role	other
Other role	Family member of 17 year old boy with Crohns
Location	England
Conflict	no
Notes	My nephew has been having Infliximab treatments for one year, most recently moved that treatment to Addenbrookes hosp. The treatment has been successful and allowed him a real quality of life without pain. This teratment has been instrumental in allowing this youngster to attend A level college. Notice from the hospital last week told his mother the payment for this treatment woudl most porbably end shortly. Perry has severe Crohns, has tried numerous drugs and this has been a life saver for the young boy. We have been told the treatment would only be available if he fell out of remission yet if treatment would stop he will fall out of remission. At 17 he says he would rather die than have a colostomy which Im sure you can

	understand. Please help us give him the quality of life he deserves and the ability to complete his education before having to face falling out of remission once again. Its hard to imagine something ending that is actually working for someone. Thank you.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (clinical need and practice)	Please note the young man in question was 11 when diagnosed with chrohns.
Section 3 (The technology)	cONDRADICTION here as it now states it can be given as maintenance treatment. Can this be assessed according to the individual then rather than a blanket scenario? and hence funding be individually assessed?
Section 4 (Evidence and interpretation)	In considering adolescents please consider what they are trying to achieve at this point in their lives such as GCSEs , A levels and university. Without the Infleximab we believe Perry would not be able to complete his ongoing education.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	If this is ongoing please contact Debra Noble 01763 852345 to discuss her sont participation re any of the above. Perry is now 17.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 13:50

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I suffer from Crohns disease and rely on infliximab to keep me healthy. I receive an infusion once every 8 weeks (I have been doing so for 5 years) and so would be very worried that if these new recommendations were enacted, I would be refused treatment. I am aged 27 and have had Crohns disease for 12 years. Infliximab is now the only drug which works in controlling my Crohns disease, so without it there would be no alternative. At the end of every 8 week period I become very ill and so am desperate for the next infusion of infliximab. Without infliximab I would not be able to work, would probably be confined to my home and my quality of living would decrease significantly. I urge you to reconsider these recommendations against providing infliximab and adulimumab for maintenance treatment.
Section 2	

(clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	I fully agree with these recommendations as further research will give further knowledge as to the effects of these drugs.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 13:48

Name	[redacted]
Role	other
Other role	Patients relative
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patient?s consultants
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 13:19

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	

Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	[redacted]
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Is full and proper account of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 13:10

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontnue giving these drugs on a maintenance basis, where the drug has proved to be effective and is supported by the patients consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective the patient incurs virtually no other costs as they do not need to attend hospital for further treatment
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use on anti-TNF drugs on a maintenance basis, I would request an ealier review date.
Date	07/10/2008 13:01

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe maintenance infliximab is absolutely essential for Crohns patients and failure to provide it will jeopardise their future health
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 12:37

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	

Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier re view date.
Date	07/10/2008 12:36

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	These drugs need to be available on a maintenance basis in certain circumstances too - the patients consultant should be able to determine this. If someone is already on them for maintenance and have found its the only thing that works, it would be wrong to take them off it.
Section 2 (clinical need and practice)	Agree - its a horrible disease.
Section 3 (The technology)	Seems a fair summary
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	Seems reasonable to me
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Unless the decision on drug provision in maintenance cases is changed, I would ask for an earlier review date specifically so that point can be reconsidered earlier.
Date	07/10/2008 12:09

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I have had chrohns disease for several years any treatment that gives a patient some better quality of life should always be available.
Section 2 (clinical need and practice)	I have now had surgery I am now in my early sixties. If taking medication will pronglong the operation I feel that can only be a better quality of life for somebody in the teenage years.
Section 3	

(The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 11:50

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Evidence available in the literature does not support the use of Infliximab as episodic treatment. If the patients respond to the initial induction course, treatment should be given at regular intervals to maximise efficay as well as to minimise possible infusion reactions
Section 2 (clinical need and practice)	Exclusive enteral nutrition for 6 to 8 weeks is now widely used to induce remission in children and adolescents and it is a much preferrable option compared to steroids
Section 3 (The technology)	Point 3.5 outlines the current use of Infliximab in paediatrics, underscoring the need for regular treatment following the induction course
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 11:45

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no

Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Surely 1.6 should include the phrase despite clinical trial evidence that this is effective in some patients.
Section 2 (clinical need and practice)	None
Section 3 (The technology)	None
Section 4 (Evidence and interpretation)	4.3.10. UK patients treated with these drugs probably have more severe disease than average in trials where there is a pressure to include patients. They are likely to need ICD treatment relatively more frequently and it is unethical to allow them to relapse severely (to the same state as prior to induction) before retreatment. NICE should recognise this explicitly. ICD treatment may result in greater use of concommitant immunosuppressants with associated adverse events and lifestyle impact (esp Methotrexate).
Section 5 (implementation)	The constraint of 1200 character boxes may be convenient for NICE but completely stifles reasoned responses.
Section 6 (proposed recommendations for further research)	6.7 is key. I would be willing to submit audit data for all patients that I treat with these drugs.
Section 7 (related NICE guidance)	We have been waiting more than 3 years for the update on the 2002 guidance (due May 2005).
Section 8 (proposed date of review of guidance)	A national audit to inform future guidance (6.7) would be helpful. Please dont let things slip by years again.
Date	07/10/2008 11:44

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	I have submitted on behalf of the Royal College of Physicians. This is to make doubly sure!
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	This is a new definition of severe Crohn? s disease and not one that has been validated. It has not been a stratification in any clinical trial of which I am aware nor analysed as a secondary end point. It is likely that the higher the CDAI the less likely it is that remission (CDAI <150) would be achieved. A CDAI of >300 represents a heterogeneous group of patients. Some may have new disease, are treatment naive and respond promptly to conventional therapy (antibiotics, enteral nutrition, corticosteroids), others may be on steroids or other therapy and still have very active disease, whilst another group may have complications of CD, in particular intra-abdominal or other abscess. Anti-TNF-alpha would be contraindicated in the latter group.

	Those patients with a CDAI of 220-300 are also a heterogeneous group. A patient can have disease significantly impairing quality of life and on maximum conventional therapy and therefore anti-TNF-&#61537 is an excellent treatment option. It is not clear why this cut off has been chosen and the evidence-base for this decision. The inclusion of weight loss as a factor is also not evidence-based and again it is not clear the basis for t
Section 2 (clinical need and practice)	The evidence that maintenance therapy prolongs surgical remission is weak. Regular 5-ASA at high doses may increase the time in remission in about 7% of patients. Many people are unable to remain adherent to the dosing regimen.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Validity of Health Economic model There is clear general agreement that there is a lack of meaningful data on clinical course of disease with conventional medical therapy and that the economic models we have available are far from ideal. The model over-estimates the effect of surgery, does not recognise that there are patients in whom surgery is never an option, underestimates the relapse rate in severe CD, does not recognise the clinical benefit of reduction in symptoms but not remission It is unfair and unnecessary to provide care for a patient that deliberately needs them to suffer recurrent severe symptoms to justify further treatment which has previously been successful. There are clear benefits to maintenance therapy: ?anti-TNF-alpha therapy often has a dramatic effect in improving (or gaining complete remission) CD and can maintain this effect with maintenance therapy ?patients much prefer maintenance therapy because of better disease control, convenience and reassurance. Relapse, or fear of relapse, has a major effect on the quality of life in people with CD. ?anti-TNFs may be the only therapy option ?scheduled regimes can be very flexible and allow patient
Section 5 (implementation)	A major concern is the unnecessary, unfair and illogical hardship that lack of maintenance with anti-TNF-alpha therapy will cause for many patients with severe CD who require such therapy. I have concerns that this guidance will be difficult to implement at a local level with regards to how responsive and flexible an organisation will be to deal on a week to week basis to patients having ?as required? anti-TNF-alpha. It is a genuine worry that the guidance as it stands would lead to widely different interpretation and thus to inequality of treatment of CD in the UK, at a time when we are striving to provide good quality care throughout the UK.
Section 6 (proposed recommendations for	These recommendations are excellent. There is work underway to gain funding to investigate the above.

further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	A general comment is that the guidance has attempted to be fair and flexible. However the flawed cost-effectiveness model gives unacceptable costs per QALY and is clearly a major issue in the decision to not allow maintenance therapy. This could be overcome by further consultation to agree on a fair and reasonable cost-effectiveness model.
Date	07/10/2008 11:44

Name	[redacted]
Role	Carer
Other role	Professional
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a mantenance basis to patients, where their consultants support the decision. I believe it is unethical to discontinue giving these drugs on a mantenance basis, where the drug is effective and supported by patients consultant. I believe these drugs should be given on either an episodic or maintenance basis, as recommended by the patients consultant.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to ant TNF, it seems unethical to with draw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs,as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date.
Date	07/10/2008 11:38

Name	[redacted]
Role	other
Other role	Local Government Councillor
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	

Section 1 (Appraisal Committee's preliminary recommendations)	If the doctor approves and the patient responds well then it is plainly unethical to take this drug away.
Section 2 (clinical need and practice)	Where there are long periods without remission and the patient responds well to anti TNF treatments it is unethical to withdraw the teatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If a patient can get by on alalumibab and not require further services from the NHS then thats evidently cost-effective. It seems wrong to increase a patients suffering and to impose additional costs on the Health Service in order to enjoy the short-sighted benefit of withdrawing the drug.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	The review needs to take place now. Anti-TNF drugs are already used abroad for maintenance purposes.
Date	07/10/2008 11:33

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am a patient currently in remission on 8 weekly doses of infliximab. Having been diagnosed at 7 and now nearly 21, various courses of steroids, months of polymeric diets and two operations failed to keep me well for more than a few months. Infliximab has allowed me to complete my A-Levels and gain a place at Cambridge University, a feat which continual absence would have prevented without Infliximab maintenance. When trying to increase the gap of treatments, I begin to relapse and my quality of life returns to the pain and symptoms Infliximab keeps at bay. Without it I would have spent a great deal of the past 3 years in hospital and trying unsuccessful regimes, costing far than the treatment itself. I sincerely urge a re-think on this recommendations, it will cause many repercussions and a great deal of pain for a huge number of people. Thank you
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	

Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 11:16

Name	[redacted]
Role	Patient
Other role	Crohns sufferer.
Location	England
Conflict	no
Notes	I have suffered from Crohns desease for the past 25 years.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	07/10/2008 11:13

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients who have had a long and fluctuating history of Crohns disease and where the trial has proved effective, where their consultant support this action.

Section 2 (clinical need and practice)	It seems unethical to withdraw the treatment from a patient who had no remission for a long period until trialed with adalumimab
Section 3 (The technology)	From the patients perspective the treatment is much to be preferred to the distress and wastage of the disease
Section 4 (Evidence and interpretation)	In estimating cost effectiveness, there seems to be no account taken of a patients ability, if the teatment is effective, to lead a productive life - pursue a career, pay taxes and make other contributions to the community. The only consideration seems to be the, hopefully, lesser demand on the Health Service
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Since the use of anti-TNF drugs on a maintenance basis is supported by consultants and is widely practiced in other countries, I would request an earlier review date.
Date	07/10/2008 11:12

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	If maintenance treatment is not approved for patients with Crohns disease, I believe this will be the most serious setback for the mangement of patients with IBD in recent history. Such guidance would be out of line with practice in the whole of Western Europe, USA and Australia. We will be condemning patients with IBD in the UK to a standard of care more often found in developing nations.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The large majority of patients in the UK treated with biologics have severe debilitating Crohns disease. Most have failed treatment with every other available therapeutic option and have had poorly controlled disease for long periods of time. The effects of this can be unreversible. The studies used by the Committee to define the cost efficacy of biologics for maintenance therapy recruited a much less severe group of patients than the average patient who receives biologics in the UK. Leaving these people to relapse before retreating is (a) less effective clinically (b) likely has an effect on long term prognosis (c) increases the risk of loss of response (in a group of patients who have no other therapeutic

	options)(d) requires exposure to additional immunosuppression (which is known to increase the risk of infections and of developing lymphoma) (e) will, in some people, lead to complications that would have been avoided. Mucosal healing is thought likely to alter the natural history of Crohns disease - allowing ongoing inflammation to occur, as will inevitably happen with intermittent retreatment, is likely to have long term cost implications that will not have been identifie
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	A randommised controlled trial comparing infliximab and adalimumab is probably unnecessary. It is well recognised form the data available that the two drugs are broadly similar in efficacy. Accordingly, a head to head trial would need to be large: I think the resources required to perform this trial could be much better utilised.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 11:00

Name	[redacted]
Role	other
Other role	relative of patient
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on either an episodic or maintenance basis as recommended by the patients consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period but respond to anti-TNF, it seems unethical to withdraw the treatment unless the consultant recommends such action.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis for some patients I recommend an earlier review date.
Date	07/10/2008 11:00

Name	Lynne Worthington
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I dont consider it ethical to discontinue a drug that has proved so effective where it is supported by the patients consultant.
Section 2 (clinical need and practice)	I think these drugs should be taken on a maintenance basis should they be recommended by the consultant
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Taking adalumimab on a maintenance basis could mean that the patient could lead a productive life,incurring on this account no further costs to the health service but rather contributing to it in taxes.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 10:57

Name	[redacted]
Role	other
Other role	retired SRN and godparent of patient
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be prescribed on either an episodic or maintenance basis, as recommended by the patients consultants.
Section 2 (clinical need and practice)	No two Chrohns patients will respond to treatment in the same way and therefore we should be advised by the consultant on the best form of treatment in each case. It is good that these two non corticosteroid drugs have become available as an alternative line of control for some severe cases.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	I only know one adolescent patient. The improvement in his health has been outstanding since he commenced treatment with adalimumab. He has had no further setbacks and has been able to complete his schooling. It would be such a pity if he had to interrupt, or not complete,his university education due to long periods of severe illness.

Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis for some patients I should like to recommend an earlier review date.
Date	07/10/2008 10:49

Name	[redacted]
Role	other
Other role	long term friend
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	treatment should not be withdrawn from children adolesent and young adults where the consultant reccomends it.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	clinical tests should be continued to improve drugs and undertanding if Crohns disease.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 10:33

Name	[redacted]
Role	Public
Other role	
Location	US
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients where their concultants support this decision. I believe it is unethical to discontinue giving these drugs on a maintenance basis to patients where the drug is effective and

	supported by the patients consultants. I believe these drugs should be given on either an episodic or maintenance basis, as recommended by the patients consultant.
Section 2 (clinical need and practice)	Where patients have no remission for a long period, but respomd to TNF, it seems untehical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adaumimab is effective, the patient incurs virtually no other cost as they do not need to attend hospital or other treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti Tnf drugs are on a maintenance basis in other countries, I would ask for an earlier review date.As consultants already support the use of anti- TNF drugs on a maintence basis I would request an earlier review date.
Date	07/10/2008 10:24

Name	[redacted]
Role	other
Other role	Friend
Location	Europe
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I strongly believe that it is unethical to withdraw a patients treatment when they have responded positively to treatment on a continuous basis and have regained their life back from it as a result.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period of time, but respond very well to anti TNF, it is unethical to withdraw the treatment.
Section 3 (The technology)	Where treatment with adalumimab is effective, the patient will incur virtually no other costs e.g. hospital costs
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Since consultants already support the use of anti-TNF drugs and these are used on a maintenance basis in other countries, I would ask for an earlier review date.
Date	07/10/2008 10:23

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants. These drugs should be given on a maintenance basis to patients, where their consultants support this decision.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment. Not to mention the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, and as consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	07/10/2008 10:22

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further

	treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date.
Date	07/10/2008 10:18

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period of time, but respond to anti-TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	NICE have not taken account of the benefit of this drug in terms of the patients ability to earn money, pay taxes and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-TNF drugs are used on a maintenance basis in other countries, I would ask for an earlier review date As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	07/10/2008 09:45

Name	[redacted]
Role	Healthcare Other
Other role	Company Director
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's	I believe it is unethical to discontinue giving these drugs on a

preliminary recommendations)	maintenance basis, where the drug is effective and supported by the patient?s consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment. No account appears to be taken of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health services. These factors suggest the financial benefit is higher than that identified in the studies - and warrants review & probably the economic case for prescribing for maintenance is made.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries & as consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	07/10/2008 09:41

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8	As anti-Tnf drugs are used on a maintenance basis in other

(proposed date of review of guidance)	countries, I would ask for an earlier review date As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier re view date.
Date	07/10/2008 09:33

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	After being diagnosed with Crohns Disease in 2000 I found myself being admitted to hospital between 2 and 5 times a year, with each period amounting to a minimum of 7 days stay plus 2 to 3 weeks recovery period afterwards. This had quite an impact on my daily life (both home and work), as I am sure it does with many other sufferers, especially as we had two very young children at the time. In 2005 I had my first Infliximab infusion and have been on regular maintenance ever since. This has changed my way of life completely as since the first infusion I have not been admitted to hospital and I feel so much better in my general health and well being. It has also made me feel a lot more confident in my daily routine which has obviously been helped mainly by the Infliximab but also the excelllent treatment from the Specialist IBD Nurses. From a selfish point of view I do not wish to go back to how things were before the treatment and surely the cost difference between being admitted 2 to 5 times per year (plus then possibly surgery) is probably more expensive than the maintenance treatment. Not to mention the impact on my family life.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 09:32

Name	[redacted]
Role	NHS Professional
Other role	
Location	N Ireland
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Clinicians do not enter into a discussion about these treatments with IBD patients lightly. The group of patients we treat with biologics are at the severe end of the spectrum and have failed multiple therapies. If a patient therefore responds to an induction course of an anti-TNF, I would consider it inhumane to say to my patients
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	As stated by the expert panel, the CDAI is a poor indicator of the activity and severity of Crohns disease and clinical trials need to be interpreted in the light of this. Recently, real world data (Schnitzler F, Fidder H, Ferrante M et al. Long term outcome of treatment with infliximab in 614 Crohns disease patients: results from a single centre cohort. Gut online first 2 Oct 2008) have been published from Belgium showing much higher response and remission rates (as defined by thorough clinical assessment) and the advisory group should consider these data before making their final recommendation.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	I agree that this is a very good wish list for research to clarify these important issues
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 09:30

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment

Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 09:23

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is completely unethical to withdraw drugs which are effective in treating patients, particularly where consultants support the use of the drug on a maintenance basis for their patient.
Section 2 (clinical need and practice)	It also seems completely unethical to withdraw a drug from a patient who has had no remission for a long period of time but for whom anti TNF drugs work.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	In analysing cost effectiveness no consideration has been given to the fact that many people will not need other support, such as healthcare support or benefits, if they are given this drug and it allows them to lead a lifestyle that they would not be able to without anti TNF drugs.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Since consultants in this country and other sountries support the use of anti TNF drugs on a maintenance basis, an earlier review date would be appropriate.
Date	07/10/2008 09:22

Name	[redacted]
Role	other
Other role	Research Analyst

Location	England
Conflict	no
Notes	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date
Date	07/10/2008 09:09

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patient?s consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	No account of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8	As consultants already support the use of anti-TNF drugs on a

(proposed date of review of guidance)	maintenance basis, I would request an earlier review date.
Date	07/10/2008 09:05

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	If the patients consultant has reccomended an episodic or maintenance basis for administering the drug, they should be able to continue to do so where it enables effective management of the disease.
Section 2 (clinical need and practice)	In cases where patients have had no remission for a long period of time, but respond to anti-TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they are not likely to attend hospital for further treatment. Not withstanding the implications of removing this drug in terms of a patients general quality of life, there does not seem to have been a consideration its benefits in enabling a patient to work, pay taxes, and require no additional support from health or social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis (and as they are used as such in other countries), I would request an earlier review date.
Date	07/10/2008 08:51

Name	[redacted]
Role	Carer
Other role	Parent of Crohns disease sufferer
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on either an episodic or maintenance basis, as recommended by the patient?s consultant.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment

Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date
Date	07/10/2008 08:46

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision and believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier re view date.
Date	07/10/2008 08:26

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patient?s consultants
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 07:48

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision and it is unethical to discontinue giving these drugs on a maitenance basis
Section 2 (clinical need and practice)	It seems unethical to withdraw the treatment, where patients have had no remission for a long period, but respond to anti TNF,
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for	

further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 07:45

Name	[redacted]
Role	other
Other role	Friend of someone who has Crohns disease
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I have seen how great one of these drugs has been for one of my friends, compared to how ill they were before. I really think it is wrong not to allow these drugs to be given on a maintenance basis to Crohns patients where they have proved to work, and where the consultant wants to continue giving the drug to them. I dont think these drugs are given to people unless their disease is really bad, and so although it is expensive, the benefits for the patient are that much greater.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 06:58

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	As a young person myself, I cant imagine what it would be like to have my good health taken away from me. If these drugs work, and the doctors support their use, I think they should be available.

Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 06:46

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/10/2008 00:58

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no

Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date
Date	07/10/2008 00:56

Name	[redacted]
Role	Healthcare Other
Other role	Wound Care Specialist Canada
Location	Other
Conflict	no
Notes	Chair MEDEC wound care committee
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	No account of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date
Date	07/10/2008 00:47

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision. I believe it is wrong to stop giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants. These drugs should be given on either an episodic or maintenance basis as recommended by the patients consultant.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period of time, but respond to anti-TNF, it seems wrong to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	It appears as if NICE have not taken account of the benefit of this drug in terms of the patients ability to earn money, pay taxes and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-TNF drugs are used on a maintenance basis in other countries, I would ask for an earlier review date As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	07/10/2008 00:46

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to stop the maintenance use of the drug where it is successful and approved by the patients consultants.
Section 2 (clinical need and practice)	

Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 23:41

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	It is unethical to stop the use of the drug for maintenance purposes if the patients consultant has agreed it.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 23:37

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	

Section 1 (Appraisal Committee's preliminary recommendations)	I belive it unethical to discontinue giving these drugs on a maintenance basis where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 23:29

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it would be unethical to stop the drug for maintenance where the patients consultant has authorised use.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 23:28

Name	[redacted]
Role	Public

Other role	
Location	England
Conflict	no
Notes	If the patients consultant recommends maintenance use of the drug then this should be available
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Should be brought forward
Date	06/10/2008 23:25

Name	[redacted]
Role	other
Other role	parent
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	treatment should be patient centred and based on clinical need following discussion between the consulant and patient. My son is currently receiving Infliximab on a maintenance dose basis and as such is able to live independently whilst continuing with his nurse training course. Surely, this must be better for him (and many others in a similar situation)and more cost effective than waiting for a relapse in his, condition,decline in quality of life and potential admittance to hospital.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed	

recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 23:13

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	No account of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 23:07

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	it is completely unethical to discontinue giving these drugs on a maintenance basis, where the drug is proven to be effective and supported by the patient?s consultants.

Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it is completely unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 23:04

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The implication of this recommendation is that the current use of these drugs on a maintainance basis would have to be discontinued which I believe is unethical where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	There appears to be no account taken of the benefit of the use of this drug on a maintenance basis to enable the patient to earn money, pay taxes and not require additional support from social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Since anti-TNF drugs are used on a maintenance basis in other countries I think an earlier review date would be appropriate.
Date	06/10/2008 22:44

Name	[redacted]
Role	other
Other role	Friend of a Crohns sufferer

Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I object to limiting the treatment of Crohns patients with these drugs to an episodic basis only. If the consultant wants to give these drugs on a maintenance basis, and the drug is effective, it should be within the scope of NICE guidance for that to be possible.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	I object to the comparison of the cost of adalimumab for maintenance treatment against its use on an episodic basis, instead of the usual cost comparisons where I understand it would fall within normal guidelines.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	There is already a lot of research on these drugs which support their use.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Advances in this area of drug development is very fast, and I think they should be reviewed more quickly.
Date	06/10/2008 22:38

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Knowing how one particular patients life has been transformed following treatment on a maintenance basis of severe active Crohns disease I cannot believe anyone could consider the withdrawal of this medication for use in this way. It seems totally unethical when a consultant had made the decision that this is the appropriate treatment for a patient.
Section 2 (clinical need and practice)	In cases where patients have been unfortunate enough not to have had any remission for a long period, but have responded positively to anti TNF to consider the withdrawal of their medication - their lifeline- seems unethical.
Section 3 (The technology)	For those patients who have suffered no contraindications the results can be miraculous, enabling them to live normal lives, earning a living and contributing to society, rather than being a burden on the state being dependent on benefits, requiring hospital treatment and emotional support.
Section 4 (Evidence and interpretation)	

Section 5 (implementation)	There seems to be very little time given for responses to this review. This heightens the feeling that decisions are being forced upon the public with unfair pressure and undue haste - and insufficient research and evidence to support the decisions.
Section 6 (proposed recommendations for further research)	Time for further research and seeking the views of more people directly affected would be valuable.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Anti-Tnf drugs are used on a maintenance basis in other countries. Three years is too long for some sufferers to anticipate being deprived of the medication that makes their lives bearable - it is the length of a university course for example - consider how a first year student might be feeling at this moment - looking into the abyss. I would ask for an earlier review date please.
Date	06/10/2008 22:21

Name	[redacted]
Role	Public
Other role	
Location	Scotland
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe adalimumab or infliximab should be used either for episodal use or for maintainance ,according to the consultants considered opinion.
Section 2 (clinical need and practice)	In cases where patients have had remission for a long period of time, and respond to anti TNF it seems wrong to withdraw it.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adulumimab is effective, the patient does not incur other costs, as he /she does not need to attend hospital or receive hospital treatment. Also the patient is more likely to be able to work and pay taxes.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 22:15

Name	[redacted]
Role	other
Other role	Friend of patient
Location	Europe

Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe that the choice of whether they are given on a maintenance basis or a episodic basis should lie with the patients consultants.
Section 2 (clinical need and practice)	It is unethical to withdraw the treatment if the patienthas had no remissions but responds to anti-TNF
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	With this drug NICE have not taken into affect the patients ability o lead a normal life.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 21:56

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	It is completely unethical to discontinue these drugs to people who have benefitted from them so much, and should definately be given on a maintenance basis to prevent remission.
Section 2 (clinical need and practice)	it is unethical to withdraw the treatment to those who have responded so well to anti -TNF, where this has been the only drug to work.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment. As an NHS professional, I am fully aware of the implications of bed blocking and overcrowding. Further benefits to the patient include the ability to be a working member of society, thus being able to pay taxes and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7	

(related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-TNF drugs are used on a maintenance basis in other countries, I would ask for an earlier review date. As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date
Date	06/10/2008 21:54

Name	[redacted]
Role	Carer
Other role	Mother
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	My son suffers from Crohns and has been treated for the last year with infliximab it has toatlly changed his life. He was treated with azathioprine for 8 years but during his gcses year was taken off it. This totally ruined any chance of good results as he became very ill within 6 months. He is now in the same situation with his 2nd year of alevels...how is this fair? My son has stayed in remission for a year and with Infliximab is able to attend college like anyone else and stands a good chance of obtaining good results...now his future is in jepody. This is the most important time of his life he has already suffered so much in his young life he lost his father to cancer at 7 and developed this disease at 9, he has spent so much time travelling to and from and staying in hospital. His career choices are limited because of this disease can he not be given the hope of good health during his last years of education? If he is taken off of this treatment reintroducing it a a later stage is not very successful he has already been advised he runs the risk of cancer because of use with this drug and azathioprine , no funding then the other choice is total bowel removal at 17..who has
Section 2 (clinical need and practice)	If this funding for infliximab is taken away , if he comes out of remission the drug is not always successfull 2nd time around the only option to my 17 years old son is total bowel removal as he is so severe.....what an option to a young man just starting off in life!!!!!He says he would rather die.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	My understnading of 4.3.13 tells me maybe addenbrookes are mis advising me. My son is in this category so i believe hsi treatment may not be at risk????
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	Yes i agree
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	

Date	06/10/2008 21:43

Name	[redacted]
Role	other
Other role	Veterinary student
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be available for regular maintenance treatment in cases where a patients life is significantly improved by this type of usage, and where their consultants support this decision.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I believe the review date should be earlier.
Date	06/10/2008 21:43

Name	[redacted]
Role	other
Other role	Relative
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am a Crohns sufferer and stongly support the use of this drug where appropriate on a maintanence basis. It would be unethical to discontinue giving these drugs where it is supported by the patients consultant.
Section 2 (clinical need and practice)	In cases where patients have had no remission and continual suffering for a long period of time, but respond to anti TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment. This benefit needs to be considered.
Section 5	

(implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 20:57

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	My feeling is that these drugs should be given on a maintenance basis to patients, where their consultants support this decision I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patient?s consultants. I believe these drugs should be given on either an episodic or maintenance basis, as recommended by the patient?s consultant
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs. The patient does not need to attend hospital for further treatment. It seems as though no account of the benefit of this drug in terms of the patients ability to be self supporting earn money, pay taxes, and not require additional support from health and social services have been considered.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would suggest pushing for an earlier review date. The fact that consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review

	date.
Date	06/10/2008 20:48

Name	[redacted]
Role	other
Other role	Relative
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on either an episodic or maintenance basis, as recommended by the patient?s consultant.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment. As well as this the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services MUST be taken into consideration.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date
Date	06/10/2008 20:48

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4	If adalumimab is effective, the patient incurs virtually no other

(Evidence and interpretation)	costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 20:47

