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

Role	Patient
Other role	
Location	Wales
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The format of these comments on this site seems to have been created with the sole purpose of putting the average member of the public off from bothering. I hope youre happy with that?! As a crohns patient on Infliximab who has been on umpteen drug types over the years and had a hemi-colectomy some years back, I find it truly remarkable that youre considering removing the drug after 12 months. To put it blunty, its the first drug that I have been on that has made any outstanding difference. Other drugs made little impact, and I?ve been wavering in between the threat of going under the knife again, having trouble to hold down a job due to sickness record, and ?just about getting by? for years. Infliximab has finally brought some quality to my life back, where I can get back to sport and put my business back on the rails and go back to employing people once again ? before it was all too much due to not being able to get up / stand up straight / not go to the loo 20 times a day, let alone run a business in a professional manner employing others. Judging by the reactions of the other patients I see in the infusion sessions, the changes to their lives has been equally astounding
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	10/12/2009 23:58

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

Role	Carer
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Taking the decision on whether to continue treatment with Infliximab away from the clinician and their patient is to take away hope from the sufferer. This disease at its worst robs the individual of their right to a normal life, replacing lifes aspirations with the constant fear of future flair ups. Young people are affected and repeated illness can ruin their chances of a successful family life and career. Infliximab is a life line that must be made available to all who need it and the decision making be left in the hands of the doctor and patient.
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	10/12/2009 23:46

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

Role	Public
Other role	parent of a son with Crohns
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The proposal would have an adverse effect on young Crohns patients who have to face the prospect of having their progress through school and higher education and then their career development severely disrupted due to the impact of severe Crohns. The cut off point is very arbitrary with the clinician seemingly unable to make a decision for an individual patient.
Section 2 (clinical need and practice)	Where are the estimates of the numbers of people who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The drug seems to fall within NICE guidelines for cost effectiveness for maintenance therapy. It seems wrong to remove the decision whether to continue on the drug from the clinician and patient. Is there any research into the effects of stopping and restarting these drugs?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	10/12/2009 23:27

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

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 young man with severe Crohns disease, who is currently studying at University, and who has gone through some very bad times with the condition. If it wasnt for Adalimumab his quality of life would be very different. He has such a positive attitude to life and is making fantastic contributions both in his studies and in his advocacy work for Crohns sufferers. It would be extremely sad - and probably very short-sighted - for the administering of this drug to be controlled by a time limit. What if this young man were to fall ill again because of an arbitraty time limit rather than through an informed clinical decision? The treatment of Crohns is complex enough without having a fixed cut-off point imposed. Think what would be lost if these sufferers were unable to work and enjoy some sort of life but instead had to endure the pain of uncertain and second choice treatments. I know that Adalimumab can work well for some sufferers: the reasons given for changing to a 12 month cut off are by no means clear to me.
Section 2 (clinical need and practice)	Is it known how many people with severe Crohns disease are likely to be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	It seems to me that a range of effective treatments needs to be available for sufferers. Being such an unpredictable disease and notoriously hard to treat it would be almost immoral to deny sufferers what might be their best chance of living as normal a life as possible and be given the chance to study, earn a wage, pursue a career and make positive and valuable contributions to society. The condition is hard enough to cope with without seemingly being used as pawns in a game of chance. Please think again about the effect that these preliminary recommendations would have on the quality of life of those who are at present benefitting from the drugs that are giving them a 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	10/12/2009 22:39

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

Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Twelve months is a completely arbitrary cut-off figure. There is no evidence whatsoever to support this decision. Consequently, it is clinically unacceptable.
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	10/12/2009 21:26

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

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 with the above and do not agree that Infliximab should be discontinued after 12months - this is against current clinical practice in UK and around the world and would be damaging for those patients who have ongoing benefits from treatment. As a pharmacist I have seen Infliximab keeping people well. Certain patients have had huge improvements in their quality of life and ability to keep working and carrying out most activities thus reducing the burden on the economy in relation to inability to work but also use of NHS services. Very often they have not gone into full remission and deteriorate slightly prior to each infusion indicating ongoing benefits of the infusion. These patients would experience a flare-up or return of their symptoms with consequent damage to their mental health as well as their physical health. Only then would they requalify for a new course of treatment when treatment may not have the same benefits and outlook for them would be poor. I think there should be an annual clinical review of treatment with specialists continuing treatment where there is clinical evidence(using other symptom indicators besides CDAI)
Section 2 (clinical need and practice)	People with Crohns suffer greatly with their symptoms - psychologically and physically - response to medication and benefits from treatment have a huge impact on their ability to cope with their illness and manage residual symptoms. Confidence in an effective treatment that has worked for them is essential for recovery. There does not seem evidence to stop infliximab at 12months and risk full relapse when the treatment is obviously continuing to keep symptoms under control and preventing the development of fistulae etc
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Indicators for remission are given as CDAI scores when these do not always relate to the clinical picture for the patient. Many patients have CDAI scores indicating remission but are experiencing intolerable symptoms of their illness which are reduced by ongoing infliximab treatment. For patients who stop treatment and then relapse it is very often difficult to get the same level of response to infliximab as before and there is no reference to this in the evidence above but it is a clinical fact. The trials do not appear to extend over 1 year so what is the evidence that they should stop at that time. i agree patients should be reviewed regularly and stopped if there is no response but it would appear clear that some patients benefit from continuation of treatment over 1 year
Section 5	I think costing should take into account people being

(implementation)	maintained in work and not using nhs resources - surgical or otherwise because of ongoing treatment.
Section 6 (proposed recommendations for further research)	I think to stop current clinical practice which is nationally and internationally recognised because no trials have continued over 1 year is very concerning.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	10/12/2009 21:04

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	I am 31 years old and was diagnosed with Crohn?s 12 years ago. I have been receiving infliximab as a maintenance treatment for the past 3 years. Prior to receiving infliximab I suffered frequent periods of considerable pain and diarrhoea, accompanied by extreme tiredness and depression. For me, Crohn?s was extremely debilitating and had a significant impact on the latter part of my education and early working life. During the 2 years prior to infliximab treatment I had 4 surgical operations for fistulae and was extremely grateful for the support of my family and friends. I know my experience is similar to many other people with Crohns. Infliximab changed my life. I receive the treatment by infusion which involves half a day at the hospital every 8 weeks. It dramatically reduced my symptoms and has been responsible for keeping me in remission, enabling me to live a reasonably normal life. I am now able to work full time in a responsible position, needing time off only to receive the infusion treatment. Outside of work, I enjoy a satisfactory life, but which I have to balance to ensure full commitment to my Company. I have had no operations since receiving infliximab and consider the treatment has been responsible for recently closing the fistulae. My condition is most certainly controlled by infliximab. My wellness reaches a peak shortly following each treatment and is at a low immediately prior to the next treatment. Should I not be able to receive infliximab regularly, I fear my life will return to what it was like 3 years ago. Albeit that infliximab treatment might be permitted when symptoms reappear, I expect the period coming out of remission and the time it will take for treatment to be reapplied will result in my having significant periods of being unwell. Furthermore, I anticipate I will have to return to steroid treatment, which had, for me, as it does for many others, various negative side effects. I dread these possibilities and the implications it will have on my life. I understand that the preliminary proposal of NICE to recommend that infliximab and adalimumab should not be used as a maintenance treatment for Crohn?s disease is based on cost, which for infliximab at intervals of 8 weeks is estimated to be £12,584 per annum. I?m sure you will understand that I consider NICE?s current view to be, in the least, wholly unreasonable. With maintained wellness, the contribution I am able make to commerce, and society, far outweighs the cost of infliximab treatment. I?m also very sure that the annual cost to the NHS, prior to my receiving infliximab, was considerably

	more than £12,584. The preliminary proposal as it stood at 14th September 2009 was reasonable and fair. The continuing deliberations by NICE on the matter are psychologically very damaging to patients like me who have to live with the disease every moment of their lives. Please let me live a reasonably normal life.
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	10/12/2009 20:50

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	It hasnt been proved that anti-TNF treatment has increased harms to users, furthermore, users are seen to be regularly monitored and also should be able to make an informed decision as to whether or not they wish to continue. Would arbitrary cut-off points really have any benefits? And is there any proof that it is necessary?
Section 2 (clinical need and practice)	Why is there not an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Treatments specifically have never been seen to have be greatly affective. The important thing is to have a range of treatments available, particularly for those with severe Crohn?s disease. Also, time limits seem unnecessary and it is dependent on the individual where or not there are any effects, both negative and positive.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	10/12/2009 20:46

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	A review at 12 months taking into account all internal and external factors seems more reasonable.It is unfair to expect a patient to drift back out of remission to qualify for an extension to the Infliximab/Adalimumab drug.
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	10/12/2009 19:55

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

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 unreasonable to stop treatment and require the patient to relapse when the anti TNF treatment is maintaining the patient in an improved state. Given the health professionals are experienced with the TNF therapy it is essential they agree with the patient whether to continue treatment or move to a different treatment. Clinicians will only continue treatment where essential and necessary. They can also take account of any special circumstances impacting the patient at the time of transition.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	A lot of data included in this summary appears to be outdated as it uses the wrong assumption about relapse rates. I do know the adjusted relapse rates for severe Crohns patients are included, but seemingly as an afterthought.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	10/12/2009 17:46

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There do not seem to be good reasons for changing the prelimminary recommendations to a cut off of 12 months . This may lead to a patient being made severely ill again before being eligible for further treatment. This would be costly distressing and disruptive .
Section 2 (clinical need and practice)	Where is the estimate of numbers affected severely.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	It is particularly important in Crohns disease that a range of treatments are available for doctors to use as they deem appropriate. This is a disease which affects many young people who need to be able to have treatment tailored for them enabling them to lead as healthy and productive lives as possible
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	10/12/2009 15:09

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

Role	Private Sector Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I write as a concerned member of the public, with no medical qualifications. My interest is that my close friends son, a Crohns disease sufferer aged 19, is currently benefiting very much from adalimubab. It is only this which is enabling him to continuing studies at a top uniiversity. I urge the committee to continue making the drug available without any arbitrary cut off points.
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	10/12/2009 14:53

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

Role	other
Other role	father
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)	I would hate to see my daughter with the terrible problems she has with Crohns disease before she was started on the Infliximab treatment. She is a different person now. She is married, a mother of 1 and soon to be mother of 2. She holds down a demanding job in engineering which she would not have been able to manage before, This treatment must continue for the people who need it.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	As above
Section 5 (implementation)	As above
Section 6 (proposed recommendations for further research)	Please carry on the Infliximab for the thousands of people that suffer with this debilitating disease until a cure is found, to help these people lead nearly normal lives.
Section 7 (related NICE guidance)	As above
Section 8 (proposed date of review of guidance)	
Date	10/12/2009 14:12

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Decision to prescribe and continue treatment should be with the clinical expert. All the patients on above drugs should be monitored clinically and if any side effects steps taken at that stage, not an arbitrary cut off point of a successful treatment which has returned a persons quality of life and ability to function fully as a human being.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Chronic conditions being treated successfully should not be withdrawn arbitrarily, only is there is a medical reason. The suggestion is to allow well patients to become ill again before allowing further treatment, after which the drug is withdrawn completely with no hope of recovery and possibility of leading a meaningful and useful existence.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	10/12/2009 13:37

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	If a patient is well on adalimumab and being monitored by his clinician why the need to stop? What proof is there that stopping the treatment has any benefits and why the 12 month cut off - any evidence to support this?
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	A person successfully being treated with this drug can follow their chosen educational and career paths - not possible when ill. Quality of life at the young age most new cases are diagnosed at is necessary to grow into a repsonsible adult contributing to the country and not always taking. Decision to prescribe and maintain treatment which is extremely successful is the only ethical one.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	10/12/2009 13:28

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

Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Withdrawing the drug at 12 months and waiting for relapse is unwise and increases the risk of loss of response / reactions to the drug. Furthermore, since this is the sickest group of patients with Crohns disease, their best chance of avoiding admission and surgery is to keep their disease in remission rather than allowing them to relapse. However, the need to consider an exit strategy is, of course, important. A much more sensible plan would be to reassess at 12 months with a combination of clinical, endoscopic and radiological investigation (as appropriate) and trial withdrawal in those who are in a deep remission (this is the group who have been identified as most likely to withdraw successfully). With regard to the deifinition of severe active Crohns, alhtough the CDAI is useful, it is very difficult to use clinically, requiring a weeks data. The HBI corresponds well with the CDAI and is far easier to use.
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	10/12/2009 12:35

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

Role	other
Other role	I am aware that I now know of at least 3 families where one or more of them suffers with this condition. Having heard your new proposals I am simply aghast at your lack of understanding and the consequences of what you are about to do. I believe you are behaving extremely immorally given the nature of some of the more severe cases of Crohns. What are you doing? Which is why I am responding!
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Here is a drug that for many young people with severe Crohns disease has given them back their lives. They are now able to lead and enjoy (quite rightly) independent normal lives. I know of one such young man who is now thriving at a top university confident in the knowledge that his very severe Crohns symptoms are being eased and controlled by a drug that now works for him. This young man is devastated to think this is going to be ripped from him because the Committee does not seem to understand what it means to suffer from Crohns. I give my reasons below: i) I understand there is no evidence that anti-TNF treatment increases harm to the patient after 12 months. All patients are monitored regularly when on these drugs and if the treatment proves clinically ineffective, the clinician will stop treatment anyway ii) Extraordinary that there seems to be no provision to continue treatment after two periods of 12 months if proving effective iii) It seems very unclear what the reasons are for changing the preliminary recommendations to a cut-off of 12 months iiii) It seems inhumane to be made to be severally ill again before being eligible for a further course of treatment
Section 2 (clinical need and practice)	We do not understand why the Committee has not given an estimate of the likely numbers of people with severe Crohns who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	i) The Committee seems unconcerned that 50% of newly-diagnosed patients are under age 30 and that for this section of society it is crucial that they are given every possible support to undertake let alone complete their educational studies or professional training or establish a career. Disruption through being taken off an effective drug and being made to be ill again is undoubtedly going to adversely impact their life chances not to mention the emotional trauma they will again be put through as well as their families. ii) Does the committee have evidence elsewhere in the world regarding the withdrawal and restarting of these drugs? There is a potential for complications when patients re-start anti-TNF drugs.

	iii) Has the Committee received any evidence from Patients to indicate any concerns about the long term effects of these drugs that they should be withdrawn after 12 months? iiii) Treatments for Crohns disease never prove to be uniformly effective. The important thing is to have a range of treatments available, particularly for those with 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	10/12/2009 12:23

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

Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	I have attended educational meetings which have been sponsored by the manufacturers of both adalimumab and infliximab
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	A blanket policy of stopping at twelve months removes any degree of flexibility and discretion on behalf of the clinicians. For many patients the withdrawal of disease controlling medication at an important time of their life may have potentially devastating effects. We often agree to treat patients with maintenance therapy up to a predefined timepoint, often determined by key life events for the patient. For example, the university sutudent who has final exams in June, the engaged couple due to be married in september or the middle aged patient with a terminally ill parent, if any of these patients were to have their treatment stopped "by the clock" rather than by an holistic assessment, a flare up could result in a period of hospitalisation at a potentially critical time in their life. I think there needs to be an element of clinical judgement around the timing of withdrawal of therapy although fully agree that these treatments should not be considered as indefinite and a defined time limit of treatment should be established, just not a "one size fits all" twelve moonth or nothing policy.
Section 2 (clinical need and practice)	We would very much appreciate guidance on what to do with those patients who either fail to respond to one biological agent or those who do respond but ultimately lose efficacy to that drug. At present we often change to an alternative agent in these patients and there is a definite response to the new agent. This has been demonstrated in research studies and also observed in clinical practice. I think NICE need to give some consideration to this issue
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	10/12/2009 12:06

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	After the initial set up treatment I have received a total of 20 infliximabe infusions, one every 12 weeks. This treatment was prescribed for severe diarrhea and perianal disease. I was already on prednisalone, Azathioprine, Asacol suppositories, Predfoam, Colifoam and Pentasa. After the fifteenth infusion I experience a rapid decline in health over 4 to 5day period towards the end of the 12 week period. I wanted to contact my gastroenterologist to ask him if I could self manage the last two weeks i.e. between the 10th and 12th weeks. Access to him in between booked appointments is difficult and timely. Eventually after a number of weeks I received a copy of a letter sent to the infusion unit asking them to accommodate my request. The point I am trying to make is that your plan to allow a one year treatment followed by a second year if necessary does not allow sufficient leeway to cope with the nature of the disease. In cases of sudden unexpected relapse or a highly probable relapse weeks could go by before getting further treatments. In perianal disease this could cause irreparable damage. As a final note I understood that there is a risk in stopping and re-starting treatmen
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	10/12/2009 10:43

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

Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Generally ok but not sure about stopping in everbody at 12 months
Section 2 (clinical need and practice)	
Section 3 (The technology)	We need to discuss the easier use of adalimumab in patients who work who can have the drug delivered to their home and self administer.
Section 4 (Evidence and interpretation)	There are some patients who have had life threatening CD who are not amenable to surgery in whom it would not be a good decision to stop either drug a t12 months.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	10/12/2009 10:24

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

Role	NHS Professional
Other role	
Location	Scotland
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I think a quicker review should be mentioned for infliximab. After 3 induction doses review should be taken at 3 months to assess if there is a significant response ie the clinician should determine if the patient is a primary non responder. If they have not responded to an induction course there is no logic to continuing treatment further.
Section 2 (clinical need and practice)	
Section 3 (The technology)	3.3 and 3.5 In children studies "the REACH study" was designed to assess response to induction therapy after 3 doses not 2 and response determined 10-12 weeks after the 1st dose. The way data is presented here it seems children automatically go on to maintainance this is not the case and need for evaluation of primary response to therapy should be made clear. Is there clear evidence of failure to mount antibodies to adalimumab and that the need for escalation of treatment to weekly is not as a result of antibody formation?
Section 4 (Evidence and interpretation)	the indirect cost of inpatient vs outpatient administration for IFX and ADA respectively im sure was built in to costing models but this was not stated explicitly.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	All studies should seek to include children and young people with Crohns disease too. The role of biological clinics where standard monitoring and sharing of vials to reduce costs should be explored.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	10/12/2009 10:03

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	In my opinion, treatment with both drugs should be REVIEWED, NOT WITHDRAWN, every 12 months. Automatic withdrawal after 12 months will mean that patients like myself will have a high risk of long term sickness. The result of this has a massive effect on quality of life and can often mean that patients stop working and stop paying tax! IBD is a chronic condition but not normally life threatening and I believe that these drugs are giving a vast number of severe sufferers the chance of a normal life with long term treatment. If NICE go ahead with these proposals we will never know how effective these drugs are as a maintenance treatment as trials will not be allowed to exist.
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	10/12/2009 07:29

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	I have a cousin with Crohns disease on adalimumab, who might lose this vital lifeline if NICE get this wrong.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	? There is no evidence that anti-TNF treatment increases harm to the patient after 12 months. All patients are monitored regularly when on these drugs, and should be able to make informed decisions as to whether to continue, given the balance of risks. They should not be considered unable to make these choices. ? The new document has removed all clinical input to continuing treatment at the end of 12 months. It appears to be an arbitrary cut off point. If the treatment proves clinically ineffective, the clinician will stop treatment anyway. ? There seems to be no provision to continue treatment after two periods of 12 months if proving clinically effective? ? What account has been taken of the stress of being ?made? to be ill again before being eligible for a further course of treatment? ? The proposals adversely impact on young Crohn?s patients who face having further education/ professional training/ early careers severely disrupted due to the nature of severe Crohn?s disease. ? It seems unclear what the reasons are for changing the preliminary recommendations to a cut off of 12 months.
Section 2 (clinical need and practice)	? Why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	? The committee still seems unaware that patients with severe active Crohn?s disease find it difficult to successfully pursue a course of study, hold down a job or take part in most normal community activities. The social cost to society is completely ignored. ? The committee seems to have paid little attention to the fact that 50% of the newly diagnosed are under age 30. For those people it is crucial that they can complete their studies/professional training/establish a career. Disruption through being taken off an effective drug and being required to be ill is likely to adversely impact their life chances. ? Adalimumab appears to fall within NICE guidelines for cost effectiveness for maintenance therapy. It seems wrong to remove the decision whether to continue on the drug from the clinician and patient. ? Has the Committee looked for evidence elsewhere in the world regarding the withdrawal and restarting of these drugs? There is a potential for complications when patients re-

	start 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)	
Date	10/12/2009 00:22

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	I am a patient presently being treated with Adalimumab
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am not a scientist. I am a patient suffering from Crohns disease. I am young (still in my mid-twenties) and was diagnosed with Crohns disease when I was eleven years old. Aged fifteen, I had major surgery to remove my large intestine. At the time of surgery, treatment such as Prednisolone and Azathioprine had failed to maintain my disease at a manageable level. Infliximab was in its nascency and to my knowledge Adalimumab was not in existence. During my lifetime, the only thing that has maintained my disease at a manageable level has been Adalimumab. It will never cure me Crohns as yet has no cure. And so why create a policy which suggests these drugs will cure. The scientists created these drugs in order to maintain disease at a manageable level. A cure would be nice, NICE, but in the meantime, please allow our doctors to maintain our diseases with ongoing treatment - a treatment, which should of course be constantly reviewed, but certainly never routinely removed.
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	09/12/2009 23:58

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

Role	Carer
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I have not come across any evidence at all that anti-TNF treatment harms patients after 12 months. In any case, patients are monitored regularly when on these drugs, and should be able to make informed decisions about the therapy themselves. Twelve months is an arbitary length of time and deeply inhumane. It is outragous to force patients into the stress of being ill again before they are entitled to recommense these drugs. Uncontrolled IBD can severely impact on an individuals ability to lead a normal life, hold down a full time job or attend college. These proposals would force many sufferers back onto the dole queue!
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Different treatments are effective on different patients - so choice is crucial. Surely a 12 month limit is inhumane - especially when the drug is successfully controlling the condition. Anti-TNF treatments have transformed the lives of so many people! Why single out anti TNFs - after all, medical professionals are not asked to remove the drugs which control other chronic health conditions. Patients with severe IBD find it difficult to study, hold down a job or take part in most normal community activities. NICE has ignored the social cost to society of this conditon.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	09/12/2009 22:59

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	This is completely against current clinical practice in the UK and around the world. It means that instead of the NHS continuing treatment and keeping people well, those patients who have not gone into full remission will in many cases have to experience a flare-up or return of their symptoms with all the disruption that means for their health, work, well-being etc. Only then would they requalify for a new course of treatment with antiTNF drugs for a further 12 month period. What NACC and all of the gastroenterologists wish to see is a review system ? at 12 months the hospital would review a patient?s symptoms ? if they are in full remission, treatment would stop, but if they have continuing symptoms, treatment would continue uninterrupted.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	This is completely against current clinical practice in the UK and around the world. It means that instead of the NHS continuing treatment and keeping people well, those patients who have not gone into full remission will in many cases have to experience a flare-up or return of their symptoms with all the disruption that means for their health, work, well-being etc. Only then would they requalify for a new course of treatment with antiTNF drugs for a further 12 month period. What NACC and all of the gastroenterologists wish to see is a review system ? at 12 months the hospital would review a patient?s symptoms ? if they are in full remission, treatment would stop, but if they have continuing symptoms, treatment would continue uninterrupted.
Section 2 (clinical need and practice)	This is completely against current clinical practice in the UK and around the world. It means that instead of the NHS continuing treatment and keeping people well, those patients who have not gone into full remission will in many cases have to experience a flare-up or return of their symptoms with all the disruption that means for their health, work, well-being etc. Only then would they requalify for a new course of treatment with antiTNF drugs for a further 12 month period. What NACC and all of the gastroenterologists wish to see is a review system ? at 12 months the hospital would review a patient?s symptoms ? if they are in full remission, treatment would stop, but if they have continuing symptoms, treatment would continue uninterrupted.
Section 3 (The technology)	This is completely against current clinical practice in the UK and around the world. It means that instead of the NHS continuing treatment and keeping people well, those patients who have not gone into full remission will in many cases have to experience a

	flare-up or return of their symptoms with all the disruption that means for their health, work, well-being etc. Only then would they requalify for a new course of treatment with antiTNF drugs for a further 12 month period. What NACC and all of the gastroenterologists wish to see is a review system ? at 12 months the hospital would review a patient?s symptoms ? if they are in full remission, treatment would stop, but if they have continuing symptoms, treatment would continue uninterrupted.
Section 4 (Evidence and interpretation)	This is completely against current clinical practice in the UK and around the world. It means that instead of the NHS continuing treatment and keeping people well, those patients who have not gone into full remission will in many cases have to experience a flare-up or return of their symptoms with all the disruption that means for their health, work, well-being etc. Only then would they requalify for a new course of treatment with antiTNF drugs for a further 12 month period. What NACC and all of the gastroenterologists wish to see is a review system ? at 12 months the hospital would review a patient?s symptoms ? if they are in full remission, treatment would stop, but if they have continuing symptoms, treatment would continue uninterrupted. FORGET COST-EFFECTIVENESS - YOURE TALKING ABOUT THE LIFE AND WELLBEING OF REAL PEOPLE!
Section 5 (implementation)	This is completely against current clinical practice in the UK and around the world. It means that instead of the NHS continuing treatment and keeping people well, those patients who have not gone into full remission will in many cases have to experience a flare-up or return of their symptoms with all the disruption that means for their health, work, well-being etc. Only then would they requalify for a new course of treatment with antiTNF drugs for a further 12 month period. What NACC and all of the gastroenterologists wish to see is a review system ? at 12 months the hospital would review a patient?s symptoms ? if they are in full remission, treatment would stop, but if they have continuing symptoms, treatment would continue uninterrupted.
Section 6 (proposed recommendations for further research)	This is completely against current clinical practice in the UK and around the world. It means that instead of the NHS continuing treatment and keeping people well, those patients who have not gone into full remission will in many cases have to experience a flare-up or return of their symptoms with all the disruption that means for their health, work, well-being etc. Only then would they requalify for a new course of treatment with antiTNF drugs for a further 12 month period. What NACC and all of the gastroenterologists wish to see is a review system ? at 12 months the hospital would review a patient?s symptoms ? if they are in full remission, treatment would stop, but if they have continuing symptoms, treatment would continue

	uninterrupted.
Section 7 (related NICE guidance)	This is completely against current clinical practice in the UK and around the world. It means that instead of the NHS continuing treatment and keeping people well, those patients who have not gone into full remission will in many cases have to experience a flare-up or return of their symptoms with all the disruption that means for their health, work, well-being etc. Only then would they requalify for a new course of treatment with antiTNF drugs for a further 12 month period. What NACC and all of the gastroenterologists wish to see is a review system ? at 12 months the hospital would review a patient?s symptoms ? if they are in full remission, treatment would stop, but if they have continuing symptoms, treatment would continue uninterrupted.
Section 8 (proposed date of review of guidance)	This is completely against current clinical practice in the UK and around the world. It means that instead of the NHS continuing treatment and keeping people well, those patients who have not gone into full remission will in many cases have to experience a flare-up or return of their symptoms with all the disruption that means for their health, work, well-being etc. Only then would they requalify for a new course of treatment with antiTNF drugs for a further 12 month period. What NACC and all of the gastroenterologists wish to see is a review system ? at 12 months the hospital would review a patient?s symptoms ? if they are in full remission, treatment would stop, but if they have continuing symptoms, treatment would continue uninterrupted.
Date	09/12/2009 22:52

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Having a friend who has been able to commence his tertiary studies solely because he is being treated using Adalimumab, I must express grave concern that he would need to cease such treatment after 12 months and only go back on the drug if his codition then deteriorates and then for only a maximum of a further 12 months. Surely, if such treatment is allowing him to unertake his studies, it should be allowed to continue as long as his clinician decides and not cease because of an arbitary cut-off time.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	As a diabetic I would be in severe difficulties if my insulin was stopped after a defined period of treatment. It would seem to me that a patient with Crohns Disease would experience similar difficulties if their treatment was stopped simply on the grounds of time rather than a doctors opinion on whether continued treatment would continue to be successful.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	09/12/2009 22:11

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

Role	Carer
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	infliximab has been invaluable to my husband. he was thin and wizened and generally unwell before taking infliximab but the drug gives him energy, appetite, feeling of well being and good colour and enables him to lead a normal life.
Section 2 (clinical need and practice)	my husband has had several bowel resections before taking inflimab. he would like to avoid further serious surgery especially as he had a surgical procedure which went wrong and he very nearly died and has left him traumatised. infliximab has made such a difference to my husbands quality of life and gives him hope that he might avoid further resections .Resections cannot be limitless, they cause malabsorption of nutrients, scarring, and incontinence.
Section 3 (The technology)	The cost of infliximab is obviously your prime consideration but you need to look at its benefits to people it helps considerably, such as my husband. He is able to work full time whilst taking infliximab and supports his family. If infliximab is withdrawn from him he is likely to end up on state benefits due to ill health and our family would then cost the state far more than the cost of his infliximab.
Section 4 (Evidence and interpretation)	inflimimab has been effective for my husband
Section 5 (implementation)	further to my comments in earlier sections, succesful treatment by infliximab such as in my hubands case must be better financially then months as an inpatient in hospital which has happened to him on several occasions in the past
Section 6 (proposed recommendations for further research)	you need to take note of the quality of life information
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	09/12/2009 22:07

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The recommendation to withdraw treatment after 12 months is difficult to justify. Later parts of the document refer to a paucity of evidence on long term effects ? but given the adverse consequences of such withdrawal that paucity is no justification. As mentioned fleetingly, there is a particularly high probability of relapse among younger patients ? yet the document does not take into account the extraodinary impact of a relapse on this group. The adverse impact of a relapse on some younger patients is simple: it will destroy their future prospects. The disease is so debilitating that it prevents normal schooling, study at university/college, or the efforts needed to get established early in a career. The inescapable conclusion is that young patients will, if the treatment is withdrawn, see their schooling, university studies or early careers terminated. This is clearly an unacceptable outcome if it can be avoided ? and this outcome clearly can. Not only is there strong evidence of a very negative effect of this recommendation, the document fails to present any evidence that patient?s health can be improved in any way by withdrawing treatment after 12 months.
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	09/12/2009 21:44

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There seems to be no provision to continue treatment after two periods of 12 months if proving clinically effective? What account has been taken of the stress of being ?made? to be ill again before being eligible for a further course of treatment? The proposals adversely impact on young Crohn?s patients who face having further education/ professional training/ early careers severely disrupted due to the nature of severe Crohn?s disease. It seems unclear what the reasons are for changing the preliminary recommendations to a cut off of 12 months. The term ?planned course of treatment? is not a clarification for patients, who understand the terms ?episodic? and ?maintenance? therapy in respect of these drugs.
Section 2 (clinical need and practice)	Why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	No comments to add
Section 4 (Evidence and interpretation)	Treatments for Crohn?s disease never prove to be uniformly effective. The important thing is to have a range of treatments available, particularly for those with severe Crohn?s disease. Time limits are an inappropriate way of treating severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is inhumane medical treatment. Is there similar pressure on medical professionals to remove drugs that are effectively controlling a chronic health condition such as diabetes, epilepsy or high blood pressure ?to see what will happen, such as a coma, brain damage or a stroke? The committee seems to have paid little attention to the fact that 50% of the newly diagnosed are under age 30. For those people it is crucial that they can complete their studies/professional training/establish a career. Disr
Section 5 (implementation)	No comments
Section 6 (proposed recommendations for further research)	No comments
Section 7 (related NICE guidance)	No comments
Section 8 (proposed date of review of guidance)	No comments

Date	09/12/2009 20:54

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	i am absolutely staggered that consideration is being given to stopping a patient from receiving Infliximab after a 12 month period. I have suffered from Crohn,s disease for nearly thirty years and been receiving infliximab on eight week intervals for 2 years and quite simply cannot do without it. For a two year period prior to receiving my first course of Infliximab i was constantly unwell, far below my normal weight and suffered from Fistulae and fistula. I could barely function in my job and was in constant pain.The Infliximab has changed my life to the point that i can function at about 80%, despite still suffering from fistulae. During the period of time after i have received the infliximab i have renewed energy, can function with a more positive attitude and cope with the affects of having Crohns disease. By the time that the next infusion is required, after 8 weeks, i am desperate. My energy levels have fallen considerably, my apertite has dropped to picking at food and i am on the verge of depression.I am unable to function properly at work, often going to bed as early as 6pm after working an 8 hour day and during the two week period leading to the next infusion i have strong suicidal thoughts and dreams.At this stage St Marks hospital in Harrow are considering reducing the time between infusions to 6 weeks to improve my well being. Stopping my Infliximab Infusion would have a catastrophic affect on my health, returning me to the condition i was in before the treatment started. My health and quality of life would decrease to such a level that i would struggle to perform at a satisfactory level at work and give my familly the support it requires.The continued infusions are absolutely necessary to control Crohns which is constantly threatening to return, and lead to a fourth Resection. It is imperative that Infliximab treatment is allowed to continue to those who need it to retain some level of quality of life. Removing the treatment would condemn crohns sufferers to a life of pain, depression and inability to function properly. Please reconsider.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	i am absolutely staggered that consideration is being given to stopping a patient from receiving Infliximab after a 12 month period. I have suffered from Crohn,s disease for nearly thirty years and been receiving infliximab on eight week intervals for 2 years and quite simply cannot do without it. For a two year period prior to receiving my first course of Infliximab i was constantly unwell, far below my normal weight and suffered from Fistulae and fistula. I could barely function in my job and was in constant pain.The Infliximab has changed my life to the point that i can function at about 80%, despite still suffering from fistulae. During the period of time after i have received the infliximab i have renewed energy, can function with a more

	positive attitude and cope with the affects of having Crohns disease. By the time that the next infusion is required, after 8 weeks, i am desperate. My energy levels have fallen considerably, my apertite has dropped to picking at food and i am on the verge of depression.I am unable to function properly at work, often going to bed as early as 6pm after working an 8 hour day and during the two week period leading to the next infusion i have strong suicidal thoughts and dreams.At this stage St Marks hospital in Harrow are considering reducing the time between infusions to 6 weeks to improve my well being. Stopping my Infliximab Infusion would have a catastrophic affect on my health, returning me to the condition i was in before the treatment started. My health and quality of life would decrease to such a level that i would struggle to perform at a satisfactory level at work and give my familly the support it requires.The continued infusions are absolutely necessary to control Crohns which is constantly threatening to return, and lead to a fourth Resection. It is imperative that Infliximab treatment is allowed to continue to those who need it to retain some level of quality of life. Removing the treatment would condemn crohns sufferers to a life of pain, depression and inability to function properly. Please reconsider.
Section 2 (clinical need and practice)	see comments made in section 1
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	09/12/2009 20:54

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no evidence that anti-TNF treatment increases harm to the patient after 12 months. All patients are monitored regularly when on these drugs, and should be able to make informed decisions as to whether to continue, given the balance of risks. They should not be considered unable to make these choices. The proposals adversely impact on young Crohn?s patients who face having further education/ professional training/ early careers severely disrupted due to the nature of severe Crohn?s disease.
Section 2 (clinical need and practice)	Why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Has the Committee looked for evidence elsewhere in the world regarding the withdrawal and restarting of these drugs? There is a potential for complications when patients re-start anti-TNF drugs. Has the Committee received evidence from Patients that they are so concerned about the long term effects of these drugs that the drugs should be withdrawn after 12 months? Is the recommendation of two planned courses of treatment designed to take relevant patients through to the next proposed review by the Guidance Executive?
Section 5 (implementation)	No comments to add
Section 6 (proposed recommendations for further research)	No comments to add
Section 7 (related NICE guidance)	No comments to add
Section 8 (proposed date of review of guidance)	No comments to add
Date	09/12/2009 20:48

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	What is to be advised if after two periods of 12 month treatments has been clinically effective? Has it been taken into consideration the stress of being ?made? to be poorly again before being eligible for a further course of treatment?
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Is there evidence internationally with regard to the withdrawal and restarting of these drugs? Could there be a risk for complications when patients re-start 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)	
Date	09/12/2009 20:45

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The proposals adversely impact on young Crohn?s patients who face having further education/ professional training/ early careers severely disrupted due to the nature of severe Crohn?s disease. It seems unclear what the reasons are for changing the preliminary recommendations to a cut off of 12 months. The term ?planned course of treatment? is not a clarification for patients, who understand the terms ?episodic? and ?maintenance? therapy in respect of these drugs. Nowhere else in the developed world uses an arbitrary cut-off point when using these drugs. Where is the evidence to show this would benefit patient health?
Section 2 (clinical need and practice)	Why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Treatments for Crohn?s disease never prove to be uniformly effective. The important thing is to have a range of treatments available, particularly for those with severe Crohn?s disease. The committee seems to have paid little attention to the fact that 50% of the newly diagnosed are under age 30. For those people it is crucial that they can complete their studies/professional training/establish a career. Disruption through being taken off an effective drug and being required to be ill is likely to adversely impact their life chances. Adalimumab appears to fall within NICE guidelines for cost effectiveness for maintenance therapy. It seems wrong to remove the decision whether to continue on the drug from the clinician and patient. Has the Committee looked for evidence elsewhere in the world regarding the withdrawal and restarting of these drugs? There is a potential for complications when patients re-start anti-TNF drugs.
Section 5 (implementation)	No comments to add.
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	09/12/2009 20:41

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

Role	other
Other role	Sibling to person with chrons and NHS trainee psychologist
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am disturbed to hear that infliximab treatment should be stopped after tweleve monthes. I would like to know more about the type of evidence that support this please. My sister recieves infliximab and I have seen the incredible impact it has had on her physically and the secondary psychological affects as she gets her life back together. I believe that these drugs are used for maintenance, the impact of infliximab lasts only so long before my sisters pain returns, I strongly believe that the 12 month cap does not betray the severity of the symptoms people experience that would warrant a far longer engagement with infliximab in order to help them heal. I think its a sweeping guide and Nice should say 12-24,etc based on evidence) months. I do not think one should have to go off the drug at 12 monthes show improvement and then relapse when off it to go back on to it again. It is like setting someone with severe chrons for failure and is extremely disruptive to that persons 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	09/12/2009 20:07

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Nowhere else in the developed world uses an arbitrary cut-off point when using these drugs. Where is the evidence to show this would benefit patient health?
Section 2 (clinical need and practice)	Why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Is the recommendation of two planned courses of treatment designed to take relevant patients through to the next proposed review by the Guidance Executive?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	09/12/2009 19:54

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The proposals adversely impact on young Crohn?s patients who face having further education/ professional training/ early careers severely disrupted due to the nature of severe Crohn?s disease.
Section 2 (clinical need and practice)	Why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Has the Committee looked for evidence elsewhere in the world regarding the withdrawal and restarting of these drugs? There is a potential for complications when patients re-start 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)	
Date	09/12/2009 19:51

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The new document has removed all clinical input to continuing treatment at the end of 12 months. It appears to be an arbitrary cut off point. If the treatment proves clinically ineffective, the clinician will stop treatment anyway.
Section 2 (clinical need and practice)	Why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The committee still seems unaware that patients with severe active Crohn?s disease find it difficult to successfully pursue a course of study, hold down a job or take part in most normal community activities. The social cost to society is completely ignored.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	09/12/2009 19:49

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no evidence that anti-TNF treatment increases harm to the patient after 12 months. All patients are monitored regularly when on these drugs, and should be able to make informed decisions as to whether to continue, given the balance of risks. They should not be considered unable to make these choices.
Section 2 (clinical need and practice)	Why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Treatments for Crohn?s disease never prove to be uniformly effective. The important thing is to have a range of treatments available, particularly for those with severe Crohn?s disease. Time limits are an inappropriate way of treating severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is inhumane medical treatment. Is there similar pressure on medical professionals to remove drugs that are effectively controlling a chronic health condition such as diabetes, epilepsy or high blood pressure ?to see what will happen, such as a coma, brain damage or a stroke?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	09/12/2009 19:48

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The new docuement has removed all specialist medical input to continue treatment after 1 year. The cut off point appears arbitary - if the clinician believes that it is working and it should continue then it should. Nowhere else in the world uses an arbitary cut off point when these drugs are used with clear success.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	For those with severe Crohns disease it is important to have a range of treatments available and when one is found to be effective that it is available for as long as the patients expert medical experts require. Stopping treatment after one year and waiting for the patient to get ill again is barbaric. Has the overall social cost of patients getting ill again been considered? Clearly the quality of life for severe Crohns sufferers has not 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)	
Date	09/12/2009 19:38

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	We have friends whose son has Crohns disease.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	We believe that the 12 months plus 12 months proposed periods for treatment are arbitrary and that these decisions should be made by a clinician on a case by case basis. We are concerned that someone with a severe form of the disease, being taken off treatment, will face a recurrence of the symptoms with severely damaging effects to work and/or study. Our friend who is on the drug is doing well at university. Before this treatment he was not able to function normally at school. We would hate to see him reverting to his formmer position.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	This is a chronic disease but it can be kept under control with treatment. We are concerned that the Committe should give full weight to the severe impact on quality of life and economic activity of someone who would be taken off the drug under the proposed rules. People with other chronic illnesses do not have to face this kind of time limitation to their treatment. Even if these drugs have side effects, patients and clinicians should have the right to decide if they want to continue with the drug. We also feel that it is important that there should be as wide a range as possible of treatment options available, so that patients can receive the most effective treatment for them.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	09/12/2009 19:33

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	1.1 There is evidence that stopping treatment for any period will rtesult in the body developing some immunity to the drug. Crohns is a chronic condition and the decision to terminate treatment after 12 months treats it only as an acute condition, whereby there will be some return to normalcy.
Section 2 (clinical need and practice)	The committee has given no indication of the likely take up of the 60,000 or so people in this country of thisd sort ot treatment i.e the number of people who have failed to respond to the other drug treatments
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Adalimumab would appear to fall within the prescribed NICE guidelines for adequate cost effectiveness for a maintenance therapy. Why then should an aritrary timescale be set for its usage, rather than leave the clinical decision to the clinicians?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	09/12/2009 18:17

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

Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	I am concerned about routinely stopping antiTNFs at 12 months without reassessment. If you need to restart it when the patient flares they are then more likely to be allergic to teh next dose than if they had continued it without a break. Fistulising Crohns often takes significantly longer than 1 year to heal & this patients care will be compromised if you stop after a year.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am concerned about routinely stopping antiTNFs at 12 months without reassessment. If you need to restart it when the patient flares they are then more likely to be allergic to the next dose than if they had continued it without a break. A better strategy might be to reassess for disease activity at 1 year & only discontinue treatment if there is no disease activity & they are on another immunomodulator such as azathioprine. For those who are only on infliximab & are still getting symptoms prior to the next infusion they should have the option to carry on. Fistulising Crohns often takes significantly longer than 1 year to heal & these patients care may be compromised if you stop after a year. Patients should have the option to try adalimumab if they can no longer have infliximab due to loss of response or an allergic reaction & vice versa as there is good data that they will have a response rate to the 2nd agent of about 50-60%.
Section 2 (clinical need and practice)	
Section 3 (The technology)	It is important to be able to change the dose of these drugs according to patient response ie to be able to decrease the interval of infliximab to 6 weekly or increase the dose to 10 mg/kg temporarily to recapture the response without needing to apply for exceptional funding. This will ensure the best cost effectiveness.
Section 4 (Evidence and interpretation)	Vial sharing is a good idea. Infliximab infusions can be given faster in those that have had it a few times before to reduce associated costs. If the high dose induction is used for adalimumab patients are less likely to need the higher dose as maintenance.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	09/12/2009 18:03