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I was originally diagnosed with Crohn?s disease when I was 16 and ended up having part of my intestine removed as medication did not work. I was then in remission for 8 or 9 years until after the birth of my third child who is now a year old. My symptoms came back about 6 months ago and increased rapidly in their severity, I was put on oral steroids as I am allergic to methotraxate and azothoprine, to try and elevate the symptoms, unfortunately the steroids did not help. I was constantly in pain throughout my body, having diarrhoea around 8 times a day and vomiting, as you can appreciate having 2 young children this made life almost impossible. I ended up housebound due to the pain and the constant need for the toilet, I could not look after my two small children properly and had to rely on my family considerably for help. I was unable to continue to work and suffered major financial hardship as I was not paid for being sick. I became anaemic and extremely lethargic, I was unable to sleep at night due to the constant pain throughout my body ? my joints in my hips and back in particular. continued in next comment box...
Section 2 (clinical need and practice)	Continued from previous box - My husband was not always able to go to work and risked losing his job as I could not look after the children or even myself. This placed terrible strain on our marriage and my children became upset and distressed. My total quality of life suffered greatly and it was like being in a black hole and I was desperate for an end to this. I was given a lifeline by my consultant when he advised me of Infliximab ? although I was initially concerned about the possible side effect these paled into insignificance when compared to my physical and mental state without the treatment. Within two days of receiving my first infusion I was 100% normal and could lead a totally normal life with my husband and young children, I was extremely grateful to my

	consultant for giving me my life back. Continued in nex comments box
Section 3 (The technology)	Continued from previous box - Since learning from my consultant that I am at risk of receiving no further maintenance treatment I have become totally distressed and extremely anxious that I will not be able to cope with my life without the aid of maintenance doses of this treatment. If I have to wait each time for my Crohn?s disease to destroy my life before I can receive treatment I will live in constant fear and anxiety that my children and husband will have to periodically go through this nightmare and each time my health will deteriorate. I implore you to ensure that this life line is not pulled away from myself and others in a similar position who are reliant on the maintenance doses of Infliximab to give us some quality of life. Without this treatment I would have no hope as there is no alternative treatment which works for me. Please give some thought to those of us out there who will be effected by your decision ? without this treatment we have no life. Sorry that this is split but your comments boxes do not allow patients to clealy express their views. Thank you for taking the time to read this.
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 20:46

Name	[redacted]
Role	other
Other role	Friend of Patient
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on either an episodic or maintenance basis, as recommended by the patients consultant.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period of time, but respond to anti-TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4	If adalumimab is effective, the patient incurs virtually no other

(Evidence and interpretation)	costs, as they do not need to attend hospital for further treatment, therefore further costs to the NHS are reduced and can be spent elsewhere.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-TNF drugs are used on a maintenance basis in other countries, I would ask for an earlier review date As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 20:45

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe the drugs should be given on a maintenance basis to patients, where the consultants support this decision.
Section 2 (clinical need and practice)	where the patients have had not remission for a long period but respond to TNF it seems unethical to withdraw treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 20:36

Name	[redacted]
Role	Public
Other role	
Location	Scotland
Conflict	no
Notes	
Comments on individual sections of the ACD:	

Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants, to do so would be cruel.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period of time, but respond to anti-TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	NICE have not taken account of the benefit of this drug in terms of the patients ability to earn money, pay taxes and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-TNF drugs are used on a maintenance basis in other countries, I would ask for an earlier review date As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 20:33

Name	[redacted]
Role	other
Other role	Literacy and Numeracy Subject Specialist Teacher
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical and inhumane to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants. I have, over several years, watch the decline and deterioration of a wonderful teenager due to recurring episodes of Crohns disease. I have wondered, in the height of summer, why he has worn several layers of clothing including a thick jacket, only to realise that this was to conceal his embarrassment at his ever decreasing weight and frame. I have watched as my own teenager has enjoyed normal social activites and pursuits and this young man has been unable to participate due to the uncertainty of his illness and the accompanying humiliation and embarrassment that aspects of it entail. I have seen the return of the positive and healthy young man I once knew over the last year when he has been receiving treatment with adalumimab and the realisation that he will retun to the physical pain and discomfort and emotionally depressing and exhaustive state that he was in prior to receiving these drugs fills me with dread and anger when this is totally unavoidable.
Section 2 (clinical need and practice)	If a patient has had no remission for a long period, but responds to TNF, it is unethical to withdraw treatment without the patients best interest in mind. If the use of TNF can delay, minimise or

	even prevent the need for surgery, it would seem ethical and good practice not to withdraw it.
Section 3 (The technology)	Although this medication is expensive, the cost of withdrawing it in human terms is indescribable. Without the drug, for many people suffering from Crohns Disease, life becomes very simply intolerable.
Section 4 (Evidence and interpretation)	In assessing cost effectiveness, maintenance treatment should be compared with episodic treatment (the next best option) rather than standard care. According to your report, costs when compared with episodic treatment were approximately Ã¯Â¿Â½5,030,000 and Ã¯Â¿Â½4,980,000 per QALY gained, respectively. The additional costs incurred with this treatment should be weighed against the the life improving effect this drug has, and the fact that the patients need virtually no other medical expenditure, but can become active contributors to the society to which they belong. The costs of other treatments for the disease, surgery and the strong possibility that psychological and emotional illness are likely to occur if the drug is withdrawn should be considered. To have a debiliating and chronic long term illness and then receive medication that returns health to normal and then have the prospect of certain return the the debilitation, pain and exhaustion of the illness due to the withdrawal of drugs will have a major psychological impact on the most determined and positive human being.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Anti-Tnf drugs are provided on a maintenance basis in other countries and I sincerely request that an earlier review date is made that will prevent this drug from being withdrawn.
Date	06/10/2008 20:32

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	It seems hard to withdraw use of these drugs for patients who have been using them on a maintainance level, and found helpful, even if new patients are only be given them on an episodic basis
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and	

interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 20:30

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe that it is unethical to stop giving these drugs on a maintenance basis where the drug has been effective and fully supported by the patients consultation team
Section 2 (clinical need and practice)	Where patients have had no remission fo a long period but respond to anti-TNF treatments, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effectve, then this is the only health cost incurred and the person can then lead a normal life with no other demands on health care and social services
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-TNF drugs are used on a maintenance basis in various other countries, lets have an earlier review date
Date	06/10/2008 20:28

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients,where their consultants support this decision.

	I believe it is unethical to discontinue giving these drugs on a maintenance basis , where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	where patients have no remission for long period, but respond to anti TNF, it seems unethical to withdraw the treament.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	no account of the benefitof this drug in terms of patients incurs virtually no ther costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	as consultants already support the use of anti TNF drugs on a maintenance basis I would request an earlier review date
Date	06/10/2008 20:22

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I know a Crohns sufferer whose life has been transformed by adalumimab. He is now 19 years old and has gone from being regularly ill and requiring medical intervention to a more normal existence. I believe this drug should be prescribed where recommended by a consultant
Section 2 (clinical need and practice)	It seems to me to withdraw a drug from a patient who is responding well on it is not sound medical practice
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The financial logic of keeping a 19 year old crohns sufferer well controlled and contributing to society as against one who is regularly ill and cannot work seems overwhelming. The social security cost and hospital/doctor intervention easily outwieghing any drug cost
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 20:22

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	No account of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date
Date	06/10/2008 20:21

Name	[redacted]
Role	Local government professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patient?s consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	No account of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services has been considered.
Section 5 (implementation)	
Section 6	

(proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 20:14

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision I think it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patient?s consultants. These drugs should be given on either an episodic or maintenance basis, as recommended by the patient?s consultant.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review dateAs consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 20:09

Name	[redacted]
Role	Healthcare Other

Other role	HCA
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	- I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision - I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supporte
Section 2 (clinical need and practice)	If patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	No account of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier re view date.
Date	06/10/2008 20:09

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	- I think these medications should be given on a maintenance basis to patients, where their consultants support this decision - I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supp
Section 2 (clinical need and practice)	If patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Surely if adalumimab is effective then the patient wont incur other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6	

(proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier re view date.
Date	06/10/2008 20:07

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	I have suffered from Crohn?s Disease since adolescence. As is normal for the condition, the severity in my case has varied from a state of remission to severe symptoms. Historically my treatment has been based upon a mix of corticosteroids and immunosuppressant drugs. This treatment, though successful at certain times for certain periods during my past, was never effective in suppressing the condition, and in relation to the corticosteroids, included a number of very unpleasant side effects. I suffered frequent flare ups of the disease, affecting quality of life and resulting in extended periods of absence from work. Since moving to Cambridge in 2000 I have been treated at Addenbrookes Hospital. Subsequent to continuous flare ups of the condition, and after the results of an endoscopy showed severe inflammation, in 2007 my consultant took the clinical decision to place me on infliximab. I am currently on a 290mg infusion every 8 weeks. My response to this drug was very favourable leading to ongoing remission, including reduced fistula activity, the opportunity to work with no absence and significantly enhanced quality of life. Unfortunately when the interval between infusions was extended the symptoms returned. Once a ?flare-up? occurs the condition deteriorates to the point where I cannot carry out daily tasks. The last extreme episode i endured (which determined my placement on infliximab) involved frequent trips to the toilet during the day and night for periods of 1-2 hours each time, squirming with a sickly pain due to severe ulceration of the bowel and a constant aching and draining fistula. It was more than I could tolerate for too long. I was absent from work for 6 1/2 weeks. Each ?flare-up? has caused more scarring and thickening of the intestinal wall, and has led to narrowing of the bowel in a couple of places fistula development and weakened anal muscles. The possibility of a procedure leading to a stoma is always present. I have had a

	number of small operations for abscesses and fistulae in recent years. A procedure to ?glue? a fistula was only temporarily successful. Although antibiotics helped initially they were only a short term solution and were in some cases, difficult to tolerate. Infliximab has definitely been very effective in my treatment. Its withdrawal as a maintenance drug would be nothing short of a disaster for me personally. The cost would mitigate against me acquiring the drug privately. I appeal to you to reverse your preliminary recommendation at 1.6 below.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The preliminary recommendation suggests that I must relapse into a severe state of the disease before I qualify for treatment with infliximab effectively meaning that I yo yo between extreme states of health, a situation which could potentially be avoided by maintenance under strict review by my consultant.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 19:54

Name	[redacted]
Role	other
Other role	friend of patient
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Why are they not recommended for regular maintenance treatment? Are there severe side-effects, or do the treatments beome less effective with continued use?
Section 2 (clinical need and practice)	Surely any treatment which reduces the need for surgery must be beneficial as well as cost-effective?
Section 3 (The technology)	Can pressure be applied to drug companies to reduce the cost, or is the administration of the drugs the cause of expense?
Section 4 (Evidence and interpretation)	Have not studied this in detail, but any treatment which increases the chances of a child/adolescent to lead a normal life should be followed. At the very least, patients who are

	currently being treated should not have the treatment withdrawn.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	Should be implemented.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	No comment
Date	06/10/2008 19:27

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	This is not an appropriate response given the efficacy of treatment. Continued treatment is essential for all maintenance cases.
Section 2 (clinical need and practice)	If clinical management is viable, why is it prospectively being denied to suffers who could be treated?
Section 3 (The technology)	No comment
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 19:26

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	My friend has been suffering from severe active Crohns disease for nearly 6 years. Before going on adalimumab last September he had atleast 2 serious relapses each year during which he

	suffered intense abdominal pain. After each episode he had to keep to a liquid diet, slowly building up to an almost complete and balanced diet over the course of several months, only for another relapse to occur. As a result of this, he lost a lot of weight and was often unable to participate in activities that he enjoyed, such as sport, which any teenager should be able to enjoy. Moreover, the illness forced him to miss a lot of school and had a serious impact on his exam results, most notably his A-levels. Since receiving adalimumab as a regular maintenance treatment, his quality of life has improved hugely. He looks healthier, he can now eat everything and has regained the weight he lost. He retook some of his A-level exams, achieved top grades and is now studying in the university of his choice, having had a fulfilling and enjoyable gap year. Adalimumab allows him to live a full and normal life and it would be wrong to rob him of this by reducing his treatment to mere episodic treatment.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	I believe that patients, who receive regular maintenance treatment and for whom the drugs are effective, will incur almost no additional costs, as they will not be affected by relapses and therefore need not attend hospital for treatment. In addition to this, these patients will be more able to earn money, pay taxes and as a result they will not need to depend on support from the social and health services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Considering that other countries, including the USA, use such drugs as regular maintenance treatments, I ask that the date of the review be brought forward.
Date	06/10/2008 19:23

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	Please replace NICE Reference: NF-0110-0005734 with this submission. When submitting last, I was not aware that each section should be up to 1200 characters therefore got confused and did it under pressure and in a bit of a rush... Now I have had time to re think about it.
Comments on individual sections of the ACD:	
Section 1	1987 ? 2005 I was frequently ill (longest remission 4 months).

(Appraisal Committee's preliminary recommendations)	Symptom: Section 2. As a result I was bed ridden, long absence from work, finally gave up work, unable to look after my kids (my husband had to return from an overseas work journey), hospitalisation, depression, fear of leaving house (urgent need for toilet), of travelling & operation, no quality of life, inability to see family sufficiently, & help my daughter when her 4 week old baby was critically ill, no socialiing. Steroids (for 4 years), caused osteopenia, severe insomnia (took zopicloon 7.5 mg & amitriptilyne 200mg nightly still struggling to come off the latter), frequent oral candida. In 2005 I was prescribed episodic Infliximab. My symptoms were alleviated had relapses after 5 months, 3, then 2. Unpredicatability of my illness stopped me from planning, making commitments, for work, social & family life. I lived in fear of a relapse. In 2006, I was prescribed infliximab every 8 weeks. I gained my life again, mostly symptom-free, good health, confidence, happiness, exercise, healthy varied diet, increased work, social life, able to travel to see my family (Indonesia, Israel, France, Devon). Different perso
Section 2 (clinical need and practice)	Symptoms: frequent diarrhea(16+ a day), a lot of blood, mucous, urgency, wind, abdominal pain and cramps, anemia, loss of apetite and weight. Treatment: mesalazine, steroids for 4 years (2003 to 2007), some of the time at maximum dose of 40 mg per day, methotrexate caused me an inflammed liver after 5 years, azathioprine ? caused liver inflammation after 6 weeks, hospitalisation. My disease has become corticosteroid resistant. I take nutritional supplements and eat a carefully selected diet. That by itself does not stop my disease from flaring up.
Section 3 (The technology)	In the 3 years I have been given infliximab, I have develop NO side effects either during or between infusions.
Section 4 (Evidence and interpretation)	The regular use of infliximab for mainstenance, has eliminated symptoms, thus bringing healing of the inflamed tissues. A colonoscopy I had in December 2007 showed no activity and healed tissues. My experience of biological treatment has been positive, with prolonged remission (2 years). Axing the maintenance treatment, means a return to where I was before (as described above), with frequent episodes of illness that take toll on me physically, mentally & emotionally. I refuse to take steroids (reasons as above). That may mean increased need for surgery, a colectomy, possibly a permanent stoma, potential further hospitalisations & surgeries due to complications. It is UNACCEPTABLE. I live in fear of the increased risk of bowel cancer, and other complications of the disease. The potential loss of work, will leave me relying on state benefits (sick, income, disability). The risk of death is indeed cost effective, no need for health care, state benefits & pension. In the case of episodic treatment, there is an increased potential of the development of antibodies to the drug and possible for loss of effect. So that is not cost effective.
Section 5 (implementation)	
Section 6 (proposed recommendations for	

further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	It?s long time for us to wait if the episodic treatment proves inadequate.
Date	06/10/2008 19:14

Name	[redacted]
Role	NHS Professional
Other role	
Location	Wales
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	this proposal is at odds with how these biogenics are used is Europe and USA. Most pts are kept on maintence therapy and to suddenly force us to stop in these pts is unreasonable. We will have to pick up the aftermath when these pts after being so well for so long suddenly are starting to have a significant deterioration in there quality of life.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 18:39

Name	[redacted]
Role	NHS Professional
Other role	Mother
Location	England
Conflict	no
Notes	Cousin of Pt with Crohns Disease
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	from a personal experience with patients who have benifitted from this drug as a maintainance therapy, I feel that it is unethical not to license the drug for this purpose. Removing the drug from those who have benefitted will cause an immeasurable negative physical, psychological and social impact on quality of life.

Section 2 (clinical need and practice)	
Section 3 (The technology)	Giving a young person the quality of life to be able to study, work and contribute to the economy would more than pay the costs of the treatment in the long term, also would avoid the need for many young persons to live off sick benefits
Section 4 (Evidence and interpretation)	Once been given infliximab as a child/adolescent, would it be removed when they turn 16. If this is the case, then you may cause a severe decline in quality of life at a very sensitive, important age. I feel to do this would be unethical.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 18:35

Name	[redacted]
Role	other
Other role	Friend of Crohns patient
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patient?s consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	No account of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date.
Date	06/10/2008 18:21

Name	[redacted]

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective. I believe these drugs should be given on either an episodic or maintenance basis, as recommended by the patient?s consultant.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment. No account is given towards the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 18:20

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6	

(proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 18:10

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	where a consultant recommends the use of Adalimumab for the maintenance of a patient it should be provided. to discontinue the presciption where it is seen to be successful is unacceptable
Section 2 (clinical need and practice)	for patients benefitting from anti TNF it should not be withdrawn
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	should adalumimab be seen as effective allowing a patient to return to a normal working life the cost benifits to the community are achieved also further medical costs are eliminated
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	consultants support the use for maintenance of anti-tfn drugs in this and other countries so an urgent review is essential to safeguard the progress of current participants
Date	06/10/2008 18:06

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and	Where patients have had no remission for a long period, but respond to

practice)	anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 18:04

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti TNF drugs are used on a maintenance basis in other countries, and the consultants in this country already support the use of the drug, i would request an earlier review date.
Date	06/10/2008 18:00

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no

Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	No account of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 17:52

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe that the drugs should be given on a maintenance basis to patients where their consultants support the decision.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti-TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient causes virtually no other costs, as they do not need to attend hospital for further treatment
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-tnf drugs are used on a maintenance basis in other countries I would ask for an earlier review date.
Date	06/10/2008 17:48

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients where their consultants support this decision.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period of time, but respond to anti-TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 17:34

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	I have parcipitated in Advisory boards for Schering-Plough in relation to Infliximab therapy and chaired a meeting sponsored by Abbott.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am a Consultant Gastroenterologist, and currently have around 100 patients recieving scheduled maintenance Infliximab for Crohns disease under my care. For these patients the treatment has been life changing. We know from both study data and extensive anecdotal evidence that there is a significant risk of relapse after stopping Infliximab, particularly as we tend to use this treatment for the minority of patients with severe disease that has been resistant to conventional therapy. It therefore follows that using anti-TNF therapy as epsiodic

	therapy will lead to more patients relapsing. This will have a significant impact on healthcare utilisation, as the patients who relapse will need assessment and repeat investigation to confirm relapse before being re-treated. We also know that episodic therapy increases the risk of developing antibodies against the drugs, which will ultimately reduce the efficacy of treatment. Consequently I am concerned that NICEs decision to restrict anti-TNF use to episodic therapy will cause harm to patients, whilst only delivering a fraction of the anticipated financial saving due to the limited cost of relapse used in your modelling.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 17:34

Name	[redacted]
Role	Carer
Other role	Mother, teacher and Parent to Parent Advisor for NACC (National Crohns and Colitis) Charity
Location	England
Conflict	no
Notes	As a mother and someone who has seen what happens to individuals with the above conditions on a daily basis, I feel eminently qualified to express my feelings about this review as I speak from both personal experience and close observation of others with the above conditions.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe that the above drugs should be given on a maintenance basis, where the drug is effective and supported by the patients consultant. I also believe that it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants. It is importanat to give these drugs either episodically or as maintenance as recommended by the patients consultant as they are the ones who understand that patients condition and requirements and their treatment needs to be the one which will give that patient the most effective treatment for their personal condition.
Section 2	Where patients have had no remission for a long period, but

(clinical need and practice)	respond to anti TNF it seems retrograde and unethical to withdraw treatment. Again, the patients quality of life is important and they deserve to be given the most effective treatment available to give them the best possible quality of life.
Section 3 (The technology)	As above, the best possible treatment with the best possible outcome for the patients needs to be decided by the consultant and the patient together so as to ensure that the patient is kept in the best possible condition throughou their lifespan. It is difficult enough living with the condition, without limitations being put on which drugs may or may not be administered by those who do not have access to a patients immediate needs and state if being.
Section 4 (Evidence and interpretation)	If treatment with adalumibab or infliximab is effective, the patient incurs virtually no other, or very limited costs, as they do not need to attend hospital for further treatment. Therefore, the patient can earn money, pay taxes, not require support from health and social services and this is then cost effective as they are contributing to society as their condition is being effectively maintained. If we leave treating the patients until they have flare-ups, those flare-ups are often very much more severe and therefore more costly to get under control, thus effecively costing more money in the long run.
Section 5 (implementation)	Please try to think of the patient in all of this as living with Crohns and Ulcerative Colitis is not easy at the best of times and they do need the best possible maintenance for their condition so that they do not end up in despair and in and out of medical care with severe symptoms.
Section 6 (proposed recommendations for further research)	Research is extremely important in order to continue to give patients the best possible care as new treatment possibilities become available.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti TNF drugs are used on a maintenance basis in other countries, and consultants already support the use of them on a maintenance basis, I would ask for an earlier review date.
Date	06/10/2008 17:25

Name	[redacted]
Role	Public
Other role	
Location	US
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The drug works and has had a significant positive impact on the quality of life of a friend. It has changed him from being constantly on a roller coaster if pain and suffering to a productive youth who has just started university. Before being prescribed with this drug that would have seemed impossible. The drug should be made available for maintenance if Crohns if prescribed by a consultant. If it is being over prescribed then the NHS should educate consultants appropriately. The cost of the drug has to be weighed against the positive impact on the

	quality of the patients life and their ability to contribute to society, pay taxes etc.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 17:24

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe that the drug should be available on a maintenance basis if it is effective at improving their quality of life and is supported by their consultant.
Section 2 (clinical need and practice)	If the patient has not experienced remission and responds to anti TNF it would be unethical to deprive them of this treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Withdrawing the treatment on the basis of costs seems short-sighted. If the patient responds well to the drug, they may lead a normal life, have a job and pay taxes without requiring the continual treatment, hospital visits and surgery that many Chrons patients require.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Since the treatment is supported by consultants both in the country and elsewhere, I would suggest an earlier review date.
Date	06/10/2008 17:21

Name	[redacted]

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patient?s consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier re view date.
Date	06/10/2008 17:17

Name	[redacted]
Role	Public
Other role	
Location	US
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The drug should be made available for patients on a maintenance basis if their consultant prescribes it. It is unethical to withdraw effective treatment that could result in significantly greater suffering for the patient. We have a friend in the UK whose life has been transformed since the drug was prescribed for him. Even the suggestion that it might not be available is causing him stress. NICE should continue to make the drug available.
Section 2 (clinical need and practice)	The drug works well in maintenance situations improving the quality of life significantly.
Section 3 (The technology)	This analysis appears to not include the offsetting cost of treating the patient when crohns causes a flare up. It is also not possible to put a cost on the value of the positive impact the drug has the patients life.
Section 4 (Evidence and	The positive impact of the drug has been significant. It appears

interpretation)	he will have a more productive life. His school results significantly improved because he was not as sick. He has just started university. With the help of this drug he will graduate, get a good job, pay taxes and be productive. This has to offset some of the costs in the model you describe.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 16:57

Name	[redacted]
Role	Carer
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I disagree strongly with this recommendation. I disagree because of the beneficial effects I have seen with my husband of being on maintenance treatment with infliximab and the huge concern I have that he would under these proposals have had to wait until his symptoms met the severe condition before he could be treated again. It makes me cry just to think about the pain and suffering he would have to endure until that point would be reached - let alone the pain and anger that would be suffered by me and our children, while we saw him suffer. Given my experience with my husband - Im a nurse and pay close attention to his symptoms, treatment and care - I can only conclude that this potentially harmful proposal has been reached on a basis independent of the effect that it will have. I cannot object in stronger terms. Please listen to those who will suffer from this proposal.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	I dont have the time now to give a detailed response to this except to say that the reasoning is muddled and flawed as to both process and conclusion. I am sure others have said the same and have given considered reasons, which I would support.
Section 5 (implementation)	I have already written about the effects on individuals. I cannot believe that in a civilized society that this will be allowed. Perhaps I should have less faith.
Section 6 (proposed	The fact that 6.2 is proposed just emphasises what I have said

recommendations for further research)	about the flawed process and conclusions.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Just dont implement this until the research evidence is better reasoned.
Date	06/10/2008 16:47

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period of time, but respond to anti-TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	NICE have not taken account of the benefit of this drug in terms of the patients ability to earn money, pay taxes and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 16:42

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patient?s consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3	

(The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date
Date	06/10/2008 16:41

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I feel strongly that these drugs should be given (on a maintenance basis) to any patient whose consultant supports that decision.It seems unethical to withdraw the drug if it has been effective.
Section 2 (clinical need and practice)	If patients have responded well to anti TNF, after a long period with no remission, it would seem unethical and extremely cruel to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If the condition has been brought under control by adalumimab there are virtually no other costs incurred as no further treatment is required.If the condition is untreated by this drug there would be many other direct and indirect costs - hospital treatment for flare-ups, and the costs of other drugs which may be only partially effective inability of the patient to study or work thus being dependent on state benefits and therefore not paying taxes or national insurance contributions possible mental health issues as Crohns can be an extremely depressing condition
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	I feel there should be a much earlier review date as consultants in this country already support the use of anti TNF drugs on a maintenance basis and these drugs are used on this basis in other countries.
Date	06/10/2008 16:14

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to > patients, where their consultants support this decision > > - I believe it is unethical to discontinue giving these drugs on a > maintenance basis, where the drug is effective and supported by the > patient?s consultants. > > - I believe these drugs should be given on either an episodic or > maintenance basis, as recommended by the patient?s consultant.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 16:10

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	I have had CD for 14 years, with 2 major surgeries in that time. I have been on maintenance infliximab for 12 months.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am very concerned about recommendation 1.6. From my experience, detailed in section 2, this could seriously impact on my health and quality of life, and that of other patients with very severe CD.

	I wonder if the research really takes into account the economic burden of very bad CD, or the effects on the lives of the sufferers. Are the committee confident that they understand the difference maintenance infliximab has made to patients with severe CD? If not, the decision would be not only premature, but (my experience suggests) could have a serious adverse effect on quality and length of life for those with CD as bad as, or worse than, mine.
Section 2 (clinical need and practice)	Prior to maintenance IFX I relapsed frequently, had 2 major operations (with TPN in 1st) had at most 2-3 months at a time off medication there were many obstructive episodes with vomiting other CD related hospital visits countless days off work, especially 2/3 months operations pain and fatigue at other times many GP appointments, phone calls, blood tests I took: 1000s of painkillers steroids almost constantly usually <40mg/day many dietary supplements) many courses of antibiotics (inc. 8 in one year) for abcesses and diaorrhea immunosuppressants over 9 of these years 2 periods on elemental diet I had 2/3 infusions of IFX, which were effective for 3 months, then relapsed rather badly, with very bad associated sacro-iliitis. Since starting IFX every 2 months I?ve had: no surgery no hospital visits (except clinic appts & these infusions) no sacro-iliitis no steroids no NSAIDs/codeine painkillers, but some paracetomol for migraines/colds stopped immunosuppressants 6 months in, none since 1 course antibiotics my CRP has been below 10 for the first time since diagnosis (reached 110 twice in 2005-6). My quality of life has improved beyond measure.
Section 3 (The technology)	Please bear with me here: as far as Quality of Life is concerned, before maintenance IFX: - there were many very painful, very unpleasant episodes of obstruction with vomiting. - extreme fatigue, leading to depression. Anxiety due to uncertainty. I never felt far from the next flare-up - last October, my sacroiliac disease became so bad once I took 40 minutes to get to the next room to eat so I could take the painkillers (which I knew were harmful but felt I couldn?t live without) The pain from this was unquestionably worse than that of the 2 major surgeries I have had for CD. The episodes of this debilitating level of pain were frequent pre regular INFLX. - I barely held onto a job, and did so partly because my employers understood my condition. Obviously, not all severe CD sufferers will be this fortunate.

	In the last year none of these has been a problem. Maintenance infliximab has changed my life. If my story is in any way typical for serious CD patients, I would beg you to reconsider recommendation 1.6.
Section 4 (Evidence and interpretation)	What about hospital/GP time/resources not just for CD but for the many associated conditions, common with severe CD? My experience suggests that this cost to the NHS on top of the medical/surgical costs must be great. Also, I am acutely aware how close I was (before maintenance infliximab) to being unable to hold down a job, and needing sickness/unemployment benefit ? instead I work as an IT consultant and pay tax. Indirect costs to NHS and the state. Does the analysis look at whether maintenance Infliximab would be cost effective for just the most serious cases of CD? And does it do so accurately, taking into account all the factors above, common to severe CD patients? Also I have serious reservations about CDAI, having worked with a group looking at these instruments. These formulae are absurdly simplistic, given how differently CD affects different patients This seems to say we are waiting for better evidence in the debate. If the argument runs:
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 15:58

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision. I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants. I believe these drugs should be given on either an episodic or maintenance basis, as recommended by the patients consultant.
Section 2	NICE have not taken account of the benefit of this drug in terms

(clinical need and practice)	of the patients ability to earn money, pay taxes and not require additional support from health and social services.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 15:28

Name	[redacted]
Role	other
Other role	Former Headmaster to a patient
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am in favour of these drugs being given on a maintenance basis to patients where their consultants support this decision. It must surely be unethical to discontinue giving these drugs on a maintenance basis where the drug has been shown to be effective and its continued use is supported by the patients consultant.
Section 2 (clinical need and practice)	Where patients have had no remission for a long time but respond to TNF inhibitors, it would seem both cruel and unethocal to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	I see no evidence that NICE have taken into account the benefit of this drug in terms of the patients ability to earn money, pay taxes and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti TNF drugs on a maintenance basis, I would press for an earlier review date.
Date	06/10/2008 15:20

Name	[redacted]

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe that these drugs should be given to patients for regular maintenance treatment to prevent relaps of Crohns disease when recommended by they patients consultant.
Section 2 (clinical need and practice)	It would appear unethical to withdraw treatment to patients with no remission for a long time, but respond to anti-TNF treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 15:12

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	No
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8	As consultants already support the use of anti-TNF drugs on a

(proposed date of review of guidance)	maintenance basis, I would request an earlier review date.
Date	06/10/2008 14:23

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe that the lack of recommendation for maintenance treatment should be reconsidered in severe cases.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	These figures suggest that maintenance treatment with adalimumab is more cost-effective in severe cases, and they havent taken into account the patients increased ability to become a productive member of society (eg. working, paying taxes (and therefore helping to cover the cost of their own treatment), etc.).
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	I would ask for an earlier review date.
Date	06/10/2008 14:19

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am a patient who has been on maintenance infliximab for 18 months for severe recurring sympomts. I am unable to tolerate steroids for long periods of time, which caused a steroid induced psychosis and relapsed very quickly on Methotrexate and pentasa, and intolerant (vomiting, flu like symptoms) of 6-mercaptopurine and azathioprine. Not having infliximab for maintainance leaves me with no treatment whatsoever.
Section 2 (clinical need and practice)	Before I started infliximab Crohns disease was ruling my life, with chronic severe pain, severe diarrhoea, weakness, lack of

	appetite and lethargy. Steroids had affected my psychological well being and my illness was not getting any better. My life revolved around finding the nearest bathroom. After a bowel resection operation in 2006 and recurrence of the illness within 6 weeks of the operation, I was restarted on infliximab and received 3 treatments. I became a different person overnight, able to eat again, able to start walking and leave the house without too much fear about needing the toilet, and recommence work. After being off infliximab the sympotms returned within 3 months and I had to go through. Some people become steroid resistant, and some people are not able to tolerate azathioprine or 6 mercaptopurine (despite 3 tires at each drug), so for the small minority of patients in my category, if we cant have infliximab then we will end up hospitalised anyway. There is a small minority of patients who are relying on these drugs to keep their life and dibilitating symptoms under control.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 14:02

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patient?s consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6	

(proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 13:29

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Why should patients have to wait until they have a flare-up until they get the treatment and the drugs they need to help them to live a bearable life? Consultants should have the right to use their extensive medical knowledge to decide for each individual case when these drugs are needed. The decision shouldnt be made by the government, on a generalisation.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Three years is much too long a time for people living and suffering with Crohns diesease daily. They need these drugs now, and if this
Date	06/10/2008 13:19

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	I was involved in the review of adalumimab/infleximab in August 2008. I am currently being treated using adalumimab.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I think it is unethical to require patients with a history of regular relapse to fall ill before treating them, then remove the treatment that prevents them relapsing, until they fall ill again.