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

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 it would be a huge error to stop treatment after 12 months.I believe the point is that,these drugs are maintenance drugs & so by nature are ongoing.Where is the evidence to support 12 months being the optimum time to stop treatment?I have greatly benefited from Infliximab & I am appalled at the prospect of the drug being stopped,for me to then relapse before it can be reintroduced-this is extremely disruptive towards my getting my life back.
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	09/12/2009 17:55

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

Role	other
Other role	Carer and scientist
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	These recommendations are flawed both clinically and in terms of patient welfare. The primary clinical flaws in these recommendations are 1) treatment outcome results in either failure or remission 2) that outcomes will be obvious after an arbitrary 12 month period and 3) that stopping then subsequently resuming treatment carries no clinical risk. Patients that do not respond to conventional therapies often have complex disease which, although responsive to anti-TNF, does not go into remission. A 12 month period is therefore unsuitable for what is, effectively, a maintenance therapy, and represents withdrawal of effective treatment. In addition, recommencing treatment after relapse could carry significant risks in terms of hypersensitivity etc. The withdrawal of therapy from patients that have finally responded to anti-TNF after potentially months or years of bad reactions to conventional drugs would have a massive impact on patient welfare, both psychologically and in terms of quality of life. Crohns patients are often young adults and these therapies allow them to conduct normal lives for the first time in many years. They also represent the last option for many.
Section 2 (clinical need and practice)	These points highlight the complexity observed in Crohns patients and the inevitability of surgery following conventional therapy. Anti-TNF treatment could prove incredibly cost-effective in extending the period between medical treatment and surgical intervention. In addition, these statements do not reflect the proportion of patients that require anti-TNF therapy, which is only administered after conventional treatments.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	It is hard to reconcile the 12 month limit with the content of this section. All the evidence stated above points to the great efficacy of these agents in treating complex Crohns and that the mode of application is critical to their effectiveness. I also echo my comments from section 1 on the effects of arbitrarily halting treatment on both patient wellbeing and health and would urge the committee to apply the approach stated in 1.7, i.e that the doctor/patient partnership should decide the course of treatment without imposed time constraints. Adalimumab in particular, does not appear to fall outside of NICE guidlines on cost-effectiveness so the need to limit treatment in this way is unclear. One would not remove treatment in this way for other chronic conditions prone to relapse (e.g. MS, heart conditions etc) after all.
Section 5 (implementation)	

Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	09/12/2009 17:50

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

Role	NHS Professional
Other role	
Location	Wales
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	During the past 6 years I have helped to treat approximately 150 patients with Infliximab/Adalimumab. I completely disagree with the recommendation made in section 1.3 that treatment should stop automatically after 12 months. There is no evidence base for this and in my experience patients could be severely affected if this happens. There is a risk that these patients could become severely unwell and this could mean a major disruption to their life, work and well-being. In our trust all patients are reviewed regularly and many undergo a colonoscopy at 12 months. If patients are found to be in remission their treatment is stopped. Also there is a risk that if patients have a substantial gap between treatments they could develop antibodies to anti-TNF treatment and increase the risk of developing reactions to these drugs and potentially their effectiveness could be lessened. I believe there should be a review system where patients are reviewed at 12 months, if they are in full remission, treatment should stop, however if they have continuing symptoms treatment should continue uninterrupted.
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	09/12/2009 17:48

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	As a Crohns sufferer I would like to say that I do not agree with the proposed change. If a patient taking infliximab or adalimumab is not in full remission, but is managing to lead a near normal life with their symptoms controlled then they should be allowed to continue with the treatment rather than being taken off it and waiting for a relapse to occur before initiating treatment again.
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	09/12/2009 16:40

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	As many people have probably already said, the choice of 12 months seems very radnom to me. There does not seem to be any evidence that anti-TNF treatment increases harm to the patient after 12 months. Why stop the treatment at this point if it is being effective? If the treatment is ineffective then the clinician would stop treatment anyway.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	As with many illnesses, there is no one treatment that is effective in the treatment of all Crohns disease patients. It is crucial to have a range of drugs, especially as the trials have shown that these drugs do work. Adalimumab seems to fall within the NICE guidelines for cost effectiveness for maintenance treatment. It just seems wrong to remove the decision from the clinician and patient, especially when these drugs can make such a huge difference to peoples lives.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	09/12/2009 16:30

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The choice of 12 months seems very arbitrary. I would like to know the reasons why this specific length of time has been chosen. Also this does not take into account the fact that there a varying levels of severity of the disease. It seems highly unethical that you treat these individuals for a period of time and then terminate the treatment, knowing that it will inevitably result in them becoming seriously ill again.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	A lot of emphasis is being placed on the cost effectiveness of these drugs, but there is no mention of the social cost of not providing them. 50% of newly diagnosed people are under 30. I am not sure whether the committee is aware that sufferers of severe Crohns disease find it very difficult to hold down a job or pursue a course of study. The cost of not providing these drugs is monumental. I completely disagree with the fact that the decision about whether treatment should continue is being taken away from the clinician and patient. The doctors are the individuals who deal with the patients on a day to day basis, they should have much more of say in the treatment of these patients. I would also like to know whether NICE are placing these arbitrary time limits on drugs for other chronic illnesses, and if not, why single out 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	09/12/2009 14:03

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

Role	Public
Other role	
Location	US
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no evidence that anti-Tnf treatment increases harm to the patient after 12 months. All patients are monitores regularly when on these drugs and should be able to make informed decisions as to whether to continue, given the balance of risks. They should not be considered unable to make these choices. The new document has removed all clinical input to continuing treatment at the end of 12 months. It appears to be an arbitrary cut off point. If the treatment proves clinical ineffective, the clinician will stop treatment anyway. There seems to be no provision to continue treatment after two periods of 12 months if proving clinically effective? What account has been taken of the stress of being "made" to be ill again before being eligible for a further course of treatment? The proposals adversely impact on youn Crohns patients who face having further education/professional training/early careers severy disrupted due to the nature of severe Crohns disease.It seems unclear what the reasons are for changing the preliminary recommendations to acut off fo 12 months. nowhere ele in the developed world usse an arbitrary cut-off point when using these drugs.
Section 2 (clinical need and practice)	Why has the committee not given an estimate of the likely numbers of people with severe Crohns disease who would be eligible for the treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Treatment for Crohns disease never prove to be uniformly effective. The important thing is to have a range of treatments available, paticularly those with severe Crohns. Time linits are an inappropriate way of treating severly ill patients. an annual reivew with a consultant an Mri or colonoscopy are all reasonable requirements to etermine whetther continued treatment is appropriate, but a 12 month cut off is inhumane medical treatment. is there similar pressure on medical professionals to remove drugs that are effectively controlling a chronic health condition? Adalimumab appears to fall within NICE guidelines for cost effectivness for maintenance therapy. It seems wrong to remove the decision whther to continue on the drug from the clinician and patient. Has the committee looked for evidence elsewhere in the world regarding the withdrawal and restarting of these drugs? There is potential for complications when patients restart anti-TNF drugs. The Commmittee needs to consider that there are more than two outcomes - failure, cpmplete remission, but also an active disease that is being kept under control by the drug. Clinical

	judgement is essential to determine outcome.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	09/12/2009 13:46

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

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 incredible that there would be an arbitrary cutoff point for the drug when its working effectively and helping the patient lead a normal life i.e. studying, working and contributing more effectively to society (paying taxes if working). Why have the patient go through a period of illness and related stress before allowing the drug. What are the reasons for changing the original recommendation.
Section 2 (clinical need and practice)	Why not have a provision to continue treatment after two periods of 12 months if its proving clinically effective.
Section 3 (The technology)	Although I appreciate cost is a factor in medicine it seems immoral to cut off treatment that is being effective, particularly for young people where it is helping them to lead a normal life. If the medical assessment is that the patient will become sick again without the drug surely it would be better to keep them under that treatment.
Section 4 (Evidence and interpretation)	The committee should consider that patients with severe active Crohns disease have difficulty in pursuing active study, working and contributing to society to their full extent or participate in general community activities. Clinical judgement is key in determining if the patient has an active disease that is being controlled by the drug. 50% of people newly diagnosed are under the age of 30. Surely their contribution to society and their personal needs for wellness are core to the values of the NHS. This seems a very arbitrary decision.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	If the committee feels further research is required why is it changing the preliminary decision now.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	The Committee should clarify if the recommendation of two planned courses of treatment is designed to take relevant patients through to the next proposed review by the Guidance Executive.
Date	09/12/2009 13:37

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	A blanket stop of infliximab after 12 months is very short sighted. I understand the need to check if myself or others are in remission, but if the 12 months co-insides with exams or other important events common sense should prevail and the treatment only stopped after exams etc. Re starting treatment if patients do not stay in remission needs to be simplified and needs to be covered in this report, as once off a programme the only option appears to be admitted via A&E or a doctor, which can take weeks.
Section 2 (clinical need and practice)	
Section 3 (The technology)	You have focused on the cost of the drugs. If I were to have an operation or as I am in the early stages of attempting to control my disease the cost of my continuing hospital admissions must be factored in. I am also only 16, a high achiever and hopefully will get a well paid job again this has to be balance against me not being treated, not being able to go to university, claiming dole and disability and contributing nothing.
Section 4 (Evidence and interpretation)	Perhaps i have missed this but, you have also not factored in the price drop when the drug is out of licence, so enabling people to continue an existence in work, at university etc in the shorter term this must be a price worth paying
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	I understand this report is for infliximab and adalimumab, however more research needs to be put into the cheaper drugs, this should be in parallel with the high end research. Azathioprine worked very well for me but gave me pancreatitis. If some of the side affects of steroids, Azathioprine etc could be resolved more of the population could use the cheaper drugs and not the more expensive ones.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	09/12/2009 13:09

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	No
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The choice of drug should be made on clinical suitability to the particular patient In the current proposal, the opportunity for clinical discretion about when to stop treatment is removed. That means that the patient would have to ?relapse? with all the disruption to personal well-being, education, work, family roles which that entails, before being able to start a further course of treatment. It is essential that the decision about the course of action should be in the discretion of the clinician, based on the circumstances of the particular patient. A patient who is not in full remission, but is managing to lead a near normal life with their symptoms controlled, can suffer greatly under the new NICE proposal, which does not take individual circumstances into consideration. The earlier proposal for a review at 12 months is the correct approach ? reflecting a proper balance between safety, good clinical practice, cost-effectiveness and patients? wellbeing.
Section 2 (clinical need and practice)	As per 2.5, treatment aims to reduce symptoms, and to maintain or improve quality of life. Stopping treatment after 12 months, could potentially result in the opposite. As per 2.6, disease activity can be different for different people. How can a rigid time scale of 12 month be appropriate for all?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	No new evidence was presented that justified the change in NICE recommendations. They simply chose arbitrarily to change their earlier recommendation in order to limit treatment to a defined time. This is not very scientific or safe.
Section 5 (implementation)	The earlier proposal for a review at 12 months is the correct approach ? reflecting a proper balance between safety, good clinical practice, cost-effectiveness and patients? wellbeing. If a patient has initially responded well to one antiTNF, but then lost response, they should have the opportunity to switch to the other antiTNF treatment. This has still not been appraised by NICE.
Section 6 (proposed recommendations for further research)	Check the impact on patients quality of life and wellbeing in both cases, when the clinician reviews after 12 months, and when the clinician stops the treatment rigidly after 12 months and waits for the paitent to relapse again. Examine the difference.
Section 7 (related NICE guidance)	

Section 8 (proposed date of review of guidance)	
Date	09/12/2009 12:45

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

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 unclear what the reasons are for changing the preliminary recommendations to a cut off of 12 months - this treatment is the end of the line for some, if not most patients. Why stop it if it works. Is cost a hidden agenda here?
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	This kind of time limit is an inappropriate way of treating patients. Illness of this severity does not adapt itself to neat time periods. It responds when it responds. Annual or more regular reviews are obviously required and these shoudl be the yardstick used to determine what to do next.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	09/12/2009 12:36

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

Role	Carer
Other role	Parent of sufferer being treated with infliximab
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Why is there no provision for more that two 12 month treatments? These are life changing treatments which enable people suffering from a horrible disease to lead a near normal life. Making someone well and them letting them fall ill again is inhuman and uncaring. Drs should be allowed to treat their patients as they see fit. How awful for a health professional to be told they have to ration well being. Its akin to taking treatement away from someone with high blood pressure and saying "youll be okay, you can have it back after you have a heart attack". Stress is a known trigger for flare ups of IBD, has any thought been given to this. Put yourself in a sufferer shoes and think of the stress of having to be made sick before you can have treatment. Also, from speaking to gastro professionals there seems to be a general feeling that use of these drugs may well lead to less likelihood of surgery. Flares can cause the bowel to scar and the lining to thicken causing strictures which need surgery. Surely drug treatment is better than this for everyone concerned? Young people need to be allowed to become participating and contribuing members of society. Please let them.
Section 2 (clinical need and practice)	Corticosteroids can treat flares but side effects mean they are not suitable for long term use. I have met many many people with crohns, most of whom have been treated with steroids. None of them have ever gone into remission after a course of steroids. Every person I have met on anti TNF therapy has been amazed at the effectiveness of the treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Our son is currently on infliximab (He is 7). The effects are a miracle. We swear it began working within hours. It really was amazing to see a toilet without blood in it. Young people on these treatments must be terrified looking at this document. How can anyone suggest that theyre life line is taken away just as they are about to join adult society, start work, go to university. My son was unable to go to school regularly before he started infliximab. Now he leads a relatively normal life. There should be no price tag on that.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	Research and monitoring is clearly needed and a register is an excellent idea
Section 7 (related NICE guidance)	

Section 8 (proposed date of review of guidance)	
Date	09/12/2009 12:24

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

Role	other
Other role	Councillor
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	From my understanding I am unaware that anti-TNF treatment would increase harm to the patient if taken for a period in excess of one year. What evidence has been presented for me to think otherwise. I do know someone who is taking this drug and it has been quite life changing - what provision would they have to continue treatment at the end of twelve months. Surely it should only cease if the treatment proved ineffective. What is the cost to the patient if he/she were to relapse to their previous condition both in terms of quality of life and financially. The effect could be quite detremental, particularly if in education or working. The impact could be life-changing and permanently damaging. There doesnt appear to be any clarity around the benefit of this one year cut off point and I can only urge that further investigation into the consequences of cessation after one year be looked into before the lives of those that are dependent on this drug are changed foreve
Section 2 (clinical need and practice)	It would be helpful if the committee could furnish us with an estimate of the likely numbers of people with severe Crohns who are eligible for treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Each case must be treated individuall and as such various treatments can neber provide to be uniformly effective. I understand that there must be a range of treatments available for the obvious range of conditions, which is particularly important in severe cases. Time limits should not be a reason to stop any specific treament - consultants should be able to make those decisions based on thorough consultation and reasonable investigative work. Quality of life is essential. It is particularly devastating to a young person who is unable to follow his career or aspirations because of health conditions. Should the committee have the right to take away that opportunity. This could involve a cost to society for the duration of that persons life. In conclusion, the committee needs to consider, evidence from those patients on the drug who are concerned about their future, the consequences of their actions, the limitation of the evidence that they have in general and evidence must include a world input regarding the withdrawal and restarting of these drugs. I also understand that the cost of the drug Adalimumab appears to be within NICE guidelines for cost effectiveness
Section 5 (implementation)	
Section 6 (proposed recommendations for	

further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	09/12/2009 12:10

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

Role	Public
Other role	
Location	Scotland
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	According to close friends who are experiencing this treatment and issues around it: There is no evidence that anti-TNF treatment increases harm to the patient after 12 months. All patients are monitored regularly when on these drugs, and should be able to make informed decisions as to whether to continue, given the balance of risks. They should not be considered unable to make these choices. ? The new document has removed all clinical input to continuing treatment at the end of 12 months. It appears to be an arbitrary cut off point. If the treatment proves clinically ineffective, the clinician will stop treatment anyway. ? There seems to be no provision to continue treatment after two periods of 12 months if proving clinically effective? ? What account has been taken of the stress of being ?made? to be ill again before being eligible for a further course of treatment? ? The proposals adversely impact on young Crohn?s patients who face having further education/ professional training/ early careers severely disrupted due to the nature of severe Crohn?s disease. ? It seems unclear what the reasons are for changing the preliminary recommendations to a cut off of 12 months.
Section 2 (clinical need and practice)	? Why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	? Treatments for Crohn?s disease never prove to be uniformly effective. The important thing is to have a range of treatments available, particularly for those with severe Crohn?s disease. ? Time limits are an inappropriate way of treating severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is inhumane medical treatment. Is there similar pressure on medical professionals to remove drugs that are effectively controlling a chronic health condition such as diabetes, epilepsy or high blood pressure ?to see what will happen, such as a coma, brain damage or a stroke? ? The committee still seems unaware that patients with severe active Crohn?s disease find it difficult to successfully pursue a course of study, hold down a job or take part in most normal community activities. The social cost to society is

	completely ignored. ? The committee seems to have paid little attention to the fact that 50% of the newly diagnosed are under age 30. For those people it is crucial that they can complete their studies/professional training/establish a career. Disruption through being taken off an effective drug and being required to be ill is likely to adversely impact their life chances. ? Adalimumab appears to fall within NICE guidelines for cost effectiveness for maintenance therapy. It seems wrong to remove the decision whether to continue on the drug from the clinician and patient. ? Has the Committee looked for evidence elsewhere in the world regarding the withdrawal and restarting of these drugs? There is a potential for complications when patients re-start anti-TNF drugs. ? The Committee states in 4.3.10 the limitations of the evidence suggesting that it may be reasonable to try withdrawing treatment in people who demonstrated a complete response, yet has concluded to do just that. ? The Committee needs to consider that there are more than two outcomes ? failure, complete remission, but also an active disease that is being kept under control by the drug. Clinical judgment is essential to determine the outcomes and consequent treatment regime. ? Has the Committee received evidence from Patients that they are so concerned about the long term effects of these drugs that the drugs should be withdrawn after 12 months? ? Is the recommendation of two planned courses of treatment designed to take relevant patients through to the next proposed review by the Guidance Executive?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	09/12/2009 12:01

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	? There is no evidence that anti-TNF treatment increases harm to the patient after 12 months. All patients are monitored regularly when on these drugs, and should be able to make informed decisions as to whether to continue, given the balance of risks. They should not be considered unable to make these choices. ? The new document has removed all clinical input to continuing treatment at the end of 12 months. It appears to be an arbitrary cut off point. If the treatment proves clinically ineffective, the clinician will stop treatment anyway. ? There seems to be no provision to continue treatment after two periods of 12 months if proving clinically effective? ? What account has been taken of the stress of being ?made? to be ill again before being eligible for a further course of treatment? ? The proposals adversely impact on young Crohn?s patients who face having further education/ professional training/ early careers severely disrupted due to the nature of severe Crohn?s disease. ? It seems unclear what the reasons are for changing the preliminary recommendations to a cut off of 12 months. ? The term ?planned course of treatment? is not a clarification for patients, who understand the terms ?episodic? and ?maintenance? therapy in respect of these drugs. ? Nowhere else in the developed world uses an arbitrary cut-off point when using these drugs. Where is the evidence to show this would benefit patient health?
Section 2 (clinical need and practice)	? Why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	? Treatments for Crohn?s disease never prove to be uniformly effective. The important thing is to have a range of treatments available, particularly for those with severe Crohn?s disease. ? Time limits are an inappropriate way of treating severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is inhumane medical treatment. Is there similar pressure on medical professionals to remove drugs that are effectively controlling a chronic health condition such as diabetes, epilepsy or high blood pressure ?to see what will happen, such as a coma, brain damage or a stroke?