	Thus I feel that the refusal to recommend regular maintenance treatment is outrageous.
Section 2 (clinical need and practice)	If maintenance therapy can fulfil the objectives of treatment, that is giving a normal quality of life, when other treatments have failed to put the disease into remission, it seems hypocritical to suggest that it shouldnt be used.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	I feel that the recommendations regarding episodic/maintenance therapy cost effectiveness were made based on limited awareness of the implications of Crohns disease on the wider life of the patient, namely their ability to work, which itself has implications on whether they are a burden or an asset. Patients who are constantly falling ill cannot hold down regular work, so cannot contribute through taxes, national insurance, by spending surplus in their wages and so on. This is a severe flaw in the reasoning behind allowing episodic treatment and not maintenance treatment. For patients who are in a cycle of regular relapse, I would suggest that it is more beneficial to have maintenance treatment, when taking wider factors into account. Significantly, maintenance therapy is also backed by the opinions of the clinical experts, for medical reasons, over episodic.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Since many other countries have approved the use of anti-TNFs on a maintenance basis (e.g. USA) I would propose an earlier review date, especially as clinicians are supportive of their use.
Date	06/10/2008 13:18

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Although you say the drug is successful, you have to wait for the flare up to be able to give the drug which is very painful for the patient. Although some sufferers have infrequent flare ups those with regular flare ups require the drug to maitain their health more often. Particularly with younger people who require good health to fulfill their potential at school or university.
Section 2 (clinical need and practice)	
Section 3 (The technology)	

Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Three years is too much of a long time to wait, especially if you are ill in between that time. The date should be brought forward a considerable amount due to the advances in science that will go on during this period of time.
Date	06/10/2008 13:12

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	It is wrong to not allow this treatment to be given as a maintanance drug. Why should patients have to become ill, and their lives be ruined, before treatment? Surely the consultant should be allowed to decide when the drug is required as a maintanance drug, to the requirements of particular patients. These diseases vary greatly in severity, and many young people need the drug in order to continue with a normal lifestyle.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	The research and development of these drugs is happening at such a fast rate, why is it necessary to wait such a long time for a review of guidance? The amount that can change over this period of time could have an effect on patients that cannot be reversed after the review - an effect that could well be life changing, especially taking young peoples lives into account.
Date	06/10/2008 13:12

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I belive that it is unfair to only provide the drug to those who are already ill when there are so many people who will suffer from the disease in the near future and their suffering can be prevented by providing them with the necessary drugs beforehand.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	The date should be brought forward to the nearer future to ensure that the amount of people that will suffer from this disease can be decreased
Date	06/10/2008 13:11

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	These drugs have shown that they help young people living with Crohns disease to live a normal life. They shouldnt be permitted only on a maintenance level when they clearly help people when permitted on a permanent basis. Why should a patient have to suffer before getting drugs to help them?
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed	

recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	This date is too far in advance and should certainly be brought forward.
Date	06/10/2008 13:10

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Not permitting the anti-TNF drugs to be used at a maintenance level is wrong on all accounts. Why should people become ill before treament, when the drugs have proven they can help young people live normally whilst suffering from Crohns disease?
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	The development is so fast, the review date has to be sooner rather than later. The date should therefore be changed from September 2011 to sometime in the nearer future.
Date	06/10/2008 13:06

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	It is good that the importance of the anti-TNF drugs has been recognised, however taking them away from the patients who are in need of these drugs at a maintenance level is morally and ethically wrong. As a friend of a sufferer of Crohns disease,I have seen firsthand how these drugs have made his life better in every way imaginable and he is now able to live

	like a normal adolescant. Surely it should be a joint decision of the patient and his/hers consultants as to the type of treatment taken and when these drugs are needed to be used, depending on each individual patient, not on a generalisation of all suffererers of this disease?
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Personally I believe that the review date should be brought forward because the development in this area is very rapid, and the review date should therefore reflect this.
Date	06/10/2008 13:00

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	You are taking away the anti-TNF drug from the people who need this and this is so unethical. Sufferers need this drug and rely on it, you taking this away is taking all their opportunities away from them and they are not being allowed their lives to the best level that it could be - with the anti-TNF drug. It is not your decision to say that they are not allowed to have the drug. you are really ruining their lives and chances that they have with university etc, will be taken away and this is not fair. Surely you can leave it to the consultants to decide????
Section 2 (clinical need and practice)	You taking the ability of the sufferers to be able to have this drug is meaning that they are forced to go through unnecessary pain - pain that can be stopped by the anti-TNF drug. This is so unethical, if you CAN stop this suffering, surely you should take oppertunity that you can to help the sufferers and patients to get better, to get a better life? Please, dont take this drug away from them.
Section 3 (The technology)	Surely you shouldnt be looking at the cost as a problem, if you can help to stop their pain, the cost shouldnt matter. It is more important to save the health, education and lives of the patients than to worry over money.
Section 4 (Evidence and interpretation)	

Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Three years is far too long, considoring the devolepment occuring in this area. Lots can change in three years and these could be three years of misery for the sufferers. If you bring the date forward, this would make such a big difference to so many lives, differences that will affect them forever.
Date	06/10/2008 12:58

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Glad that youve seen the importance of Anti-TNF drugs but the fact that taking them from the patients who need them at a maintenance level is not morally and ethically right. Surely the consultant should be able to decide whether the drugs should be given or not?
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	The development made in this area is happening very rapidly, and three years before a review will harm many of its sufferers, especially young people, as studying is practicly impossible during flare ups. It is a sentence on many lives not to review this earlier.
Date	06/10/2008 12:56

Name	[redacted]
Role	other
Other role	medical student
Location	England
Conflict	no

Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision
Section 2 (clinical need and practice)	If the drug effectively prevents relapse and has changed the life of the patient for the better, it is unethical to withdraw the drug
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 12:48

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	No
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-THF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 12:42

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe that these drugs should be given on a maintenance basis to patients where their consultants support this decision. Further I believe that it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	Where patients had had no remission for a long period, but respond to anti TNF, it is unethical to withdraw the trreatment.
Section 3 (The technology)	Having paid National Health all my life and not asked for any medication whatsoever, I see no problem that what I have put in cannot be used for another person. There can be NO price attached to human life.
Section 4 (Evidence and interpretation)	If Adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti TNF drugs on a maintenance basis, I see no reason why an earlier review date cannot be made.
Date	06/10/2008 12:37

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I strongly believe that these drugs should be given on a maintenane basis to patients where their consultants believe these drugs to be appropriate.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient occurs virually no other costs as they do not need to be hospitalised for further tratment. It would therefor be cheaper to keep appropriate patients on the drug than to withdraw it and then incur the costs of hospital

	treatment. Account should also be taken of the fact that if a patient is kept well by taking adalumimab, he/she will be able to have a career, earn a salary, pay taxes and national insurance as opposed to a life on benefits which will cost more than the drug.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 12:20

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision. I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants. I believe these drugs should be given on either an episodic or maintenance basis, as recommended by the patients consultant.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period of time, but respond to anti-TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-TNF drugs are used on a maintenance basis in other countries, I would ask for an earlier review date As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 12:20

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I strongly disagree with the recommendation that infliximab should only be available for episodic treatment. As a Crohns patient I have benefited from infliximab to a great extent. The very idea that I should have to await the return of severe symptoms before having treatment is beyond belief Do you know what it is like to wait for ones health to deteriorate into very poor general health with weight loss? Do you appreciate the family, social and economic consequences of being off work waiting for your condition to deteriorate before treatment is allowed? This is equivalent to prove to us how ill you are or show us your pain before we will treat you. This is frankly unacceptable human behaviour one to another.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Para 4.3.9 is a confused approach to the issue. To compare episodic with maintenance rather than standard care ignores the personal, family and economic costs of the proposed decision.
Section 5 (implementation)	The implementation of this guidance would mean that many patients currently doing well on infliximab would be denied further treatment until they were subjected to the disgrace of wating for severe symptoms to occur.
Section 6 (proposed recommendations for further research)	The fact that 6.2 is needed and the wording used undermines the recommendation utterly.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Clearly too long!
Date	06/10/2008 12:03

Name	xxxxxxxxxxxxxxxx
Role	other
Other role	Parent / carer
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's	I am responding to the consultation re the above in relation to my son Mike. You have advised me that you will not accept an

preliminary recommendations)	email which for the reasons set out below is very inconvenient and you suggested simply putting my responses in the first box. As this is not possible I have had to split my response between the different boxes. After many years of alternating health Mike was eventually diagnosed with Crohn?s disease after he had become very ill at age 17 while in his final year of A levels. Having not been able to get him back to a reasonable level of health with alternative medications, he was given infliximab which brought the symptoms within manageable proportions. Since then he has had infliximab about every 3 months when he starts to ?go downhill?. He is now age 22 and will have been on infliximab for about 4 years. Whilst not ideal this has given him a tolerable quality of life. As you are presumably aware Crohn?s significantly impairs the qualify of life of a sufferer. The treatment Mike is presently having enables him to work at his chosen career, which as a professional sports coach / squash player, involves him maintaining a very high level of
Section 2 (clinical need and practice)	fitness. This is very difficult with his disease but he copes very well and has recently obtained a prestigious new job despite his illness. The present consultation proposing to withdraw maintenance treatment from patients is, in my view fundamentally unsound for the reasons set out in this letter. However, apart from the inappropriate technical approach to the review it seems to have complete disregard for the personal consequences of refusing in the future an existing treatment. I am appreciative of the fiscal constraints which have received much publicity recently in relation to licensing of new cancer treatments. However, there is I would suggest a significant difference between refusing a new treatment, which may or not work in a particular case, and withdrawing treatment from existing patients where such treatment clearly does work for particular individuals. Each case is different but the effect of you withdrawing maintenance treatment in my son?s case undoubtedly may well mean that he is unable to work in his chosen profession. Your own consultation document effectively admits this will be the effect on patients.Apart from the devastating personal implications
Section 3 (The technology)	(enhanced by the difficulties he has overcome to get to where he is now) the result is that he will of necessity be reliant on financial assistance from the State which also then would no longer have the benefit of the taxes he presently pays. I suspect this could in many cases be more than the cost of the treatment. I would make the following specific comments on your consultation:

	1 In relation to your web site consultation document this is written in a technical manner thus making it not very accessible to a lay person. I would suggest if you are genuinely seeking non technical input, as your site suggests, this is inappropriate. Whilst you may need to use technical terms the meaning of these should be readily accessible to the reader of the document and statistics should be explained as to their meaning and relevance. 2 The document has frequent places for making comments but because you have structured comments based on the structure of the document it makes it very difficult to make overall comments (which is why I am writing this letter) which do not fit neatly into your ?compartments?. This seems to me a flaw in the consultation process and I would suggest your
Section 4 (Evidence and interpretation)	web site design should be such as to invite more rounded comments by, for example, starting with an email link specific to that consultation for emailing general comments. 3 Your preliminary recommendations appear to be ignoring expert medical views. Mike?s consultant, to whom I am copying this letter, says they were asked: What would be the effect on the efficient organisation of your IBD service if you had to operate an episodic rather than a maintenance regime? and advised It would remove an important therapeutic option and put back the management clock by 10 years. and they also responded to the consultation saying Emphasise the need to allow scheduled re-treatment before relapse in those who have had recurrent episodes of severe CD that has needed and responded to anti-TNF therapy and demonstrably failed maximal maintenance therapy In making your preliminary recommendations you seem to be completely ignoring expert advice over the benefits of maintenance treatment.4 You make the point at 2.1 of your consultation that ?The clinical features of Crohns disease vary? but you do not seem to take account of this in your preliminary recommendations which are drawn from
Section 5 (implementation)	general statistics. My understanding is that severity, frequency of recurrence, location of the disease and response to treatment will vary dramatically between individuals and also may well vary over time for a particular individual. To produce your recommendation from general statistics therefore is to misuse the statistical process which by definition takes no account of this. 5 Then at 2.6 you say ?As Crohns disease is unpredictable, successful treatment focuses on inducing and maintaining clinical remission?. Your preliminary recommendations are in direct contradiction to this objective as you are saying treatment can only be given once the patient is out of remission which is the antithesis of what you define as clinical need and practice. 6 Then at 2.5 you say ?Treatment aims to control

	manifestations of Crohns disease to reduce symptoms, and to maintain or improve quality of life while minimising short- and long-term toxicity.? Your preliminary recommendations again are in contradiction to this as you are forcing people to become very ill before they can have further treatment. How does this improve the quality of their life ?7 Your cost analysis takes no account
Section 6 (proposed recommendations for further research)	of the loss of taxes and the necessity for State support due to your preliminary recommendations, if implemented, resulting in the patient no longer being able to work. Frankly this in many cases will be more than the cost of using the drug to maintain a quality of life so that individuals, like my son, can continue to work. Never mind the emotional costs to individuals it would seem perverse for the result of your decision to cost the Sate overall more. 8 I cannot see you have properly taken into account the extra cost, if your preliminary recommendations, are confirmed of other treatments, eg surgery becoming required more often as a result of the patient deteriorating due to the effect of the withdrawal of maintenance therapy. Whilst there is a cost to the drug by keeping patients in remission this reduces the necessity for in-patient visits and assessments and consultations which could quickly become more expensive than the use of the drug itself for maintenance therapy. It may be this information is included in the technical statistics you have provided but if so I would suggest it should be set out in a simpler way to show it has been costed into the decision making
Section 7 (related NICE guidance)	process. I have responded to the sections in your online consultation as follows: - please see submission NICE Reference: NF-0310-0005785
Section 8 (proposed date of review of guidance)	In conclusion, I would suggest for the reasons set out above your preliminary recommendations are incorrect, inappropriate and premature. It does seem to me appropriate to have guidelines which avoids the use of these medications for unnecessary maintenance and it may be you feel they are overprescribed. If they were being overprescribed then this would be a reason for looking into and understanding the reasons for such over prescription. However the statistics we have from Dr Travis over the number of people on maintenance therapy compared to the number in your consultation as the percentage of the population suffering from the disease seems, on the face of it to me, quite small. A perceived over prescription (if that is the case) is not a reason for a simple blanket withdrawal of treatment.
Date	06/10/2008 12:00

Name	xxxxxxxxxxxxxxxx
Role	Public
Other role	
Location	England
Conflict	no
Notes	

Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patient?s consultants.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 11:49

Name	xxxxxxxxxxxxxxxx
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period of time, but respond to anti-TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	NICE have not taken account of the benefit of this drug in terms of the patients ability to earn money, pay taxes and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-TNF drugs are used on a maintenance basis in other countries, I would ask for an earlier review date As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 11:43

Name	xxxxxxxxxxxxxxxx
Role	other
Other role	Relative of crohns sufferer
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Where a patients history shows severe and recurring crohns which has subsequently been sucessfully controlled by the use of these drugs on a maintenace basis then where a consultant recommends the continued use of them I believe they should be made available. Where the quality of life of an acute sufferer has been markedly improved by the use of these drugs and ceasing to use them is likely to lead to frequent relapse and remission (and consequently a cycle of relapse, prescription of the drugs, short term revovery, relapse, prescription, etc) then I think it unethical to discontinue consultant supported maintenance based treatment thereby knowingly subjecting the sufferer to episodes of crohnes (and consequent deterioration of quality of life) which would otherwise have been avoidable. At base the drugs should continue to be made available on both an episodic and maintenance basis depending on a consultants recommendation for each individual case.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period but respond to anti TNF it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Without sounding trite, surely there are cases where on a financial basis prevention by maintenace based prescription is better and more cost effective than the frequent need for hospital visits and all associated GP and medical staffing time and resource. On a wider perpective, for someone to be able to keep their illness in check and contribute fully to society, holding down a permanent job, paying taxes and minimising draw on the heath and social services, this ought to be a major consideration.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Request for an earlier review date given (a) anti-TNF drugs are used on a maintenance basis in other countries and (b) consultants in England already support the use of anti-TNF drugs on a maintenance basis.
Date	06/10/2008 11:43

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patient?s consultants. I believe these drugs should be given on either an episodic or maintenance basis, as recommended by the patient?s consultant.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	No account has been taken of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 11:36

Name	[redacted]
Role	Public
Other role	
Location	Europe
Conflict	no
Notes	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period of time, but respond to anti-TNF, it seems unethical to withdraw the treatment.

Section 3 (The technology)	
Section 4 (Evidence and interpretation)	NICE have not taken account of the benefit of this drug in terms of the patients ability to earn money, pay taxes and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 11:35

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period of time, but respond to anti-TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-TNF drugs are used on a maintenance basis in other countries, I would ask for an earlier review date As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 11:33

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no

Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	- I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision - I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supporte
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	No account of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier re view date.
Date	06/10/2008 11:25

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on either an episodic or maintenance basis, as recommended by the patients consultant.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	

Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 11:23

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe that these drugs should be given on a maintenance basis to patients, where their consultants support this decision.
Section 2 (clinical need and practice)	It seems unethical to withdraw the treatment where patients have had no remission for a long period, but respond to anti TNF.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimmab is effective, then the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	I would request for an earlier review date as anti-Tnf drugs are used on a maintenance basis in other countries.
Date	06/10/2008 11:14

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I think it should be available on a maintenance basis when the doctor has advised it. To withdraw it when it is working well is ridiculous.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period but repond well to anti TNF, it seems wrong to withdraw it.
Section 3 (The technology)	
Section 4 (Evidence and	Surely if this drug works the patient is able to lead a full and

interpretation)	productive life incurring no cost other than that of the drug. They will be able to work and pay taxes like the rest of the population.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	If anti TNF drugs are available in other countries on a maintenance basis surely the UK needs to review this as soon as possible and ensure UK citizens have the same access to effective treatment.
Date	06/10/2008 11:13

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patient?s consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 11:00

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	

Section 1 (Appraisal Committee's preliminary recommendations)	The panel that reviewed the evidence seemed to lack much Gastroenterology input. If you had included that they would have told you that we stopped using episodic treatment for Crohns a few years ago as used in this way it is less effective as the development of antibodies is higher (you are effectively immunising patients against it). There have been many papers published on this matter in the last 5 years. Your appraisal seems to put too much emphasis on a paper from 1999 (nearly 10 years out of date!). Nearly all units I know of use regular infliximab infusions 8 weekly. I would have strong objections to using these drugs episodically.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Most Gastroenterologists stopped using episodic treatment for Crohns a few years ago as used in this way it is less effective as the development of antibodies is higher (you are effectively immunising patients against it). There have been many papers published on this matter in the last 5 years. Your appraisal seems to put too much emphasis on a paper from 1999 (nearly 10 years out of date!). Nearly all units I know of use regular infliximab infusions 8 weekly. I would have strong objections to using these drugs episodically.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 10:40

Name	[redacted]
Role	other
Other role	Friend of patient
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	If the drug is demonstrated to have a marked improvement on the patients (my friends) life to the point where his hospital costs are zero and he is able to live a normal life, hold a job, pay taxes, etc, then it seems unethical and unreasonable to withdraw the drug from regular use and expect him to undergo painful relapses.
Section 2 (clinical need and practice)	In the case of my friend, the drugs fulfill amply the aims in 2.5, in that his quality of life has been raised from difficult to normal thanks to the maintenance use of the drugs. It seems unethical to suggest that he undergo relapses and have to attend hospital

	when such a thing is easily avoidable with the use of these drugs.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If a patient is able to hold a job, pay taxes, and has no hospital costs as a result of the use of these drugs, the cost may (as in the case of my friend) be justified, ethical considerations notwithstanding.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Given that consultants support the use of anti-TNF drugs and they are widely used in other countries on a maintenance basis, an earlier review date would be welcome, given the evidence available on the efficacy of the drug in other countries and on the experience of medical practitioners.
Date	06/10/2008 10:34

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Where the drug is given on a maintenanace basis to a patient with the support of the consultant it would be totally wrong and unthical to discontinue the drug.
Section 2 (clinical need and practice)	If no remission has occurred for a long period, but the patient positively responds to anti TNF drugs, it would appear wrong to withdraw treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Maintaing a patient on the drug could reduce associated costs of hospitalisation etc.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti tnf drugs are used for maintenance basis in other countries an earlier review date should be considered.
Date	06/10/2008 10:31

Name	[redacted]

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Each case is best understood by the patients consultant. Therefore the consultant ought to recommend whether the drug should be given either on an episodic or maintenance basis. It would be unethical to overrule the consultants view on the treatment required for his patient.
Section 2 (clinical need and practice)	When a patient has no remission over a prolonged period, but does respond to the anti TNF then it is vital to maintain this improvement. It would be unethical to remove the treatment and wait for the symptoms to worsen.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If we consider only the financial benefit we must take into account the ability of the patient who responds to the treatment to earn his living, contribute his taxes, not draw benefits and not require additional support from health and social services. Also hospital appointments and other medical treatment is reduced. On balance therefore extremely cost effective, for those patients to whom it is beneficial. This is best measured by the consultant.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	September 2011 is three years away. Consultants are supporting the use of anti-TNF drugs on a maintenance basis and indeed they are used on this basis in other countries. I would urge an earlier review date.
Date	06/10/2008 10:16

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is totally unethical to discontinue these drugs on a maintenance basis, where the drug is effective and supported the the patients consultant. Plunging patients into a roller-coaster of chronic disease and recovery is at best unethical, at worst bordering on the sadistic. The consultant is the person best suited to directing appropriate medication for their patient to ensure continued quality of life and ability to undertake full-time work without risk of unnecessary absences.

Section 2 (clinical need and practice)	Where patients have suffered Crohns for a long time without remission, then respond to anti TNF, it is unethical to withdraw the treatment.
Section 3 (The technology)	This appears to be more about cost than effect - and no account has been taken of the fact that providing this medication means that the patient incurs virtually no other costs as they do not have to attend hospital for treatment and can therefore earn money, pay taxes and not require additional support from social services. It is the net balance that must be applied, not the simple cost.
Section 4 (Evidence and interpretation)	I really dont understand how you can balance cost against quality of life. See comments above.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	I believe this work has been undertaken in other countries - why is it necessary to waste money replicating research when the money could be used to fund patient treatment with these drugs.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	I see no reason to wait until 2011 to review, as anti TNF drugs are used on a mainentance basis in other countries and are supported in the UK by qualified clinicians. Experience outside the UK should be taken into account in these matters. An administrative delay will do nothing to help affected patients.
Date	06/10/2008 10:07

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I think that adalimumab and infliximab should continue to be given to patients on a maintenance basis, if their consultants support this decision.
Section 2 (clinical need and practice)	Where TNF alpha inhibitors are effective and the patient has not had remission for a long time, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If the anti-TNF drugs are effective they would be more cost effective than stated as the patient will not have to return to hospital for further treatment. Furthermore, they would not be prevented from working, paying taxes etc
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	

Section 8 (proposed date of review of guidance)	As anti-TNF drugs are already used on a maintenance basis in other countries, I would suggest that the review date was brought forward.
Date	06/10/2008 10:07

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Where the drug is manifestly having a positive effect on a patients quality of life it unethical and wrong to then discontinue making such drugs available on a maintenance basis.
Section 2 (clinical need and practice)	Where patients are responding to ant-TNF it is plainly unethical withdraw such treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	While the cost of this treatment may seem expensive, when it is effective it means that there is NO FURTHER EXPENSE TO THE NHS. I suggest that by withdrawing such treatment in cases where it is now working will cause a far higher degree of cost to the NHS.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-TNF drugs are being routinely prescibed on a maintenance basis in other countries, I believe that its use here be reviewed at the earliest opportunity, especially as we know that many consultants in the UK already support its use on a maintenance basis
Date	06/10/2008 10:04

Name	[redacted]
Role	Carer
Other role	
Location	England
Conflict	no
Notes	jkkj
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	lkllk
Section 2 (clinical need and practice)	kklklk

Section 3 (The technology)	klklkl
Section 4 (Evidence and interpretation)	lklkk
Section 5 (implementation)	lklklk
Section 6 (proposed recommendations for further research)	lklkk
Section 7 (related NICE guidance)	klklk
Section 8 (proposed date of review of guidance)	llklkl
Date	06/10/2008 09:54

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patient?s consultants
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 09:51

Name	[redacted]
Role	other
Other role	Friend of a carer
Location	England
Conflict	no
Notes	

Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 09:11

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it would be unethical to discontinue giving these drugs where they are known to be effective and where the patient?s consultant supports their use.
Section 2 (clinical need and practice)	Where a patient has had no remission for a long period, but responds to anti-TNF, I believe it would be unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective there is virtually no other cost incurred because the patient does not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-TNF drugs are already used on a maintenance basis in other countries, I would ask for an earlier review date.
Date	06/10/2008 09:05

Name	[redacted]
Role	other
Other role	Friend of a patient
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	No account of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date
Date	06/10/2008 09:05

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I personally know someone whose life has been transformed by taking these drugs on a maintenance basis. It would be unthinkable and unethical to withdraw them so as to force him to await another flare of Crohns disease, that causes suffering, before the drugs can be prescribed.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	

Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 09:04

Name	[redacted]
Role	other
Other role	Friend of a patient
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it would be unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	No account of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date.
Date	06/10/2008 09:02

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I think it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patient?s consultants. Particularly since in section 2 it states As Crohns disease is unpredictable, successful treatment focuses on inducing and maintaining clinical remission.
Section 2 (clinical need and practice)	Where patients have not had remission for a long period, but do respond to anti TNF, it appears unethical to withdraw the treatment

Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The cost effectiveness recommendation as shown below does not take into account the abitility of the patient to earn a living, pay taxes and require no other support from NHS etc. Nor does it take into account the concerns of the clinical specialists with regard to loss of effect. The committee heard evidence from clinical specialists that episodic treatment was not favoured by clinicians because of concerns about the development of antibodies to the drug and the potential for loss of effect. However, in the light of the results of the cost-effectiveness analyses, the Committee considered that episodic treatment with infliximab and adalimumab should be recommended as an option for the treatment of severe Crohns disease.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 08:54

Name	[redacted]
Role	other
Other role	Uncle of a Crohns victim
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given to patients on either an episodic or maintenance basis as recommended by the patients consultant. Further, I believe it would be unethical to discontinue giving these drugs where they are known to be effective and where the patients consultant supports their use.
Section 2 (clinical need and practice)	Where a patient has had no remission for a long period, but responds to anti-TNF, I am of the opinion that it would be unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective there is virtually no other cost incurred because the patient does not need to attend hospital for further treatment. Other financial benefits also accrue, such as the patients ability to earn money and pay taxes. The patient will also require less additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for	

further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis I would request an earlier review date.
Date	06/10/2008 08:53

Name	[redacted]
Role	Healthcare Other
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	My understanding is that these drugs, particularly adalimumab are highly effective in preventing recurrence of the debilitating symptoms of Crohns disease. I have seen this in action, with a young man whose life has been transformed by the drug. As such, I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patient?s consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	In considering cost effectiveness, it is important to factor in the efficacy of the drugs when used to prevent relapses, and the consequent reduction on costs to the NHS in hospital visits and treatments on the one hand and the patients ability to live a full life, and be economically independent on the other.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Please consider an earlier review date, in light of consultant support for the use of these drugs for maintenance and the established use for maintenance in other countries.
Date	06/10/2008 08:53

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported

preliminary recommendations)	by the patient?s consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Cost to the public purse must be balanced against the benefits of a patients increased ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-Tnf drugs are used on a maintenance basis in other countries, I would ask for an earlier review date.
Date	06/10/2008 08:45

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants supports this decision. Furthermore, I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultant.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it is unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment. No account of the benefit of this drug in terms of the patients ability to earn money, pay taxes and not require additional support health and social services has been taken.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-TNF drugs are used on a maintenance basis in other countries and as consultants already support the use of anti TNF drugs on a maintenance basis, I would ask for an earlier

	review date.
Date	06/10/2008 08:37

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patient?s consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	No account of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 08:29

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	No
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on either an episodic or maintenance basis, as recommended by the patient?s consultant.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment. Also, no account has been taken of the benefit of this drug in terms of the patients ability to earn money, pay

	taxes, and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 08:12

Name	[redacted]
Role	other
Other role	Teacher
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period of time, but respond to anti-TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	NICE have not taken account of the benefit of this drug in terms of the patients ability to earn money, pay taxes and not require additional support from health and social services
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As anti-TNF drugs are used on a maintenance basis in other countries, I would ask for an earlier review date
Date	06/10/2008 08:07

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's	I believe these drugs should be given on a maintenance basis to

preliminary recommendations)	patients, where their consultants support this decision
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/10/2008 08:02

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	No.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment. Also, no account has been taken of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date. Patients lives are at stake.
Date	06/10/2008 07:52

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 07:29

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision. I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants. I believe these drugs should be given on either an episodic or maintenance basis, as recommended by the patients consultant.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	

Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment. No account has been taken of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 07:08

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Recommendation 1.6 appears to be unsupported. Why are infliximab and adalimumab not recommended for regular treatment? Chrohns disease is not curable, so a relapse is surely a certainty. If there is no cure, then prevention should be the highest priority, ie maintenance treatment.
Section 2 (clinical need and practice)	If anyone has become dependant on treatment to the point of relapsing on withdrawal, it would seem cruel to withdraw the treatment. Why force people into a relapse scenario unnecessarily?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	It does not appear to be remotely cost-effective to risk a patient suffering a relapse, as every time a patient suffers a relapse the patient will be tying up NHS time & resources. Furthermore, reducing maintenance treatment risks reducing quality of life of patients, and may force people onto benefits and out of the job market, which would be false economy for the NHS.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Given the number of assumptions in the proposal, and probable false economy of reducing treatment levels, I would say an earlier review date is a necessity.
Date	06/10/2008 03:57

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I think its unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period of time, but respond to anti-TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the patient incurs virtually no other costs, as they do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 01:51

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patient?s consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	No account of the benefit of this drug in terms of the patients ability to earn money, pay taxes, and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed	

recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.
Date	06/10/2008 01:11

Name	[redacted]
Role	Public
Other role	
Location	Scotland
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period of time, but respond to anti-TNF, it seems unethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	NICE have not taken account of the benefit of this drug in terms of the patients ability to earn money, pay taxes and not require additional support from health and social services as they can lead a more normal life.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I request an earlier review date.
Date	06/10/2008 00:58

Name	[redacted]
Role	Public
Other role	
Location	N Ireland
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I find it unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patients consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period of time, but respond to anti-TNF, it seems unethical to withdraw the treatment.