	? The committee still seems unaware that patients with severe active Crohn?s disease find it difficult to successfully pursue a course of study, hold down a job or take part in most normal community activities. The social cost to society is completely ignored. ? The committee seems to have paid little attention to the fact that 50% of the newly diagnosed are under age 30. For those people it is crucial that they can complete their studies/professional training/establish a career.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	09/12/2009 11:56

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

Role	Public
Other role	
Location	Wales
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I feel that these drugs should be available to all who need them to further improve their day to day living.
Section 2 (clinical need and practice)	At such a young age we need to do all we can to enhance quality of life for this large number of sufferers.
Section 3 (The technology)	I do not believe that cost should be a factor when considering the use of drugs known to help sufferers.
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	I urgently request consideration be given to providing these drugs to assist all sufferers of this disease.
Section 6 (proposed recommendations for further research)	I agree that further research must be carried out.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	09/12/2009 09:21

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I do not consider it appropriate for treatment to be stopped after 12 months in order to see if a patient relapses. Yes, have a review of a patients symptoms after 12 months, but if a clinician then considers it appropriate for the patient to continue with the treatment, it would be wrong to then stop the treatment in order to cause a relapse. For patients such as myself who have been on infliximab and adalimumab for a number of years, this is the only treatment for Crohns disease which works. Therefore it would be almost guaranteed that I would relapse straight away if my treatment was stopped. This would lead to severe illness resulting in time off work and disruption for my personal life. I therefore consider it is essential for some patients to offer the possibility of continuous treatment.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	I would like to highlight a number of points made in this section: 4.3.2 "Effective treatment and avoidance of relapses were considered of paramount importance by people with Crohn?s disease." - As a patient I completely concur with and support this statement. 4.3.5 "the evidence from clinical practice now strongly favoured a longer-term approach to treatment to with infliximab and adalimumab." - I have benefited greatly from long term (over several years) treatment from infliximab and adalimumab which has given me a much greater quality of life than any of the treatments (e.g. corticosteroids, immunosuppressants) I have had previously. This evidence therefore indicates that, where appropriate, continuous treatment should be made possible. 4.3.10 "The Committee acknowledged the limitations of this evidence [withdrawing treatment] and noted that there may still be a significant risk of relapse." - Surely this indicates that there are patients (such as myself) who would be significantly put in risk of relapse if treatment was withdrawn.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	

Section 8 (proposed date of review of guidance)	
Date	08/12/2009 22:25

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

Role	Public
Other role	close friend of Crohns sufferer
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I?m concerned about the 12 month cut off point ? is there any evidence that beyond this point the drugs in question pose any harm to patients? I feel the rationale for this is unclear at best. Surely if treatment is proving effective and the patient is being monitored, they should be capable of making an informed decision about whether to continue or not. Enforcing this arbitrary cut off point seems incredibly unfair? will patients need to become ill again in order to continue treatment?? Considering the severe nature of Crohn?s this would be extremely disruptive - I?m thinking for example of patients in education - and possibly have adverse effects on mental health. I do think the consultation needs to take this into account.
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	08/12/2009 22:12

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

Role	Public
Other role	Personnel Manager
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Twelve months is an arbitrary period of time for withdrawal of treatment. There is evidence from the USA that withdrawaland re-instatement can be damaging.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Unclear what a complete response means and how this differs from responding to treatment while still under medication.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	08/12/2009 21:47

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

Role	Public
Other role	Student
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The proposed ending of treatment after 12 months seems arbitrary. There is no obvious evidence that the condition will improve at that stage.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	It is unclear what a complete response at 12 months constitutes: there is no distiction between this and someone in 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	08/12/2009 21:40

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

Role	Patient
Other role	Father of Crohns Disease Patient
Location	Wales
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Infliximab treatment has given my daughter a new lease of life. Prior to receiving this treatment, she had very severe symptoms which did not respond to any of the medication that she was taking. She was a sixth form student at the time and had to cancel her examinations as she was too unwell to attend school. Now, she is undertaking a full time degree course at the local college and also has a part time job at weekends. This is solely due to her infliximab treatment, which is now in its second year. She continues to be in remission, with the occasional mild flare, but towards the end of the eight weeks following each infusion some of the symptoms begin to show again, especially extreme tiredness. I am convinced that suspending or ceasing infliximab treatment will have a severe effect on my daughters continued wellbeing.
Section 2 (clinical need and practice)	Clinical management of my daughters condition is currently excellent, with infliximab infusions every eight weeks resulting in maintained remission. All other treatments attempted, including steroids and Azathioprine had no effect whatsoever on her symptoms. I strongly believe that the decision on whether to continue with my daughters infliximab treatment should be made by her gastroenterologist, who is aware of her individual needs and can regularly review her condition.
Section 3 (The technology)	Infliximab is the only treatment that has worked for my daughter. She has not had adalimumab treatment, so it is difficult for us to comment. We are aware of the treatment, however, having discussed it with local medical staff, and realise that it may be offered in the future as an alternative. We would have no objection to this (or any other treatment) provided it induced and maintained remission.
Section 4 (Evidence and interpretation)	The recommendation that infliximab (or adalimumab) treatment should be automatically stopped after twelve months and only recommenced if the patient relapses is, in my view as a father of a severe Crohns Disease sufferer, very unfair. This decision seems to me to be based on cost rather than patient welfare. I would strongly prefer to see a continuation of the current method of my daughters condition being reviewed regularly by her gastroenterologist at the local hospital. I believe it should be for him to decide whether my daughters treatment should continue on the basis of clinical need.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	I agree that further research is essential, and would be particularly interested to see the results of the trials comparing infliximab and adalimumab.

	I would also welcome continued research into the long term implications of continued infliximab treatment.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	08/12/2009 21:31

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	So your saying the patient can only be treated for 12 months, then they have to wait until they become ill again before getting on this drug? Thats outrageous! Both these drugs should be continually used for maintenance purposes. You cant honestly think that stopping the use will have any benefits to the patient?? Its going to do more harm than good!! Why the need to stop? The stress these appraisals are going to cause. ?Less Expensive drug? Are you kidding me!! Interest of the patient not your bank balance please.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Adalimumab appears to fall within NICE guidelines for cost effectiveness for maintenance therapy. It seems wrong to remove the decision whether to continue on the drug from the clinician and patient. Has the Committee received evidence from Patients that they are so concerned about the long term effects of these drugs that the drugs should be withdrawn after 12 months?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	08/12/2009 20:56

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

Role	other
Other role	parent
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The decision to stop treatment after a period of 12 months should be between the consultant and patient and based on clinical need rather than the end of a pre-determind cut off point. If proving effective, what plans are in place for the continuity of treatment after 2 consecutive 12 month periods? where is the evidence to show that such a cut off point when using these drugs will benefit the patient?
Section 2 (clinical need and practice)	The committee does not seem to have given an estimate of the number of people with severe Crohns who would be eligible for treatment. Why is this?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	For younger Crohns sufferers i.e under 30 years, continuity of an effective drug ensures that they can complete their studies and professional training, establish a career and contribute to society, including paying taxes and not claiming and becoming reliant on the benefits system. What are the potential complications for people stopping and restarting anti TNF drugs? is evidence available from elsewhere in the world? If treatment is proving effective and preventing patients relapsing and potentially being admitted to hospital,(and possible subsequent emergency surgery), Why stop it? this seems to be a short sighted and non cost effective approach. The decision to continue with treatment should remain between the consultant and patient. Each Crohns sufferers situation is different and should be considered/reviewed on an individual basis of clinical need.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	08/12/2009 20:52

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

Role	other
Other role	Leeds Patients Panel memeber and Colitis sufferer
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	? There is no evidence that anti-TNF treatment increases harm to the patient after 12 months. All patients are monitored regularly when on these drugs, and should be able to make informed decisions as to whether to continue, given the balance of risks. They should not be considered unable to make these choices. ? The new document has removed all clinical input to continuing treatment at the end of 12 months. It appears to be an arbitrary cut off point. If the treatment proves clinically ineffective, the clinician will stop treatment anyway. ? There seems to be no provision to continue treatment after two periods of 12 months if proving clinically effective? ? What account has been taken of the stress of being ?made? to be ill again before being eligible for a further course of treatment? ? The proposals adversely impact on young Crohn?s patients who face having further education/ professional training/ early careers severely disrupted due to the nature of severe Crohn?s disease. ? It seems unclear what the reasons are for changing the preliminary recommendations to a cut off of 12 months. ? The term ?planned course of treatment? is not a clarification for patients, who understand the terms ?episodic? and ?maintenance? therapy in respect of these drugs. ? Nowhere else in the developed world uses an arbitrary cut-off point when using these drugs. Where is the evidence to show this would benefit patient health?
Section 2 (clinical need and practice)	? Why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	? Treatments for Crohn?s disease never prove to be uniformly effective. The important thing is to have a range of treatments available, particularly for those with severe Crohn?s disease. ? Time limits are an inappropriate way of treating severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is inhumane medical treatment. Is there similar pressure on medical professionals to remove drugs that are effectively controlling a chronic health condition such as diabetes, epilepsy or high blood pressure ?to see what will happen, such as a coma, brain damage or a stroke?

	? The committee still seems unaware that patients with severe active Crohn?s disease find it difficult to successfully pursue a course of study, hold down a job or take part in most normal community activities. The social cost to society is completely ignored. ? The committee seems to have paid little attention to the fact that 50% of the newly diagnosed are under age 30. For those people it is crucial that they can complete their studies/professional training/establish a career. Disruption through being taken off an effective drug and being required to be ill is likely to adversely impact their life chances. ? Adalimumab appears to fall within NICE guidelines for cost effectiveness for maintenance therapy. It seems wrong to remove the decision whether to continue on the drug from the clinician and patient. ? Has the Committee looked for evidence elsewhere in the world regarding the withdrawal and restarting of these drugs? There is a potential for complications when patients re-start anti-TNF drugs. ? The Committee states in 4.3.10 the limitations of the evidence suggesting that it may be reasonable to try withdrawing treatment in people who demonstrated a complete response, yet has concluded to do just that. ? The Committee needs to consider that there are more than two outcomes ? failure, complete remission, but also an active disease that is being kept under control by the drug. Clinical judgment is essential to determine the outcomes and consequent treatment regime. ? Has the Committee received evidence from Patients that they are so concerned about the long term effects of these drugs that the drugs should be withdrawn after 12 months? ? Is the recommendation of two planned courses of treatment designed to take relevant patients through to the next proposed review by the Guidance Executive?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	08/12/2009 20:31

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	As a life-long Crohns sufferer (diagnosed at 3) I find it alarming that the defining symptoms for a flareup are stated in such narrow textbook terms. I have been severely ill from the condition at various points in my life and can honestly say not every flare up is the same and not every patient suffers the same way. Also, the 12 month time limit on either medication is less reasonable than a review at 12 months. Adalimumab can take up to 3 months to take effect on a patient. There is no guarantee that a further 9 months is long enough to stabilise the patient sufficiently for them to remain healthy once treatment is stopped. I have been suffering with a flareup for some time, and am now on adulimumab, having built up antibodies to infliximab which made my body react and reject the infusion when I was re-prescribed the drug. The thought of being taken off adulimumab in 12 months, regardless of my condition, makes me very anxious - something which can exacerbate the disease. I was treated with infliximab 4 years ago. I was on the drug for 18 months and treatment only stopped when tests had been carried out to ascertain that my Crohns disease was not active.
Section 2 (clinical need and practice)	Without doubt there is a need for these drugs. Many patients react badly to other treatment and may already have had some surgery. These drugs are a way of helping us to regain control of our condition.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	There is no doubt as to the effectiveness of these drugs. I was given infliximab after prolongued steroid use meant there was no longer an option of steroids to manage my condition. I had been on azothiaprine and had a bad reaction. My consultant didnt want to put me on methotrexate due to the specific way my condition manifests itself and my very low body weight and blood pressure - the risks would outweigh the potential gains. I was given infliximab and it was like having a new lease of life!
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	I think real evidence from real cases is crucial. As long as it is taken into account that every patient is an individual and no two are the same. Generalisations should not be made, which is

	why patient review is so crucial.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	08/12/2009 19:36

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	I am the Vice-Chair of my local National Association for Colitis and Crohns Disease (NACC) group
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no evidence that anti-TNF treatment increases harm to the patient after 12 months. All patients are monitored regularly when on these drugs, and should be able to make informed decisions as to whether to continue, given the balance of risks! They should not be considered unable to make these choices. The new document has removed all clinical input to continuing treatment at the end of 12 months. It appears to be an arbitrary cut off point. If the treatment proves clinically ineffective, the clinician will stop treatment anyway. Also, what account has been taken of the stress of being ?made? to be ill again before being eligible for a further course of treatment? As a patient myself who has had uncontrolled disease for 7.5 years, the thought of returning to the great emotional and physical trauma of a flare just to prove I need a drug which I know helps me seems madness. As a young woman of 28 yrs, my life has already been hugely disrupted by this disease and my career, education and chance to start a family have suffered as a result. It seems cruel to potentially take away any longed-for stability achieved through these drugs after just 12 months.
Section 2 (clinical need and practice)	It would be useful to have an estimate of the number of people with severe Crohns who are eligible for this treatment so that we can get a clear idea of the number who are affected by this proposal.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Firstly,treatments for Crohn?s disease never prove to be uniformly effective. The important thing is to have a range of treatments available, particularly for those with severe disease. There is also a lack of understanding here that patients with severe active Crohn?s disease find it difficult to successfully pursue a course of study, hold down a job or take part in most normal community activities. 50% of the newly diagnosed are under age 30. For these patients it is crucial that they can complete their studies/professional training/establish a career. Disruption through being taken off an effective drug and being required to be ill is likely to adversely impact their life chances.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	

Section 8 (proposed date of review of guidance)	
Date	08/12/2009 18:51

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The new document has removed all clinical input to continuing treatment at the end of 12 months. This appears to be an arbitrary cut off point. If the treatment was ineffective the clinician would cease the treatment in any case.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Treatment for Crohns disease never proves to be uniformly effective. The important thing is to have a range of treatments available, particularly for those with severe Chrons 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	08/12/2009 17:43

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

Role	Public
Other role	
Location	US
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	? There is no evidence that anti-TNF treatment increases harm to the patient after 12 months. All patients are monitored regularly when on these drugs, and should be able to make informed decisions as to whether to continue, given the balance of risks. They should not be considered unable to make these choices. ? The new document has removed all clinical input to continuing treatment at the end of 12 months. It appears to be an arbitrary cut off point. If the treatment proves clinically ineffective, the clinician will stop treatment anyway. ? There seems to be no provision to continue treatment after two periods of 12 months if proving clinically effective? ? What account has been taken of the stress of being ?made? to be ill again before being eligible for a further course of treatment? ? The proposals adversely impact on young Crohn?s patients who face having further education/ professional training/ early careers severely disrupted due to the nature of severe Crohn?s disease. ? It seems unclear what the reasons are for changing the preliminary recommendations to a cut off of 12 months. ? The term ?planned course of treatment? is not a clarification for patients, who understand the terms ?episodic? and ?maintenance? therapy in respect of these drugs. ? Nowhere else in the developed world uses an arbitrary cut-off point when using these drugs. Where is the evidence to show this would benefit patient health?
Section 2 (clinical need and practice)	? Why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	? Treatments for Crohn?s disease never prove to be uniformly effective. The important thing is to have a range of treatments available, particularly for those with severe Crohn?s disease. ? Time limits are an inappropriate way of treating severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is inhumane medical treatment. Is there similar pressure on medical professionals to remove drugs that are effectively controlling a chronic health condition such as diabetes, epilepsy or high blood pressure ?to see what will happen, such as a coma, brain damage or a stroke?

	? The committee still seems unaware that patients with severe active Crohn?s disease find it difficult to successfully pursue a course of study, hold down a job or take part in most normal community activities. The social cost to society is completely ignored. ? The committee seems to have paid little attention to the fact that 50% of the newly diagnosed are under age 30. For those people it is crucial that they can complete their studies/professional training/establish a career. Disruption through being taken off an effective drug and being required to be ill is likely to adversely impact their life chances. ? Adalimumab appears to fall within NICE guidelines for cost effectiveness for maintenance therapy. It seems wrong to remove the decision whether to continue on the drug from the clinician and patient. ? Has the Committee looked for evidence elsewhere in the world regarding the withdrawal and restarting of these drugs? There is a potential for complications when patients re-start anti-TNF drugs. ? The Committee states in 4.3.10 the limitations of the evidence suggesting that it may be reasonable to try withdrawing treatment in people who demonstrated a complete response, yet has concluded to do just that. ? Has the Committee received evidence from Patients that they are so concerned about the long term effects of these drugs that the drugs should be withdrawn after 12 months? ? Is the recommendation of two planned courses of treatment designed to take relevant patients through to the next proposed review by the Guidance Executive?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	08/12/2009 17:15

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	No
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There seems to be no provision to continue treatment after two periods of 12 months if proving clinically effective. Has any account been taken of the stress and disruption to life of being made ill again before being eligible for further treatment. This ruling will adversely affect young people with Chrohns, interrupting education and training and job prospects may be severely diminished. Where is the evidence that making this arbitrary cut off point will benefit the patients health.
Section 2 (clinical need and practice)	The committee does not give an estimate of the likely number of people with severe Chrohns who would be eligible for treatment. Is this information available?
Section 3 (The technology)	No comment
Section 4 (Evidence and interpretation)	Time limits are an inappropriate way of treating severely ill patients and is likely to be very damaging for some people. Each case needs to be treated on an individual basis without clinicians being restricted in their selection of appropriate treatments by NICE guidelines. The social cost of lost education, and work hours because of ill health is ignored in this document. Adalimumab seems to fall within NICE guidelines for cost effectiveness for maintenance therapy. Has the committee looked for evidence regarding the effects for patients of withdrawing and re starting anti TNF drugs? Has the committee sought the opinion of the 50% of newly diagnosed people under 30 years with Chrohns who will be affectd by this proposal of a 12 month cut off period?.
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	08/12/2009 15:59

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

Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	I am an NHS consultant gastroenterologist
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Whilst there is no doubt that adalimumab and infliximab are effective drugs for the treatment of some with severe Crohns disease, the cost effectiveness of these medications must be taken into account if the NHS (and the country as a whole) is to continue functioning. The summaries of clinical and cost effectiveness seem to be reasonable interpretations of the evidence and as a result the suggestion that treatment should be stopped at 12 months and only restarted if relapse occurs (rather than continuing indefinitely) seems appropriate and also safe practice for drugs about which we still have little long term experience.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The cost effectiveness is hard to asssess because the results from the different groups are so varied - I am more persuaded by the results that are not influenced by vested interest - ie the drug companies, although the low relapse rate used by the assessment group is perhaps a concern
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	08/12/2009 12:13

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There seems to be no provision to continue treatment after two periods of twelve months if proving clinically effective?
Section 2 (clinical need and practice)	Why has the Committee not given an estimate of the likely numbers of people with severe Crohns who would be eligible for treatment?
Section 3 (The technology)	no comment to add.
Section 4 (Evidence and interpretation)	Has the Commitee received evidence from Patients that they are so concered about the long term effects of these drugs that the drugs should be withdrawn after 12 months?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	08/12/2009 09:18

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	This disease is very debilitating to younger patients who should be maintained on this drug which is very beneficial to them and enables them to lead a productive and value added life which benefits both themselves and society. It makes no sense to cut off treatment after 12 months - any such change should be subject to the decision of their specialist. In summary society benefits from those patients who benefit from the drug remaining on it for as long as their specialist recommends so that they can lead productive lives.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Arbitrary time limits for stopping drug treatment for seriously ill patients who are responding well to the drug prescribed by clinical specialists is both inhumane and economically unsound given the contribution that impacted patients who are well controlled by drug therapy can make to society. Supported by effective drug therapy that works enables these patients to study, secure degrees and hold down jobs that benefit both themselves and society. I base this on the hugely beneficial impact adalimumab has made to the life of a son of a close friend .
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/12/2009 21:36

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

Role	other
Other role	Family friend of a sufferer
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	No provision to continue treatment after 2 periods of 12 months is proving clinically effective.
Section 2 (clinical need and practice)	Why has the committee not given an estimate of the likely numbers of people with severe Chrohns who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The social side to society seems to have been ignored by the committee. Many of these young people find it hard to pursue a course of study, hold down a job and take part in normal community activities.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/12/2009 19:37

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

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)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	I dont really understand all of the information in this document, but want to express my concern that as a patient on infiximab I would not want to be subjected to a possible flare up or surgery if my treatment had to stop after twelve months.
Section 8 (proposed date of review of guidance)	
Date	07/12/2009 18:52

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

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 an NHS professional, I am well aware of the financial strains involved. However, my good friend who was diagnosed with Crohns at an early age, has led a healthy, normal and fulfilling life due to the medication that he is on. As far as I am concerned, it appears to be a waste of a good life should his drug be withdrawn, and he become ill again, especially after all he has achieved. There is such limited evidence of the anti TNF treatment actually causing harm to the patient and I have not heard of another example of a cut off point for the use of such drugs.
Section 2 (clinical need and practice)	Surely there are many Crohns sufferers who would benefit from the same treatment that my friend is on, given the opportunity.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	As an occupational therapist, the social cost is one of great interest to me and I am sure that many people would be unable to live independent lives, should it now be for anti-TNF. This includes being unable to be active members of the community in work, learning and leisure.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/12/2009 18:20

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	If patients health is improved massively by use of adalimumab, whilst at the same time being monitoried by their clinician, what good reason is there for withdrawing it? How can a time limit for use be set when it will lead to re-emergence of the disease?
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	If there is evidence of improved health without sides affects from this drug, what ethical reason can be given for withdrawing it. A patients quality of life is disrupted causing added costs to the NHS and society in general in terms of their potentil careers.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/12/2009 17:35

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	After years of ill health and limited quality of life adalimumab has brought enormous improvements with no side affects - why stop the drug when the patient is well only to allow its re-instatement when ill again?! This ill health surely incurs added expense to the NHS? Patients are monitored by their clinician so if any side affects become apparent necessary action would then be taken.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Having found medication that is effective for a particular Crohns sufferer why refuse it?! Why use a time limit for use of an effective drug for Crohns when such a time limit would not be put on medication for other chronic health problems like diabetes etc. Is it ethical to let a person become ill when the NHS can treat that person successfully? Nor is it cost effective and the cost to society is overlooked.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/12/2009 17:24

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am concerned that there seems to be no provision to continue treatment after two years even if the treatment is being clinically effective, which seems to be a retrograde step. If the patient is currently benefitting from the treatment why stop it and effectively cause unnecessary suffering which could easily be avoided by continuing with a drug which has proved successful?
Section 2 (clinical need and practice)	Has the Committee got any factual information of the numbers of people with Crohns disease who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Has the Committee looked elsewhere in the world for evidence regarding the whithdrawal and restarting of the drugs such as Adalimumab? Has the Committee considered that there are more than two outcomes, not just failure or complete remission, but there is also the fact that an active disease is being kept under control by the drug. Clinical judgement, therefore, is essential to determine the outcomes and consequent treatment regime.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/12/2009 15:46

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	As a patitent who has been treated with infliximab and understand the trials a sufferer of this illness goes through, I think its unacceptable to stop treatment with infliximab if the illness is not fully in remission. If a good quality of life can be sustained with infliximab, then there is every reason so maintain its use. This proposel effectively means patients will have to stop treatment, and then wait to become ill in order to carry on (potentially at greater cost to the NHS). As long as a drug is having a positive affect on the patients condition, it is unfair to stop that treatment purely for reasons of cost.
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	07/12/2009 14:46