Section 3 (The technology)	
Section 4 (Evidence and interpretation)	NICE have not taken account of the benefit of this drug in terms of the patients ability to earn money, pay taxes and not require additional support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	NICE have not taken account of the benefit of this drug in terms of the patients ability to earn money, pay taxes and not require additional support from health and social services.
Date	06/10/2008 00:57

Name	[redacted]
Role	Carer
Other role	
Location	England
Conflict	no
Notes	I would like to submit this statement for your consideration regarding the use of Inflixamab as a maintenance treatment for Crohn?s disease. My daughter, Sarah Vaughan, is currently being treated by Dr David Casson at Alder Hey Children?s Hospital in Liverpool. She has been treated with Inflixamab as a maintenance treatment for just over two years. Before you decide to withdraw this treatment from her I think you should understand the implications. Sarah was first diagnosed in April 2005. During the year that followed she spent most of her time exclusively on the feed, Modulen. Every time she came off Modulen she quickly relapsed. The drugs she was prescribed, including a course of steroids, seemed to do nothing to improve the situation. During the many times when Sarah relapsed and suffered the symptoms of Crohn?s disease, her quality of life was severely affected. She was always exhausted. Although she insisted on going to school, she suffered waves of abdominal pain and nausea when she was there. She was too weak to do PE and could not manage the twenty minute walk home. She was too tired to attend any of her evening activities or to socialise with her friends at the weekend. She suffered severe and prolonged pain after going to the toilet. During the night she was sometimes in such pain that she would get up to have a bath two or three times to try to ease the discomfort. Since Sarah has been treated with Infliximab regularly her quality of life has improved dramatically. It is quite difficult to describe in words the difference the treatment has made to her.

	Apart from two brief relapses, from which she recovered remarkably quickly having been given further treatment with Infliximab, she has been free of all the problems described above. Perhaps the most notable change has been in Sarah?s ability to cope with the disease and in her psychological well-being. She is no longer so afraid of the disease. She is less worried when she recognises the symptoms returning, as she feels there is an alternative to the loathed Modulen and boiled sweets regime which takes about two weeks to become fully effective. Sarah can eat ordinary food alongside her friends at lunchtime. She has the energy to do PE and to be involved in the extra-curricular activities she loves. To sum up, using Sarah?s own description, she feels ?normal?. At the moment, this treatment is allowing her to enjoy life in the same way she did before she became ill. If Sarah had not been put on this treatment then to keep the symptoms under control she would have to be exclusively on Modulen almost all of the time. I cannot believe that you think this is an acceptable life for anyone of any age, let alone a young woman of 15 years old. I realise that treatment with Inflixamab is expensive, but in the end not much more than permanent feed. You also need to take into account the cost of admission to hospital. Sarah has not needed to be admitted over night since this treatment began. I realise that you are not proposing to remove treatment with Inflixamab altogether, but it is obvious to me that you have underestimated how quickly deterioration takes place if you wait for a complete relapse. We waited for one in September and Sarah spent most of a week doing nothing but lying on the settee because she didn?t have the energy to do anything else. She lost 6lbs in weight in that time because she could not eat anything without pain and nausea. It takes her about 6 months to put such a weight loss back on. I would ask that you reconsider your decision. Crohn?s disease is a ?Cinderella? condition as it is, but it can make life just as miserable as some of the more headline grabbing conditions. Please feel free to contact me if you would like any further communication.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	My 15 year old daughter has been treated with Inflixamab as a maintenance treatment for just over two years. Before being treated, she was on the feed Modulen for most of the time. Since she has been treated with Infliximab regularly her quality of life has improved dramatically. Apart from two brief relapses, from which she recovered remarkably quickly having been given further treatment with Infliximab, she has been largely free of the problems associated with the condition. Perhaps the most notable change has been in her ability to cope with the disease and in her psychological well-being. She is no longer so afraid of the disease. She is less worried when she recognises the symptoms returning, as she feels there is an

	alternative to the loathed Modulen and boiled sweets regime which takes about two weeks to become fully effective. Sarah can eat ordinary food alongside her friends at lunchtime. She has the energy to do PE and to be involved in the extra-curricular activities she loves. To sum up, using Sarah?s own description, she feels ?normal?. I think that you have severely underestimated the implications of limiting this life enhancing treatment.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	05/10/2008 23:55

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe it is unethical to discontinue giving these drugs on a maintenance basis, where the drug is effective and supported by the patient?s consultants.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it seems unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Where adalumimab is effective, the patient incurs virtually no other costs to the NHS, as they do not need to attend hospital for further treatment thus saving additional costs to the NHS.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would request an earlier review date.

Date	05/10/2008 23:22

Name	[redacted]
Role	other
Other role	Parent of Crohns sufferer
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Severe Crohns diseases effectively stops people continuing with life on a normal basis. Their educational chances are impaired, their ability to work affected, and the opportunity to participate normally in society much curtailed. If an anti-TNF drug works, the patients consultant believes they should be treated on a maintenance basis, and the PCT is prepared to fund it, I believe it is wrong for NICE to recommend that it should not be a treatment option - albeit for those with the most persistent and stubborn forms of the disease.
Section 2 (clinical need and practice)	I do not understand how it can be considered good clinical practice to insist a drug is withdrawn from patients who have had long periods without remission, and for whom and anti-TNF drug is effectively working. I do not understand why clinicians in other countries are allowed to prescribe anti-TNF drugs on a maintenance basis, whereas this is being forbidden in the UK
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	I find the calculations of cost effectiveness incomprehensible. I understand that the drug costs just under Â£10,000 per annum. Where in the calculations is the consideration of the societal costs for these severe sufferers who are likely to be unable to maintain emplyment, and consequentially cost society money. In addition, I have seen how depressed people with a chronic illness become, and I would think that would lead to additional health costs. I feel the costing model should be based on a more holistic approach to costs and benefits.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Developments in anti-TNF drugs are very fast moving. I strongly object to the next review being in 2011. I would ask that there is a review next year, should these proposals be implemented.
Date	05/10/2008 23:01

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no

Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis where their consultants support this decision.
Section 2 (clinical need and practice)	Where patients have had no remission for a long period but respons to anti TNF it seemsunethical to withdraw the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumumab is effective the patient incurs virtually no costs.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti TNF drugs on a maintenance basis I would request an earlier review date
Date	05/10/2008 22:58

Name	[redacted]
Role	other
Other role	Close family member of sufferer
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	A member of my family has been severely ill for many years with crohns. He has only regained his health after adalimuminab on a regular basis, not episodically. Without this he could not have acheived his goal of attending university. I strongly oppose the withdrawl of this drug from the severely ill. Surely his consultant should be allowed to make this decision.
Section 2 (clinical need and practice)	Surely you have not considered the effect of withdrawing treatment from a patient who has had a long period without remission, but does respond to an anti-TNF drug.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	I can only tell you my experience, but my brother has not needed any other NHS care during his course of anti-TNF drug, and as you earlier stated many crohns patients require surgery. Surely you should take this into account when examining the cost-effectiveness of this drug in relation to its use as a maintenance drug.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	

Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	The review ought to be brought forward, as development in biological drugs is so fast moving, and this drug has been approved for maintanance use in other countries. Waiting nearly three years will cause many people a lot of harm, and effectively sentence them to a life connected to a hospital.
Date	05/10/2008 22:47

Name	[redacted]
Role	other
Other role	very concerned relative
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe these drugs should be given on a maintenance basis to patients, where their consultants support this decision. I believe that not to do so in these circumstances is unethical. For these patients it is the difference between a almost normal life and a life of being normal and then sick in rotation for potentially their whole life. It seems an obvious, essential and moral use of taxpayers funds
Section 2 (clinical need and practice)	Where patients have had no remission for a long period, but respond to anti TNF, it is unethical to withdraw the treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If adalumimab is effective, the NHS incurs virtually no other costs, as sufferers do not need to attend hospital for further treatment.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	As consultants already support the use of anti-TNF drugs on a maintenance basis, I would suggest that an earlier review date is essential.
Date	05/10/2008 22:43

Name	[redacted]
Role	Carer
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary	I am pleased that NICE recognised and is giving guidance that recognises the benefits of the anti TNF drugs concerned. I note ?Effective treatment and avoidance of relapses was considered

recommendations)	of paramount importance to people with Crohns disease.? The guidance that anti TNF should not be used as a maintenance treatment is like saying ?we know brakes are the sensible thing to put on a car but we will only supply them after you have crashed ? oh and then we will take them away again once you are on the move again. Or ?Yes, we know by our own definition that you have severe active Crohn?s disease with all that entails but:- ? Don?t worry about the pain discomfort, and dislocation of your life that an attack will have ? Don?t worry about being unable to function in your normal life during an attack ? Don?t worry about the time doctors and other medical services will devote to reassessing you during an attack ? Don?t worry about the depression and nerve wrangling when you know that you will relapse ? Don?t worry about the stress on your carers and family Or ?Yes, we know you have a record of frequent attacks, but until we withdraw the medication we will not know how effective it is? So it is unethical to test certain treatments with a control group on a placebo, because we know a drug is effective, but in the case of anti-TNF therapy, we will endorse an unethical approach to the use of the treatment.
Section 2 (clinical need and practice)	It seems unethical to withdraw the treatment from patients who have had no remission for a long period, but respond to antiTNF.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Does the method used to arrive at the costing the benefit consider the economic consequences for the individual of being ill and unproductive, irrespective of whether life expectancy is extended? Based on my experience of an individual suffering from severe Crohn?s I regard these costs as massive for the individual and the consequential costs, both money and emotional, for the carer and family. It seems no account is taken of the benefit of the little support from health and social services.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	I appreciate that you recommend further research on trials on maintenance treatment and collecting health-related quality of life information in people with Crohns disease. Do you ever recommend maintenance treatment in retained during periods of further trialling. Are you able to propose harder negotiation with the drugs companies to reduce the absolute cost per treatment? At what cost per patient would you be predisposed to recommend maintenance treatment is retained ? which must be a consideration of the outcome of adjusting the dose and frequency of maintenance programs?
Section 7 (related NICE guidance)	

Section 8 (proposed date of review of guidance)	As consultants already support using anti-TNF drugs on a maintenance basis, I request an earlier review date.
Date	05/10/2008 22:31

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	How can withdrawing a drug that is effective be seen as good clinical practice, if the patient is responding well and leading a normal life. It is cruel to subject these young people to a see-saw life and maybe even suicidal tendencies.
Section 2 (clinical need and practice)	As the aim of treatment is to control the flare ups surely where a patient has had no remission for three years with conventional treatment the use of adalimumab as maintenance must be considered, if it works.These patients should be allowed to live as normal a life as possible.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	It is difficult to comment on the costings as they are not easy to understand. However, if a patient is self medicating, on a maintenance dose, symptom free and leading a full and productive life then the cost must be considerably less as there are no other medical costs incurred.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	I would hope that if there are further trials of maintenance treatment those who are on the drug at the moment will be the first to trial it so they dont have to go through the trauma of being denied a drug that works for them and gives them a life worth living.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Surely a review date should be much sooner than September 2011.
Date	05/10/2008 21:43

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	I am writing to you because I have been informed that NICE has recently undertaken a review on the use of Infliximab for patients suffering from Crohn?s disease. I understand that the conclusion of this review is that Inflixmab should only be used for symptomatic relapse. At present I receive Inflixmab infusions at roughly three month

	intervals. This regime has maintained my health for almost six years, after two difficult years battling the disease, during which time ?traditional treatments? seemed to be ineffective. This active management of my disease has enabled me to complete my degree and hold down a challenging job for three years. The proposal to replace effective management with symptomatic treatment seems very short sighted. For me personally it is almost certain to lead to increased suffering and a more uncertain future. How will my employer feel when I am off work sick for extended periods of time waiting for treatment for ?symptomatic relapse?? When you live with a disease like Crohn?s it is a constant battle to live a ?normal? life removing active management would make the battle unwinnable. However, I also think that active management is more beneficial to the NHS. I have no doubts that this review was probably brought about money I understand that Infliximab is an expensive treatment. However, it is important to look at the wider picture in these situations. Patients no longer receiving regular Inflixmab will most likely require an increased incidence of hospital admission and possible surgeries to deal with complications. This will negate any of the savings brought about the reduced level of Infliximab treatment. For me personally, a worst case scenario for this proposal would lead to a complete relapse. It is unlikely I would be able to hold down a job with the uncertainty that would come with the removal of active management. My income taxes could turn into disability benefits, further increasing the costs of this decision. I hope that during your final discussions you consider not only my views but the countless others who will also be affected. Yours sincerely, [redacted]
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	

Section 8 (proposed date of review of guidance)	
Date	05/10/2008 21:31

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	Sirs, As Lead for IBD in a London teaching hospital, I fear I have to express garve concerns over the suggestion that anti-TNFa be provided episodically. This approach has been shown, in a blinded trial to be less advantageous to patients. The major concern, however, lies in the accelerated loss of response that such an appoach will provide. This is a particular worry as the patients I treat often have more severe disease than those in the clinical trials for whom anti-TNFa therapies provide a much needed salvage therapy. If these patients lose response to these treatments, there is nothing else available. Yours, [redacted]
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	By preventing maintenance treatment, patients with often severe disease will have greater rates of loss of response, left with no other proven therapy for a life-long severe disease. Better, that NICE allow maintenance treatment but promote more trials examining loss of response & when to withdraw maintenance therapy.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The committee appear to skim over the fear of loss of response, which has been shown to be a real problem in follow up cohort studies. It is likely that many patients will be disadvantged by the committees recommendations as there are no other available treatments for these young patients with life-long severe Crohns.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	The current recommendations should be withheld pending more data from the very well advised trials above (and also trials of withdrawal).
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	This is a rapidly changing field & review should occur no more than 18 months hence.
Date	05/10/2008 21:24

Name	[redacted]
Role	Carer
Other role	Research Fellow in Education
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am the partner, and carer, of a Crohn?s sufferer (with associated sacroiliitis) who has received maintenance therapy with infliximab for 1 year. Prior to this he was taking 2 or 3 different medicines at the same time including corticosteroids, methotrexate, antibiotics, painkillers. He has had time off work from hospital stays (one major operation, several obstruction episodes), and pain and fatigue from the Crohn?s and associated sacroilliitis. Currently he is on no medication except the infliximab infusions. Having lived with my partner and his condition for over 10 years, I have noted the major improvement in his condition since receiving maintenance therapy. His improved condition has had a very positive effect on quality of life for both of us, and my role as carer has become much easier. I am extremely concerned about this preliminary guidance, for reasons outlined below. I welcome the recommendation of not relying on CDAI as the only indicator of severity of Crohn?s, and would stress the importance of clinical judgement regarding individual patients and their condition (1.2).
Section 2 (clinical need and practice)	The report stresses the chronic nature of the condition (2.5) and the need for management of symptoms. I would like to emphasise the importance of patients managing the symptoms while holding down other family and employment commitments, and to stress the difference that a maintenance dose of infliximab, in preventing relapses in my partners condition, has made to my partner?s (and my own) ability to do so. The unpredictability of relapses was a major source of stress which more effective management of the condition with maintenance therapy with infliximab has reduced significantly.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	I am extremely concerned that cost effectiveness appears to have been given more weight than clinical and quality of life arguments. The clinical arguments in favour of a maintenance dose rather than episodic dose on the grounds that this can prevent relapses do not appear to have been given adequate weight. Relapses, which can be linked to more surgery and more time in hospital, are clinically problematic and costly for the NHS. In severe cases of Crohn?s, if not kept in remission, there can be multiple admissions from a number of causes, including associated conditions which are more likely in severe cases, and also other costs to the NHS (e.g. medicine, GP,

	consultant and nurse time). Relapses also cost the patient and their household in time off work (for patient and carer) and the ability to hold down jobs. The report says very little about the quality of life data examined. During relapse the patient can suffer pain, discomfort and fatigue while carers can also suffer from lack of sleep, timep pressure, and financial costs associated with hospital visits. Have calculations taken into account other costs to the patient and their household which rise if relapses are not prevented (time off work, inability to hold down a job, costs of pain killers and/or hospital visits during relapses), and potential costs to the state, e.g. patients? inability to pay income tax, costs of unemployment and sickness benefit?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	Having seen the condition first hand for more than 10 years I welcome the recommendations for an evidence base, on this as on many other aspects of Crohn?s disease. I particularly welcome the recommendation of obtaining quality of life data. However, it could be extremely damaging for CD sufferers like my partner if the benefits of maintenance therapy ? maintaining remission, effective management of the condition, and associated improvement in quality of life for the patient and carer/household ? are denied while this evidence is being collected.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	05/10/2008 19:46

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The change that I have experienced since starting my humira treatment has been incredible. My studies were regularly disrupted by spells in hospital following fistulas and absesses. Humira has given me hope that I can progress in the career of my choice - regular visits to hospital and time off for operations was a real barrier to this. I have also suffered from considerable pain in my knees from arthritis for many years - this has often restricted my choices in life. Since starting on humira this pain has gone and I am able to walk with out pain. I currently use humira for maintenance treatment and believe that my quality of life would be considerably reduced if this were reduced to treatment only when I became ill. This would mean my life was regularly (>4 times per year) put on hold while I recovered from a severe attack. The thought of returning to such a quality of life is extremely depressing. Further, I am not

	the only person who is impacted by my relapses. My wife also suffers both through worry and through having to take care of me - this is difficult for her with a high pressure, full time job. I am a 23 year old male who was diagnosed with Crohns disease in 1996
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	05/10/2008 18:15

Name	[redacted]
Role	Public
Other role	relative of sufferer
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I understand that my young relatives life has been transformed by the use of infliximab.Instead of continual pain from early childhood she has been leading an active and creative life, and helping other people.
Section 2 (clinical need and practice)	I understand that since treatment with Infliximab was started my young relative has not needed other treatment, or the frequent attention of the medical profession as she had hitherto. She is leading a positive and outgoing life.
Section 3 (The technology)	The costs of Infliximab treatment should be seen in the context of cost of other, less effective treatments, and in the relief of suffering of the patient.
Section 4 (Evidence and interpretation)	4.3.13 sounds as though infliximab could be cut off once patients left adolescence. Surely this is not acceptable.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	Should not all this be carried out before any decision to remove infliximab, or limit its use further?
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	

Date	05/10/2008 17:34

Name	[redacted]
Role	other
Other role	Parent of 6-year-old child with IBD
Location	England
Conflict	no
Notes	I feel most passionately that Infliximab should be used as a long term maintenance therapy - and not just for the treatment of acute episodes of IBD. It has transformed the life of my young son - whose symptoms are now well controlled thanks to this amazing drug. Without his eight-weekly dose of Infliximab our lives would be hell. I cant imagine how NICE could justify such an appalling decision or how the public would stand for it.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I feel most passionately that Infliximab should be used as a long term maintenance therapy - and not just for the treatment of acute episodes of IBD. It has transformed the life of my six-year-old son - whose symptoms have been well controlled thanks to this drug over the past 12 months. He had been taking steroids during long periods over at least two years - and the effects on his mental and physical well being of such prolonged steroid use were pretty awful. Nothing else worked and his IBD seemed to be indestructible - sometimes even the steroids didn?t seem to work. The effect of the Infliximab was dramatic and instant when all else had failed. Over the past year, he has grown, is now progressing well at school and is getting on with the business of being a happy and settled six-year-old. Without his eight-weekly dose of Infliximab the hell of 12 months ago would again be a reality. The terrible pain, the bleeding, weight loss and massive frequency are just too frightening to contemplate ? especially in a six year old. I cant imagine how NICE could justify such an appalling decision or how the public would stand for it.
Section 2 (clinical need and practice)	I feel most passionately that Infliximab should be used as a long term maintenance therapy - and not just for the treatment of acute episodes of IBD. It has transformed the life of my six-year-old son - whose symptoms have been well controlled thanks to this drug over the past 12 months. He had been taking steroids during long periods over at least two years - and the effects on his mental and physical well being of such prolonged steroid use were pretty awful. Nothing else worked and his IBD seemed to be indestructible - sometimes even the steroids didn?t seem to work. The effect of the Infliximab was dramatic and instant when all else had failed. Over the past year, he has grown, is now progressing well at school and is getting on with the business of being a happy and settled six-year-old. Without his eight-weekly dose of Infliximab the hell of 12 months ago would again be a reality. The terrible pain, the bleeding, weight loss and massive frequency are just to frightening to contemplate ? especially in a six year old. I cant imagine how NICE could justify such an appalling decision or how the public would stand for it.

Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	05/10/2008 16:55

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I disagreee that the Committee should recommend episodic treatments. This seems at variance with current practice in may other countires in the EU and worldwide, where maintenance therapy is the norm
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Episodic treatment will increase risk and rate of adverse reactions and failure / inability to tolerate therapy. It will thus reduce the choice of therapy which is already limited. Consideration should have been given to using maintenance therapy for a defined period and withdrawing it after a prolonged relapse free period. You have noted that patients wish to be flare free so why recommend a therapy only when they have a flare. Maintaining people in a flare free state will increase their ability to work and remain productive and hence less of a burden to other organisations/ family / carers bith physically as well as financially.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	You recognise the need for trials of maintenance treatment. Surely it is important then to allow current practice as used in other countries - ie maintenance treatment, until such trials have shown benefit or not of such practice. The current decision will adversely affect a cohort of currently stable

	patients and prevent others reaching that state.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	05/10/2008 16:42

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I have been diagnosedw ith chrons for 15 years and infliximab is the only drug that has any lasting effect on the condition. However to not be able to have it as maintenance is soul destroying as you know you are going to become very ill before the doctors can give you anything to help. This knowledge and cycle impacts on everything from personal relationships to work. Be able to have a maintenance dose would improve my quality of life. I have already chnaged my job as the constant flare did not allow me to continue in my chosen carer.
Section 2 (clinical need and practice)	I have been on other drugs , which have had ill effects or ceased to be effective, 2 years ago I was part of a grug trial, for a drug that wasnt licenced in the end. Tjis made me ver uill, I had 4 months of work and infliximab was the only thing that improved my symptoms.
Section 3 (The technology)	Having already changed careers because of the illness, I feel that the small cost for health and quality of life far outweighs the mental issues fo not beign able to work , being a burden to the state and family and having to rely on benefits. What is the National Health Service for?
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	Are we not already too regimented and regulated, should we not be concentrating on providing a service to people who need it, rather than form filling?
Section 7 (related NICE guidance)	Anyone on the committee suffer from an auto immune disease or are they experts by default?
Section 8 (proposed date of review of guidance)	
Date	05/10/2008 15:23

Name	[redacted]
Role	NHS Professional
Other role	

Location	Wales
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	It will be impossible to give adalimumab as episodic treatment, when injections are usually given at 2 wk intervals. There is no trial data on using the drug in this way, but it is highly likely that antibody formation will reduce efficacy over a period of months, even if concurrent immunomodulators are used. For infliximab, at least half of patients start to develop mild symptoms after 6 or 7 weeks of therapy. These would not give them CDAI over 300, unless the next infusion is delayed for many weeks. Again the efficacy of the drug will be massively reduced by delaying further infusions until proper relapse occurs
Section 2 (clinical need and practice)	In a population-based survey in the city of cardiff, (Aliment Pharm Ther 200727:211) use of infliximab rose from 3% of patients in 1996-2000, to 10% of patients in 2001-2005. (Total no. of new patients 212 during this 10 year period).
Section 3 (The technology)	There are no trials of episodic adalimumab therapy!
Section 4 (Evidence and interpretation)	The health economic analysis is flawed if the ICER is based on maintance treatment versus standard care which includes induction therapy with infliximab or adalimumab. The epidemiological and health economic models dont factor in the effect of induction therapy in the small % of patients with severe disease treated with anti-TNF drugs. Maintenance therapy with both drugs clearly has a ICER of Â£30,000 or less when compared to standard care without induction therapy.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	If this preliminary advice is implemented in full, there will be a huge cohort of patients in the UK on maintenance therapy who are well, who will inevitably relapse over a period of months. Whilst this would provide a unique opportunity for research, it would not be passed by an ethics committee as the evidence for benefit from continuing therapy is so strong
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	04/10/2008 13:45

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	In the 2002 NICE guidance, Infliximab is recommended for use in the treatment of severe active Crohn?s disease (with or without fistulae) where treatment with immunomodulating drugs & corticosteroids has failed or is not tolerated & when surgery is

	inappropriate. Treatment may be repeated if the condition responded to the initial course but relaxed subsequently.(As quoted in the British National Formulary)I am extremely surprised that NICE have now reversed their decision in what appears to be a very perverse and arbitrary manner and it appears, without responsive consultation.This decision appears to have been made without consideration for the patient welfare or duty of care.Â Â
Section 2 (clinical need and practice)	This decision appears to have been made without consideration for the patient welfare or duty of care and must put a large number of Medical Practitioners, including Dr Mee at The Royal Berkshire Hospital, in the unenviable situation, where the disease progression will increase, the patient health and well being will deteriorate raising the risk of severe complications. This situation will inevitably lead to future treatments being more complicated and expensive, thus increasing the cost against that of the current, established and proven management of the disease which will be exceeded in both clinicians input and alternative ineffective preparations that NICE have previously discounted. Their decision appears to be entirely Cost Based, rather than clinically based
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Where treatment of patients with severe active Crohn?s disease, with or without fistulae, is withdrawn but no clear improved or approved regimen is put forward, (as in this case), then patient care will fall below the current medical guidelines as proposed by government.As for my own case, I feel deeply disturbed that the one thing that keeps me going forward and contributes to my quality of life as the level of medication drops and my life becomes more difficult, is, that in a few days or so I will have the opportunity to get my life back together once I have received my treatment.The current treatment regimen also allows me to follow my current occupation which would otherwise be impossible and I would either be unemployed or on Disability Allowance.
Section 5 (implementation)	NICE, it seems, have also failed to recommend an appropriate, effective alternative, which will yield the same level of positive results for the treatment of this seriously debilitating condition.With the above in mind I request that the current regimen be continued until such time that treatment with Infliximab becomes ineffective and my quality of life deteriorates requiring entirely new examination of my case.
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/10/2008 21:24

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	yes
Notes	I have attended advisory boards for both Schering plough and Abbott.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	We have treated 177 IBD patients at Leeds General Infirmary with infliximab, virtually all for Crohns disease and the majority have received maintenance therapy. We presented our outcome data at the BSG last March. In 2005 we established a prospective databse of patients treated with infliximab to include disease duration, distribution of disease, steroid dose, concommitant immunomodulator use and outcomes. At every visit we record the HBI so that we have subjective and objective outcome data. Our strategy has been to discuss biologic use with the patient who is then counselled by Lisa Warren our IBD nurse specialist. Once TB etc has been excluded they receive a 3 dose induction of 5mg/kg. They are then assessed in clinic for response. Those who respond receive 8 weekly maintenance. Those who present wth acute severe Crohns colitis who receive IFX as top down rescue therapy will have 3 dose induction therapy as a bridge to azathioprine and then have maintenace IFX if they then relapse. Those patients who have primary and secondary loss of response are considered for adalimumab. Our trust/PCT have made adalimumab second line for IFX failures/loss of response but we have to apply via email to our PCT for each and every case. My own view is that they are essentially equal in efficacy and the relative merits of each should be discussed with the patient. Our results are attached but I would like to point out a few specifics: According to HBI our response rate is about 85% and remission rates at 6 months of therapy is 46%. This is higher than clinical trial rates but very much in keeping with the Leuven experience. 90% of our patients who embarked on episodic treatment switched to maintenance because of relapses. 75% of out patients either completely discontinued (2/3) or reduced their steroid dose. Initial mean HBI score was 9 ie consistent with severe disease
Section 2 (clinical need and practice)	
Section 3	We are lucky enough to have established an Immune Mediated

(The technology)	Inflammatry Disease (IMID) infusion centre. We have access to this day case unit on Wed and Fri afternoons and infuse about 8-10 patients each afternoon. This facilitates Infliximab vial sharing which according to our own pharmacy figures leads to a cost saving of Â£10 000 per month. In Leeds we have also developed an accelerated infusion protocol. Patients receiving IFX over the first 5 infusions do so over the standard 2hrs. From infusion 6-10 they revceive it over 1 hour and after 10 infusions have it over 30 minutes. This is safe and effective with no increase in infusion reactions and clearly advantageous for patients. This paper has been accepted for publication in Eur J Gastro and Hepatol.
Section 4 (Evidence and interpretation)	In our extensive clinical experience we are in no doubt that carefully selected patients treated with infliximab maintenance therapy do better. This is in maintenance of remission and quality of life. I think with a disease such as Crohns disease it is unreasonable and frankly cruel to wait for clinical disease relapse before administering further therapy. Even a response to therapy in a patient with severe peri-anal fistulising Crohns disease can mean the difference between working and not being able to work and indeed being able to sit comfortably or not. Mike Sprakes, my research fellow, is in the process of looking at cost effectivenesss of treatment. He is analysing all the costs of care of treatment for 12 months pre-infliximab therapy and for every 12 month period post IFX therapy. This is to include costs of blood tests, radiology, all surgeries, hospitalisations etc. We have the full clinical outcome data on 115 of the 177 patients thus far. He has looked at 25 /177 in terms of full cost-effectivess so clearly this data is incomplete but he hopes to have it ready for the BSG deadline at the start of Nov.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/10/2008 21:16

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I have had Crohns for more than 19 years. I have, at some time, tried every available treatment. I have had surgery 5 times. Infliximab is the only treatment that keeps me well. Since

	I started regular treatment, I have put on weight, met and married my wife, taken on a mortgage, had a child and found a good job for a small firm. In the days before Infliximab I was single, underweight and forced to work at large companies who could (generally) deal with repeated absence through ill health. I was unable to go out anywhere with no toilet. I suffered from depression and saw councillors and physychiatrists (at NHS expense). I cannot emphasise enough or express succintly in words the enormity of the difference this drug made to the quality of my life. If my current regimen of maintenance treatment is taken away from me, I will become ill. I will be forced to change job, my family and social life will become severely curtailed as I become more and more ill until I am considered worthy of treatment each time. Each episode of ill health puts great emotional and financial strain on those close to me. You severly underestimate the impact on day to day life.
Section 2 (clinical need and practice)	2.6 states that successful treatment focuses on inducing and maintaining clinical remission. From experience, without maintenance doses of Infliximab, I do not stay in remission. Therefore, removing my regular infusions is, by definition, not succesful treatment. Surely I have the right to receive a known and available successful treatment? What cost do you place on my ill health?
Section 3 (The technology)	3.2 Personally, I have never experienced any adverse events, only a massive increase in the quality of my life. I cannot say either of these statements is true for any of the other treatments I have tried over the 19 years since I was diagnosed.
Section 4 (Evidence and interpretation)	I have had Infliximab treatment for seven years, initially on an episodic basis and, more recently, on a maintenance basis. I know from 19 years of Crohns that, without this treatment, I will become ill. If NICE consider the only cost effective option is standard care, then I will become and remain ill, until my condition warrants further surgery. How does your analysis account for quality of life? What will the cost of my future operations (I had 5 prior to the advent of Infliximab) and aftercare (both phyical and physcological) be by comparison?
Section 5 (implementation)	No comments
Section 6 (proposed recommendations for further research)	It seems logical that this should be done but it must include patients on a voluntary basis where treatment is to be changed, reduced or stopped. Point 6.5 is a huge, huge area of importance to which you can place no monetary value. People who suffer regular flare-ups which do not respond to other treatments MUST be allowed to have the only drug that can keep them well. I was once asked whether I considered myself to be a well person who was sometimes ill, or an ill person who was sometimes well. Without infliximab, I revert to the latter.
Section 7 (related NICE guidance)	No comments
Section 8 (proposed date of review of guidance)	No comments
Date	03/10/2008 19:15

Name	[redacted]
Role	NHS Professional
Other role	Chair, BSG IBD committee
Location	England
Conflict	no
Notes	I have been on advisory boards of Shering Plough and Abbott Laboratories
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	See comments in section 4. In my opinion this will result in a significant number of patients with Crohns disease being denied a clinically effective treatment with detriimental effects to their quality of life. While it may be reasonable to limit the use of maintenance Infliximab or Adalimumab, there should be provision for a small numer of sick patients who frequently relapse on standard therapy to be given maintenance treament with these agents
Section 2 (clinical need and practice)	Rubin et al (APT 2000) calculate a prevalence of 145/100,000 in the UK, giving about 87,000 affected people in the UK. They report about 30% of patients under regular hospital follow up.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	There are major problems with the committees interpretation of the data on maintenance treatment. The appraisal relied considerably on the health economic assessment of the Silverstein cohort. This paper was published in 1999 and relates to a population with Crohns disease of mild severity in Rochester county, minnesota. Costs of treatment of this population will be very much less than the true comparator population (either that with moderate to severe Crohns disease, or the population treated with induction therapy and then relapsing- depending on the comparator group used). There is very little data on costs of follow up of patients in the UK already treated with anti-TNF antibodies. The data in ACCENT 1, imperfect though it is in terms of long term follow up, shows substantial benefits in terms of hospitalisation and surgeries in the maintenance group. One major problem is the lack of stratification into subgroups including those with difficult or refractory disease, which is precisely the group targeted for maintenance treatment by most UK experts
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	I agree with these recommendations but they are not very helpful regarding teh current usage. One solution would be to amend the committees recommendation to allow maintenance therapy in a subset of severe patients likely to relapse after episodic therapy.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/10/2008 18:23

Name	[redacted]

Role	other
Other role	Parent / carer
Location	England
Conflict	no
Notes	Letter being emailed today with comment that does not fit on this form
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The preliminary recommendations I believe are flawed for the reasons set out in the letter emailed to you today.
Section 2 (clinical need and practice)	The preliminary recommendations I believe are flawed for the reasons set out in the letter emailed to you today because they do not take account of the clinical need and practice as set out in this section and if confirmed would result in the antithesis of the actual clinical need.
Section 3 (The technology)	This seems to suggest treatment with Infliximab on a regular basis at set periods. This is not how it has been used by my son who has been having treatment when needed because he has found his condition has deteriorated to a point where his quality of life and ability to work effectively is impaired. In practice this has been about every 12 weeks to date. This seems to me a better approach rather than simply having treatment every 8 weeks if there has been no deterioration at that stage. However, my son?s present use is clearly very different to waiting until symptoms are as severe as you are intending.
Section 4 (Evidence and interpretation)	Much of the analysis here is technical and as a layman I cannot tell how meaningful the assessment is or whether a proper analysis has been carried out. For a public consultation document I think this is inappropriate. The impression I am left with from reading this section is that there is no definite conclusion to be drawn from the evidence reviewed. In this case to withdraw treatment as is proposed in the preliminary recommendations would seem to be inappropriate.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	In view of statements made at section 4, where it seems to be admitted that the information presently available is incomplete, it would seem to me the further studies suggested should be carried out before the possibility of maintenance treatment being withdrawn is considered.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/10/2008 17:02

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	

Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	i believe that either infliximab or adalimumab should be made available for regualr maintenance. I have suffered with Crohns for 7 years and have had both treatments. If i was given them regularly i might not have gone through the pain, stress and discomfort i have experienced. I have had numerous relapses where i have felt unwell for a period of time. If i had had regular treatment then 1. i might not have been unwell for so long 2. i might have felt well for longer 3. i might have avoided some other procedures that i have had to go through
Section 2 (clinical need and practice)	
Section 3 (The technology)	if a treatment is right and suitable for a person then i dont think they should be denied it especially if it means that Crohns is kept at bay
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/10/2008 16:37

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	Have had 3 infusions of infliximab to treat Crohns Disease over the last 5 years at intervals of 2-3 years.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (clinical need and practice)	
Section 3 (The technology)	When given infliximab I have one dose, with no additional treatment until symptoms returned, on each occasion (Ive had it three times) the symptoms would take 2-3 years to return and then one further dose is given.
Section 4 (Evidence and interpretation)	Each dose for me will keep me symptom free and able to lead a normal active life, one dose every 2-3 years in my case is extremely cost effective and means I do not have to claim any benefit as am fit and able to work.

Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/10/2008 16:13

Name	[redacted]
Role	other
Other role	Partner to Patient
Location	England
Conflict	no
Notes	I have had a look at this item before but this is the first time I have left feedback
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I think that stopping maintainance treatment of those who have suffered from severe sympoms of Crohns, fistulating or otherwise, especially those who have a history of other medicines being unsuccessful is exceptionally unwise if not inhumane. I wonder if the committe have taken into account the total cost of standard treatments. I refer to more frequent hospital consultations, also an increased need for exploratory tests and investigations - such as colonoscopy, endoscopy, MRI scans and CT scans and such like, the cost of trying lesser medications - to little or no effect, the potential costs of counselling/therapies (coping with a long-term illness is not easy), and eventually the cost of surgery. This is before we count the cost to the Quality of life for these sufferers. My own parter has suffered since she was less than ten years old, she is now 29 and in all those years only the last three or four have been with good health and that is thanks to infliximab.
Section 2 (clinical need and practice)	This section of Clinical need and practice is accurate as far as my own knowledge of the disease goes. However it does not in anyway take into account the effect it has on the quality of life for sufferers. This is a lot higher than most non-sufferers realise many sufferers that I have met talk about the stigma attached to not being able to work or partake in other things because you have
Section 3 (The technology)	As far as my knowledge goes this section on Technologies is accuate.
Section 4 (Evidence and interpretation)	Firstly, Id like to congratulate the writer of this section on producing a body of text that uses, acronyms, abbreviations and statistical jargon to corroborate the desires of bean-counting holders of purse strings. The term QALY is freely used without being clarified or expanded upon, yet they are used in conjunction with Incremental Cost-Effectiveness Ratios (ICERs) to batter the reader into submission. I suppose I should be greatful that the abreviation ICER was expanded upon, that way I can rest assured that my TLA tally and MFA count tie in nicely

	together. In para 4.3.10 the committee decided that if the amount of relapses that the drugs prevented increased then it would become less cost effective How can this possibly be? If the cost of treatment is Â£12,584 per annum and that would prevent say two relapses then the cost of preventing each relaps is Â£6,292. If the sufferer would have had four relapses in that same year then the cost of preventing each of those relapes would have been Â£3146. The more relapses the treatment prevents, the MORE cost effective that treatment becomes not less.
Section 5 (implementation)	I recommend that the NICE committee think carefully about taking away the use of these drugs as maintainence treatment or in fact any treatment. I think they should also consider that in Europe the use of these drugs is now almost standard practice and their use is increasing.
Section 6 (proposed recommendations for further research)	More research is definately required before ANY action to change current practices takes place. The total holistic cost should be taken into account, including the cost of sickness benefits, housing benefits, the cost to business because employees have more time off work, etc.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	The date of September 2011 is fair enough.. but NOTHING should be changed until a full and dedicated study has been carried out.
Date	03/10/2008 15:09

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I cannot stress highly enough how infliximab has changed my life. I was very ill in March with fistulising Crohns disease and as a result of this treatment am now 100% fit and healthy, and on minimum medication, which I hope to be free of entirely by 2009. It is nothing short of miraculous as the alternative for me would have been a stoma which ultimately would have been more expensive, not to mention affecting my quality of life and personal happiness.
Section 2 (clinical need and practice)	The John Radcliffe hospital treated me in 1993 for severe Crohns disease, I had an ileostomy for 18 months while my perianal Crohns disease healed up. If infliximab wasnt available to me, I would now be waiting for expensive surgery and a change in the way that i live my life. When it flared up in February I was offered infliximab, have made a full recovery in weeks and am now training for the London marathon. I implore you not to withdraw this treatment as it is a lifeline for sufferers like me.
Section 3 (The technology)	

Section 4 (Evidence and interpretation)	As a patient who has had complex fistulising Crohns disease, I believe that there is no other cost effective treatment available, and without it I would be severely dehabilitated, before treatment I could not walk, work, or even sit down without being in pain. Recovery after the infusion was within weeks, and surgery free.
Section 5 (implementation)	I accept that I am passionate about this issue due to the nature of my disease. It should also be considered that the waiting area in the Crohns disease clinic at the John Radcliffe hospital often looks like a waiting area at Gatwick airport. These consultants are working with very little thanks or recognition for their dedication. To remove this treatment from their grasp when, in my opinion, it is nothing short of a miraculous cure for patients like me, is not cost effective or humane.
Section 6 (proposed recommendations for further research)	I agree that research should continue. I was on the research programme for several years after the reversal of my ileostomy and would be happy to do so again. If I had had repeat surgery for my condition, it should be noted that it would probably be several years before the fistulae healed up properly, and I would still be taking up time and money in hospital being monitered. As I am today, I am completely cured and am having a healthy and active life again.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/10/2008 10:20

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am writing to inform you that I would strongly be against any decision for NICE to remove the availability of regular NHS adalimumab treatment for Crohns patients.
Section 2 (clinical need and practice)	To give you some background I am a 38 year old lady (non-smoker), married, with one son who is 10 years old. I am very fortunate to be under the excellent care of the Gastroenterology team at the John Radcliffe Hospital Oxford, who I must add have provided me with the best possible medical treatment I could ask for. I was diagnosed with Crohns disease at the Christmas of 2001 following an emergency laparotomy. After which time I was prescribed Pentasa (Mesalazine) in tablet form, then to help with the absorption of the drug I changed from the tablet form to granules. Unfortunately the Pentasa failed to keep the Crohns disease at bay, I changed to azathioprine and I also required steroid

	treatment (budesonide), regrettably this did not work and I required my 2nd bowel resection in January 2006. I had a tough time with this surgery, a couple of days after I needed to receive an emergency blood transfusion. This was a very worrying time for my family. Although the surgery was successful, I continued on the azathioprine but the disease was active again late in 2006 and I required my 3rd bowel resection in April 2007.
Section 3 (The technology)	At the end of 2007/beginning of 2008 my condition was giving cause for concern and I had an colonoscopy carried out where thankfully this time they found no narrowing of the bowel as yet, but detected some crohns ulcers again, therefore previous treatments were not working so I started the infliximab treatment, unfortunately I experienced a number of side effects to this drug (severe joint and muscle pain in knees and legs, rash and itch skin) and was transferred on to adalimumab, to date I have had no problems with this drug. Also to add complications to my condition, I am a patient who unfortunately the normal CRP Ã¢??inflammationÃ¢?? triggers are not conclusive as mine in general the maintain the same level, therefore the only true diagnosis is through a colonoscopy examination.
Section 4 (Evidence and interpretation)	Removal of my access to regular adalimumab treatment would cause me: Ã¢?Â¢ Almost certainly daily discomfort, I am finally able to lead a life free from abdominal distension, at severe times causing me to be vomit. If you have ever experienced this you will know how painful this can be. Ã¢?Â¢ I would also be at risk to an increased amount of Crohns ulcers at the site of my small bowel, which would lead to further narrowing of the bowel, thus the need for further bowel resection surgery. Surely the costs associated with this surgery and the subsequent weeks of hospital care would out way the costs of the use of adalimumab? Ã¢?Â¢ Having access to probably the best colorectal surgeon in the UK (Professor Neil Mortensen), having already had 3 bowel resections (Dec 2001, Jan 2006 & April 2007), any type of surgery poses risks, a risk I do not wish to take lightly. Certainly for me further surgeries would also run the risk of a colostomy bag Ã¢?? I cannot even contemplate my life with this. Continued..
Section 5 (implementation)	Although I have a supportive employer, BMW (UK) Manufacturing Ltd, this tolerance will not continue. I have already exhausted the majority of my company sickpay, further absence will cause me & my family financial hardship, in the current financial climate putting my mortgage payments at risk. Prior to receiving the adalimumab treatment I was off work for

	170 days (34 weeks) in 2006, 267 days (28 weeks) in 2007. What company could possible sustain an employee being absent for work for this amount of time? Since starting the adalimumab treatment on 6 March 2008 I have only been absent from work for 10 days this was as a result of kidney stones. When I was admitted as an emergency on 24 August 2008, the initial diagnosis was a stricture or perforation to the bowel, thankfully due to the success of my adalimumab treatment it was only kidney stones. During 2006 & 2007 had to put my career on hold, I was a HR Manager but due to my condition at the time I felt I wasnt able to fulfil that role. I am now starting to rebuild my career again & have just accepted a HR Specialist position. Removing me from the adalimumab treatment would have a detrimental affect on my health.
Section 6 (proposed recommendations for further research)	I would ask that you please think long and hard about the decision you are about to make, Adalimumab is working for me. I appreciate the position you are in but please do not remove something, that since my diagnosis in 2001 is really working for me, that is just not fair. My husband and I have both been full NHS and taxpayers for 22 years. I also believe that removing adalimumab access for Crohns patients will be a step backwards in the relief of the symptoms of this chronic illness.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/10/2008 09:37

Name	[redacted]
Role	other
Other role	Parent
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Ref.1.6. My daughter currently has Infliximab infused every 8 weeks. On this regime she remains well. Her Consultant has periodically tried to extend her treatment but this has never been successful. My daughter, Kayleigh, has had Crohns disease since the age of 7, she is now almost 21. She is currently a 3rd year student at Trinity College Cambridge studying Natural Sciences Tripod(NST). Had she not had Infliximab over the last 3 years Crohns disease would have prevented her from getting there. Over the years she has had this disease she has been treated by continual maintenance drugs of Mesalazine and Azathioprine and courses of steroids. Then for months on end she would go on a polymeric diet (the first time at 9 years old). During this time she had 2 major operations. Five years ago she was introduced to Infliximab and received infusions for one year. She then enjoyed a full year of remission. However, she relapsed in her A level year and was

	put back onto Infliximab, which she has been on since. It is unimaginable Kayleigh being denied Infliximab at this critical stage of her career. Please, please, reconsider.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/10/2008 09:06

Name	[redacted]
Role	NHS Professional
Other role	Clinical Senior Lecturer in Gastroenterology
Location	England
Conflict	no
Notes	I am on the advisory board of several pharmaceutical companies including Schering Plough, Abbott Pharmaceuticals and Shire. In addition to receiving honoraria for attending these meetings, I have received expenses to attend and speak at national and international conferences from these companies. I have received unrestricted educational grants for service development within our NHS trust from Schering Plough and Abbott. I have also been awarded a research grant for an investigator led basic science research project from Schering Plough
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am a consultant gastroenterologist with a specialist interest in IBD Ã¢?? specifically adolescent CrohnÃ¢??s disease, and run a large adolescent clinic at Barts and the London NHS Trust. I am also a clinical senior lecturer and have been involved in many of the clinical trials of biological therapies. I am absolutely amazed at the ACD published recently for Infliximab and Adalimumab in CrohnÃ¢??s disease and struck by selective use of data, the inappropriate comparator in the cost analysis and the inequity between diseases that will inevitably occur if these recommendations are ratified. Our primary role as physicians is to improve the quality of life of

	patients and to do no harm: There is clear evidence from multiple well conducted investigator led clinical trials that scheduled maintenance infliximab is more effective (when looking at hard endpoints such as avoiding surgery and mucosal healing) and less harmful (in terms of avoiding infusion reactions, preventing hospitalisations) than episodic therapy.
Section 2 (clinical need and practice)	The data presented does not take into account that there is a small minority of patients with an incredibly poor prognosis in whom the risk of surgery hospitalisation and disability is almost 100% - those who present with disease young, have extensive small bowel disease, require steroids at diagnosis and have bad perianal disease. The introduction of infliximab and subsequently Adalimumab has revolutionalised the lives of these patients who were previously condemned to multiple hospitalisations and surgeries at a pivotal time in their development. With maintenance therapy they are able to progress normally through puberty, take A levels attend university free from symptoms. I would NOT advocate use of infliximab in the vast majority of patients at any age. However, the minority of patients with clear evidence of refractory disease and poor prognostic features who require this therapy deserve to be given it using the strategy that is most effective and with the least risk. The absolute numbers here are minute compared to Rheumatoid arthritis. We have one of the largest IBD practices in the UK: of about 1000 patients with CrohnÃ¢??s, just 36 are currently on maintenance IFX, and 13 on regular ADA (ie approx 5%).
Section 3 (The technology)	It is important to consider that most units vial share to reduce infliximab costs
Section 4 (Evidence and interpretation)	The practical implications of the recommendations would be that these patients would have to come for regular review to assess disease activity after induction therapy Ã¢?? waiting until they relapsed. Given that we know that episodic therapy allows more disease progression such as stricture formation, they would then require a further colonoscopy / biopsy or xray examination to exclude alternative causes for their symptoms before having another episodic treatment. These additional costs / risks are not included in your analysis. The extra lymphoma risk from the additional CT scans / barium studies would be significant in a population that has been shown to already be at high risk from iatrogenic radiation exposure. Your economic analysis is based upon out dated epidemiological data that vastly underestimates the disease burden of this patient group. The relapse rate will be far higher than estimated, and the costs of reinvestigating and managing the symptomatic flares associated with episodic therapy are not included.
Section 5 (implementation)	We should not expose patient to unnecessary risk, thus our current practice is to stop concomitant immunosuppression after 6 months of biological therapy to reduce the risks associated with dual immuosupression. If we were to use episodic therapy, we would be mandated to continue

	immunosuppression with thiopurine therapy or methotrexate alongside episodic infusions of infliximab / Adalimumab. There is clear evidence that this strategy results in a significant increase in opportunistic infections and has recently been associated with 15 cases of an invariably fatal hepatosplenic T cell lymphoma. Current NICE guidance allows the use of maintenance infliximab for athritides for the reason that (as in CrohnÃ¢??s disease) it has been shown to improve outcome compared to episodic therapy Ã¢?? why should our patients be disadvantaged? How will we treat the not insignificant number of our patients who have IBD related arthropathy AND CrohnÃ¢??s disease? Will they be allowed maintenance therapy whilst their peers in the same infusion unit have to have progressive disease before being allowed another infusion. We would not only have a postcode lottery (compared to the rest of the world where scheduled therapy is standard) we would have a disease lottery for the same drugs.
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/10/2008 08:52

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	Consultant Gastroenterologist DGH
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe the evidence is there to support using these agents on a maintenance basis and certainly this is my clinical experience and the wish of my patients who have responded to infliximab. By definition they have failed
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	

Section 8 (proposed date of review of guidance)	
Date	02/10/2008 23:34

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I currently have maintenance treatment for Crohns although I would describe it as Quality of Life treatment and am deeply concerned that the availability of infliximab is potentially to change to wait until you relapse treatment As a patient who had to stop eating for nearly a year and weighed less than 7.5 stone I cant begin to explain the difference the drug has made to my life. The cost to the NHS prior to treatment of regular hospital admissions, monthly supply of substitute food source, pumps and accessories has to be a consideration rather than the cost alone of providing the drug. Nearing my infusions I experience tiredness and sometimes stomach cramps and to adopt anything but a preventative approach would in my opinion be counterproductive and in certain cases arguably reckless. Whilst I appreciate the necessity to scrutinise & justify costs the recognition of a childs environment and social interaction being adversely affected should not surely not be separated from that of an adults. Having read the trials I also find the evidence in areas quite weak and worry when estimations of outcomes are given on small populations rather than relying on hard evidence of larger ones
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	02/10/2008 23:11

Name	[redacted]
Role	other

Other role	Uncle of a Crohns sufferer
Location	England
Conflict	no
Notes	I have witnessed the development of the disease in my neice since 1982, when she was 3years old.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	What does a Consultant do then when every other medication has failed to induce or maintain clinical remission ? Especially when the use, over a significant period of time, of corticosteroids has resulted in the iatrogenic onset of osteoporosis ?
Section 2 (clinical need and practice)	Of all the treatments listed in 2.7 only the TNF alpha inhibitors are effective in prolonging remission following two resections of the small bowel.
Section 3 (The technology)	My niece has responded to Infliximab and it is being administered as a maintenance treatment to good effect. It has improved, and maintains, her quality of life. When, from time to time, antibodies develop then Adalimubab is administered for a short period before a return to Infliximab.
Section 4 (Evidence and interpretation)	It would appear from the trials that in many instances the Infliximab groups had statistically significant improvements in CDAI.
Section 5 (implementation)	I fail to see how you could ignore the fact that there are going to be exceptional cases in which the possibilities in further surgery have come to an end and the only treatments to control manifestations of Crohns disease and reduce symptoms and maintain any quality of life are TNF alpha drugs. Consideration must be given to exceptional cases.
Section 6 (proposed recommendations for further research)	These recommendations appear to be very sound. The research is urgently required.
Section 7 (related NICE guidance)	This guidance should be retained.
Section 8 (proposed date of review of guidance)	No comment.
Date	02/10/2008 21:29

Name	[redacted]
Role	Carer
Other role	Crohns sufferer (currently in remission)
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary	I write as a parent and carer of a young CrohnÃ¢??s patient to express my extreme concern about changes to policy on

recommendations)	regular Infliximab and Adalimumab. My daughter was diagnosed with CrohnÃ¢??s at the age of 16. She has been described as a Ã¢??challengingÃ¢?? case. She has not responded to conventional treatments Ã¢?? steroids, immuno-modulators , mesalazine . She initially responded to Infliximab used in conjunction with azathioprine. She relapsed within 12 weeks. Infliximab was reintroduced and she failed to respond, developing antibodies. Conventional therapies were not able to allow my daughter to have anything resembling a normal life - at school whilst studying for A levels she managed to attend barely half her classes, spending much of her life curled up in pain. Supporting her in this condition is a significant demand on all other family members.
Section 2 (clinical need and practice)	Self administered Adalimumab has been prescribed and the improvement in her health and quality of life has been significant. This has enabled her to take her A levels and she has just gone to University.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	As a sufferer of CrohnÃ¢??s myself (currently in remission) I am aware of the impact and debilitating effect that the disease can have on oneÃ¢??s life, and the lives of oneÃ¢??s immediate family. If Adalimumab is only available when symptoms are severe this will have an appalling impact on the quality of life for my daughter and potentially affect her ability to complete her education and ultimately establish a career and an independent life. For patients like my daughter who have failed to respond to conventional treatments for this disease this drug is the only option available. If she is deprived of this medication then it is hard to see how she can complete her education and establish an independent life. Cost effectiveness needs to be measured also against potential losses by virue of the patient being unable to contribute to the economy - the annual cost of the drug does not seem great set against this potential loss.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	02/10/2008 19:51

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	

Section 1 (Appraisal Committee's preliminary recommendations)	I am just nineteen and was diagnosed with CrohnÃ¢??s disease shortly after my 16 th birthday. The past three years of school have been marred by diarrhoea, severe debilitating pain, nausea, malaise and at times joint pains in my knees and hands, which have prevented me from walking and writing without pain. These horrible symptoms have meant that my activities have been severely restricted & I have been absent from school for more than 50% of sixth form. My CrohnÃ¢??s disease has been described as Ã¢??challengingÃ¢?? by both consultants I have seen. It is distributed throughout the gut - surgery is not a viable option. Conventional therapies have not worked Ã¢?? these include : Mesalazine and Azathiaprine & I experienced an adverse reaction to steroids an elemental diet had a minor impact. Infliximab after 5 treatments resulted in some relief Ã¢?? this was withdrawn and I was left on immuno-modulators and relapsed within three months. On resuming Infliximab I developed antibodies. I felt utterly miserable at a time when others were energised and excited about their future and all I had to look forward to was pain, nausea and diarrhoea every day and no prospect of a future. Self administered treatment with Adalimumab removed the pain, nausea and joint pains in my hands and knees Ã¢?? it has changed my life and given me hope of a relatively normal life and a future career.
Section 2 (clinical need and practice)	I am horrified at the prospect of Adalimumab only being offered if I am severely ill. Infliximab was withdrawn following 5 treatments and I relapsed even though I was on Azathaprine. Treatment was resumed after three months but antibodies had developed and it was ineffective. If this were to occur with Adalimumab where does this leave me? I am nineteen, and potentially in a desperate situation, having just started University. Adalimumab surely has to be cost effective as it does not involve hospital space and staff , keeps me out of hospital and has tobe measured against someone who is potentially a high contributor to the economy of the country. Adalimumab is the only therapy which has offered relief of my symptoms Ã¢?? surely Maintenance therapy is cost effective in such circumstances as well as being humane response.
Section 3 (The technology)	The cost effectiveness of Adalimumab in terms of being self administered and therefore not using hospital resources seems evident.
Section 4 (Evidence and interpretation)	The quality of my life since taking Adalimumab on a regular basis has improved immeasurably. Whilst I still have tiredness and some diarrhoea I can, and am, for the first time in three years, leading a normal life. Episodic treatment on Infliximab proved ineffective Ã¢?? I imagine that this could be the case if treatment with Adalimumab was withdrawn from me and only offered if I become severely ill. At 19 this is a horrendous prospect to contemplate.
Section 5 (implementation)	
Section 6 (proposed	The proposed recommendations of further research on Infliximab and Adalimumab seem appropriate.

recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	02/10/2008 19:37

Name	[redacted]
Role	Patient
Other role	Also mother of a patient
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	My views are from the perspective of a CrohnÃ¢??s patient with a daughter who is also a CrohnÃ¢??s patient. I am only too well aware of the severe pain and debilitation that CrohnÃ¢??s causes not only to the patient, but also their families. Regular maintenance treatment has been the only successful treatment that has enabled my daughter to regain her life. The maintenance programme was not entered into lightly, but it is the only option for her as the alternatives have either proved ineffective or produced more severe complications. In the 2 years prior to commencing this programme she was in hospital for a total of more than 15 weeks, was unable to work lengthy periods and therefore had to apply for benefits. Infliximab was tried, initially as an episodic treatment, but the very nature of the disease and the rapid downhill spiral meant that each episode required hospitalisation, and this was recurring every three months. (Continued below)
Section 2 (clinical need and practice)	As a Crohns patient who has had surgery which has led to other complications and yet more surgery, it is not something that I would wish for my daughter. Fortunately, she has avoided surgery so far and this is only due to the infliximab maintenance programme. Withdrawing regular maintenance treatment would not be cost effective for anyone, and it would also condemn my daughter to a life of continued pain, without hope, without a career and with a very bleak and possibly short future. I strongly urge the Committee to reconsider withdrawing funding for the maintenance programme. For my daughter, it would turn her back into an ill person who is occasionally well rather than a well person who is occasionally ill.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for	

further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	02/10/2008 18:25

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no data that states that pts will benifit from episodic doses. Patients are more likely to relapse and get worse, it will ruin patients lives, especially when they are already dealing with a life long debilitating disease. Patients who are having regular infussions are able to live their lives be in employment.Remain out of hospital, and know that if their disease is showing signs of relapsing then the next infussion can be administed according to their clinical need.
Section 2 (clinical need and practice)	All the clinicians I have ever worked with, would always ensure that each patients needs are assessed prior to commencing a new therapy. All possible side effects are discussed and the patient is involved in the decision making process.Therapies which have been used for many years will be used in the first instance before looking at new drugs.
Section 3 (The technology)	There are patients who have previously been controlled on 5ASAs and immuno-suppressive medication. Now we are dealing with diease which needs more intensive therapy, i am not implying that just because a drug is available it should be used. Every patient is assessed on their clinical need .
Section 4 (Evidence and interpretation)	There are patients whose lives are affected by Crohns disease but do not have fistulating disease, these patients are being denied medication enabling them to a good quality of life.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	02/10/2008 17:26