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

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 illogical to compulsorily remove treatement after 12 months without consideration of ongoing benefits of treatment. Infliximab may not have completely allievated a patients symptoms, most probably leading to a relapse after withdrawal of treatment. A relapse in symptoms may potentially cost more to treat than continued administration of Infliximab.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Whilst 4.3.10 states that it may be reasonable to try withdrawing treatment in people whose disease demonstrated a complete response, this does not draw a distinction between a complete response and remission of Crohns, abeyed by Infliximab. It therefore seems inadvisable to remove treatment from all sufferers after 12 months, regardless of individual circumstances. Furthermore, it is difficult to differentiate between a complete response and a disease in remission due to the continued use of Infliximab.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/12/2009 13:27

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no evidence that anti-TNF treatment increases harm to the patient after 12 months. All patients are monitored regularly when on these drugs and should be able to make informed decisions as to whether to continue, given the balance of risks. They should not be considered unable to make these choices. There seems to be no provision to continue treatment after 2 periods of 12 months even if it is proving to be clinically effective. Where is the evidence to show that a cut-off at 12 months would benefit the patients health?
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Time limits are an inappropriate way of treating severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is inhumane medical treatment. Is there similar pressure on medical professionals to remove drugs that are effectively controlling a chronic health condition such as diabetes, epilepsy or high blood pressure just to see what will happen? The committee seems to have paid little attention to the fact that 50% of the newly diagnosed are under age 30. For those people it is crucial that they can complete their studies/professional training/establish a career. Disruption through being taken off an effective drug and being required to be ill is likely to adversely impact their life chances. Has the Committee received evidence from Patients that they are so concerned about the long term effects of these drugs that the drugs should be withdrawn after 12 months?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/12/2009 11:37

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

Role	other
Other role	Mother
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	My Daughter has been having infliximab for over a year and it has been a God send. She responds very well to the treatment, but just before her infusion tends to get symptoms, which clear up just after the infusion. If she had been taken off the infliximab after 12 months she would have had a relapse and had to go back on it again. Due to the infliximab she has been able to get through her A levels and start university. If she were to be taken off it, it would probably stop her continuing with university or at least hold her back.
Section 2 (clinical need and practice)	My Daughter was diagnosed at the age of 7 with crohns disease and has had two operations to have sections of intestine removed due to strictures. She has also had several operations to stretch her rectum due to strictures and still has to dilate her rectum every day. However the operation was having to be repeated every 6 months until she started infliximab. She was always under weight and suffered most of the symptoms mentioned. This has only improved since she started having infliximab.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	As my Daughter had Crohns disease from the age of 7 it severely impaired her growth and prevented her from going through puberty at the same time as her school friends. Once she started infliximab at the age of 17/18 her life began. She started her periods and she started to develop. She did manage to grow in height a little, but I think it was just too late for that. Her quality of life has improved so much.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/12/2009 11:15

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The reasons for changing the prelimiary recommendations to a cut off of 12 months are unclear. The proposals adversely affect young Crohns patients whose education would be severely disrupted.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Little attention appears to have been paid to the fact that 50% of newly-diagnosed sufferers are under 30 and at a stage when they are still in education/professional training. If they are taken off an effective drug at this stage, this could have a disastrous effect on their ability to complete their training and establish a successful career.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	07/12/2009 08:44

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

Role	Public
Other role	Secondary School Teacher who works with a child who has Crohns
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There seems to be no provision to continue treatment after two periods of 12 months if proving clinically effective? Having to become ill again before being eligible for a further course of treatment will cause considerable stress and anxiety. Has this been aspect of withdrawal been thoroughly considered in both medical terms and also in human? The proposals adversely impact on young Crohn?s patients who face having further education/ professional training/ early careers severely disrupted due to the nature of severe Crohn?s disease.
Section 2 (clinical need and practice)	It would be both helpful and sensible for the Committee to give an estimate of the number of people with severe Crohns who would be eligible for treatment. Why has this basic information not been provided?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Time limits are not appropriate when treating severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all desireable requirements to judge whether continued treatment is beneficial, but a 12 month cut off is inhumane medical treatment. Is there similar pressure on medical professionals to remove drugs that are effectively controlling a chronic health condition such as diabetes, epilepsy or high blood pressure ?to see what will happen, such as a coma, brain damage or a stroke? The committee still seems unaware that patients with severe active Crohn?s disease often find it impossible to successfully complete a course of study, hold down a job or take part in most normal community activities. The social cost to society and the human cost to the individual seem to be of no significance to the committee. The committee have paid little attention to the fact that 50% of the newly diagnosed are under age 30. For those people it is crucial that they can complete their studies/ professional training/establish a career. Disruption through being taken off an effective drug and being required to be ill will almost certainly adversely impact their life chances.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8	

(proposed date of review of guidance)	
Date	07/12/2009 02:29

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

Role	Patient
Other role	Northamptonshire NACC membership secretary
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	It seems from this that the choice of medication is being taken away from the patients and doctors. I also think that by stopping successful medication until a relaps occurs may not be cost effective, as flare-ups which include hospital admission and possible surgery will also cost money, not to mention the pain and distress of the patient. If surgery is required, the resulting problems that can occur are a constant cost to the NHS too. Although Infliximab did not work for me (anaphylactic shock at 2nd infusion), if it does work for patients then they should take it when they need it, as it is hard enough to find which drugs work for which 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	06/12/2009 23:19

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Why is an arbitrary cut-off of twelve months being proposed? There does not appear to be any evidence of harm to patients after twelve months of treatment. Surely therefore any decision to suspend treatment should be a decision solely for the clinician and the patient. This is particularly so given that a relapse is known to be seriously debilitating and that episodic treatment can reduce its eficacy.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The committee has noted (4.3.10) the limitations of the evidence for withdrawing treatment and that there may still be a significant risk of relapse. How then can it then propose an arbitrary twelve month cut-off? This appears to be a condition principally affecting the young (50% of new cases being under 30). Surely it is therefore counter-productive to risk disrupting such peoples studies, early careers etc. through relapse caused by enforced termination of an effective maintainance 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	06/12/2009 22:14

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

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 concerned that the decision to only allow 12 months of treatment and then waiting for a relapse may have serious consequences for many patients, including massive disruption to school/college/work and or family life. It seems a rather cruel way to treat people if their treatment is working. Furthermore, in my case, after being taken off Infliximab treatment after 18 months (my own decision), I had a major relapse and ended up with surgery. I suggest that this situation was probably far more costly to the NHS than if I had continued on the treatment, and whilst unavoidable in my case, highlights a potential cost issue with the proposed recommendation, as people who are prescribed Infliximab or Adulimimab have severe disease which by its very nature is likely to relapse.
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	06/12/2009 22:10

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The proposals adversely impact on young Chrones sufferers who face having their education, professional training and early careers severely disrupted.
Section 2 (clinical need and practice)	Why has the Committe not given an estimate of the likely numbers of people with severe Chrones who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The Committee seems to have paid scant regard to the fact that young sufferers are particulary prone to severe adverse effects on education and career development. The drug appears to fall within NICE guidelines for cost effectiveness for maintenance therapy, cost savings from its withdrawal could well be outweighed by increased costs to the Government accruing elsewhere.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/12/2009 21:38

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Reading the above section, I have concerns that this treatment would not be available to keep severe Crohns disease under control in patients like myself, where risking another severe flare up could potentially be life threatening. After already having multiple operations (acute and planned), not having much gut left - and what is left severely diseased, the ulimited use of these drugs may enable myself and others to carry on going out to work and living a normal 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	06/12/2009 21:24

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

Role	Private Sector Professional
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)	"the Committee considered that repeated induction or episodic treatment with infliximab or adalimumab should not be considered as the preferred option for the treatment of severe Crohn?s disease": it seems extraordinary that as one gathers, NICE has recommended episodic treatment. It is apparent from the evidence submitted that continuous treatment is required and that one years treatment is insufficent, especially for students (perhaps even students of medicine) who need the assurance of freedom from the threat of a recurrance during their time at study in order to maximise the benefit of their time at school or University, time punctuated by stressful yearly examinations where success can be threatened by a recurrence of this debilitating disease.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	Certainly one is in favour of more research. The treatment is (of necessity with any new medicine where manufacturers need to recoup the enormous cost of developing and testing a new medicine) extremely costly but having known suffers benefit so hugely from the availability of this drug, and able for the first time in years to live a normal life, everything should be done to optimise its use, for example by research on reduced dosages, rather than patients having to suffer a relapse before they can again have access to the drug.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/12/2009 21:20

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am concerned that it is being recommended that treatment is only being offered for a twelve month period. Rather than a patient being allowed to relapse having been on the course of treatment, would it not be beneficial to allow them to continue with the drug? It seems to be an arbitrary cut off point ~ is it a clinical decision or one based on cost? It can be seen that up to 30% of Crohns sufferers are younger than 20. If these young people are given the treatment for just a year and then suffer a relapse when the drug is stopped, they may be at a crucial time in their education. This would have a huge impact on their lives. Would it not be beneficial for them to continue with the drug if they are responding well. To suffer a "flare" could mean more costly treatment or major surgery which would disrupt greatly their education. It is stated that two courses of the drug could be given. If the drug is proving to be clinically effective then why would it be stopped at this point when there is no evidence that anti TNF treatment increases harm to the patient?
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	As Crohns is a chronic disease which varies greatly from patient to patient in its severity, it seems wrong to have a "one size fits all" approach to the administration of the drug. Having a time limit applied to a severely ill patient is an inappropriate way of controlling their condition.If they are responding well it would be irresponsible to withhold treatment and perhaps contribute to a major deterioration of their health and well being. The decision whether to continue on the drug should be made jointly by the clinician and the patient.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/12/2009 20:50

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The new document has removed all clinical input to continuing treatment at the end of 12 months. It appears to be an arbitrary cut off point. If the treatment proves clinically ineffective, the clinician will stop treatment anyway. It seems unclear what the reasons are for changing the preliminary recommendations to a cut off of 12 months.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Adalimumab appears to fall within NICE guidelines for cost effectiveness for maintenance therapy. It seems wrong to remove the decision whether to continue on the drug from the clinician and patient. Has the Committee received evidence from Patients that they are so concerned about the long term effects of these drugs that the drugs should be withdrawn after 12 months?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/12/2009 20:48

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

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 that if there is no evidence of the drug being more harmful than conventional treatments after the 12 month period of recommendation and the treatment has been found to be effective in cases, to make the treatment unavailable is unethical and unproductive.
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	06/12/2009 20:43

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Where is the evidence/research to suggest increased harm to patients after 12 months? Why has this arbitrary cut off point been chosen? What are the reasons for changing the preliminary recommendations ie limiting treatment to 12 months? What happens after the second 12 months, should continuing treatment be found to be necessary? Surely it should be the clinicians and informed patients decision whether to continue treatment or not? Progress can be checked without stopping the treatment eg MRI or colonoscopy. The idea behind the withdrawal is to check whether there is still a need for the medication ? i.e. to ?see what will happen?. However, it is recognised in the consideration of evidence that there is a high probability of a relapse. When treatment is episodic there is a greater risk of complications e.g.developing antibodies to the drug and the potential for loss of effect. Such proposals would most severely impact on young people coping with the prospect of a life time of Crohns - a relapse is recognised to be most debilitating- seriously affecting motivation, energy levels and concentration - all essential in education/early working life.
Section 2 (clinical need and practice)	What proportion of those people with severe Crohns disease is it estimated would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Research overall is recognised to be fragmented and limited. Decisions which may have a seriously, long lasting, drastic effect on the quality of life of thousands of young people are being made without sufficient reliable evidence to support arguments. Has the committee looked for evidence elsewhere in the world regarding withdrawal and restarting of these drugs? There is potential for complications when patients restart anti-TNF drugs. Those living with the disease have made it clear that effective treatment and avoidance of relapses are considered of paramount importance - has the committee really considered things from their perspective? With a chronic, severe condition it is not appropriate to manage treatment using blanket time limits. What happens after 2 12 month courses of treatment are completed? It is recognised that relapse causes serious disruption to

	sufferers- it is difficult to successfully continue studying/training/establish a career. It therefore seems wrong for the decision for patients who are facing a lifetime of discomfort,to be taken off an effective drug, thus risking further relapse, to be taken away from the clinician and patient.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/12/2009 20:40

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The new document appears to stick to a 12 month cut off point for the drug which is in contrast to everywhere else in the developed world where no such arbitary cut off points are used. This removes any input from the clinician and the patient as to whether continuation of the drug would be appropriate or effective. As a professional the clinician will surely stop treatment if it is ineffective anyway and there appears to be no consideration or provision to continue the drug after 12 months even if it proves effective after the 12 months. If the drug is just stopped when it is making an apparent difference to a patient then this is surely going to put considerable emotional stress on a patient knowing that if they stop taking the drug they may become seriously ill again before being allowed to start a second course. Is it fair to inflict this on patients? On top of this currently there is no evidence that anti-TNF treatment increases the risk of harm to the patient after the 12 months. As a consequence surely with regular monitoring by a clinician patients are capable of making informed decisions and balancing the risk of carrying on treatment after the 12 month period themselves
Section 2 (clinical need and practice)	Is there a justifiable reason why the Committee has not given any indication of the likely numbers of patients with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Crohns should be considered in the same manner as any other chronic condition that people can suffer from, such as diabetes or eplilepsy. Is there the same pressure on clinicians treating patients with these chronic conditions to withdraw a drug that has proven effects for a patient just to see whether there could be an adverse effect such as a coma? It is apparent that Adalimumab falls within NICE guidelines for cost effectiveness for maintenance therapy therefore why remove the decision whether to continue a patient on the drug from the clinician and patient and base it on a 12 month time period. Particularly when other treatments may not be effective or appropriate for a patient. Surely if it is cost effective as a maintenance drug it is important to give people the option to continue on the drug to ensure there is a range of treatments avaliable. On top of this if it is effective and used as maintenance therapy then the social cost to society as well as the life chances of the patient are increased as a patient is more likely to be able to complete educational courses, training and remain in full time employment.
Section 5	

(implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/12/2009 19:44

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	At present there is no evidence that the TNF treatment causes an increase in the risk of harm to the patient after 12 months and given that patients are monitored regularly on these drugs they are perfectly capable of making rational decisions about whether to carry on treatment given the balance of risk. It seems incredibly arbituary to select a cut off point of 12 months regardless of whether the treatment is effective or not. A professional clinician will no doubt stop the treatment if it is ineffective. Further to this there is no other country on the world that has this cut off point. Furthermore it seems irrational to ensure that a patient has to become ill again before they are allowed a second treatment of 12 months. This will put immense pressure and emotional stress on an already ill patient, alongside causing long periods of disturbance in the life of the patient (eg disruption to education, training etc).
Section 2 (clinical need and practice)	It appears that there is no statistic to represent how many Crohns patients would be eligible for treatment. Why has this not been considered or published.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Each patient suffering from Crohns is an individual and it is unrealistic that there is one universally effective course of treatment that is effective for all. It is therefore important that a range of treatments are made avaliable, particularly for patients that are suffering from severe cases. Surely there are more effective ways of determining whether any treatments are effective than purely issuing a 12 month time period and then cut off point. Regualar monitoring by a clinician alongside other tests such as MRIs or colonoscopys are reasonable requirements to assess whether continued treatment is appropriate rather than a simple 12 month cut off point. There is still no acceptance of the committee that there is a social cost to taking patients off the treatment as patients with severe Crohns still find it hard to complete education courses or maintain employment. This problem becomes even more acute when it is apparent that 50% of newly diagnosed Crohns patients are under the age of 30 so therefore their life chances in terms of education, training and employment are significantly reduced.
Section 5 (implementation)	
Section 6 (proposed recommendations for	

further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/12/2009 19:19

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	Newsletter Editor, Norfolk & East Suffolk Group, NACC With regard to Crohns and Ulcerative Colitis, NACC are by far the more experienced in the effects and treatments of these diseases. Consequently NICE would be failing in their duty to the NHS and to patients if they instituted changes contrary to the experience and advice of NACC.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	A) So, according to 1.1, and 1.3, NICE would recommend stopping treatment with Infliximab or Adalimumab after 12 months, even if it is still being effective in controlling Crohns in a patient (".. until treatment failure (including the need for surgery), or until 12 months after the start of treatment, whichever is shorter. ..) B) According to 1.2, "Treatment as described in 1.1 should normally be started with the less expensive drug .." - surely treatment should be started with whichever drug the clinician considers to be most likely to have a positive effect! After all, he/she is the one with experience of the patient, and their particular symptoms, not NICE! Why waste time and money on "the cheaper drug" only to later have to change over to a different drug, having put the patient to unnecessary extra discomfort, pain and worry.
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	06/12/2009 17:02

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	Biochemical Engineering Student
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is provision for continuing treatment after two periods of 12 months even if the drug is proving clinically effective.
Section 2 (clinical need and practice)	Why has the Committee not given an estimate of the likely numbers of people with severe Crohn&#8217s who would be eligible for treatment?
Section 3 (The technology)	The committee would appear to have not given an estimate of the likely numbers of people with severe Crohn&#8217s who would be eligible for treatment?
Section 4 (Evidence and interpretation)	Time limits are an ridiculous way of treating severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is inhumane medical treatment. Is there similar pressure on medical professionals to remove drugs that are effectively controlling a chronic health condition such as diabetes, epilepsy or high blood pressure &#8220to see what happens."? The committee still seems unaware that patients with severe active Crohn&#8217s disease find it difficult to successfully pursue a course of study, hold down a job or take part in most normal community activities. The massive social cost is ignored. Has the Committee looked for evidence elsewhere in the world regarding the withdrawal and restarting of these drugs? There is a potential for complications when patients re-start anti-TNF drugs. The Committee states in 4.3.10 the limitations of the evidence suggesting that it may be reasonable to try withdrawing treatment in people who demonstrated a complete response, yet has concluded to do just that.
Section 5 (implementation)	None.
Section 6 (proposed recommendations for further research)	None.
Section 7 (related NICE guidance)	None.
Section 8 (proposed date of review of guidance)	None.
Date	06/12/2009 16:15

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no evidence that anti-TNF treatment increases harm to the patient after 12 months. All patients are monitored regularly when on these drugs, and should be able to make informed decisions as to whether to continue, given the balance of risks. They should not be considered unable to make these choices. The new document has removed all clinical input to continuing treatment at the end of 12 months. It appears to be an arbitrary cut off point. If the treatment proves clinically ineffective, the clinician will stop treatment anyway. There seems to be no provision to continue treatment after two periods of 12 months if proving clinically effective? What account has been taken of the stress of being ?made? to be ill again before being eligible for a further course of treatment? The proposals adversely impact on young Crohn?s patients who face having further education/ professional training/ early careers severely disrupted due to the nature of severe Crohn?s disease. It seems unclear what the reasons are for changing the preliminary recommendations to a cut off of 12 months. Nowhere else in the developed world uses an arbitrary cut-off point when using these drugs.
Section 2 (clinical need and practice)	Why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Treatments for Crohn?s disease never prove to be uniformly effective. The important thing is to have a range of treatments available, particularly for those with severe Crohn?s disease. Time limits are an inappropriate way of treating severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is inhumane medical treatment. Adalimumab appears to fall within NICE guidelines for cost effectiveness for maintenance therapy. It seems wrong to remove the decision whether to continue on the drug from the clinician and patient.