Name	[redacted]
Role	other
Other role	Father of patient
Location	England

Conflict	no
Notes	No
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	As referred to in 1.3 above, the decision to use infliximab or adalimumab for particular Crohns sufferers should be made by the healthcare professional responsible for the care and treatment of the patient involved, in cosultation with the patient and carers.This decision will necessarily include the use of the two drugs in question for regular maintenance, in order to prevent the re-occurrence of the associated painful and distressing symptoms linked to Crohns disease.
Section 2 (clinical need and practice)	My daughter has had the disease since the age of 8 years and has undergone the whole gamut of treatments ,including the administering of steroids and stricture-removal surgery. Regrettably, surgery included the removal of the part of the upper intestine which processes Vitamin B12, which has necessitated the use of injections and oral supplements to make up for the deficiency.The prolonged use of steroids has had the effect, in my daughter, of bringing the onset of osteomylitis.The drug, infliximab, has given her remission from the hitherto distressing symptoms and has enabled her to enjoy, maybe for an unquantifiable period, a quality of life unknown to her during her childhood, teens and earlier twenties.
Section 3 (The technology)	Revealed in the financial data is the relative annual costs, (infliximab Ã‚Â£12,584,as opposed to Ã‚Â£9,295 for adalimumab). Maintenance use of infliximab, as is currently the case with the treatment of my daughter, appears to settle on 8-week intervals between infusions, which is much less disruptive of of her life and time than the more frequent administration of adalimumab. The cost of the use of infliximab has to balanced against the cost of alternative treatment regimes, including likely surgery for stricture- removal, frequent reliance on the time of consultants, clinics, GPS and specially- trained Crohns nurses. The plight of the healthcare staff involved with treating the disease must also be a consideration, if the option of prescribing infliximab were to be withdrawn. Imagine being a consultant, faced with a Crohns patient, having to inform them that the treatment locker is bare and that nothing effective can be offered for their condition. The net effect of that must be a future flight of consultants from that particular field of medicine.It would otherwise be a too-distressing branch of their profession.
Section 4 (Evidence and interpretation)	From the foegoing there appears to be no doubt regarding the effectiveness in the treatment of Crohns disease using infliximab infusions in maintenance programmes.The consideration of using episodic infusions of infliximab and then picking up the patient when a relapse occurs with the disease, appears to be less than compassionate. The views of patient- sufferers with the disease must carry a weighting to set against that of cost-reducing political direction. Additionally, on a less emotionally-driven level, clinicalspecialists have expressed their concern that episodic treatment of Crohns could lead to the development of anti-

	bodies to the drug,infliximab,with loss of effectiveness. This would lead to a clinical dead end.
Section 5 (implementation)	NICE has an unenviable task in advising on the cost effectiveness of drugs and treatments, bearing in mind the improvements in the means of combatting disease and associated suffering. It occurs to me that ultimately, whereas clinical specialists are desperate that drugs and treatments, developed for patient care, should be made available for those unfortunate enough to have contracted Crohns disease, the decision will be based on political grounds.
Section 6 (proposed recommendations for further research)	Recommendations for further research are important and essential, but the needs of contemporary sufferers must be met today.The most important clause in those itemised above is 6.5, the health-related quality of life considerations.T
Section 7 (related NICE guidance)	The technology appraisal is, of course, important and has to be on-going but the needs of patients, the end users, must always be ultimately paramount.
Section 8 (proposed date of review of guidance)	The date for review of the technology does seem to be distant, particularly if a decision has been taken to reduce the use of Crohns relieving drugs.
Date	02/10/2008 16:37

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	patients who are already on maintainence infliximab how can a clinician justify stopping the treatment? patients who recieve episodic treatment only are at an increased risk of developing antibody formation and reduced response between treatments.
Section 2 (clinical need and practice)	usually patients who require Anti TNF treatment have gone through 5ASA, steroids, immunomodulating drugs and are desparate for treatment to bring their symptoms under control so that they can carry out their normal day to day activities. The need for anti TNF should be based on clinical need of each individual patient by experienced clinical practitioners. Patients do not want to risk stopping the treatment when they are stable to risk a relapse which could take months to induce remission, patients do not want to be reminded of how bad their symptoms were before anti TNF therapy.
Section 3 (The technology)	expensive drugs! measures should be identified to reduce costs such as vial sharing, designated areas to give multiple infusions. Could Remicade look at having smaller vials to reduce the wastage. Patients do not have to take time off work/college etc with Adalimumab thus is economically more appealing to some
Section 4 (Evidence and	from a quality of life perspective patients report the treatment as lifechanging. It enables them to conduct their day to day

interpretation)	activities without having pain, lethargy, diarrhoea etc. They report less time off sick which economically more viable to them.Relationships eg personal and working, have improved
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	agree with the above
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	02/10/2008 16:09

Name	[redacted]
Role	Patient
Other role	Health Professional within the NHS
Location	England
Conflict	no
Notes	None
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Re 1.6 I have had Crohns disease for just over 5yrs. In the early stages of my disease I was prescribed standard treatments which included Mesalazine, Steriods including Budesonide, and Azathioprine. With the exception of higher dose steriods all have had little effect and the crohns disease marched relentlessly on. In recent years I have managed on Mercaptopurine with Infliximab when required. Varying doses of Mercaptopurine have been tried but side effects have prevented the ability to maintain higher doses. Following infliximab infusions I returned to almost my pre crohns state. In the last yr the disease has relapsed, once again making me feel desperately ill, and requiring several outpatient attendances, investigations and infliximab infusions. I have now started regular infusions with positive effect so far. I cannot rely on steriods as maintenance because I now have another condition which prevents this treatment option. It has been said its likely the steriods caused this condition. So far I have never had surgery, somehow maintained a full time job and am a single parent supporting a child through university.I fully contribute to society and want this to continue.
Section 2 (clinical need and practice)	From a patients perspective Crohns disease is a non curable, debilitating, distressing, embarrassing, sometimes very socially isolating disease. It results in sometimes huge perscription costs as crohns is not an exempt condition. It has a major effect on employment and employability.
Section 3 (The technology)	Re point 3.6, surely the cost of major abdominal surgery and prolonged post op inpatient care on already very sick patients would exceed the cost of maintenance therapy with Infliximab. Add to this the cost of not working and having to rely financially on the state for oneself and dependants. Currently I pay my own prescription costs but if I lost my job through ill health I

	would be reliant on the statutory authorities. I also carry out a degree of caring for elderly parents, which is only likely to increase but if I couldnt be maintained in the degree of health which I am now this would probably fall on statutory authorities or others. I feel Infliximab does not just give one an extra few months of life, as some other disputed high profile therapies for other conditions, but as shown by my previous comments, it has taken me from feeling so desperately ill and basically in a state where I didnt really care if I lived or died but just wanting the pain and constant distressing circumstances to stop, back to a full, active life. I would ask the committee to reconsider their recommendation and to allow maintenance therapy with infliximab for adults to prevent relapse of Crohns.
Section 4 (Evidence and interpretation)	See previous comments
Section 5 (implementation)	No comment
Section 6 (proposed recommendations for further research)	I would ask the committee to reconsider its recommendation and allow maintenance therapy to continue whilst persuing the research mentioned in points 6.1 - 6.7 above.
Section 7 (related NICE guidance)	See all previous comments.
Section 8 (proposed date of review of guidance)	See all previous comments.
Date	02/10/2008 13:49

Name	[redacted]
Role	Public
Other role	
Location	England
Conflict	no
Notes	I have two family members with active long-term Crohns
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Re: 1.6 regular maintenance treatment with infliximab is the only treatment which has enabled my daughter to lead a reasonably normal life and hold down a job as a teacher. Azathioprine and corticosteroids have both proved ineffective or inappropriate to the task. Her own doctors tell me they have no clinical reason to support the withdrawal of this type of use and I am both puzzled and disappointed to find that the Committee has come to this conclusion. I notice that the cost of treatment is an element which has figured in the Committees deliberations and would point out - if it has not been considered - that offset against this cost should rightly be the cost to to the Health Service of increased in-patient time with its concommitant procedures, not to mention the very real likelihood of state support of some category or another for a patient who may well become reliant on benefits as a result of an inability to secure or retain paid employment.

	These are real and justified concerns, not hyperbole: Anyone who has seen - as I have - the chronically debilitating effects of Crohns on a patient will not need convincing that the Committee is quite correct (Cont. in box 2)
Section 2 (clinical need and practice)	...when it says at 2.6 that
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	02/10/2008 13:18

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	There appears to be an assumption in the recommendation that standard care (ie use of corticosteroids) will always be an option to induce remission. This is simply not the case for all patients. In my view, it should be permitted for clinicians to consider a maintenance infliximab or adalimumab regime for those patients who they know do not respond to corticosteroids, rather than run the risk of that patient developing antibodies to the drug. Once a patient has developed antibodies to both infliximab and adalimumab, if that patient does not respond to corticosteroids, then the only option is surgery. In other words, there is something of a hole in the safety net for a substantial number of patients. In the absence of specific data on the risk of antibody development when an immunosuppressant is used for maintenance, and one of these drugs is used episodically, I

	think this recommendation is a risky one for those patients for whom standard treatment to induce remission is not an option. I have already commented on this proposal (a couple of days ago) but this thought has only occurred to me since. I would be interested to hear the thoughts of the commmittee on this.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	I commented on the proposed recommendation a couple of days ago, but Ive just re-read this. There are two other areas of further research which are required:- (1) Trials (or analysis of existing studies if any are available) of episodic treatment with adalimumab and infliximab combined with an immunosuppressant for maintenance, to identify the real likelihoods of antibody development. This is essential, since once a patient has developed antibodies to one of these drugs, that particular drug is no longer an option to that patient in the future. To those patients who, such as myself, do not respond to standard treatment (i.e. corticosteroids) the inability to use these drugs to control relapses would prove a major and serious problem. The current proposal has the possible outcome of leaving us up the proverbial creek. (2) A specific element of 6.4 should be to identify whether or not removal of maintenance infliximab from patients who have already been on it can increase the frequency of relapse compared with the frequency before they were on the regime. If this is the case, then NICE could actually be running the risk of increasing relapse frequency in a number of patients.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	02/10/2008 11:30

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Maintenance therapy is standard practice in Europe and the US based on very good evidence showing better efficacy, safety and probably a reduction in need for surgery. We will be failing our patients if these drugs are given episodically.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4	

(Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	02/10/2008 09:04

Name	[redacted]
Role	other
Other role	NICE Guidance Coordinator
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Dr Mark Dalzell, Consultant Paediatric Gastroenterologist: I see no convincing evidence, either clinically or within the literature, that managing children with CrohnÃ¢??s disease should include the biologics reviewed. Children can be managed effectively with attention to detail and conventional therapies. The reported risks associated with biologic therapy are of concern to me. Biologics are used by colleagues, and I await the results of auditing this practice although i agree with the NICE recommendation that if we are to really make a decision on their usage, that multicentre studies need to be carried out.
Section 2 (clinical need and practice)	Dr David Casson, Consultant Paediatric Gastroenterologist: I have considerable experience in the treatment of paediatric CrohnÃ¢??s disease but have only one patient in whom we have just started to use Adalimumab as she was failing on Infliximab. Overall the experience of my patients has been extremely positive. It has yielded a significant subjective improvement in quality of life and objective measures such as inflammory markers and clinical features have been in keeping with this. Although the majority of my experience has been with severe luminal disease I have also had one patient with remarkable resolution of very severe perianal disease with Infliximab- extensive surgery was avoided in this patient. Dr Marcus Auth, Consultant Paediatric Gastroenterologist: Although based on a limited number of patients, my experiences with Infliximab are also very positive in keeping with DaveÃ¢??s experiences and the review, indications more related to luminal disease than to perianal disease.
Section 3 (The technology)	Dr David Casson, Consultant Paediatric Gastroenterologist:

	Although the majority of my experience has been with severe luminal disease I have also had one patient with remarkable resolution of very severe perianal disease with Infliximab- extensive surgery was avoided in this patient. Dr Marcus Auth, Consultant Paediatric Gastroenterologist: Although based on a limited number of patients, my experiences with Infliximab are also very positive in keeping with DaveÃ¢??s experiences and the review, indications more related to luminal disease than to perianal disease.
Section 4 (Evidence and interpretation)	Dr Marcus Auth, Consultant Paediatric Gastroenterologist:NICE guidance is important with regard to issues of evidence-based treatment,funding and litigation as there will be patients developing lymphoma if this successful treatment is more commonly used. I would appreciate all national and international coordinated initiatives to identify patients at risk and further guidance on Adalimumab which I have not used. Dr David Casson,Consultant Paediatric Gastroenterologist: Practical issues such as seeking written consent, an acknowledgement of the potentially fatal side effect profile and the need to co-prescribe Azathioprine and when it is reasonable to cease Azathioprine should be included. The need to consider an entry and exit strategy when considering use of these drugs should be highlighted as pre-requisite to use. Care needs to be taken when growth and pubertal impairment are significant in paed patients. Whilst these drugs may provide a boost to these features they may also delay or prevent recourse to surgery such that the vital Ã¢??window of opportunityÃ¢??for optimizing growth and puberty is lost.These are important drugs which have considerably improved what we offer patients
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	02/10/2008 08:58

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	6 month funding for IBD nurse specialist is fro Schering Plough
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	pt 1.6 as a paediatric gastroenterologist am seriously concerned maintenance treatment is not to be recommended. Children and adolescents need to stay in remission to achieve growth and puberty and maintenance not episodic will achieve this. only most severe cases need inflix and study quoted misrepresents this as cohort is mainly of well patients. cost

	benefit is there as avoids long term hospitalisation, artificial nutrtion,surgery. for perianal fistulising disease/ rectovaqginal fistulae- remission needs to maintained -prior to this all had rectum removed- have data on 5yrs pre inflix and 5 yrs post
Section 2 (clinical need and practice)	steroid treatment in children is often avoided due to adverse effects on growth,alternative is enteral nutrition. inflix has i our cohort ahs reduced surgical rate and enhanced growth to allow normal puberty- not an issue in adults
Section 3 (The technology)	maintenance treatment with inflix has significantly reduced morbidity in children, less hospitalisation, increased school attendance, completeeducation, maximise growth, allow puberty and lead normal lives achieve education . no data on children with crohns and adalimumab but multicentre trial inprogress which UK centres should participate to get the evidence but for those children with severe disease who satisy criteria for inflix but then have anaphylaxis- Adalimumab is only alternative and should be offered in line with NSF for children for optimal treatemnt
Section 4 (Evidence and interpretation)	4.3.13 effects in children on growth/peer interactions /schooling/ quality of life need to be mantained - not a short term outcome /measure. Risk of loss of effect due to antibodies if episodic not maintenance too high maintenecewould becost effective.silversteins study used for cost effective not valid as not representative of severestgroup
Section 5 (implementation)	need to await feedback from major groups such as BSG/BSPGHAN before any implementation Patient QALY suggests benefit so refusing maintance treatment based on inappropriate data re cost effectiveness is against patient choice?
Section 6 (proposed recommendations for further research)	Anti TNFs have been use for years worlwide data already exists to show benefit over non anti tnf treatment and is standard of care for severe cases.Patients already on fortnihgtly adalimumab relapserequiring escation tretament so no place for increasung interval further National IBD audit is in progress. Appropriate trials in children difficult due to prevalence and ethical issues
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	feedback by oct 6th - too short a time to get maximal relevant feedback from all appropriate persons
Date	01/10/2008 23:53

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	Infliximab has changed my life, it have given me almost full health, Im now able to work full time, so the 8 weekly maintenance does work, otherwise Ill only relapse having more time away from work and my quality of life will suffer.
Comments on individual sections of the ACD:	
Section 1	If a maintenance treatment works, why stop giving it? The only

(Appraisal Committee's preliminary recommendations)	other option would be if a different drugs has the same results. To be denied this treatment and to be allowed to relapse, then have to go on steroids, time away from work is not an option for many people. I agree this should be only done for servere Crohns.
Section 2 (clinical need and practice)	No comment.
Section 3 (The technology)	Adalimumab is cheaper than Infliximab? If this is the case and it gives the same results, why not ask doctors to start people on this treatment first?
Section 4 (Evidence and interpretation)	No comment
Section 5 (implementation)	No comment
Section 6 (proposed recommendations for further research)	No comment
Section 7 (related NICE guidance)	No Comment
Section 8 (proposed date of review of guidance)	No Comment
Date	01/10/2008 23:27

Name	[redacted]
Role	Patient
Other role	Student Nurse
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	1:6, I have had crohns disease for over 11 years now and i have been placed on many other maintenance drugs, of which a few have caused allergic reactions or simply have not worked, i have also had three surgerys and those too have not worked, i commenced on inflimab 8 months ago and it is the only drug that is maintaining my health and allowing me to live a normal life and not have recurrent episodes of crohns and allowing my crohns to be managed, without my 8 weekly infliximab i would be back in hospital all the time as nothing has worked for me, and as i am in my last year of university the thought that i would have to wait until my crohns flares again to recieve treatment puts doubts in my mind that i would be able to continue my career
Section 2 (clinical need and practice)	2:8 i agree
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	

Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	01/10/2008 18:12

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Having been very ill for many years with diarrhea blood and mucus, in August 2005 I was prescribed Infliximab, episiodically. It immediately alleviated my symptoms. I relapsed after 5, 3, and 2 months. During that peiord, the unpredicatability of my illness stopped me from planning ahead, for work, social life, family. I constantly lived in fear of relapse. I was bound to bed for prolonged periods. During that time my quality of life was not good. I couldnt take on work commitment, socialise, see family, felt depressed, fearful. In August 2006, I was prescribed infliximab as maintenance (every 8 weeks). During this period, my life changed completely. It was a miracle cure. I gained my life again, mostly symptom free, less hospital visits, less colonosocpies, less medication. I came off the steroids (after 4 years) and most of the sleeping pills (which were the result of the steroids). Benefits: good health, confidence, happiness, exercise, healthy varied diet, increased work, social life. I was able to travel to Indonesia, Israel, France and Devon to see my family. My ankylosing spondolitis became quiet.
Section 2 (clinical need and practice)	I was diagnosed 31 years ago. Since 1987 I suffered frequent eposodes of flare up: frequent diarrhea(16+ /day), blood, mucous, urgency, wind, abdominal pain and cramps, anemia, loss of apetite and weight. Drugs: mesalazine, steroids (4 years), up to 40 mg p/day, methotrexate caused inflammed liver, as did azathioprine. Prednisolone caused borderline osteoporosis, severe insomnia, muscle loss, frequent oral candida. For insomnia I took zopiclon 7.5 mg & amitriptilyne 200mg nightly for a prolonged period. I am still struggling to come off the latter. Physically, I was often confined to bed. I was absent from work for long periods, which resulted in poor working relationships. I resigned as tt was too distressing. In 1977 I was unable to look after my kids, and called my husband to return from overseas work to help. I was hospitalised in 1999 for 10 days with hydrocortisone. In June 2005 my 4 week old grandson was critically ill in Vietnam. My daughter was on her own with her 5 year old. I couldnt travel to help her. Very disressing. Mentally, it was a torture,no quality of life, no

	socializing, depression, fears. AS was very painful.
Section 3 (The technology)	In the 3 years I have been given infliximab, I have develop NO side effects either during or between infusions.
Section 4 (Evidence and interpretation)	The regular use of infliximab for mainstenance, has eliminated symptoms, thus bringing healing of the inflamed tissues. A colonoscopy I had in December 2007 showed no activity and healed tissues. My experience of biological treatment has been positive, with prolonged remission (the longest since 1987), and gaining quality of life. Since 1987, the longest remission I experienced until I started infliximab was 4 months! In the case of episodic treatment, there is an increased potential of the development of antibodies to the drug and possible for loss of effect. So that is not cost effective.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	Should you axe the maintenance treatment by infliximab, and offer it as episodic treatment, I dread returning to where I was before (sa described above), with frequent episodes of illness which take their toll on me physically, mentally and emotionally. I refuse to take steroids for reasons as mentioned above. That might mean an increased need for surgery,. For me that would mean colectomy and the possilbity of a permanent stoma. It is therefore UNACCEPTABLE. Surgery will end up more expensive than Inflixmab, as it involves two initial operations, with potential further operations and hospitalisations due to complications, I will suffer from depression (for losing my colon), social embarassment. I will need NHS counselling once again. I fear the increased risk of bowel cancer, and other complications. My unbearable chronic pain of ankylosing spondolitis will return, with increased doses of pain killers, visits to doctors, specialists, MRI, Xray etc. The potential loss of work, will leave me relying on sick benefits, disability benefits, income benefits. Further expenditure and more pressure on limited and valuable NHS resources. Death is cost effective: no more health care
Section 8 (proposed date of review of guidance)	ItÃ¢??s long time for us to wait if the episodic treatment proves inadequate.
Date	01/10/2008 17:45

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	

Section 1 (Appraisal Committee's preliminary recommendations)	1.6 ie both of these drugs are not recommended for maintanance is completely baffling. These drugs have a high incidence of systemic rections and also antibody formation when given intermittantly. when develop antibodies they become ineffective. These drugs have transformed my mangement of patients with severe Crohns (a handful of patients in anyones practice) who would otherwise have no options other than possible sevelerly mutilating surgery. Please please listen and change this advice!!! The committe seem to have said that they do not believe the studies and have made up own QALY data to suit own argument. please read maintance studies again John Linehan . Consultant gastroenterologist
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The advice that both of these drugs are not recommended for maintanance is completely baffling. These drugs have a high incidence of systemic rections and also antibody formation when given intermittantly. when develop antibodies they become ineffective. These drugs have transformed my mangement of patients with severe Crohns (a handful of patients in anyones practice) who would otherwise have no options other than possible sevelerly mutilating surgery. Please please listen and change this advice!!! The committe seem to have said that they do not believe the studies and have made up own QALY data to suit own argument. please read maintance studies again John Linehan . Consultant gastroenterologist
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	01/10/2008 17:22

Name	[redacted]
Role	other
Other role	Patients Sister
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am deeply concerned to hear that you are considering stopping my adalimumab treatment due to costs. This treatment is much more than just Ã¢??maintenanceÃ¢?? as it keeps my crohns disease under control. Since receiving the

	treatments, I have less nausea/less diarrohea/less abdominal pain and infections/abscesses have cleared up. I have had crohns for 20 years and my health has been deteriorating each year, I am now feeling better than I have done in years and my quality of life has improved immensely. If treatment stops, my symptoms will return and my quality of life will be deeply affected. In the long run this will cost you more money than my current treatment. Prior to receiving the injections, I had over 30 operations for the crohns/infections, but since starting the injections, I have not had ANY surgery. Before I went on these treatments I had numerous operations to try and clear up the anal fistula and infections. When I was put on the treatment both the fistula/infections have dried up. My consultant explained that these treatments are a last resort because other treatments were not effective. It will cost you a lot more in the long run if treatment stops. Angela Mann
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	01/10/2008 15:04

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	As a gastroenterologist I go to meetings sponsored by a wide range of pharmaceutical companies. Without this support I would be unable to attend many national or international meetings.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am a clinician working with patients with Crohns disease. I am a NACC medical adviser. I have clinical experience of over 100 patients who have received infliximab and approximately 20 patients who have received adalimumab. Both drugs can change dramatically the course of the disease in those most severely affected. I am very concerned that the committee are not going to recommend maintenance treatment. From the original trial data only 12-15 % of patients with mod-severe Crohns disease who

	responded to infliximab were in remission after 1 infusion at 1 year. My own clincal experience mirrors the trial data very well. We started out with the intention of using episodic treatment. The majority of patients can have a very quick response (often allowing discharge from hospital) but the majority of responders developed symptoms within 6-8 weeks and therefore ended up requiring maintenance treatment. I only use short courrse treatment when using anti-TNF agents as a bridge to second line treatment. Episodic treatment will increase the risk of reactions which severely limits treatment options in a disease that is not curable surgically. I would urge the committee to re-think.
Section 2 (clinical need and practice)	Need to discuss role of top down treatment to change natural history of disease in the worst cases. Problem identifying those cases.
Section 3 (The technology)	No comment.Seems accurate
Section 4 (Evidence and interpretation)	How do you measure costs of surgery ? How do you measure impact of surgery of individuals ? particularly lifelong stoma.
Section 5 (implementation)	No comment
Section 6 (proposed recommendations for further research)	Welcome all these points. Need more studies in all these areas. The only registries curently are those supported by Schering Plough and Abbot
Section 7 (related NICE guidance)	No commment
Section 8 (proposed date of review of guidance)	
Date	01/10/2008 11:02

Name	[redacted]
Role	Healthcare Other
Other role	
Location	England
Conflict	no
Notes	I am a consultant gastroenterologist in a busy DGH with a large cohort of IBD patients.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	I am most concerned by the rejection of infliximab and humira as maintenance therapy in selected groups. These drugs are used in a very limited population in our practice, and after all other medical therapies have failed. Once patients respond, relapse is very frequent once the biological therapies are

	discontinued. The cost of relapse in terms of patient suffering, repeated admissions and in this sub-group danger of death from surgery (up to 3%) is far greater than ongoing treatment with biological therapy. In practice it will be extremely difficult to persuade patients or healthcare providers to accept guidelines such as these which reject maintenance therapy for a sub-group of IBD patients. NICE should be congratulated on the majority of this document which is clear and balanced, but should urgently reconsider the issue of maintenance therapy.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	01/10/2008 09:14

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I was originally diagnosed with CrohnÃ¢??s disease when I was 16 and ended up having part of my intestine removed as medication did not work. I was then in remission for 8 or 9 years until after the birth of my third child who is now a year old. My symptoms came back about 6 months ago and increased rapidly in their severity, I was put on oral steroids as I am allergic to methotraxate and azothoprine, to try and elevate the symptoms, unfortunately the steroids did not help. I was constantly in pain throughout my body, having diarrhoea around 8 times a day and vomiting, as you can appreciate having 2 young children this made life almost impossible. I ended up housebound due to the pain and the constant need for the toilet, I could not look after my two small children properly and had to rely on my family considerably for help. I was unable to continue to work and suffered major financial hardship as I was not paid for being sick. I became anaemic and extremely lethargic, I was unable to sleep at night due to the constant pain throughout my body Ã¢?? my joints in my hips and back in particular. My husband was not always able to go to work and risked losing his job as I could not look after the children or even myself. This placed terrible strain on our marriage and my children became upset and distressed. My total quality of life suffered greatly and it was like being in a black hole and I was desperate for an end to this. I was given a lifeline by my consultant when he advised me of

	Infliximab Ã¢?? although I was initially concerned about the possible side effect these paled into insignificance when compared to my physical and mental state without the treatment. Within two days of receiving my first infusion I was 100% normal and could lead a totally normal life with my husband and young children, I was extremely grateful to my consultant for giving me my life back. Since learning from my consultant that I am at risk of receiving no further maintenance treatment I have become totally distressed and extremely anxious that I will not be able to cope with my life without the aid of maintenance doses of this treatment. If I have to wait each time for my CrohnÃ¢??s disease to destroy my life before I can receive treatment I will live in constant fear and anxiety that my children and husband will have to periodically go through this nightmare and each time my health will deteriorate. I implore you to ensure that this life line is not pulled away from myself and others in a similar position who are reliant on the maintenance doses of Infliximab to give us some quality of life. Without this treatment I would have no hope as there is no alternative treatment which works for me. Please give some thought to those of us out there who will be effected by your decision Ã¢?? without this treatment we have no life.
Section 2 (clinical need and practice)	I was originally diagnosed with CrohnÃ¢??s disease when I was 16 and ended up having part of my intestine removed as medication did not work. I was then in remission for 8 or 9 years until after the birth of my third child who is now a year old. My symptoms came back about 6 months ago and increased rapidly in their severity, I was put on oral steroids as I am allergic to methotraxate and azothoprine, to try and elevate the symptoms, unfortunately the steroids did not help. I was constantly in pain throughout my body, having diarrhoea around 8 times a day and vomiting, as you can appreciate having 2 young children this made life almost impossible. I ended up housebound due to the pain and the constant need for the toilet, I could not look after my two small children properly and had to rely on my family considerably for help. I was unable to continue to work and suffered major financial hardship as I was not paid for being sick. I became anaemic and extremely lethargic, I was unable to sleep at night due to the constant pain throughout my body Ã¢?? my joints in my hips and back in particular. My husband was not always able to go to work and risked losing his job as I could not look after the children or even myself. This placed terrible strain on our marriage and my children became upset and distressed. My total quality of life suffered greatly and it was like being in a black hole and I was desperate for an end to this. I was given a lifeline by my consultant when he advised me of Infliximab Ã¢?? although I was initially concerned about the possible side effect these paled into insignificance when compared to my physical and mental state without the treatment. Within two days of receiving my first infusion I was 100% normal and could lead a totally normal life with my husband and young children, I was extremely grateful to my

	consultant for giving me my life back. Since learning from my consultant that I am at risk of receiving no further maintenance treatment I have become totally distressed and extremely anxious that I will not be able to cope with my life without the aid of maintenance doses of this treatment. If I have to wait each time for my CrohnÃ¢??s disease to destroy my life before I can receive treatment I will live in constant fear and anxiety that my children and husband will have to periodically go through this nightmare and each time my health will deteriorate. I implore you to ensure that this life line is not pulled away from myself and others in a similar position who are reliant on the maintenance doses of Infliximab to give us some quality of life. Without this treatment I would have no hope as there is no alternative treatment which works for me. Please give some thought to those of us out there who will be effected by your decision Ã¢?? without this treatment we have no life.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	I was originally diagnosed with CrohnÃ¢??s disease when I was 16 and ended up having part of my intestine removed as medication did not work. I was then in remission for 8 or 9 years until after the birth of my third child who is now a year old. My symptoms came back about 6 months ago and increased rapidly in their severity, I was put on oral steroids as I am allergic to methotraxate and azothoprine, to try and elevate the symptoms, unfortunately the steroids did not help. I was constantly in pain throughout my body, having diarrhoea around 8 times a day and vomiting, as you can appreciate having 2 young children this made life almost impossible. I ended up housebound due to the pain and the constant need for the toilet, I could not look after my two small children properly and had to rely on my family considerably for help. I was unable to continue to work and suffered major financial hardship as I was not paid for being sick. I became anaemic and extremely lethargic, I was unable to sleep at night due to the constant pain throughout my body Ã¢?? my joints in my hips and back in particular. My husband was not always able to go to work and risked losing his job as I could not look after the children or even myself. This placed terrible strain on our marriage and my children became upset and distressed. My total quality of life suffered greatly and it was like being in a black hole and I was desperate for an end to this. I was given a lifeline by my consultant when he advised me of Infliximab Ã¢?? although I was initially concerned about the possible side effect these paled into insignificance when compared to my physical and mental state without the treatment. Within two days of receiving my first infusion I was 100% normal and could lead a totally normal life with my husband and young children, I was extremely grateful to my consultant for giving me my life back. Since learning from my consultant that I am at risk of receiving no further maintenance treatment I have become totally distressed and extremely anxious that I will not be able to cope with my life without the

	aid of maintenance doses of this treatment. If I have to wait each time for my CrohnÃ¢??s disease to destroy my life before I can receive treatment I will live in constant fear and anxiety that my children and husband will have to periodically go through this nightmare and each time my health will deteriorate. I implore you to ensure that this life line is not pulled away from myself and others in a similar position who are reliant on the maintenance doses of Infliximab to give us some quality of life. Without this treatment I would have no hope as there is no alternative treatment which works for me. Please give some thought to those of us out there who will be effected by your decision Ã¢?? without this treatment we have no life.
Section 5 (implementation)	I was originally diagnosed with CrohnÃ¢??s disease when I was 16 and ended up having part of my intestine removed as medication did not work. I was then in remission for 8 or 9 years until after the birth of my third child who is now a year old. My symptoms came back about 6 months ago and increased rapidly in their severity, I was put on oral steroids as I am allergic to methotraxate and azothoprine, to try and elevate the symptoms, unfortunately the steroids did not help. I was constantly in pain throughout my body, having diarrhoea around 8 times a day and vomiting, as you can appreciate having 2 young children this made life almost impossible. I ended up housebound due to the pain and the constant need for the toilet, I could not look after my two small children properly and had to rely on my family considerably for help. I was unable to continue to work and suffered major financial hardship as I was not paid for being sick. I became anaemic and extremely lethargic, I was unable to sleep at night due to the constant pain throughout my body Ã¢?? my joints in my hips and back in particular. My husband was not always able to go to work and risked losing his job as I could not look after the children or even myself. This placed terrible strain on our marriage and my children became upset and distressed. My total quality of life suffered greatly and it was like being in a black hole and I was desperate for an end to this. I was given a lifeline by my consultant when he advised me of Infliximab Ã¢?? although I was initially concerned about the possible side effect these paled into insignificance when compared to my physical and mental state without the treatment. Within two days of receiving my first infusion I was 100% normal and could lead a totally normal life with my husband and young children, I was extremely grateful to my consultant for giving me my life back. Since learning from my consultant that I am at risk of receiving no further maintenance treatment I have become totally distressed and extremely anxious that I will not be able to cope with my life without the aid of maintenance doses of this treatment. If I have to wait each time for my CrohnÃ¢??s disease to destroy my life before I can receive treatment I will live in constant fear and anxiety that my children and husband will have to periodically go through this nightmare and each time my health will deteriorate.

	I implore you to ensure that this life line is not pulled away from myself and others in a similar position who are reliant on the maintenance doses of Infliximab to give us some quality of life. Without this treatment I would have no hope as there is no alternative treatment which works for me. Please give some thought to those of us out there who will be effected by your decision Ã¢?? without this treatment we have no life.
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/09/2008 21:27

Name	[redacted]
Role	other
Other role	patients dad
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Ive very annoyed and upset about this proposal could you please tell me what medication people with crohns are to use for remission or are they going to have to go on drugs with severe side effects or endure several surgergies this is an outragous disision and is purly down to money and not patient care.I also take offence to the name nice as several patients who will have to endure further pain/complications will not consider you nice at all.This is a sad day for this country.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/09/2008 21:17

Name	Nathan Wilcox
Role	Patient

Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I ,as a patient currently on a continous course of adalimumab, used to fit into the criteria in 1.2. Also as an adolescent I also fit into the 1.5 criteria. This drug was a last resort for my consultants. After not responding to any drugs that are usually functional for normal crohns disease patients. Adilimumab was pescribed to me as I reacted badly to infliximab, getting bad rashes over my face, though the drug seemed to work for me. So my doctors decided to pescribe adulimumab. Without the use of the drug I would immediatly revert back to a bad spell of crohns. Meaning I miss school work and not achieving as highly as I can in school. Also affecting my social life, not being able to go out with friends as I need to go to the toilet frequently. For me this drug does wonders, and keeps my life stable. As a patient on the drug at the moment, I was extremely upset to hear this would be taken away from me. It seems like my freedom was being taken away, as I would not be able to lead a normal life like my freinds and family.
Section 2 (clinical need and practice)	
Section 3 (The technology)	I do not understand the sciences behind these drugs, but the inventors deserve a hell of alot of credit. For creating a drug that allows me to lead a normal life.
Section 4 (Evidence and interpretation)	In this section there is nothing I feel impelled to comment on. Apart from the cost. No cost can be put upon someone being able to lead a normal life. I understand the NHS doesnt have unlimited funds. But it has shown me to be grateful about what I have.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/09/2008 21:07

Name	[redacted]
Role	NHS Professional
Other role	
Location	Scotland
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1	Section 1.2: Too vague. Symptoms should be defined in terms

(Appraisal Committee's preliminary recommendations)	of mild, moderate and severe and give clear definitions of each.
Section 2 (clinical need and practice)	Section 2.7: Azathioprine, 6 mercaptopurine and Methotrexate are used as maintenance of remission treatments - not as control for active disease.
Section 3 (The technology)	Section 3.3: Re-administration increases the risk of antibody formation and subsequent infusion reaction. Dose escalation to what? Needs to be specified. Also non-response to infliximab is an indication for the use of adalimumab. Section 3.4 & 3.5: Why is this regime different? Section 3.3 states 2 doses then review for response. Section 3.6: The costings for this document are based per infusion. In practice, many units have several patients a day on infliximab therefore there is reduced waste per infusion. This will have a significant impact on the costings and is unaccounted for in this document. section 3.7: Why should Adalimumab be given with corticosteroids?
Section 4 (Evidence and interpretation)	Section 4.1.1: This implies that infliximab is used as an induction of remission agent. this is not the case. Steroid or nutritional therapies are used for this. Section 4.2 3: where is the evidence for this? Infliximab clinical discretion is too vague. Needs clarity in terms of model for assessment and indications for treatment. Section
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/09/2008 18:07

Name	[redacted]
Role	NHS Professional
Other role	
Location	Scotland
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	the recomendations in section 1.2 do not make any mention of other treatments meaning someone could have infliximab as a first line treatment. I do not agree and think a statement should be made about failing other treatments eg steroids, thiopurines

	and perhaps methotrexate. in 1.5 you refer children to 1.2 but only quote an adult disease activity score you could also insert a paediatric PCDAI score although the number will be different suggest 30 or 35 1.6 is the most controversial and will prevent patietns with the most severe disease being denied treatment. episodic treatment is good for many but some children and adults do need periods of maintainance infliximab for dsiease control. The scottish medicines committee has given approval for maintaince treatment in children for upto 1 year.
Section 2 (clinical need and practice)	2.7 the statement regarding azathiporine and 6mp is confusing as these have no effect in active disease they are used to prevent active disease recurring
Section 3 (The technology)	3.5 Children should have response assessed after 3 doses at 0,2 and 6 weeks so around 10-12 weeks after the first infusion. If responding and clinically indicated then can go onto maintainance. this statement currently reads as if they all go onto maintainance and no assessment of response is needed.
Section 4 (Evidence and interpretation)	I am surprised that safety has not had a higher priority and it not mentioned. I think in relation to children especially there needs to mandatory guidance from nice that treatment registries are needed. Im sure the committee is aware of the fatal lymphomas that have been described especially in young males. I am not clear whetther the recommendation for children relates to induction of remission or maintenance or both?
Section 5 (implementation)	There needs to be a fully funded national register for the use of these drugs because of the real safety concerns that are present. I feel this should be independent of the companies that make the drugs themselves to ensure objective data collection.
Section 6 (proposed recommendations for further research)	What about childrens studies? They are the group who will be exposed to these drugs over the longest time period yet there are only 2 studies in infliximab and none in adalimumab.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	Many things may change in 3 years so i would take advice as to how many trials are likely to report over the next 2 years and if there are projected to be a significant number then review in 2 rather than 3 years.
Date	30/09/2008 14:23

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Resticting the use to episodic treatments for severe relapse of disease is a false economy. By the definition of severe symptoms, these patients will need admission to hospital for further assessment of their disease including expensive investigations such as MRI or CT to rule out sepsis before they can be retreated safely. This will mean increased exposure to

	ionising radiation and more time ill and off work. Patients given episodic infusions are much more likely to develop antibodies to the drugs and therefore lose their repsonse than those given maintenance treatment. Infliximab and adalimumab are already only used only for patients with severe disease that has not resonded to other treatments. These are prdominantly young adults who while in remission can lead normal lives. These patients will be left with no other treatment option. Apart from a huge impact on resources for increaesed hopital admissions for Crohns disease this is also going to lead to a group of chronically disabled patients and quite likely an increase in mortality from the disease. I do not believe that the cost effectiveness planning can have taken into account how sick these patients are going to be.
Section 2 (clinical need and practice)	mortality data for Cohns disease is for for all patients. To my knowledge there is no data concentrating on the group of patients with severe disease resistant to other treatments (as those who require maintenance therapy with anti-TNF agents are), but these are likely to be the patients who lead to the slightly increased all cause mortality.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Episodic treatment has been suggested as the same as the cross over to active in the ACCENT 1 study. In this case patients went on to maintenance treatment. Is this waht the rest of the modelleing has been based on? Are NICE suggesting that for those patients who have a relapse of symptoms after induction of remission with infliximab, they could then go onto maintenance treatment? I do not think this is clear form the recommendations and I have my doubts that PCTs would interpret the recommendations to mean this. It is very important this is made clear
Section 5 (implementation)	Who is going to tell the patients whose lives have been transformed from chronic ill-health to normal by maintenance treatment with an antiTNF agent that they can no longer have their treatment on the NHS? Who is going to pay for their consequent lost work days, failed university courses, carers for their children or parents while they get regularly admitted to hospital with relapses for which no long term effective treatment will be available on the NHS.
Section 6 (proposed recommendations for further research)	What on earth is the point of spending what would have to be public funds, comparing two already proven effective therapies which the committee has proposed not to approve for use for the reasons they were designed? we already have an extremely cheap and effective epsidoic treatment for relapse in crohns disease...corticosteroids. What we need is a drug, like these, which have ongoing efficacy to maintain remission with minimal side effects. Using them in a way which is known to increase relapses, reduce efficacy and increase side effects seems pointless. Spending money repeating large efficacy trials which have already been done seems pointless (although may provide an extremely expensive way to get patients treated properly rather than half heartedly). A registry seems like a very good idea.

Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/09/2008 13:10

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	I was the winner of the Hospital Doctor Gasroenterology Team of the year award for 2007 based on my IBD clinic.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The problem is with 1.6. If you dont give maintenance treatment the patients get ill again. If they have just healed a longstanding and debilitating fistula, it is crazy to suggest they must re-fistulate before giving further treatment.
Section 2 (clinical need and practice)	The objective of treatment should be to make patients well and maintain remission.
Section 3 (The technology)	It is important to understand that this treatment is only continued in patients in whom it has a major beneficial effect. So the clinical effectiveness of maintenance treatmant is extraordinarily high.
Section 4 (Evidence and interpretation)	There is a mis understanding about he utility of the CDAI. This is a research tool to standardise international trials, but has no role whatever in any clinic setting outside trials. Clinical severity relates to what the disease does to the individual patient. How incapacitating is the disease? The CDAI cannot help here, clinical judgment can. For the CDAI to be used to trigger a re-treatment would be to insist that patients become severely unwell before starting a treatment which would be clinically effective much earlier.
Section 5 (implementation)	As it stands I would suggest to patients that those that can afford it should take out insurance to cover the cost of maintenance treatment as the NHS would not cover these costs and the patients would suffer.
Section 6 (proposed recommendations for further research)	6.1 is just un-real. No-one would fund this. 6.7 is the best bit of this and NICE should insist that registering the use of anti TNF treatmant is a mandatory requirement.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/09/2008 11:52

Name	[redacted]
Role	NHS Professional
Other role	
Location	England

Conflict	no
Notes	I am a Consultant Gastroenterologist and look after 400 patients with IBD
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	It is only a small proportion of patients with Chrons who require biologicals but a proportion of these patients relapse when the treatment is stopped. The yound people in whom there may be no other alternative. I accept the need to try immunosupression with 5AZA and Methotrexate first but to shut the door on maintenence biopgicals seems wrong!
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/09/2008 11:22

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Whilst i have not had this drug yet it would be the next form of medication i would need if i had a flare like i did last year. I have exhausted all other avenues and no other medication works. The next stage after these drugs would be surgery involving a permanant ileostomy. I am only 30 and its the last thing i need. I am pregnant at the moment and there is the liklihood of a flare afterwards. Major surgery with a newborn would be a nightmare! I understand that these drugs will still be available but will not be used to maintain remission which is absolutely crazy! What would be the point in using the medication, getting well and then waiting to flare up again. Crohns disease is a chronic condition and has periods of flare ups so its common sense that you need a medication to keep you in remmision. For a large number of patients out there, there are no other options available to them. These drugs have given them their

	lives back and they are now able to leave the house. I have lived with Crohns for 15 years and hope that one day a cure is found. If i were to have surgery its final and i cant go back so please please do not take away this drug for maintaining remission.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	I definately feel further research should be carried out before making a crazy decision to stop these drugs for maintaining remission.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/09/2008 09:02

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	Member of BSG IBD committee
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	I have grave concerns over the imterpretation of this data. I appreciate that models of therapy are the only way to determine cost effectiveness, but in the issue of Crohns disease, the clinical variance is extrmemly wide and this puts doubts on the validity of the models used (in particular the evidence from Silversteins paper). Experience from within the specialty (both nationally and internationally) now firmly recognises the benefit, effectiveness and need for these therapies to be available for maintenance therapy in cetain individulas with Crohns disease. The impaired quality of life for those individuals who are reliant on biologics who may have to switch to episodic therapy would be very significant.
Section 5 (implementation)	

Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/09/2008 08:50

Name	[redacted]
Role	NHS Professional
Other role	Consultant Gastroenterologist & IBD Lead
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	This recommendation by the Committee is contrary to all published evidence showing that scheduled maintenance therapy for responders to Infliximab and Adalumimab is better than episodic therapy, and sustained remission rates at 12 months is higher in patients given scheduled maintenance doses rather than episodic therapy. It appears that the Committees recommendation is completely different from what is current practice in USA and Europe, and is based on outdated and old data rather than current evidence from 2007-2008. I feel that this recommendation not only goes against evidence based practive, but is against the interests of our patients with Crohns disease, and reflects a retrograde step in the UK. It will certainly make our patients worse in the future, and will make UK Gastroenterologists the laughing stock of the rest of the world !!!
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	29/09/2008 19:16

Name	[redacted]
Role	NHS Professional

Other role	Consultant Gastroenterologist
Location	England
Conflict	no
Notes	I look after patients with Crohns disease as a consultant gastroenterologist
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The cost-benefit analysis appears to be based on seriously flawed assumptions and this undermines Nices case against use of biologics as maintenance therapy. A major flaw is the over-reliance on data taken from Silversteins paper, published in 1999, which was based on analysis of a well controlled relatively mild group of patients in Olmstead County, Minnesota. I look after really sick patients who are absolutely dependent on Infliximab. As soon as it is stopped they relapse. It must be licenced for maintenance to prevent relapse. eg I was referred a 16 year old boy who had not entered puberty. He had been on steroids and elemental diets for years and has already had 60cm bowel resection. Azathioprine did not help. As soon as we started infliximab, he started to grow. When we stopped it, he became really ill. He is now 19 and after 3 years of therapy has finally gone through puberty. Every time I have tried to withdraw the drug or he has been late having an infusion, he has had a bad disease relapse. This boy has no other therapeutic options and withouth infliximab he would spend most of his life in hospital at high cost. There are many other patients like him in our clinics
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Pls see my comments in section 1. This drug is a necessary addition to our armamentarium for patients with severe Crohns to maintain remission.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	29/09/2008 16:33

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	I have suffered with Crohns disease for over 40 years and until recently have had to endure several surgical proceedures and have been prescribed various drugs such as anti inflanmatory

	drugs and steroids. 15 years ago I was introduced to a different regime which meant that my Crohns was mainly controlled by diet, however, the only symptoms I still had was severe fisulae which had developed both externally from the bowel to abdomen wall and internally from bowel to bladder. The external fistula resulted in severe discomfort on my skin and this necessitated the constant use of surgical dressings and stopped me being able to swim both regularly for health reasons and on holidays for recreation. The internal fistula was continually transferring severe infections from the bowel to bladder resulting in continual bladder infections such as constant cystitis, followed by surgery to repair the bladder and from various scans and x rays the bowel where the fistulae were originating from was severely ulcerated and causing diarrhoea all day and night. About 2 years ago I was put on Infliximab infusions every 8 weeks and at first the fistulae would slowly heal up but come back after about 6 weeks but after about 4 infusions I managed to get to the eight week point before tenderness on the abdomen and stinging from the bladder started. My treatment is now at 10 week intervals without any symptoms and it is my consultants plan to slowly increase the time span between infusions until I can hopefully come off the treatment completely. If PCTs refuse to allow my consultant to continue with my treatment, all the hard work put in over the last couple of years will be wasted and I will return to continuous infections, deteriorating health and more and more surgery. Please please do not let this happen.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Re 1.2 It is all very well so called experts classing frequent diarroeal stools 3-4 or more but when one suffers from Crohns disease the diarroea is more often than not continual, the patient is very often housebound because he or she cannot be more than a few seconds away from toilet facilities. I still work but was unable to do so regularly before Infliximab changed my life, without this treatment I would have been housebound unable to work and a severe burden on the state because I would not be able to continue earning my own living although as I am self employed I would have ended up homeless because I would not be entitled to benefits.
Section 2 (clinical need and practice)	
Section 3 (The technology)	On my present regime the cost of my Infliximab would be in the region of Ã‚Â£9000 p.a Without this treatment and assuming I reverted to my previous state, I would require surgery within 6 months at an initial cost of say Ã‚Â£5000 plus aftercare say Ã‚Â£2000 plus loss of earnings over 3month period say Ã‚Â£12,000 so just one surgical proceedure would cost more than twice the cost of Infliximab and this does not take into account the pain and suffering of the patient and family. Assuming surgery was required every 2/3 years the cost would be astronomical.
Section 4 (Evidence and interpretation)	It would appear that all the trials have shown a significant improvement in patients while they were being treated with Infliximab but the question is when the PCTs consider it is worth

	the expense. I can tell you that if anyone on the PCT panel has suffered from Crohns disease with fistulae then these discussions would not be taking place. Crohns disease with associated fistulae are one of the most painful and debilitating illnesses one can suffer from. We all appreciate the likes of Heart disease and Cancers are horrendous in t he extreme but it must not be forgotten that without satisfactory treatment Crohns disease can develop as a cancer.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	I am in full agreement with monitoring treatment in fact I agree to be part of any trials to enable my medical team at Addenbrookes to better understand this disease.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	29/09/2008 15:34

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Regular maintenance infusions of infliximab are significantly more effective than episodic treatment in these patients. The preliminary recommendations above are unclear -1.1 and 1.4 - and do not appear consistent with further statements in section 3.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	29/09/2008 14:31

Name	[redacted]
Role	NHS Professional

Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The use of these drugs has revolutionised the treatment of Crohns Disease. In my clinical practice patients using infliximab often become symptomatic before the end of the treatment interval and the infusion interval often has to be brought forward. I would not want to wait for a patient to become severely ill before giving treatment again. Also we would have more reactions in restarting infliximab.
Section 2 (clinical need and practice)	Yes it states here that we are dealing with a chronic disease with the aim being to maintain remission. These patients have already had many courses of steroids and a good trial of azathioprine
Section 3 (The technology)	Most units will be able to vial share infliximab
Section 4 (Evidence and interpretation)	The evidence has been interpreted in favour of low cost.
Section 5 (implementation)	I feel that I will not be able to stop treatment on my patients who are maintained on infliximab or adalimumab
Section 6 (proposed recommendations for further research)	Agree with 6.7
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	29/09/2008 14:16

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I disagree with 1.6 as I think the option should be available for a clinician to use infliximab and adalimumab for maintenance should the need arise. Some patients can maintain a remission effectively just through, for example, methotrexate. For these patients there would be no clinical need to maintain the remission through these newer drugs. However, some patients may relapse very readily following withdrawal of infliximab - once this has occurred once its likely to recur. For those patients it makes more sense to use infliximab episodically once and then switch to using it as a maintenance treatment following a severe relapse. Once a patient has antibodies to one of these drugs, its no longer a viable option. Given the fact that there are only two such drugs currently on offer, great care should be taken to minimise the risk of development of such

	antibodies (which is more likely in the event of episodic treatment)
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	4.3.10 seems to fly in the face of the recommendation. Does this mean that where a high relapse rate is experienced for a patient, infliximab should be withdrawn? The recommendation appears to state not, but in this case it would presumably be more cost effective to move to a maintenance model for patients who relapse frequently, rather than risk antibody development.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	I would encourage 6.2, 6.4 and 6.5 as a matter of urgency. I think the broad brush approach of the current recommendation is too restrictive and will lead to patients suffering unnecessarily due to loss of these drugs as an option following antibody development. I think it would be better if clinicians had the option to prescribe maintenance therapy using these drugs, until 6.2 has occurred. I do appreciate that these drugs are expensive, and I think that a recommendation to clinicians to avoid their use where remission can be maintained effectively using other means (such as methotrexate alone, or another immunosuppressant) would be sufficient.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	29/09/2008 13:53

Name	[redacted]
Role	NHS Professional
Other role	Prof of Clin Gastroenterology at Barts and the London.
Location	England
Conflict	no
Notes	I have a special interest in the treatment of inflammatory bowel disease and have acted previously as RCP and BSG expert witness to NICE on topics related to management of UC and Crohns
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am very concerned about these preliminary conclusions on how infliximab (IFX) and adalimumab (ADA) should be used in patients with complex and otherwise refractory CrohnÃ¢??s disease. I have several points: 1. Extensive trial data has shown that regular (scheduled) IFX, in patients who have responded to it in the first instance, causes fewer infusion reactions, hospital admissions and operations, and better mucosal healing (an as yet unproven surrogate for improved natural history) and response duration than when the drug is given episodically (ie when symptoms recur, as NICE proposes). 2. The lives of patients who respond to IFX (or

	ADA) and are maintained on it regularly, whether they have fistulising or non-fistulising diease), are literally transformed. Having been crippled by their disease previously, they are able to return to full work and social function, regaining confidence about their health for the first time usually for many months or years of illness. Most such patients are young adults who when well are active wage-earners. It is scarcely credible that patients should now be returned by NICE to a life of uncertainty as they wait for their next relapse.
Section 2 (clinical need and practice)	Patients who relapse on an episodic regime cannot simply be instructed to attend for a further infusion of IFX or injection of ADA. They will need (a) urgent clinical review in outpatients or A & E if very unwell (b) re-investigation to ensure that their recurrent symptoms are not due to sepsis (a strong contra-indication to IFX or ADA until eradicated with antibiotics or surgery). They will need urgent ultrasound, CT and/or MRI scans, all of which are expensive, CT having the additional disadvantage of increasing still further the radiation exposure of a group of patients already over-exposed to xrays Ã‚Â© hospital admission and/or surgery in some cases, the latter of course carrying the risk (and expense) of short bowel syndrome and consequent very costly lifelong treatment up to and including home parenteral nutrition (d) increased use of immunomodulators, with consequent need for blood monitoring and risk of side-effects, since while we now know that many patients on regular IFX can discontinue such drugs after about 6 months (van Assche Gastorenterology 2008 134:1861-8), those on episodic IFX need long-term thiopurines or methotrexate to try to control immunogenicity and maximise response duration (e) increased use (including side-effects and expense) of other drugs including steroids and antibiotics.
Section 3 (The technology)	It is not clear how NICE proposes that ADA is to be used on an episodic basis, bearing in mind that its current usage is every other week. Furthermore, should patients on episodic IFX returning after an interval to the drug for a relapse be given a 3-dose reinduction or simply a single dose (presumably with pre-infusion of hydrocortisone to try to limit the risk of anaphylaxis)?
Section 4 (Evidence and interpretation)	1. The baseline costs of management of CrohnÃ¢??s have been drawn from SilversteinÃ¢??s 1999 paper, which unfortunately looks at a whole population of patients with CrohnÃ¢??s, not the minority relevant to biological therapy, namely the 5-10% or so with severe and complex illness. Furthermore, the costs are from the US and now 10 years out of date. There is a paucity of UK-based data, but it might be worth NICE seeking the opinion of Dr Keith Bodger, a Consultant Gastroenterologist in Liverpool who has special expertise in this area. 2. The total direct saving arising from the proposed restriction to episodic therapy is likely to be relatively small across the UK indeed the absolute numbers of patients given IFX or ADA for CrohnÃ¢??s are tiny in comparison with, for example, those with rheumatoid arthritis. We have one of the largest IBD

	practices in the UK: of about 1000 patients with CrohnÃ¢??s, just 36 are currently on maintenance IFX, and 13 on regular ADA (ie approx 5%).
Section 5 (implementation)	Perhaps I should put my comments into perspective by stating that I fully concurred with the NICE recommendations about use of IFX in subacute outpatient and in acute severe inpatient ulcerative colitis (and represented the Royal College of Physicians in the latter ongoing appraisal). It is hard, however, as someone looking after patients with severe CrohnÃ¢??s disease, and having seen how regular IFX and ADA can restore them from a life of misery (no exaggeration) to a full and active one, not to become emotional, not to say incredulous, about the current NICE proposals. It is also impossible to reconcile these recommendations with the scrupulously evidence-based guidance recently issued by European Colitis & CrohnÃ¢??s Organisation (ECCO). This decision will create a postcode lottery at an international level: I cannot believe that we are to become the only country in the developed world which deliberately condemns these mostly young people to a life of recurrent illness and investigation as a result of under-treatment.It is distressing too that NICE offers recommendations which throw upside down the standard dictum that prevention of recurrent illness is the best approach to management of chronic disease.
Section 6 (proposed recommendations for further research)	Agree with 6.4-6.8, but who will fund 6.1 or 6.2? 6.3 unlikely to be feasible as we already know that many patients begin to develop recurrent symptoms in less than 2 weeks since their previous injection.
Section 7 (related NICE guidance)	The 2002 guidance became obsolete very quickly of course (see comment under 8 below)
Section 8 (proposed date of review of guidance)	A review in 2011 is far too late if the present recommendations are adopted - the literature is evolving rapidly and patients canot be condemned to the proposed management strategy for so long.
Date	29/09/2008 12:45

Name	[redacted]
Role	Healthcare Other
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	the primary objective of the treatment that we offer our patients with crohns is to get them back to a
Section 2 (clinical need and practice)	some patients prior to infliximab, have had multiple operations. the more operations someone has, the less bowel they have remaining, and more difficult and risky operations. maintenance use of infliximab for this group of patients has in some instances in my practice, meant no more operations, with consequent weight gain and normal function.
Section 3	

(The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	29/09/2008 11:59

Name	[redacted]
Role	NHS Professional
Other role	Consultant Gastroenterologist
Location	N Ireland
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	As a physician looking after large numbers of patients with IBD (>2000 clinic visits per annum) I am deeply concerned by the committees conclusion that infliximab and adalimumab should not be used for regular maintenance therapy in Crohns disease. These powerful and expensive agents may do harm as well as good. Their use is limited to a very rarified population of individuals with Crohns. Most of these people have exhausted all other treatment options, including surgery, and may already have undergone several surgical procedures. For this small group, regular scheduled therapy with infliximab has been life changing, allowing them a quality of life, including the ability to earn a living, which their disease has made difficult to achieve previously. I would strongly recommend that the committee take notice of the experience of units who have the greatest experience of the most unwell and treatment refractory patients in the consulatation process and revise the provisional decision on scheduled therapy. This decision ignores comparative data from Europe and the US which suggests that serious infusion reactions and loss of efficacy are reduced by regular infusions
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7	

(related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	29/09/2008 08:59

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am very concerned that these drugs will not be recommended for maintenance therapy in Crohns. It seems that much weight has been placed on an early study (Silverstein 1999) which focused on patients with relatively mild disease. In reality we do not use biologics for this cohort. However in my experience there is a cohort of patients with more severe active disease whose disease activity and qulaity of life is greatly improved with induction therapy and subsequent maintenance therapy. This cohort is relatively small but to deny these patients an effective therapy, particularly when there is no appropriate alternative (as they will already have failed other therapies before I use biologics), would be a huge retrograde step in the medical management of this disease. I implore the panel to reconsider this decision.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	29/09/2008 08:50

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	

Section 1 (Appraisal Committee's preliminary recommendations)	Agree with recommndations 1.1-1.5. do not agree with 1.6 if implemented this is going to cause me considerable problems managing a difficult group of patinets that have failed other regimes and are currently well
Section 2 (clinical need and practice)	no comment
Section 3 (The technology)	no comment
Section 4 (Evidence and interpretation)	I feel too much weight on Silverstein model has been given.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	Agree
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	28/09/2008 20:52

Name	[redacted]
Role	NHS Professional
Other role	Consultant Gastroenterologist
Location	England
Conflict	no
Notes	I sit on the Schering Plough Advisory boards.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is overwhelming evidence that the correct way to use these drugs is with scheduled maintenance therapy. This keeps patients in remission, but also prevents the development of antibodies to the drugs. Once these develop the drugs are very often no longer effective. Maintenance therapy is accepted best practice throughout Europe and in the USA. NICE needs to rethink this recommendation.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	