	Has the Committee looked for evidence elsewhere in the world regarding the withdrawal and restarting of these drugs? There is a potential for complications when patients re-start anti-TNF drugs. The Committee states in 4.3.10 the limitations of the evidence suggesting that it may be reasonable to try withdrawing treatment in people who demonstrated a complete response, yet has concluded to do just that. Is the recommendation of two planned courses of treatment designed to take relevant patients through to the next review
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/12/2009 16:01

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no evidence that anti-TNF treatment increases harm to the patient after 12 months. All patients are monitored regularly when on these drugs, and should be able to make informed decisions as to whether to continue, given the balance of risks. They should not be considered unable to make these choices. The new document has removed all clinical input to continuing treatment at the end of 12 months. It appears to be an arbitrary cut off point. If the treatment proves clinically ineffective, the clinician will stop treatment anyway. There seems to be no provision to continue treatment after two periods of 12 months if proving clinically effective? What account has been taken of the stress of being ?made? to be ill again before being eligible for a further course of treatment? The proposals adversely impact on young Crohn?s patients who face having further education/ professional training/ early careers severely disrupted due to the nature of severe Crohn?s disease. It seems unclear what the reasons are for changing the preliminary recommendations to a cut off of 12 months. Nowhere else in the developed world uses an arbitrary cut-off point when using these drugs.
Section 2 (clinical need and practice)	Why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Treatments for Crohn?s disease never prove to be uniformly effective. The important thing is to have a range of treatments available, particularly for those with severe Crohn?s disease. Time limits are an inappropriate way of treating severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is inhumane medical treatment. Adalimumab appears to fall within NICE guidelines for cost effectiveness for maintenance therapy. It seems wrong to

	remove the decision whether to continue on the drug from the clinician and patient. Has the Committee looked for evidence elsewhere in the world regarding the withdrawal and restarting of these drugs? There is a potential for complications when patients re-start anti-TNF drugs. The Committee states in 4.3.10 the limitations of the evidence suggesting that it may be reasonable to try withdrawing treatment in people who demonstrated a complete response, yet has concluded to do just that. Is the recommendation of two planned courses of treatment designed to take relevant patients through to the next proposed review
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/12/2009 15:59

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

Role	Carer
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)	my son is a crohns sufferer. he developed the disease at 14. without the continious treatment of inflixamab (after being unresponsive to other treatment) my son would not be able to have lived a semi normal life for the past 3 years. he is now 17 and has changed treatment to adalimumab and to be limited to a 1 years course of treatment when no other works would be devastating.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/12/2009 15:45

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

Role	Patient
Other role	
Location	Wales
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	That the recommendation in section 1.1 be ammended to allow patients and doctors to have a say in the decision to stop treatment after 12months and allow flexability rather than imposed limits. That it be make clear that if a patient has initially responded well to one antiTNF, but then lost response, they should have the opportunity to switch to the other antiTNF 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	06/12/2009 15:36

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There seems to be no option to continue treatment after the second period of 12 months even if the treatment is completely satisfactory. No other country in the world has decided on an arbitrary cut off point when using these drugs. How is this beneficial to the health of the patient?
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The committee seem to overlook the fact that patients with severe Crohns disease without treatment find it virtually impossible to undertake a course of study, hold down a job or take part in most community service voluntary work. The cost to society of their being unable to do these normal life activities seems to be completely ignored.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/12/2009 14:30

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no evidence that the treatment does increase the harm to the patients after a year. Therefore the patient themselves must be able to then make an informed descision on their own as to continue the treatment, when given the balance of risks. There is no reason to consider them unable to make these choices. Furthermore it is unclear as to why the preliminary recommendations are changing to a cut off of 12 months.
Section 2 (clinical need and practice)	Is there a reason as to why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The treatments for Crohn?s disease never prove to be uniformly effective. So the important thing is to have a range of treatments available, particularly for those with severe Crohn?s 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	06/12/2009 13:26

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no evidence that the treatment does increase the harm to the patients after a year. Therefore the patient themselves must be able to then make an informed descision on their own as to continue the treatment, when given the balance of risks. There is no reason to consider them unable to make these choices. Furthermore it is unclear as to why the preliminary recommendations are changing to a cut off of 12 months.
Section 2 (clinical need and practice)	Is there a reason as to why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The treatments for Crohn?s disease never prove to be uniformly effective. So the important thing is to have a range of treatments available, particularly for those with severe Crohn?s 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	06/12/2009 13:23

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

Role	other
Other role	Member of Public
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no evidence that the treatment does increase the harm to the patients after a year. Therefore the patient themselves must be able to then make an informed descision on their own as to continue the treatment, when given the balance of risks. There is no reason to consider them unable to make these choices. Furthermore it is unclear as to why the preliminary recommendations are changing to a cut off of 12 months.
Section 2 (clinical need and practice)	Is there a reason as to why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The treatments for Crohn?s disease never prove to be uniformly effective. So the important thing is to have a range of treatments available, particularly for those with severe Crohn?s 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	06/12/2009 13:19

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

Role	other
Other role	Member of Public
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no evidence that the treatment does increase the harm to the patients after a year. Therefore the patient themselves must be able to then make an informed descision on their own as to continue the treatment, when given the balance of risks. There is no reason to consider them unable to make these choices. Furthermore it is unclear as to why the preliminary recommendations are changing to a cut off of 12 months.
Section 2 (clinical need and practice)	Is there a reason as to why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The treatments for Crohn?s disease never prove to be uniformly effective. So the important thing is to have a range of treatments available, particularly for those with severe Crohn?s 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	06/12/2009 13:06

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

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 unclear what the rationale is for changing the preliminary recommendations to a cut off of 12 months.
Section 2 (clinical need and practice)	There is no estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment. Why is this?
Section 3 (The technology)	Little attention has been paid to the fact that half of the newly diagnosed are under age 30. For those people it is crucial that they can complete their studies/professional training/establish a career. Disruption through being taken off an effective drug and being required to be ill is likely to adversely impact their life chances.
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	06/12/2009 13:04

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There seems to be a very arbitary cut off point at 12 months which has been changed from the preliminary recommendations. Surely, if both patient and clinician feel that treatment is effective following regular check ups, and they have considered all risks then treatment should be continued. If not continued, then has the possible stress on patients of possibly being made to be ill again before becoming eligible for a further course been considered?
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Time limiting treatment to 12 months seems very inhumane. Surely, regular reviews seem more appropriate, be they annual or more often. We would not consider removing treatment for any other chronic disease, especially when being managed effectively. Treatments for Chrohns dont seem to be uniformly effective so surely it is important to have a range of available treaments, especially for those suffering severely. Admittedly, cost should be considered, but if cheaper treatments fail then infliximab or adalimumab should be considered. In fact it appears that adalimumab does fall within NICE guidelines for cost effectiveness for maintenace therapy so it seems very wrong to remove the decision on whether or not to continue treatment from the clinician and patient.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/12/2009 12:55

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

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 unjust and unfair that patients who have responded well to this drug and who have been able to live a compartiative normal life whilst taking this drug should at the end of a period of 12 months have this drug automatically removed from their treatment. It seems unclear what the reasons are for changing earlier recommendation and now imposing a cut off time of 12months.Patients should not be consisdered unable to make choices about their treatment.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	It appears that the drug Adalimumab falls within NICE guidelines for a cost effective maintenance treatment for patients suffering from severe Crohns disease. Removing patients from receiving a successful drug for their treatment will severly restrict the role they are able to play in the community. This could prevent a young person being able to continue full time studies or prevent an adult from holding down a fulltime job. What edvidence is there from patients so show that they are concerned about the long term effects of 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	06/12/2009 12:43

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	These preliminary recommendations seem perverse to me for the following reasons: 1)It seems that these new proposals have removed any clinical input in deciding whether a patient would benefit from continuing treatment after 12 months. 2) The proposal to change the preliminary recommendations to this cut off of 12 months seems arbitrary. My understanding is that nowehere else in the developed world is such arbitrary cut off points used for these drugs. This appears to be rationing without considering the consequences to long term patient health. 3) The likely effect of this proposed policy is of a yo yo effect on those who are severely effected with Crohns. So after 12 months, they will start to relapse, and only then will consideration be given to another course. 4)It is not clear what provision will be made with respect to continuing treatment after two periods of 12 months. Are you expecting some miracle cure - or just leaving it to the patient to fight for the treatment which offers them a reasonable quality of life? 5) The affect on young Crohns patients who face disruption to their education and early careers - and quality of life seems to have been ignored.
Section 2 (clinical need and practice)	You have missed out a very significant number here. What is your estimate of the number of people with severe Crohns who would be eligible for this treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	There are three main concerns I would like to raise: 1) The proposed arbitrary time limit of 12 months on those with severe Crohns. There should, rather, be an expectation that the consultant involved reviews progress, based on the specific clinical indicators of the patient under his/her care, to determine whether continued treatment is appropriate. Can you imagine the arbitrary withdrawing treatment for, say high blood pressure, after 12 months because the treatment seems to be working, without allowing for clinical judgement? 2) A high proportion of the newly diagnosed patients with Crohns are under 30. This is a period in life, where disruption to studies, and early career can have a devastating effect on their longer term life chances. The social cost to the patient and to society seems to be completely ignored. 3) Has the committee considered evidence with respect to the

	withdrawal and restarting these drugs Is your proposal so to do evidence based?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/12/2009 12:39

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The new document has removed all clinical input to continuing treatment at the end of 12 months. It appears to be an arbitrary cut off point. Nowhere else in the developed world uses an arbitrary cut-off point when using these drugs. If the treatment proves clinically ineffective, the clinician will stop treatment anyway. It seems unclear what the reasons are for changing the preliminary recommendations to a cut off of 12 months.
Section 2 (clinical need and practice)	Why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Treatments for Crohn?s are not uniformly effective. Therefore there need to be a range of treatments available, particularly for those with severe Crohn?s disease. Time limits are an inappropriate way of treating severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to decide whether continued treatment is appropriate. A 12 month cut off is inhumane medical treatment. Is there similar pressure to remove drugs that are effectively controlling other chronic health conditions such as diabetes, epilepsy or high blood pressure to see what will happen, such as a coma, brain damage or a stroke? Patients with severe active Crohn?s disease find it difficult to successfully pursue a course of study, hold down a job and pay taxes. Adalimumab appears to fall within NICE guidelines for cost effectiveness for maintenance therapy. It seems wrong to remove the decision whether to continue on the drug from the clinician and patient. The Committee states in 4.3.10 the the limitations of the evidence suggesting that it may be reasonable to try withdrawing treatment in people who demonstrated a complete response, yet has concluded to do that.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	06/12/2009 09:22

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The suggestion of a 12 month cut off period independent of doctor opinion makes no sense to me. There is no apparent evidence that an arbitrary period of this nature is of benefit to anyone. Indeed, it would seem designed to make a person with Crohns prove that they are still sick before letting them go back on a drug that has been proved to work. The additional costs to the NHS and society of dealing with a person who has relapsed into serious illness does not appear to have been taken into account. Also, what happens when the further 12 months period has expired? Are we then returning to a situation where the only option for the person is to feel seriously unwell for much of the time, leading to a requirement for surgical interventions and all the costs that that involves?
Section 2 (clinical need and practice)	While it may well be true that Crohns does not have a large impact on early death stats, it should be recognised that Crohns is a hugely disabling condition that can destroy a persons career and relationships if they have difficulty controlling the condition.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	There is obviously still scope for a lot more learning for both treatment options under discussion here. However, it is difficult to accept the concept of a 12 month limit to treatment when even the studies (see 4.1.9) look at results beyond this timeline. Where concern has been expressed about the long term effects of the drug, what has been suggested might be the outcome? This is important as it needs to be compared with the impact of a return of full Crohns symptoms and a vast diminution in quality of life.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	These all make sense, though an inclusion of the use of a placebo condition might be needed, provided that subjects in this condition can receive swift real intervention to deal with the disease.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	05/12/2009 18:43

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

Role	other
Other role	member of the public
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	? The proposals adversely impact on young Crohn?s patients who face having further education/ professional training/ early careers severely disrupted due to the nature of severe Crohn?s disease. ? It seems unclear what the reasons are for changing the preliminary recommendations to a cut off of 12 months ? Nowhere else in the developed world uses an arbitrary cut-off point when using these drugs. Where is the evidence to show this would benefit patient health? ? What account has been taken of the stress of being ?made? to be ill again before being eligible for a further course of treatment?
Section 2 (clinical need and practice)	? Why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	? Time limits are an inappropriate way of treating severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is inhumane medical treatment. Is there similar pressure on medical professionals to remove drugs that are effectively controlling a chronic health condition such as diabetes, epilepsy or high blood pressure ?to see what will happen, such as a coma, brain damage or a stroke? ? The committee still seems unaware that patients with severe active Crohn?s disease find it difficult to successfully pursue a course of study, hold down a job or take part in most normal community activities. The social cost to society is completely ignored. ? The committee seems to have paid little attention to the fact that 50% of the newly diagnosed are under age 30. For those people it is crucial that they can complete their studies/professional training/establish a career. Disruption through being taken off an effective drug and being required to be ill is likely to adversely impact their life chances.
Section 5 (implementation)	
Section 6	

(proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	05/12/2009 17:56

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

Role	Patient
Other role	Patient Panel representative, NACC volunteer
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	A 12 month cut off is arbitrary, ineffective and cruel. Patients take time to recover from relapses and may never do so entirely. waiting for a possible relapse will increase stress levels, making one more likely, which in turn places greater costs on the NHS, especially if it involves surgery. Older patients, like me, find it harder to regain any level of fitness or stability after a relapse or medical intervention. Before Infliximab I had 23 hospital visits in 2 years, plus 27 visits to my GP and specialist nurses. My quality of life was non-existent. even though I still have a fistula I have much greater control and have been free of abscesses and lesions. If this were taken to indicate remission then my enhanced quality of life would go, I would be unable to plan for the future at all, and would have to expect a return to active pain and disease.
Section 2 (clinical need and practice)	As you say in section 2.6, CD is unpredictable- ie any remission has to be treated as temporary, and the focus has to be on maintaining remission as far as possible. Which is what Infliximab does, so why risk change, unless both clinician and patient feel it is appropriate to stop the treatment?
Section 3 (The technology)	I realise that both treatments are expensive as medications, but is it possible or practical to make comparison with the cost of surgery and after-care? With regard to my earlier experiences it cannot have been cheap or cost effective to keep draining abscesses every few months, regardless of its impact on me.
Section 4 (Evidence and interpretation)	It seems that in order to achieve cost effectiveness the committee is willing to over-ride the concerns of clinicians and patients, and has chosen not to consider the cost implications of relapses, financial, physiological and mental.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	The work of NACC with patients with CD should be acknowledged here: apart from my own experience of the condition, I have 5 years experience as a volunteer to be able to make some broader based observations about quality of life issues, as do my fellow volunteers. I feel you should trawl as widely and as thoroughly as possible in gathering evidence, and allow greater time for responses to be collected than in this instance.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	05/12/2009 14:59

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no evidence that anti-TNF treatment increases harm to the patient after 12 months and as patients are monitored regularly when on these drugs, it should be possible to make informed decisions as to whether to continue, given the balance of risks. Why is there no provision to continue treatment after two periods of 12 months if proving clinically effective? There appears to be no account taken of the stress of having to become unwell again before being eligible for a further course of treatment.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	50% of the newly diagnosed are under age 30. Being taken off an effective drug causes huge disruption peoples ability to pursue a course of study, hold down a job or take part in most normal community activities. The social cost to society does not appear to have been taken into account. Has the Committee received evidence from Patients that they are so concerned about the long term effects of these drugs that the drugs should be withdrawn after 12 months? 4.3.10 acknowldeges the limitations of the evidence suggesting that it may be reasonable to try withdrawing treatment in people who demonstrated a complete response. So why it recomending a course of action that has limited evidence? What does the international evidence say about the impact and potential for complications of the withdrawal and restarting of these drugs?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	05/12/2009 14:11

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

Role	Carer
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The drugs under review are only for severely ill Crohns patients.To recommend stopping the treatment after 12 months is inhumane. This is merely an extended version of the episodic treatment proposed last year, which the gastroenterologists specifically stated to be completely out of line with current treatment in the rest of the world. What happens after 24 months? How will this approach enable people to continue in work, or pursue further education?
Section 2 (clinical need and practice)	You state in 2.5 that Crohns disease is not medically or surgically curable. If adalilumab or infliximab is successfully controlling the disease, without necessarily inducing remission, why would it be desirable to stop treatment? Would a diabetes patient have their insulin taken away? These drugs are only use by the most severely ill, and their quality of life without successful response to a drug is very poor.
Section 3 (The technology)	As Adalimumab can be administered safely at home, and monitored by blood tests, it enables a patient to have a very good quality of life,and the costs appear to be within NICE guidelines. Patients are screened before going on the drug, and monitored carefully while on it. There is no demonstrated evidence that risks increase significantly over time. Has the data from rheumatoid arthritis sufferere been examined? They are an older group, and the drug has been used for over 10 years.
Section 4 (Evidence and interpretation)	Patients with CD understand that maintenance treatment is long term, and designed to control their symptoms.Planned course of treatment is just a metaphor for controlling costs. Clinicians do review use of the drug regularly.Remission can be checked by MRI or colonoscopy before stopping the drug. Any new drug has long term uncertainties, and the patient should be made aware of possible issues both before and during treatment. Removing a drug and making people ill is unethical, and 4.3.5 summarises the problems around this. This appears to be treatment by budget control. Where is clinician input?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	How is the research going to be funded? There needs to be research on withdrawel from these drugs, and also on their re-introduction.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	If the recommendation goes through in this form, it should reviewed as soon as possible, as it will cause unnecessary pain

	and suffering for patients.
Date	05/12/2009 13:57

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	- These recommendations deny the experience of the clinician in the the continued prescription of these treatments. - Removing clinical judgment and patient input in the prescription of these drugs at the 12 month point is arbitrary. All patients are
Section 2 (clinical need and practice)	#NAME?
Section 3 (The technology)	No comments
Section 4 (Evidence and interpretation)	- The outcome of treatment can be failure, control of symptoms or remission. The latter two outcomes are successful. While the proposals hint at an understanding of this, the recommendation of ceasing treatment at 12 months to find out which of the two su
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	- The Committee is reflecting a concern about the longer term use of these drugs. In view of the longer term experience of using anti TNF drugs for other conditions, is it reasonable to obtain evidence from those regimens to conclude on the issues assoc
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	- The proposed review date should reflect the availability of further research outcomes. - If the Committee continues to recommend withdrawal of treatment after 24 months, then the timing of the review should enable the Committee to address the position
Date	05/12/2009 13:28

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	? The new document has removed all clinical input to continuing treatment at the end of 12 months. It appears to be an arbitrary cut off point. If the treatment proves clinically ineffective, the clinician will stop treatment anyway. ? There seems to be no provision to continue treatment after two periods of 12 months if proving clinically effective? ? What account has been taken of the stress of being ?made? to be ill again before being eligible for a further course of treatment? ? The proposals adversely impact on young Crohn?s patients who face having further education/ professional training/ early careers severely disrupted due to the nature of severe Crohn?s disease. ? It seems unclear what the reasons are for changing the preliminary recommendations to a cut off of 12 months. ? The term ?planned course of treatment? is not a clarification for patients, who understand the terms ?episodic? and ?maintenance? therapy in respect of these drugs.
Section 2 (clinical need and practice)	? Why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	? Time limits are an inappropriate way of treating severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is inhumane medical treatment. Is there similar pressure on medical professionals to remove drugs that are effectively controlling a chronic health condition such as diabetes, epilepsy or high blood pressure ?to see what will happen, such as a coma, brain damage or a stroke? ? The committee still seems unaware that patients with severe active Crohn?s disease find it difficult to successfully pursue a course of study, hold down a job or take part in most normal community activities. The social cost to society is completely ignored. ? The committee seems to have paid little attention to the fact that 50% of the newly diagnosed are under age 30. For those people it is crucial that they can complete their studies/professional training/establish a career. Disruption through being taken off an effective drug and being required to be ill is likely to adversely impact their life chances.
Section 5 (implementation)	

Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	05/12/2009 10:46

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	? The new document has removed all clinical input to continuing treatment at the end of 12 months. It appears to be an arbitrary cut off point. If the treatment proves clinically ineffective, the clinician will stop treatment anyway. ? There seems to be no provision to continue treatment after two periods of 12 months if proving clinically effective? ? What account has been taken of the stress of being ?made? to be ill again before being eligible for a further course of treatment? ? The proposals adversely impact on young Crohn?s patients who face having further education/ professional training/ early careers severely disrupted due to the nature of severe Crohn?s disease.
Section 2 (clinical need and practice)	? Why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	? Treatments for Crohn?s disease never prove to be uniformly effective. The important thing is to have a range of treatments available, particularly for those with severe Crohn?s disease. ? Time limits are an inappropriate way of treating severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is inhumane medical treatment. Is there similar pressure on medical professionals to remove drugs that are effectively controlling a chronic health condition such as diabetes, epilepsy or high blood pressure ?to see what will happen, such as a coma, brain damage or a stroke? ? The committee still seems unaware that patients with severe active Crohn?s disease find it difficult to successfully pursue a course of study, hold down a job or take part in most normal community activities. The social cost to society is completely ignored.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	

Date	05/12/2009 10:40

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

Role	Patient
Other role	
Location	N Ireland
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	05/12/2009 10:34

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Unless there is strong evidence that continuing treatment with infliximab or adalimumab carries long term risks I question the need to stop treatment after 12 months, wait for a relapse, then continue for a further 12 months only. In what percentage of cases is there no relapse? Particularly with patients who are young and at school, college or starting out in careers, it seems wrong to risk a period of illness at a critical time of their lives. I have lived with a type 1 diabetic for many years and can imagine the problems of discontinuing insulin to see whether he still needs it!
Section 2 (clinical need and practice)	With so many treatments available, should not clinicians be allowed to decide the best course for an individual patient across the whole range, rather than being obliged to withdraw infliximab or adalimumab after 12 months of treatment? Surely all treatments are reviewed periodically and the idiosyncrasies of the patient taken into account, rather than following guidance blindly?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Do the calculations take into account the earning capability of patients with active and debilitating Crohns disease compared with those whose symptoms are well-controlled?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	Of course further research is essential to determine the best and most cost-effective treatment, but must be able to consider all factors, including age.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	05/12/2009 10:13

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	No
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I replied to this on the 3/12/03 and submitted my view at around 6.30pm. I have thought about this for a day and wanted to add something. In my original submission I commented that I was gravely ill with Crohns. I wanted to describe my illness so we all know how important this is.Firstly I felt ill, like I had flu, all the time. Though there are some variations I was going to the toilet between 15 and 30 times a day. In this continues on and off for two years can you imagine what that does to your physical and mental health over a prolonged period. At my optimum health I weigh around 14 stone. My weight dropped to just over 9 stone. For long periods I was bed ridden. I started to get abscesses across my body including my rectum and face. I had boils across my back. I was always dehydrated. I developed anaemia. I also got Arthritis. This was in my feet, ankles, knees, hands and lower back. It started slowly at first but then became agonising, leaving me virtually unable to walk. I also suffered appallingly from haemmoroids. Infliximab makes me well, to allow myself and others like me to get sick again when we have the cure is inhuman and unthinkable. My life was not worth living.
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	05/12/2009 07:12

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

Role	other
Other role	PhysicianUnited States
Location	US
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no clinical evidence for the 12 month limit furthermore, re-treating patients for relapses after halting medication presents difficulties in re-establishing remission. In the interim, the patients lives are disrupted, and complications and/or hospitalization may supervene.
Section 2 (clinical need and practice)	While Crohns is not curable, maintenance of successful therapy improves patient performance and may reduce the risk of surgery surgery in Crohns patients entails significant risk of complications.
Section 3 (The technology)	There is no disputing the expense of the treatments, but in terms of expense (including hospitalization) as well as loss of productivity and quality of life, the medical treatment may well be the less expensive option.
Section 4 (Evidence and interpretation)	The comments above recognize the benefits of maintenance therapy and the limitation of current data is long-term follow-up in terms of cost/benefit. This deserves further study, but studying patients on long-term maintenance therapy would be more appropriate, rather than arbitrarily terminating a beneficial drug after a 12 month course. This would be particularly useful for the young patients (under 30).
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	Agree with continued study, but not at the risk of withdrawing drug for currently asymptomatic patients who are having successful treatment.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	05/12/2009 02:07

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

Role	Patient
Other role	Member of NACC
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	? There is no evidence that anti-TNF treatment increases harm to the patient after 12 months. All patients are monitored regularly when on these drugs, and should be able to make informed decisions as to whether to continue, given the balance of risks. They should not be considered unable to make these choices. ? The new document has removed all clinical input to continuing treatment at the end of 12 months. It appears to be an arbitrary cut off point. If the treatment proves clinically ineffective, the clinician will stop treatment anyway. ? There seems to be no provision to continue treatment after two periods of 12 months if proving clinically effective? ? What account has been taken of the stress of being ?made? to be ill again before being eligible for a further course of treatment? ? The proposals adversely impact on young Crohn?s patients who face having further education/ professional training/ early careers severely disrupted due to the nature of severe Crohn?s disease. ? It seems unclear what the reasons are for changing the preliminary recommendations to a cut off of 12 months. ?
Section 2 (clinical need and practice)	? Why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	? Treatments for Crohn?s disease never prove to be uniformly effective. The important thing is to have a range of treatments available, particularly for those with severe Crohn?s disease. ? Time limits are an inappropriate way of treating severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is inhumane medical treatment. Is there similar pressure on medical professionals to remove drugs that are effectively controlling a chronic health condition such as diabetes, epilepsy or high blood pressure ?to see what will happen, such as a coma, brain damage or a stroke? ? The committee still seems unaware that patients with severe active Crohn?s disease find it difficult to successfully pursue a course of study, hold down a job or take part in most normal community activities. The social cost to society is completely ignored.

	? The committee seems to have paid little attention to the fact that 50% of the newly diagnosed are under age 30. For those people it is crucial that they can complete their studies/professional training/establish a career.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	04/12/2009 22:46

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Infliximab when it works should be reviewed after 12 months but it should be within the clinicians control, along with the patient, to be able to continue the treatment uninterupted if that is what would give the patient the best quality of life.
Section 2 (clinical need and practice)	Crohns is a disease that impacts ones life in a dramatic way and makes normal events and planning impossible and painful. Lethargy and tiredness should not be underestimated as they have a negative impact on ones ability to carry out a normal life.
Section 3 (The technology)	Advice is sought for patients who have repsonded well to one antiTNF based drug to be transfered to another.
Section 4 (Evidence and interpretation)	Clinical evidence from practise rather than Clinical trials as such is now available that shows that patients can maintain a good life style while remaining on infliximab for a long time with no adverse side effects.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	This seems good.
Section 8 (proposed date of review of guidance)	
Date	04/12/2009 21:19

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

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 on Infliximab for the last 4 years, your recommendations would stop my treatment. Before this I was constantly in Hospital and unable to lead a normal life. On occasion the time between treatments has been increased I suffer a flare up. Under your recommendations I will be back to staying in hospital and wont be able to work or lead a normal 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	04/12/2009 18:59

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

Role	Patient
Other role	and carer
Location	Wales
Conflict	no
Notes	I am due to be treated with infliximab following testing in January
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	If treatment appears to be successful during the 12 month period it should be continued thereafter as it is in most European countries, US and Australia. We desperately need this drug to need a somewhat normal life.My husband is my carer and he knows more than anyone what pain I suffer during active crohns this is what we need. I never leave the house unless for hospital appointments now and having been promised the possibility of starting infliximab - I have nothing to look forward to at the end od twelve months, provding it is, as expected successful.
Section 2 (clinical need and practice)	I have had my bowel removed and now have crohns in my joints and my mouth - this drug will be a lifesaver.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Every two hours someone is diagnosed with Crohns - paperwork indicates that the majority of these are under 30. I was diagnosed at 57, never having a days illness before of anything in my life. I know many, many people belonging to NACC and who attend the hospitals I do (West Wales, Bronglais, Bridgend, St Marks Harrow etc.) all of whom were diagnosed at my age - where exactly do these figures "majority under thirty come from". Failure to diagnose Crohns at an early stage and in older people is common, people suffer for years under "Colitis" headings that turn out to be Crohns better diagnosis would change these figures.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	More research into early diagnosis for Crohns not treatment afrter the fact is essential. Correct diagnosis of patients with unknown IBD is necessary. Then we would not need infliximab if this was caught early enough. I ahve had my bowel removed because no-one diagnosed me until my bowel ruptured!
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	04/12/2009 18:40

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	I am a member of NACC
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Crohns is a chronic disease which means that most treatments are for the long term (sometimes for life). Putting a 12 month automatic stop on a treatment does not seem to make sense. I can understand the desire to be cost effective, but surely this should mean a review of the treatment and whether it is working, rather than stopping treatment. Patients on the more expensive drugs are those whose treatment with cheaper drugs does not work and they have therefore suffered from flare ups of the disease often requiring hospitalisation. By stopping treatment automatically, flare-ups and treatment of more severe symptoms (including time off work as well as disruption to ordinary life) are going to happen. If instead a clinical review is undertaken, a decision based on the patients circumstances can be made to stop or continue treatment.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	4.3.10 Whilst I understand the desire to stop the use of potentially harmful drugs, this has to be weighed against the cost (to the patient and also to the NHS) of a relapse and all that can be involved with that, including hospitalisation. If more research is needed, then surely the research should be carried out before changing the guidelines and removing discretion from the surgeon actually caring for the patient.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	04/12/2009 18:23

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	I have currantly been on Infliximab Due abcesses last year which put me in renal failer, and then a fistulae next to my Ileostomy has accured. Since being on this drug i feel better now than in over 10years. it also has improved my mobility as i have ankilosing spondilosis as will. Please allow me to stop on this wonder drug. steve dear.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I think the use of these ANTi TNF Drugs should not automaticlly be stopped after 12mouths if you are well etc. If you have gone through years of pain and stress and discomfort, and sometimes life threatning problems. It seems grazy to stop this wonder drug and just hope for the best. It should be left up to the Gastoenterologist and the patient to deside which is the best course of action for there case.It has got to be better and cheaper in the long run to keep people on these drugs rather than having to go through trumatic and costly surgury.
Section 2 (clinical need and practice)	
Section 3 (The technology)	As i said earlier the use of these anti tnf drugs should be left in the hands of the DR and the Patient,to know whether staying on these drugs is whats best for there situation. Obviously you have to explore and use the cheaper drugs first. e.g methothrexate but these dont always work
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	04/12/2009 16:11

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The proposals adversely impact on young Crohns patients who face have further education/professional training/early careers severely disrupted due to the nature of severe Crohns disease.
Section 2 (clinical need and practice)	Why has the Committee not given an estimate of the likely numbers of people with severe Crohns who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Time limits are an inappropriate way of treating severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is inhumane medical treatment. Is there similar pressure on medical professionals to remove drugs that are effectively controlling a chronic health condition such as diabetes, epilepsy or high blood pressure "to see what will happen", such as coma, brain damage or a stroke?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	04/12/2009 11:13

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	12 month enforced withdrawal of treatment seems completely arbitrary. The new document has removed all clinical input to continuing treatment at the end of 12 months. Withdrawal after 12 months does not take into account the different levels of successful response, some not leading to full remission (ie not a complete response). The evidence regarding long-term safety of the drug does not seem to merit this enforced withdrawal, since the effects are regularly monitored by clinicians. Experience of the drugs in the USA seems to indicate that there is a potential for complications when re-starting treatment after a break. Has the committee considered this at all?
Section 2 (clinical need and practice)	Why has the Committee not given an estimate of the likely numners of peopl with severe Crohns who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Section 4.3.10 highlights the fact that it may be reasonable to try withdrawing treatment in people whose disease demonstrated a complete response, however there is no distinction between people who have a complete response and people who have a response where the disease is controlled, but not in remission. Since the committee has decided that maintenance treatment is clinically and cost effective, suddenly stopping it after 12 months seems ridiculous. Is the recommendation of the two planned courses of treatment designed to take relevant patients through to the next proposed review by the Guidance Executive?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	

Date	04/12/2009 11:08

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

Role	Carer
Other role	mother
Location	Wales
Conflict	no
Notes	I know what it is to have a young man with chronic illness unwell and under employed for years. Please leave the decision on medication to the clinical experts. It is costly for people to relapse unnecessarily,- sick pay, instead of tax paying, misery instead of contributing, broken relationships .....
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Please leave it to the Doctors to decide when a treatment should be stopped. Although children are important, it is terrible to be ill all through ones 20s too as my son was. It is costly too in terms of lost work, not paying tax, lost relationships, not paying into pension, not contributing so much. Have you done those sums? Surgery does not cure this disease.
Section 2 (clinical need and practice)	How much does surgery cost? Does this drug not prevent surgery sometimes? How much better to keep people well. Clearly less expensive but effective treatments should be tried first but that is the clinicians decision. Is the NHS only to provide not-the-best? What is the position in Europe? You are opening the door to private ripoff practitioner that only the wealthy can afford. When they fail it will be back to the NHS to pick up the pieces and bill.People are family members. I became quite sad and took time off from work with stress when my son was ill for 8 years in his 20s.
Section 3 (The technology)	Cant you buy it more cheaply by forming a market with European coontries? If someone is at work because of the treatment she /he is likely to be contributing more that £12,000 to the economy and saving on benefits. If not working for money they may be making a better job of parenting etc. Lets have some joined up accounting instead of beggar-my-neighbour let a different government pot pay, (but still taxpayers.)Other family members who are fit may well be contibuting much more that this to the community tax pot.
Section 4 (Evidence and interpretation)	And not effective for young people of 18+?
Section 5 (implementation)	Maximum good scientific information is great. But leave the decision to the informed consultant. Get rid of bed blocking! Save £££££££
Section 6 (proposed recommendations for further research)	good.
Section 7 (related NICE guidance)	If you dont buy and use the drug how will the research be funded and more drugs developed?
Section 8 (proposed date of review	Will the research be done by then? you need to set upp feedbacks I presume.

of guidance)	
Date	04/12/2009 11:05

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

Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Stopping the TNF inhibitor at 1 year will be disasterous for many patients. May I urge you to re-consider this recommendation to allow those patients who are now dependent upon this treatment to continue whilst they receive benefit from it even where the duration of treatment exceeds one year.
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	04/12/2009 10:34

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I dont have experience of being treated with infliximab or adalimumab for my Crohns Disease, although infliximab has been suggested by my consultant should my symptoms worsen. My understanding about the drug is that if I were not to be in full remission after 12 months, I may well have a flare-up or return of symptoms with all the disruption that means for my health, work, well-being etc. Under the proposed NICE guidance, only then would I requalify for a new course of treatment with antiTNF drugs for a further 12 month period. I have been told by NACC that the proposed NICE guidance is therefore against current clinical practice in the UK and elsewhere in the world. What NACC and the gastroenterologists it works with would like instead is an effective review system, within which at 12 months the hospital would review a patient?s symptoms. If they are in full remission, treatment would stop, but if they have continuing symptoms, treatment would continue uninterrupted. 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	04/12/2009 09:53

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

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)	To withdraw effective medical treatment based on an arbitrary time rather than clinical data and a physicians evaluation is unethical and substandard medical care. Crohns disease is a chronic condition. Treatment allows patients to function but it does not cure the disease. Everyone on the Committee should sit with an emaciated child in severe pain, unable to eat or go to school who is unresponsive to other drug therapies. When these patients are responsive to infliximab or adalimumab, how could anyone doom these patients to relapse, fistulae and surgery by withdrawing treatment at 12 months? It makes me wonder how many people on the Appraisal Committee actively participate in the treatment of Crohns disease.
Section 2 (clinical need and practice)	Given the severity and risk of life-long complications from Crohns disease, physicians and health care professionals should decide on a patients course of treatment.
Section 3 (The technology)	This discussion should be about treating patients appropriately, not about drug prices.
Section 4 (Evidence and interpretation)	It is unethical and immoral to stop effective medical treatment in children based on cost, rather than quality of life. The question should be how does one fund this program so children can be effectively treated.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	While further research needs to be done, the treatment of children suffering from Crohns disease that is unresponsive to other treatments NOW should be the most important issue.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	04/12/2009 00:16

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

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)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/12/2009 22:36

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

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 was diagnosed with ulcerative colitis ten years ago. For the last three years i have been a member of the patient panel at kent and canterbury hospital for NACC and although i am not currently on infliximab it is thought i will be on it in the future. I also have friends who rely on this medication. Therefore i am writing to support other NACC members who also feel that this treatment should not be stopped and only administered when we are having a flare up, it would cause a lot of pain, and distruption in our lives especially for patients like me who regularly have flare ups. Please take notice of all our comments as we are the ones who know!
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	03/12/2009 20:43

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

Role	other
Other role	Father of Crohns sufferer
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	If the present ACD is confirmed the opportunity for any clinical discretion about precisely when to stop treatment is removed and we know that in the past doctors have extended treatment for short periods to take account of special circumstances such as the patient getting married, students talking their final exams, patients starting a new job. No new evidence was presented to the committee at their October meeting that justified this change in their recommendations. They simply chose to change their earlier recommendation in order to limit treatment to a defined time. I believe strongly that the earlier proposal for a review at 12 months is the correct approach ? reflecting a proper balance between safety, good clinical practice, cost-effectiveness and patients? wellbeing. An additional question raised previously and still not addressed by NICE is to make it clear that if a patient has initially responded well to one antiTNF, but then lost response, they should have the opportunity to switch to the other antiTNF 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	03/12/2009 20:18

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

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 patients on infliximab should be reviewed after 12months. Stopping treatment after a set time doesnt seem to follow best clinical practice, especially if the px is responding well to the treatment. It seems to me pxs should be treated as individuals and be reviewed by their consultant and treatment be removed if they are in full remission, not just after a set time. Removing treatment after a set time may even prove to be counter active as the px may have a flare up and end up in hospital, if needing IV steroids for approx 5 days, which may be a higher cost than the infliximab infusion itself.
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	03/12/2009 19:55

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I wish to object to the recommendation that the use of anti TNF drugs should cease after 12 months. I suffer from Ulcerative Colitis and know the distress and disruption caused by an acute flare up of inflammatory bowel disease. I strongly feel that people with Crohns disease whose condition is being successfully controlled by these drugs should not have the treatment withdrawn after this period without an assessment from their gastroenterologist. If following assessment it is felt the treatment is still necessary to maintain the patients health and ability to work then surely it should continue until such time as they are considered to be able to cope without it.
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	03/12/2009 19:51

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	Dear Sir/ Madame, I have Crohns disease. I became sick in 2005 and was gravely ill after that. In September 2007 I had Infliximab for the first time and have been on it ever since. It has changed my life. It has been a gradual process and I would say I have only become properly well at the beginning of this year (2009). This is about 14 months after starting on infliximab. Of course infliximab users are happy to discuss the ending of treatment if in remission. No one wants to be on a medicine they dont need at the expense of the NHS however to set a 12 maximum useage is draconian, ridiculous and for a patient terrifying. I urge the specialists of NICE to reconsider. Please do not end a treatment that I need so desperately. On a personaly level I hate the fact that drug companies charge so much for the treatments and I am aware that infliximab and similar treatments are perfect as they do not cure but treat an illness at additional cost. This is the system and I hope organisations such as NICE change things for the better. If this is a cost issue then there is no contest between myself on infliximab and myself without infliximab. I cost the NHS far more when I am sick. Frequent doctors visits, endless consultations, cupboards full of medicine that doesnt work, frequent hospital visits and frequent hospital stays. The subsidery cost to the state of a person unable to work. The cost and burden to social services departments. The real costs of familys unable to cope, seperations, child poverty, more social housing. The pro list to keeping me, and persons like me, well and healthy is endless. I believe the usage of this drug and the like should be closely monitered and withdrawn,slowly through consulation, from patients in remission however if a patient needs this drug to stay well then it should be given freely without the threat of withdrawal. For myself at 38 I feel that I lost 2 years of my life through illness please do not let me lose anymore. For my sake, my wifes sake and my three childrens sake. I cannot emphasise what an important decision you hold in your hands. Please make the right one. Thank you for your consideration.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Dear Sir/ Madame, I have Crohns disease. I became sick in 2005 and was gravely ill after that. In September 2007 I had Infliximab for the first time and have been on it ever since. It has changed my life. It has been a gradual process and I would say I have only become

	properly well at the beginning of this year (2009). This is about 14 months after starting on infliximab. Of course infliximab users are happy to discuss the ending of treatment if in remission. No one wants to be on a medicine they dont need at the expense of the NHS however to set a 12 maximum useage is draconian, ridiculous and for a patient terrifying. I urge the specialists of NICE to reconsider. Please do not end a treatment that I need so desperately. On a personaly level I hate the fact that drug companies charge so much for the treatments and I am aware that infliximab and similar treatments are perfect as they do not cure but treat an illness at additional cost. This is the system and I hope organisations such as NICE change things for the better. If this is a cost issue then there is no contest between myself on infliximab and myself without infliximab. I cost the NHS far more when I am sick. Frequent doctors visits, endless consultations, cupboards full of medicine that doesnt work, frequent hospital visits and frequent hospital stays. The subsidery cost to the state of a person unable to work. The cost and burden to social services departments. The real costs of familys unable to cope, seperations, child poverty, more social housing. The pro list to keeping me, and persons like me, well and healthy is endless. I believe the usage of this drug and the like should be closely monitered and withdrawn,slowly through consulation, from patients in remission however if a patient needs this drug to stay well then it should be given freely without the threat of withdrawal. For myself at 38 I feel that I lost 2 years of my life through illness please do not let me lose anymore. For my sake, my wifes sake and my three childrens sake. I cannot emphasise what an important decision you hold in your hands. Please make the right one. Thank you for your consideration.
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	03/12/2009 18:45

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

Role	other
Other role	Parent
Location	England
Conflict	no
Notes	My child has crohns disease and is on Adalimumab every 2 weeks and has been since 2007
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I agree that it should be the clinicians and patients and there parents should have the options to continue medication, My son is mointered regularly and I believe we can make informed decisions to whether to continue on treatment and assess with his consultant the balance of risk. Even when my son had weight gain his adalimamab had to be increased as it was no longer effective, no other medication has ever been effective and I worry about his future health if he is unable to have adalimamab.
Section 2 (clinical need and practice)	I am aware different treatment work for different patients and wonder how many patient it is expected will need maintence treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	I am happy to accept the risks about continued treatment and I am more concerned about the disruption of my sons studies if he is unable to have adalimamub and will then have continued flares, and I wonder if committee has had much reponse from patients worried about long term side effects. My son flares almost immediately after finishing steriods no other treatment has been effective.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/12/2009 17:52

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Why is there a random cut-off point? I am at a loss to see the point of it, how would it benefit patient health to stop treatment after two periods of 12 months if proving to be an effective form of treatment?
Section 2 (clinical need and practice)	There has been no estimate produced of the number of patients likely to have a severe case of Chrohns disease who are eligible for treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Treatments for Chrons disease vary in effectiveness, the point being that there should be a wide variety of treatments available. The last point I will raise is that it is just morally wrong to have a 12 month cut off time in treatment just to "see what will happen" without the medication, subjecting patients to risks such as a coma, a stroke or brain damage.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/12/2009 16:56

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	1 There is no evidence to suggest anti-TNF treatment increases harm to the patient after 12 months. Patients are monitored regularly if on these drugs and should be allowed to make an informed decision on whether to continue given the balance of risks. It should not be assumed they are unable to make these choices. 2 It would appear that at the end of 12 months all clinical input is removed. Why this arbitrary cut off point? If the treatment is inneffective then the clinician will have stopped the treatment. 3 Where is the provision to continue the treatment after the second period of 12 months, if proving effective? 4 These proposals adversly impact on young Crohns patients with severe symptoms. They face further disruption to education/professional training and it will continue to impact on their career. Has this been taken into account? 5 What reasons are there for changing the preliminary recommendations to a cut off of 12 months? 6 Patients with Crohns use terms such as episodic and maintenance therapy in respect of these drugs. The term planned course of treatment is not a clarification. 7 Nowhere else in the developed world uses an arbitrary cut-off point.
Section 2 (clinical need and practice)	The committee has not given an estimate on the likely numbers of people with severe Crohns who would be eligible for treatment. Why?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	1 There needs to be a range of treatments availabe as no one treatment proves uniformly effective. Removing one which is proving effective is inhumane. Is there similar pressure to remove effective treatments for other chronic conditions such as diabetes,epilepsy etc.? 2 Why is the committee unable to realise that a person suffering from severe active Crohns finds it difficult to study, hold down a job, or take part in normal day to day activities? Drugs which are effective help them establish carees and lead indepedent lives. Not become a drain on society and benifit dependent. 3 There is a potential for complications when patients re-start anti-TNF drugs wouldnt this make it more sensible not to withdraw the maintenance dose. 4 Adilumimab appears to fall within NICE guidelines for cost effectiveness for maintenance therapy. 5 Why two planned courses of 12 months? Does that take the relevant patients through to the next proposed review?
Section 5	

(implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/12/2009 16:45

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	What account has been taken of the stress of being made to be ill again before being eligible for a further course of treatment? These proposals adversely impact on young Crohns patients who face having their education and/or careers severely disrupted due to the nature of severe Crohns disease.
Section 2 (clinical need and practice)	Why has the Committee not given an estimate of the likely numbers of people with severe Crohns who would be elligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Time limits are an inappropriate way of treating severly ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is inhumane medical treatment. Is there similar pressure on medical professionals to remove drugs that are effectively controlling a chronic health condition such as high blood pressure "to see what will happen" such as a stroke?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/12/2009 16:04