Date	28/09/2008 18:39

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Use of episodic anti-tnf antibody therapy for the relatively small number of patients with Crohns disease whose disease is severe and refractory is highly problematic: there is good evidence that use of infliximab like this results in a much more rapid loss of response and higher risk of infusion reactions and there is NO clinical trial data to support use of adalimumab like this . For both drugs the data supports their use as regular maintenance therapy, and in clinical practice responsible use of the drugs like this in the small proportion of patients with severe / refractory disease allows many of them to regain a quality of life and level of disease controls which is otherwise impossible. This is now the standard of care in all centres managing significant numbers of Crohns patients in Europe and north America.
Section 2 (clinical need and practice)	The question from NICE perspective should not be the total number of Crohns patients in the UK but the number who have severe disease refractory to conventional immunosuppressants at optimized doses. In these patients the other treatment options are surgery (expensive and non-curative) or - in those with extensive disease - either long-term steroid (universally accepted as a bad option due to side effects and lack of true mucosal healing) or chronic and progressive ill-health. For some patients a single or intermittent treatment with anti-TNF therapy may be sufficient, but for those with severe disease who relapse frequently regular therapy should be maintained as an option.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	This is a complex bit of analysis with a number of assumptions some of which are valid but others of which look wrong (particularly the ICER of Ã‚Â£4,980,000 / Ã‚Â£5,030,000 per QALY gained). For patients with severe refractory Crohns whose lives were previously dominated by their symptoms but have now got a reasonable or good quality of life on regular, scheduled anti-TNF therapy the idea of stopping this and not allowing treatment until they develop recurrent severe symptoms - particularly in the knowledge that this will reduce efficacy and increase risk of reactions to the therapy (infliximab) or has no basis in trials / evidence based medicine (adalimumab) - will be difficult to comprehend and make everyone involved in caring for this challenging group of patients very angry. The recommendations should in my view be amended to allow use of regular anti-TNF therapy in patients with severe disease refractory to all other treatments or

	intolerant to all other treatments (azathioprine, 6MP or methotrexate) and where reassessment demonstrates that it has produced substantial clinical benefit.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	28/09/2008 10:55

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	Considered a key opinion leader by my professional colleagues and therefore also by industry
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I spend a great deal of time working with Non-UK specialists in the IBD field. The evidence in favour of maintenance anti-TNF therapy is sufficient that this has convinced all of them and their healthcare systems that this is not only a possible but also the recommended way to use these agents. It is certainly safer to use multiple doses moving on into maintenance and the results at one year are clearly better in almost all of the studies performed. I do not share the continental view that maintenance anti-TNF should be considered mandatory but it would be a devastating backwards step to remove this option from the many patients who are currently benefiting and those who stand to benefit in the future. I am sure I will not be alone in this opinion. We must not allow the UK to become a backwater of poor and outdated practice (not to mention something of a European laughing stock) if the proposed decision becomes a recommendation.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review	

of guidance)	
Date	28/09/2008 08:11

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I have fistulating crohns disease which could not be brought under control by standard therapies. It was decided to try a course of inflixmab. This sucessfully brought my condition under control, only for symptoms to return after a matter of weeks. For the 5 years since, my condition has returned consistently after a short period of respite. If I report symptoms, and am given episodic treatment on a regular eight-weekly basis, how does this differ from the infliximab being given as maintenance therapy? Anti-tnf is the only treatment ever to return me to good health, and I doubt I am the only patient in this situation. It is frustrating to see a NICE recommendation so contrary to my personal experience and the anecdotal evidence of the large number of gastroenterologists (not to mention those patients for whom the treatment is effective) I have met. Infliximab maintenance has a role to play in treatment of Crohns disease, and I would like to see this recommendation changed.
Section 2 (clinical need and practice)	I have experienced painful ulceration in my mouth, which doesnt seem to get a mention here, despite being a significant part of suffering at times. I disagree with statement 2.3, having never experienced a period of remission in my 6 years experience of the disease, except with the help of medication. I have never even experienced a lessening of symptoms without medication. I would suggest that this statement is a generalisation not reflecting the whole spectrum of occurences of the disease.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	27/09/2008 17:12

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	Consultant gastroenterologist 16 years in post. Managing IBD patients through out this period
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	See below. Failure to recognise the importance of maintenance treatment for those with severe Crohns means that these conclusions are flawed
Section 2 (clinical need and practice)	This section fails to identify the group of Crohns patients who need a maintenance treatment. It is those people who receive Azathioprine, mercaptopurine and methotrexate. In those where these agents fail or cannot be used, the biological agents are an important maintenance tool as well as a treatment for acute symptoms.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Most Gastroenterologists use these drugs sparingly at the end of trying all alternatives. Severe Crohns disease is not, generally, a condition where occasional relapses occur but a condition of constant illness where a maintenance therapy is crucial. If you deprive the community of access to these drugs for maintenance therapy then you will significantly increase patient distress, loss of work, hospital admissions due to severe Crohns disease. Do not underestimate the psychological burden created by a chronic relapsing condition where lack of maintenance treatment makes it impossible to get stablility in life and work. I suspect that those with frequent relapses will get the treatment just as often but it will be labelled differently - so I doubt if you will actually save a great deal. However, I agree that there is very little information for the profession on how long to continue the drugs after the induction phase: i year, 2 years - who knows? Research into this would be valuable
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	26/09/2008 16:48

Name	[redacted]
Role	NHS Professional
Other role	Consultant Gastroenterologist
Location	England
Conflict	no
Notes	I agree that we need to be sparing in the use of biologics in

	Crohns disease maintenance but for a few patients there is no satisfactory alternative.Are we going to end up with a situation like oncology where the patients have to pay to
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	26/09/2008 14:59

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The panel needs to re-assess its position on maintenance therapy. There is clear data to show that sporadic therapy gives rise to rapid tolerance / antibody formation and maintenance therapy often leads to little or no tolerance. This is more imoportant now that there are concerns over concomitant use of azathioprine + biologicals with reports of hepatosplenic T cell lymphoma. The cost-benefit analysis was based on seriously flawed assumptions and this undermines Nices case against use of biologics as maintenance therapy. A major flaw was the over-reliance on data taken from Silversteins paper, which was based on analysis of a well controlled relatively mild group of patients in Olmstead County. Infliximab therapy (in particular) and subsequent maintenance has also been shown to have beenficial effects long-term in fistulising perianal disease where continence issues remain a problem.
Section 2 (clinical need and practice)	The panel needs to re-assess its position on maintenance therapy. There is clear data to show that sporadic therapy gives rise to rapid tolerance / antibody formation and maintenance

	therapy often leads to little or no tolerance. This is more imoportant now that there are concerns over concomitant use of azathioprine + biologicals with reports of hepatosplenic T cell lymphoma. The cost-benefit analysis was based on seriously flawed assumptions and this undermines Nices case against use of biologics as maintenance therapy. A major flaw was the over-reliance on data taken from Silversteins paper, which was based on analysis of a well controlled relatively mild group of patients in Olmstead County. Infliximab therapy (in particular) and subsequent maintenance has also been shown to have beenficial effects long-term in fistulising perianal disease where continence issues remain a problem.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The cost-benefit analysis was based on seriously flawed assumptions and this undermines Nices case against use of biologics as maintenance therapy. A major flaw was the over-reliance on data taken from Silversteins paper, which was based on analysis of a well controlled relatively mild group of patients in Olmstead County. Comparisons of the Humira studies and the IFX are flawed - different patient groups, different levels of biological naivity and completely different study designs.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	26/09/2008 14:45

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Infliximab and adalimumab have revolutionised the care of patients with severe Crohns disease. In our hospital their use is restricted to patients who have progressed despite steroid and immunomodulators or are intolerant of these therapies. For this small subgroup of Crohns patients the biologicals reduce the need for surgery and the risk of short bowel syndrome with all the attendant costs. Most patients in this group progress and

	relapse frequently (ie >4x yr) making maintenance treatment necessary. There is also evidence that episodic treatment increases the risk of antibody formation and diminishes the effect of infliximab. Because of the shorter duration of effect it does really not make sense to stop Adalimumab after induction as one is likely to have to restart this a few weeks later when the disease relapses. Disease progression is more likely when relapses occur and the aim should be to prevent this with maintenance therapy. I submit that the lack of support for maintence therapy will lead to increased morbidity and misery for many patients with severe Crohns disease, will increase surgery and hospital admissions and not be cost saving.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	26/09/2008 14:34

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The guidance for the use of biologics in maintenance of Crohns disease is at variance with my clinical experience in three significant groups of patients: 1. most patients receiving biologics have already been trialled on one or usually two and are continuing to receive a therapeutic dose of DMARDS (azathioprine, mercaptopurine or methotrexate). In those patients it is my experience from earlier (non maintenance) use of infliximab that relapse after successful induction is very common. These patients cannot be maintained on DMARDS and so have been brought back into remission by further induction with infliximab and kept thus by maintenance. 2. A smaller group of patients on infliximab are clearly but not clinically (as defined in your guidance) relapsing at around eight weeks. It would be inappropriate to wait until they developed severe Crohns again only to treat. Once you have remission it

	needs to be worked at. 3. Anecdotal hypersensitivities and loss of efficacy after re-trial of infliximab amounting to perhaps 5% of my patients (a group who have no other medical therapeutic option) rightly shapes my practice toward maintenance.
Section 2 (clinical need and practice)	Your concept of flares of Crohns disease is historic and invalid, being based on the previous symptomatic management of the disease and the use os short courses of steroid. Radiology, endoscopy and faecal markers allow the chronicity of the disease and its continuous activity to be demonstrated and so modifies thinking in disease management.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	26/09/2008 13:08

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	No
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I can not agree with the suggestion that infliximab or adalimumab are not approved for maintenance use in CD. I am a DGH gastroenterologist and I try and use biologics quite sparingly. In particular in terms of maintenace use I only have a handful of patients with CD on maintenace infliximab. This is in contrast to the Rheumatologists who seem to have hundreds of patients on these drugs. However for those patients they are absolutely essential. These are patients for whom further surgery is either not possible or high risk. If there are delays in the medication administration they often experience symptomatic relapse. Infliximab represents a major leap forward in the management of these patients and its withdrawal would lead us back into the dark ages of CD treatment. I would ask you to reconsider your provisional guidance.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4	

(Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	26/09/2008 13:01

Name	[redacted]
Role	NHS Professional
Other role	Consultant Gastroenterologist
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I have numerous patients whose life has been transformed from relapsing Crohns disease (some requiring repeated surgery) to stable disease and return to work by the advent of Infliximab. I belive that trial data are consistent with my clinical impression. I have no clincal experience with Adalimumab.
Section 2 (clinical need and practice)	As above
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	26/09/2008 11:40

Name	[redacted]
Role	NHS Professional
Other role	
Location	Scotland
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's	I find the conclusion that antiTNF treatments are not recommended for maintenance therapy faintly ridiculous. This

preliminary recommendations)	conclusion has been reached by the over reliance on the paper by Silverstein et al. This makes assumptions about the patient group that are based mainly on moderately active disease. As the committee is well aware, there is conflicting evidence from the UK and North America to suggest that maintenance is a cost effective strategy. Clinically, maintenance therapy makes a huge difference to the quality of life of the small number of individuals that need it. Anti-TNF therapy is used much less frequently in the UK than the US or northern Europe. UK Patients have had to
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	26/09/2008 11:02

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	I am formally retired but still work within the NHS and private sector
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am disappointed in reccommendation 1.6. It is clear that infliximab is effective as maintenance. The use of maintenance treatment in Crohns disease is well recognised with the 5 amino compounds and azathioprine/6-MP. The suggestion that it should be used intermettently for relapse ignores a serious aspect of treatment namely improving quality of life. If a patient has to become ill to justify treatment their quality of life is obviously impaired. Furthermore the cost benefit effect on their ability to work may be significant. i.e. recurrent relapse equals recurrent work lost. Anecdotaly I have young paitents who would undoubteldy have needed major and extensive surgery if they had not been controlled on infliximab. This ruling is short sighted and will be detrimental to my patients.
Section 2 (clinical need and practice)	

Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	26/09/2008 09:49

Name	[redacted]
Role	NHS Professional
Other role	Lecturer in Nursing
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I agree that infliximab is an effective treatment for IBD and it is my belief that as the studies have demonstrated a top down apporach to this medication group , starting with biologocs, is effective in arthritis, we should be investigating this approach to its use in IBD. THat would in the long run if sucessful redude patient admissions and inpatient stays which is better for the NHS and the patient
Section 2 (clinical need and practice)	I agree that infliximab is an effective treatment for IBD and it is my belief that as the studies have demonstrated a top down apporach to this medication group , starting with biologocs, is effective in arthritis, we should be investigating this approach to its use in IBD. THat would in the long run if sucessful redude patient admissions and inpatient stays which is better for the NHS and the patient
Section 3 (The technology)	I agree that infliximab is an effective treatment for IBD and it is my belief that as the studies have demonstrated a top down apporach to this medication group , starting with biologocs, is effective in arthritis, we should be investigating this approach to its use in IBD. THat would in the long run if sucessful redude patient admissions and inpatient stays which is better for the NHS and the patient
Section 4 (Evidence and interpretation)	I agree that infliximab is an effective treatment for IBD and it is my belief that as the studies have demonstrated a top down apporach to this medication group , starting with biologocs, is effective in arthritis, we should be investigating this approach to its use in IBD. THat would in the long run if sucessful redude patient admissions and inpatient stays which is better for the NHS and the patient
Section 5 (implementation)	I agree that infliximab is an effective treatment for IBD and it is my belief that as the studies have demonstrated a top down

	apporach to this medication group , starting with biologocs, is effective in arthritis, we should be investigating this approach to its use in IBD. THat would in the long run if sucessful redude patient admissions and inpatient stays which is better for the NHS and the patient
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	You cannot offer this effective treatment to patients and then withdraw it before it has been fully effective. You are placing patients at risk of abtibody development rendering a second treatment of this drug impossible and therefore increasing in patient admissions, surgery and distress to patients. Compare the cost of infliximab 6 times a year and stoma appliences for life
Section 8 (proposed date of review of guidance)	
Date	26/09/2008 05:41

Name	[redacted]
Role	other
Other role	Parent of a patient
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Infliximab should be given as maintenance for severe Crohns as keeping the patient well will prevent frequent hospitalisation,surgery, expensive investigations such as CT and MRI scans and endoscopies. My daughter has suffered from Crohns disease most of her life (29years). She has had infliximab for 2yrs 6 months. In that time she has been able to live a near normal life and has needed no tests or hospitalisation for Crohns.Patients who are allowed to relapse due to withdrawal of infliximab may need extensive surgery resulting in the need for TPN, which is both expensive and leads to lower quality of life.
Section 2 (clinical need and practice)	My daughter has tried all other drugs available plus an elemental diet but none produced more than a very brief remission.Prolonged use of steroids have caused her to have osteoporosis for which she is now having treatment (Aclasta).Use of infliximab instead of steroids would prevent osteoporosis developing in young people.Osteoporosis may lead to fractures and eventually disability requiring adaptations to home, carers and special mobility packages all of which are costly.
Section 3 (The technology)	The fact that infliximab sometimes is ineffective and sometimes causes adverse reactions should not prevent its use after patient consultation and agreement and its continuation for those patients who are benefitting. The cost should be set against the costs of severe active Crohns if the treatment is terminated. These would include frequent and sometimes

	lengthy hospital inpatient stays, surgery, expensive diagnostic tests such as scans and endoscopies. My daughters maximum stay in hospital was a month and she continued to need community nursing for several months after that.much of that lengthy stay was in a High Dependency Unit. She has had no hospital admisiions and no investigations for Crohns since starting the infliximab treatment. It is important too to keep Adalimumab available for infliximab patients who become intolerant to infliximab.
Section 4 (Evidence and interpretation)	Due to the risk of a patient developing antibodies infliximab should be used as maintenance rather than episodic for those with severe Crohns.It appears to me to be cost effective when set against the cost of hospitalisation, investigations and surgery. Its use for maintenance may also make it possible for patients to work rather than rely on incapacity benefit.Also it is impossible to measure cost effectiveness against quality of life. Its use in children may prevent resection of bowel and poor absorption of nutrients due to inflammation or reduced bowel length and therefore allow for normal growth. Throughout childhood my daughter was underweight and is still short for her age. For the first time in her life she is of normal weight due to over 2 years treatment with infliximab.
Section 5 (implementation)	While understanding that the NHS budget is limited, it seems to me that the alternative treatment for those with severe Crohns would be just as expensive or more so and not so effective and the quality of life for those patients would be reduced quite drastically. This is especially so if frequent surgery resulted in the need for TPN with its constraints on the patients life, the risk of infection in the Hickman line and the cost of TPN itself with the price of pump, giving sets and sterilising equipment.
Section 6 (proposed recommendations for further research)	I believe ongoing trials are basically a good idea. I think it is vital to carry out more extensive surveys on the quality of life of patients on all treatment regimens and to consider the quality of life of their families, especially parents of patients and the families of patients who have children.
Section 7 (related NICE guidance)	No comment.
Section 8 (proposed date of review of guidance)	This seems a little too soon. Perhaps a review should only be conducted within 5 years if an alternative , promising treatment is developed.
Date	25/09/2008 18:09

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	No
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	1.6 I strongly disagree. Many patients do respond to regular infliximab infusions or adalimumab injections as a maintenance therapy for Crohns disease (occasionally for ulcerative colitis). If this is no longer authorised there will be a big outcry from the

	many patients already receiving this maintenence treatment. Some of these will thus need to have extensive small bowel resections which may result in the much more expensive treatment of life long home parenteral nutrition. We are very selective about who is recommended for anti TNF maintenence therapy. I agree that one of our current problems is when to stop anti TNF therapy just as we have this problem with azathioprine/mercaptopurine. The alternative to stopping the anti-TNF therapy is usually going to be active Crohns disease with the patient gnerally feeling ill. This may just be a good practice point and level D evidence but maintenence therapy must be available to clinicians especially those working in a tertiary referral centre.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	25/09/2008 17:19

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	yes
Notes	I am a clinical nurse specialist working with patients with Crohns disease and ulcerative colitis. I have considerable experience of managing patients using both of these treatments both as episodic and scheduled approaches to care. I have been involved in patient education and support initiatives sponsored by the manufacturers of both therapies, but do not allow my involvement in these projects to affect my clinical judgements.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I have grave concerns with the recommendation that these drugs are not used as maintainance therapies. There is considerable clinical experience supporting the maintainance approach to therapy, particularly in the case of infliximab, which has been used in this way for a number of years. Maintainance therapy allows for better remission, as well as providing a more consistent and timely approach to organising patient care, which ultimately improves cost effectiveness of

	healthcare resources utilised.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	It is essential to remember that current practice approaches mean that any patient started on a biological therapy for Crohns disease will by definition, have failed, or been intolerant to, the other therapies used to treat the disease. This means that they will be very limited in terms of what to use as an alterative maintainance therapy if biologics cannot be used. Ultimately, this will result in recurrence of symptoms, and the risk of antibodies developing to the biological therapies which will effectively render them useless or even dangerous. The costs of repeated clinic appointments to asess the need for treatment must also be considered. Many hospitals using maintainance approaches will have solid protocol driven clinics which allow for patients to be seen, assessed and treated without the need for an outpatient appointment. If treatments cannot be scheduled, it is feasable that each assessment in outpatients will also trigger an appointment for treatment, essentially doubling workload and cost.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	These all appear sensible, and are currently being explored by members of the gastroenterology community.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	25/09/2008 15:19

Name	[redacted]
Role	NHS Professional
Other role	
Location	Scotland
Conflict	no
Notes	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am concerned that maintenance treatment is not recommended. This treatment is helpful for some of the patients with very severe Crohns disease. European and American guidelines differ from NICE in this regard. Although this is an expensive treatment without it these patients are likely to be a) hospitalised b) require more surgery c) require increased treatment such as steroid with very significant and expensive longterm side effects such as osteoporosis d) might develop intestinal failure, requiring home parenteral nutrition or even intestinal transplant

Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	I am concerned that Silversteins data were from a milder group than those usually given biologicals for maintenance in the UK and hence the results may not be able to be extrapolated
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	25/09/2008 14:35

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	Have received support for educational meetings - UEGW from company making biologics
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	concern re episodic treatment. Have patients on maintenance treatment with Infliximab and Adalimumab, responding well, improved QOL. Unable to convert to episodic treatment, may increase chances of flare ups. Increasing evidence for step down therapy and regular biologics
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	25/09/2008 14:31

Name	[redacted]
Role	Patient

Other role	
Location	Scotland
Conflict	no
Notes	My opinion on taking away Infliximab away from Crohns Disease patients is DO NOT DO IT! Yes it is a very expensive treatment but it is also a lifeline for the people who do receive it. I know several people (including myself) who have Infliximab infusions every 8 weeks and it is the only thing that has worked properly and they feel the benefits almost straight away. It also reduces the amount of time spent in hospital with severe flare ups which in the long run is actually saving you money. I spent the best part of 8 months in and out of hospital with severe flare ups and blockages because of strictures before having surgery to remove them. For me Crohns always returns sooner than it should after surgery or after starting a new treatment. It is an outrage that you would even consider removing the availability of this drug. How would you feel if it were you or a loved one receiving the treatment? Im sure you would be just as angry at the thought as we all are. You wouldnt just be stopping a drug, youd be taking away life from a Crohns sufferer and reducing them to living life no more than 10 feet from a toilet, unable to leave the house. It is hard enough living with this disease and trying to keep living a normal day to day life. Not many people have actually heard of this disease and certainly do not understand it. This makes life even harder because more people think theres nothing wrong with you and its just for show. If it was Cancer we had it would be a whole different story.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review	

of guidance)	
Date	25/09/2008 10:35

Name	[redacted]
Role	Patient
Other role	
Location	Europe
Conflict	no
Notes	As a patient who has had severe Crohns disease since childhood (17 years since diagnosis but suspected having it much longer from the young age of about 3) who has been on Infliximab for 2 1/2 years now, I would beg you to continue approving this drug for longer term and maintenance use. Before I started on Infliximab, I was severely ill, in constant agonising pain and was frequently having major surgery - and always at a risk to me as I was constantly dangerously underweight etc. Several of my surgeries were emergencies and I nearly died several times. No other medications had helped me and I was desperate, and so were my doctors. Infliximab was given to me as a last resort. However, since starting on Infliximab, my life has completely changed around for the better, and for the first time in my life I feel well, and have put on weight. I have now been able to do things that I would never have dreamt of. If you were to withdraw this drug, it would be like withdrawing my lifeline. I know that my condition would severely deteriorate and I would be miserable again. I know that there are many others who feel the same. Please dont take away our lives (before this drug I had no life - ever since a little girl of about 3 years old). If it is a money issue, please consider the potential costs of patients NOT being given Infliximab. Think of the costs of patients being in hospital more frequently - ie, the cost of the bed, the nursing and medical staff etc, and also when a patient is ill, they require more tests such as CT or MRI scans, which I know are also costly. Please realise that you should actually save money in the longer term, by keeping people well on Infliximab. Im sure that it is a lot more costly to the government/NHS etc if people are constantly ill and require a whole range of services. PLEASE PLEASE PLEASE do not withdraw Infliximab (and Humira) for long term use. Thank you for listening.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am one of those patients who was constantly in very poor health - as outlined in 1.2. If you were to withdraw my Infliximab treatment, I know that my condition would severely deteriorate. No other drug has ever helped me like Infliximab has. It has given me back my life. Surely it is better to keep someone well, instead of letting them get so poorly that they have to resort to major surgery. I have had 6 major operations and each one has been a big risk to me as I keep losing parts of my small bowel - and when this has gone it has gone, and then I will be kept alive by TPN only. That for me is the very last resort and would make me extremely sad. I would much rather avoid more surgery please as my surgeon told me I cannot afford to lose

	any more small bowel. Please take this into consideration as Im sure that there are many others like me who feel strongly that Infliximab is the only thing that has helped keep them well and has helped them to avoid needing surgery.
Section 2 (clinical need and practice)	I have tried all the treatments listed in 2.7. Because I received high and frequent doses of corticosteroids during childhood, I am now left with osteoporosis. I know that many more patients are now being diagnosed with osteoporosis because of prolonged steroid use. However, I also know that suffering from malnutrition for so long - because of severe Crohns disease, could have contributed to me developing osteoporosis. My condition was effectively left untreated for a long long time - partly because of a GP being totally negligent, and also partly because frankly none of the medications worked for me, and they turned out to be a waste of time. The ONLY drug that has worked for me is Infliximab. Also, you say in 2.8 that between 50 and 80% of patients with Crohns disease will require surgery at some stage. Well that is probably true, however, if medics were allowed to use Infliximab for longer, then this figure should go down. I know already, that I have managed far longer than ever before, without needing surgery. Infliximab might help patients to dodge the need for surgery. Surely that is a wonderful thing. Surgery is very hard on an individual, both mentally and physically.
Section 3 (The technology)	Although I was told there is a risk of reactions etc with Infliximab, I felt that me being well, far outweighed any potential risks. If I were to develop antibodies to Infliximab, then my doctors have said they would hope that Humira (adalimumab) would be my next drug to try, and it is comforting to know that I would have a back-up. If you were to withdraw both drugs, then there would be no hope for Crohns sufferers like me. Also, some patients are only given Infliximab as a one-off dose to help give them a boost, but for me that probably would not have been enough to keep my condition under control. Also, I understand that it is more risky to just receive Inflixmab in short doses, and have long periods without it - because of the risk of developing antibodies. For this reason I really hope I can continue receiving my treatment every 8 weeks.
Section 4 (Evidence and interpretation)	I think that using Infliximab long term IS cost-effective. It will reduce the need for patients to have costly tests/investigations, and also will reduce the need for hospitalisations and the use of other drugs. Also it will reduce the need for surgery. PLEASE do not withdraw Infliximab for longer term use.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	I would only be too happy to tell you how my quality of life has changed for the better - basically I have a quality of life now, whereas I didnt before. PLEASE PLEASE PLEASE do not withdraw Infliximab or Humira. Thanks for your time.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	25/09/2008 08:56

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	I am a 33 year old Indian male. I was first diagnosed with Crohns disease after a resection in 2002, back in India. I was constantly suffering for a period of time after that. I came to England in 2003, and after several diagnostic tests, the original diagnosis was confirmed. I was put on steroid therapy and my health improved. The disease flared again in late 2005. I was on steroid therapy and azathioprine for a long time. While the health condition temporarily improved following steroids, it gradually declined. At this time I found it very difficult to perform moderate physical jobs, exercise and to eat. My weight plummeted down to 55 kilos which is very low for a person who is 6 ft tall. Several hospital admissions followed. At this point I developed per-anal disease. The consultant put me on inflixmab as no other drug worked. After the first couple of infusions, I came to remember how it was to live normally. Infliximab brought back my work and personal life up to a great extent. I was able to eat well, sleep well and exercise. Unfortunately, whilst the disease in the small bowel was controlled very well, the peri-anal fistulas and abscess got worse due to the extent of the disease. I had to have a stoma in order to rest my colon and the infliximan was stopped. Life continued farely well, but the fistula struck again. At this point, it was recommended that I have a Proctectomy, so that the diseased parts will be removed. Another option was adalimumab. I wanted to try the drug first and have been on it for about 3 months. I can positively say that I have never been this better (touch wood, touch a whole forest) in the past 4 years. My weight is good and climbing healthily. I can exercise and work 60 hour weeks without feeling constantly tired. Even though it has only been 3 months, I can see a lot of difference in my physical side of things, as well as how I feel mentally. Where few months ago I couldnt sit on the worlds most comfortable sofa, I can now cycle 5 miles to work everyday without a trace of pain. Most recent blood tests show my inflammation level at all time low of the past 5 years. My iron levels are the highest since 2005. My confidence is up and my wife and I think we are now ready to have children. We do not much know of the long-term effects of adalimumab. There is that slight what next ? fear always lingering at the back

	of my mind. But the present has never been so good. So I hope the future can be as good too. Adalimumab has made a bit difference to my lifestyle, without which I would be facing immediate proctectomy, further pain and uncertain professional life.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Infliximab controlled the disease in my small bowel. I was able to eat and digest well only after infliximab treatment, ever since my relapse. The periodic dose was mainly the cause. Now adalumumab has almost dried up the fistula and abscess tracts. I think this is also an effect of the maintenance treatment.
Section 2 (clinical need and practice)	
Section 3 (The technology)	I had severe Crohns disease of the small bowel, inflammed colon, fistulizing disease in the rectum. Only after anti-TNF treatment, the disease has been controlled thoroughly, according to latest blood test. Oral and IV steroids, Immunosupressants and antibiotics have only provided temporary relief.
Section 4 (Evidence and interpretation)	I have had absolutely no side-effects with both the drugs in the short-term (infliximab and adalimumab).
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	23/09/2008 19:35

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	I am a Consultant Gastroenterologist
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I disagree with the recommendation regarding maintenance treatment
Section 2 (clinical need and practice)	There is now evidence that maintenance infliximab reduces surgery
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	I agree that due to the complicated cross-over nature especially of the ACCENT trials that comparisons were harder to make between truly episodic and maintenance. In addition, patients with moderately active disease were

	treated, which is not my practice. In clinical practice, outside of trials, only patients with SEVERE CD are selected. This is reflected by the relatively low CRPs of the ACCENT patients cf our patients treated, ie we are limiting the treatment to a selected group of very sick individuals. When their infliximab treatments are interrupted,usually because of funding, the disease inevitably returns..I have seen this happen on numerous occasions. This is accompanied by significant rise in the CRP, to reflect active disease. Depriving this sick, young group of patients the chance to enter a sustained remission and get back to their lives is very serious and I would encourage any patient of mine to pursue treatment relentlessy, eg by petitioning the PCT directly
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	I agree, a database, cf the rheumatology TNF database is an excellent idea, as would be a direct comparison of adalimumab and infliximab and a true episodic vs maintenance trial. Costs could be cut be removing hte third induction infusion, which adds relattively small amount of gain cf a further maintenance infusion at 8 weeks. No attempt has been made to estimate the cost reduction achieved by vial sharing, this needs to be done.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	22/09/2008 10:38

Name	[redacted]
Role	NHS Professional
Other role	Pharmacist
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	It isnt clear whether maintenance can be used for children- as it is licenced for that? If
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	

Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	17/09/2008 16:32