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	As a patient with crohns disease who has benefitted from both drugs I think the decision to stop the drugs after 12 months is the wrong one. It means that if you are responding well you have to stop and wait to get ill again which is just preposturous. I have fistualsing Crohns and even though adalimumab appears to have worked in managing my everyday symptoms, it can take years for the fistulae to heal. Stopping the drugs after 12 months just because the every day symptoms seem better is a foolish and risky move that would only put my longer term recovery in jeopardy. Surely an annual review would make far more sense than to simply just stop the drug and wait to get ill again. I heartedly disapprove of these 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	03/12/2009 14:41

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

Role	other
Other role	State Registered Nurse - retired.
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The drug Adalimumab gives quality of life to the recepient. It is very cost effective in the long term when no other medical or in some cases surgical intervention is needed. Without the drug, patients are unable to study/work and it is debilitating to the patient and then costs the government much more. Also incontinence pads may be necessary in the case of surgery, dressings, and other aids are required costing a lot more to the NHS.
Section 2 (clinical need and practice)	No figure has been given by the Committee for the possible number of people with severe Crohns disease who could benefit by treatment
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	A range of treaments is necessary particularly for those with severe Crohns disease. It is ridiculous that a time limit of 12 months on medication and then cut off is recommended instead of proper clinical evaluation and the needs of the patient. The social cost to society is completely ignored. Patients find it difficult if not impossible, to successfully pursue a course of study at College or University, hold down a job or take part in normal community activities.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/12/2009 14:21

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no evidence that anti-TNF treatment increases harm to the patient after 12 months.
Section 2 (clinical need and practice)	Why has the committee not given an estimate of the likely numbers of people with severe Crohns who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Time limits are an inappropriate way to treat severely ill patients. An annual review with a consultant, an MRI or a colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate but a 12 month cut off deadline is inhumane medical 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	03/12/2009 13:25

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no evidence that the anti-TNF treatment would harm the patient after 12 months. Patients are monitored regularly, and are able to make informed decisions as to whether to continue. They should not be considered unable to do this.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Time limits are a very inappropriate way of treating ill patients. While an annual review (with a consultant), MRI or a colonoscopy are all reasonable, a 12 month cut off is inhumane. Problems auch as those with severe Crohns finding it difficult to pursue their studies, and hold down stable jobs are ignored. Is the recommendation of two planned courses of treatment designed to take relevant patients through to the next proposed review by the Guidance Executive?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/12/2009 13:23

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no evidence that anti-TNF treatment increases harm to the patient after 12 months. All patients are monitored regularly when on these drugs, and should be able to make informed decisions as to whether to continue, given the balance of risks. They should not be considered unable to make these choices. There seems to be no provision to continue treatment after 2 periods of 12 months if proving clinically effective?
Section 2 (clinical need and practice)	Why has the committe not given an estimate of the likely numbers of people with severe Crohns who would be elegible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Has the Committee received evidence from patients that they are so concerned about the long term effects of these drugs that the drugs should be withdrawn after 12 months.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/12/2009 13:16

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no evidence that the anti-TNF treatment increases harm to the patient after twelve months. Patients are monitored and checked regularly and are perfectly able to make the decision of whether to continue or not, themselves.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	A huge amount (50%) of newly diagnosed patients are under 30 years old - this is a time in your life when education is crucial. Disruption to their drug rutine is going to severely put their education and future at risk.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/12/2009 13:15

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	the new document has removed all clinical input to containing treatment at the end of 12 months . it appears to be an arbitrary cut of point. if the treatment proves clinically ineffective, the clinician will stop treatment anyway
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	03/12/2009 13:14

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The proposals clearly impact adversely on young Crohns patients, who have having to have further education, professional training and disruption to their early careers due to the highly severe nature of Crohns disease.
Section 2 (clinical need and practice)	
Section 3 (The technology)	The committee should consider that there are more than two outcomes- failure, complete remission, but also an active disease that is being kept under control by the drug. Clinical judgement is essential to determine the outcomes and consequent treatment regime.
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	03/12/2009 13:13

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	I feel I must share my thoughts and feelings regarding the possibility of medications being stopped after a 12 month period. Humira and Infliximab (both of which I have been prescribed, currently 40mg Humira weekly for Crohns Disease) are both medications which can have quite fast acting results, that do indeed wear off. I begin to feel ill when I am due medication, when I have had treatment, I begin to feel better within a few days. knowing this it seems evident to me that people like me NEED the medication to feel well and then maintain thier wellbeing. the fact that it is suggested a person would have to wait until they flare up, meaning pain, fatigue, disruption with life, work and relationships to then be represcribed medication to attempt to support their recovery- when it will probably take weeks to obtain prescriptions etc (all the local hospitals to me have no stock and when an inpatient I have been told to order my own before) It seems madness that you provide guidelines to provide medication, but not to support the individual. If this proposal is accepted, I would expect in depth proceedures and policies for patients who flare up and have no other choice but to take steroids or visit hospital. It is unacceptable to expect people to live life with fear of being struck down by a simple cold causing a full blown flare up with no immediate support 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)	
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/12/2009 12:03

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	As I understand it these drugs are not a cure for Crohns (there is currently no cure)but a means of keeping symptoms under control.Allowing a patient to only use the drug for 12 months at a time (and only 2 twelve month periods are mentioned in 1.3) and then not being allowed the drug again until the symptoms have returned is a form of mental and physical torture. The decision to be allowed to continue with this life changing treatment should solely rest with the patient and consultant involved - not some arbitrary rule made by a committee who probably havent seen the adverse impact Crohns can have on a persons life - particularly a young persons education and job prospects.
Section 2 (clinical need and practice)	Only the most severe cases will need these drugs to alleviate symptoms, but if they work in these cases then they should be continued (under medical supervision and monitoring) for as long as they are effective.
Section 3 (The technology)	The annual cost of these drugs seems a small price to pay for such a life changing treatment - particularly as a fairly small percentage of total Crohns cases are severe enough to neccessitate these drugs. If they enable the patient to play a full part in society and hold down a good job (paying tax) then I would think the cost would be repaid in full anyway. The cost of alternative drugs, hospitalisation and benefits paid if unable to work would also probably amount to the same or greater cost.
Section 4 (Evidence and interpretation)	See comments at end of section 3 regarding costs. If a treatment works then why withhold it? There are several chronic diseases where a drug regime is essential, both medically and for the associated quality of life.In these cases there is no suggestion that an arbitrary time limit be given for prescribing the drug and that the patient should suffer a stroke, heart attack, diabetic episode or epileptic fit before being put back on the drug. For young people in particular the disruption in their lives that would occur with discontinuation of the drug would have a huge impact on education (and thus future career prospects), professional training and establishment of a career let alone any associated depression.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review	

of guidance)	
Date	03/12/2009 11:28

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

Role	Patient
Other role	Volunteer member of the IBD Patient Panel for the Leeds area.
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)	The quality of life scoring system (QALY) may under-estimate the impact on CD patients lives from anti-TNF therapy - I had active CD, and the transformative infliximab treatment regime (8-weekly maintenance) I have had over the last 2-3 years has meant I can carry out productive full time work (post-doctoral University Research Fellow in biophysics). Previously I had serious difficulty in my jobs, which was affecting my future career also. I am sure that for many other CD patients the therapy moves them over the boundary between being able and being unable to work. This has immense quality of life impact (on them and their immediate family) as many are now are able to function as active and equal members of our society.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/12/2009 10:56

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	As a patient who has previously been on Infliximab which has put me in remission I feel the impact of this proposal has not been truly considered. After 12 months of infliximab my Crohns was not in remission and had it been stopped there would have been a big impact on my quality of life from the Crohns continually re-occuring at differing degrees. As a consequence to this I would have also spent time off work with the condition costing my employer and the government until further treatment was available. Instead, my treatment continued for just over 2 years which, when stopped, I was in remission and have now been for over 7 years. Due to this course of infliximab my quality of life significantly improved and after 20 years with Crohns and much surgery in the past I am still living a fulfilling and happy life which, fingers crossed may continue for many more years.
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	03/12/2009 10:45

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

Role	other
Other role	UK patient association trustee European patient association director
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)	Sirs, The rationale you propose is completely contrary to current clinical practice in the UK and around the world. It also is a poor and polarized interpretation of the clinical evidence for this therapy. These recommendations would prove inhumane and torturous for patients, as the relapsing and remitting nature of IBD means that with the treatment rationale you propose, instead of continuing treatment and maintaining quality of life, you will simply allow people with IBD to relapse, with all the grave disruption that means for their health, work, well-being and quality of life. To allow patients to become ill repeatedly, when this is easily preventable by applying the treatment consistently with well established best practice, is unethical, unprofessional, and unsupported by patients, healthcare professionals, and other guidance publishers. I urge you to reconsider this short sighted treatment guideline, for the sake of patients and people affected by IBD, and for the sake of NICEs own credibility.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	03/12/2009 10:15

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

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 evidence to support discontinuation of treatment at 12 months. This is effectively supporting episodic treatment which the evidence also does not support.
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	03/12/2009 09:01

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

Role	Patient
Other role	Committee member of NACC Torbay group
Location	England
Conflict	no
Notes	This is a vital treatment for sufferers of Crohns disease and therefore should not be withdrawn after 12 months. Relapses could reoccur at anytime and would cause untold suffering whilst NICE decide to allow ANTI TFN treatment to resume.
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	02/12/2009 21:49

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	please do not deny fellow sufferers of this horrible disease the right to drugs that will make them alot more comfortable. Crohns almost killed me. Dont let it happen to others
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	02/12/2009 21:17

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

Role	Patient
Other role	
Location	Scotland
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	how can you limit treatment to 12 months when it may require longer treatment than that. Crohns has significantly impacted my life, even after lengthy steroid treatment Ive been suffering effects of crohns. if infliximab or adalimumab help me but require longer than 12 months for treatment your recommendations effectively say my life has to be compromised again instead of maintaining the dose.
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	02/12/2009 21:09

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no evidence that anti-TNF treatment increases harm to the patient after 12 months. All patients are monitored regularly when on these drugs, and should be able to make informed decisions as to whether to continue, given the balance of risks. They should not be considered unable to make these choices.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Time limits are an inappropriate way of treating severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is inhumane medical treatment. Is there similar pressure on medical professionals to remove drugs that are effectively controlling a chronic health condition such as diabetes, epilepsy or high blood pressure ?to see what will happen, such as a coma, brain damage or a stroke?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	02/12/2009 20:55

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

Role	Healthcare Other
Other role	
Location	US
Conflict	no
Notes	As a Clinical Social Worker in the U.S., I have worked with several Crohns sufferers and their families. The pharmacological regimens being discussed in this review have proven to provide "life changing" improvements in quality of life, not only in terms of physical symptoms but also in the clients and their care givers mental health. I would ask that the Committee take this into account when considering the medical and mental health impact of discontinuing provision of these drugs beyond twelve months.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Since both infliximab and adalimumab have been shown to be clinically effective in treating sufferers of Crohns and, if withdrawn, likely to result in relapses, what is the rationale for the Committees preliminary recommendation to discontinue treatment after twelve months (an additional twelve months in the case of relapse)? The twelve month limitation seems arbitrary and, given the severity of symptoms apparent in severe Crohns cases, is likely to result in both recurrent symptomatology in sufferers, and in the increased costs of subsequent hospitalizations, medical visits and conventional (ineffective)treatment regimens. Both drugs have received approval for long term use in the U.S., Canada and other EU countries. Furthermore, private U.S. insurance companies, which are notorious for not approving the use of expensive drug regimens, have approved the use of both infliximab and adalimumab for use in controlling the sypmtoms of chronic Crohns. Given these supporting data and practice from comparable countries, it would follow that these drugs would also be effective for controlling the symptoms and suffering of patients in the U.K. as well.
Section 2 (clinical need and practice)	Since Crohns is not medically or surgically curable, the only recourse for Crohns sufferers is an ongoing drug regimen to control symptoms and to function successfully in their everyday lives. For chronic sufferers who do not respond to more conventional drug treatments, the use of infliximab and adalimumab seem the only recourse currently available to control symptoms. Further, since Crohns strikes a disproportionately younger population, to withhold proven effective drug regimens is not only discriminatory, but also limits the opportunities for younger sufferers to complete their studies, start careers and families and enjoy the successful lives that these medications can make possible.
Section 3 (The technology)	Has the Committee considered the opportunity costs of lost productivity and quality of life for the thousands of U.K. Crohns sufferers vs. the costs of providing these drugs? Since the cost of the drugs seems to be a consideration of the Committee, further economic analyses of the efficacy of providing these

	medications, versus the alternative of terminating use after twelve months, needs to be taken into account.
Section 4 (Evidence and interpretation)	"The Committee considered that repeated induction or episodic treatment with infliximab or adalimumab should not be considered as the preferred option for the treatment of severe Crohn?s disease, and that its recommendations should be based on consideration of the clinical and cost effectiveness of a planned course of treatment relative to standard care alone". Given this statement by the Committee, there is no apparent medical justification for limiting the use of these drugs to twelve months. Also, as stated in the Committees commentary, the use of these drugs should be based on clinical and cost considerations, both of which have demonstrated the effectiveness of the ongoing use of these drugs. Simply because no studies of cost effectiveness beyond twelve months have been completed, this should not be the basis for the Committees recommentation to limit use to twelve month periods, and require "relapse" before a sufferer can obtain treatment for an additional twelve months. Could the Committee kindly consider that there is a third option for drug effectiveness aside from drug failure or disease remissionthat is symptom control and management.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	Yes, all of these recommendations for further research should be considered and implemented. However, the current lack of "complete" information on the efficacy of these medications should not preclude their use when they have been shown to be clinically effective in helping Crohns sufferers manage symptoms and attain a reasonable quality of life.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	02/12/2009 20:54

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

Role	Patient
Other role	
Location	US
Conflict	no
Notes	I am on infliximab and have been for half a year. Every time I near my next infusion, I feel my body start to flare up a little again. I know that if I was not constantly on it, I would not be in remission anymore. This is a drug patients need to remain on until it no longer works for them. Stopping it could result in flare ups, which mean more hospital stays, surgeries, and more money spent by the hospital in the long run. It is a BAD idea to stop this medication if it is still working for the patient.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am on infliximab and have been for half a year. Every time I near my next infusion, I feel my body start to flare up a little again. I know that if I was not constantly on it, I would not be in remission anymore. This is a drug patients need to remain on until it no longer works for them. Stopping it could result in flare ups, which mean more hospital stays, surgeries, and more money spent by the hospital in the long run. It is a BAD idea to stop this medication if it is still working for the patient.
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	02/12/2009 19:58

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Would there be an option for patients to continue on the drug if no relapse and no adverse effects whilst on the therapy? Why has 12 months been chosen as a cut off limit for treatment?
Section 2 (clinical need and practice)	What is the estimated number of patients with crohns who would be considered for treatment with these drugs?
Section 3 (The technology)	What is known about the long term adverse effects of these drugs? What is the usual regime for stopping these drugs in patients, and do they suffer any adverse effects on withdrawel of the medication?
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	02/12/2009 19:05

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

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 surprised by the change in recommendations to stop antiTNF therapy after 12 months. If we have to stop the therapy after this period of time, it means we must suffer a relapse before being able to start another course of therapy. This will have the effect that I will most likely be unable to work, socialise or carry out everyday activities, seriously affecting my quality of life. I ask you to review your decision and return to the earlier recommendation that allowed decisions to be made between doctor and patient depending on the individuals response to therapy.
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	02/12/2009 18:39

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

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 diagnosed with Crohns disease around 8 years ago and already having to have had 3 major bowel resections as I suffer from a paticuarly aggressive form of Crohns disease I am appalled to read that the medication I am being given that is finally managing to keep my Crohns at bay is likely to be taken away from me, I have tried all other forms of medication prior to being given Adalimumab but have developed severe reactions to them and ultimatly needed more surgery. I unfortunatly do not respond to steroids so therefore to take away a medication that keeps my Crohns in remission and just wait until i get symptoms and a further attack of Crohns which with my history has already proven to happen will inevitably result in me needing further surgery because steroids dont work fills me with dread and fear, I have already had a significant amount of bowel removed and do not have much left before i will be facing the prospect of having a colostomy bag, im 32 years old and this is something i do not want to have to live with because people not suffering with the illness have decided its more cost effective to only treat for 12 months.
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	02/12/2009 18:31

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Despite the high cost of these drugs I strongly support the preliminary recommendations, having seen dramatic improvements in the condition of patients receiving adalimumab on a trial basis
Section 2 (clinical need and practice)	My experience of patients treated with adalimumab is of huge reductions in symptoms and sensitivities. Whilst the cost of these drugs is high, not using them would mean very costly hospital care and significant reduction in the patients ability to contribute to the economy.
Section 3 (The technology)	I am not competent to comment
Section 4 (Evidence and interpretation)	I dont pretend to understand all the statistical terminology but believe that you have revised proposed recommendations, removing the clinician/patient input in continuing the treatment, instead limiting it by time. I completely understand that the NHS has a limited budget, but do feel that taking patients off the drug after a predefined period rather than for clinical reasons, and exposing the patient to almost certain further illness is unethical. We feel the committee still does not understand how this treatment works, and finds it hard to understand just how ill people are with severe Crohns disease, as compared with those with a milder version. As a consequence I would argue for use of clinician and patient judgement over simple time limitations for treatment.
Section 5 (implementation)	No comment
Section 6 (proposed recommendations for further research)	I strongly support further research into this debilitating disease
Section 7 (related NICE guidance)	No comment
Section 8 (proposed date of review of guidance)	No comment
Date	02/12/2009 17:55

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

Role	Patient
Other role	NACC Organising Team Member - Aylesbury
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I understand that essentially NICE is recommending that treatment with infliximab or adalimumab should be automatically stopped after 12 months and only restarted if the patient relapses. This seems extremely unfair on those individuals who are benefiting from the treatment, but are not lucky enough to manage full remission and cannot be safely moved onto an alternative drug. That they should have to suffer a period of relapse and all the poor health, pain and employment issues associated with this before you will consider funding continuing treatment. For a few individuals this could lead to a never ending cycle of treatment, relapse, treatment with declining health.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	4.3.10 - why should people suffer all the pain, inconvenience and stress of a relapse due to "a lack of long term data" Please consider giving discretion to Drs to continue treatment past 12 months for individual cases where it might be appropriate.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	6.5 - Yes, please do this. This is a woefully under researched area. NACC are trying to obtain funding for research into Crohns and fatigue for example, which is a poorly understood area, but affects the majority of patients.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	02/12/2009 16:31

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no evidence that anti-TNF treatment causes harm to the patient after 12 months. All patients are monitored when on these drugs, and should be able to make informed decisions as to whether to continue, given the balance of risks. They should not be thought of as unable to make choices for themselves. The new document has removed all clinical input in regard to continuing treatment at the end of 12 months. It would appear to be an arbitrary cut off point. If the treatment proves clinically ineffective, the doctor will stop treatment anyway. There seems to be no provision to continue treatment after two periods of 12 months if it is proving effective - surely this would make sense in terms of wider cost/ benefit issues of preventing more costly (and needless)surgical interventions? The proposals seem to me to adversely impact on young Crohn?s patients who face having further education/ professional training/ early careers severely disrupted due to the nature of severe Crohn?s disease. Nowhere else in the developed world, to my knowledge, uses an arbitrary cut-off point when using these drugs. Where is the evidence to show this would benefit patient health?
Section 2 (clinical need and practice)	Why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Treatments for Crohn?s disease have never proved to be consistently effective for all. The important thing is to have a range of treatments available, particularly for those with severe Crohn?s disease. Time limits are an inappropriate way of dealing with severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is purely arbitrary. Patients with severe active Crohn?s disease find it difficult to successfully pursue a course of study, hold down a job or take part in most normal community activities - as well as the impact on individuals, the social cost to society is being ignored. Half of the newly diagnosed are under 30. For them, it is really important that they can complete their studies/professional training/establish a career. Disruption through being taken off an effective drug and being required to be ill again is likely to adversely impact their life chances.This strikes me as an equalities issue. Adalimumab appears to fall within NICE guidelines for cost effectiveness for maintenance therapy - surely this must count for something?

Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	02/12/2009 15:43

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	the new document has removed all clinical input to continuing treatment at the end of 12 months. It appears to be an arbitary cut off point. If the treatment proves ineffective, surely the clinician will stop treatment anyway? Why 12 months?
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	adalimumab appears to fall within NICE guidlines for cost effectiveness for maintenance therapy.Why take the decision whether to continue the drug away from the patient and the doctor?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	02/12/2009 14:50

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

Role	other
Other role	Retired School Teacher Secondary Education 11 - 18 year old boys
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	As a former secondary school teacher I am particularly concerned about the adverse impact on young Crohns disease patients who face severe disruption in their educational and professional training at school/college/university and in their early careers owing to the nature of the disease. It certainly seems unclear what the reasons are for changing the preliminary recommendations to a cut-off after 12 months. What account has been taken of the stress of being made to be ill again before being eligible for a further course of treatment? It appears to be solely an arbitrary cut-off point. To my knowledge nowhere else in the developed world is there such a cut-off point when using these drugs. There is no evidence that the treatment increases harm to the patient after 12 months. Patients are monitored regularly when on these drugs and thus able to make informed decisions as to whether they should continue or not. If the treatment proves ineffective the clinician will terminate treatment anyway.
Section 2 (clinical need and practice)	No estimate has been given of the number of people with Crohns disease who could be eligible for treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The important thing is to have a range of treatments available. They are never uniformly effective. Time limits are a most inappropriate way of treating severly ill patients. Only an input of medically determined facts such as MRI scans, colonoscopy and reviews with a consultant are valid - not a 12 month cut-off! The total cost to society of people with severe Crohns disease is completely ignored by the committee. Only with proper ongoing treatment can people with severe Crohnd disease take a full and ongoing place in society. 50% of the newly diagnosed Crohns patients are under 30 years old. It is vital that they complete their studies/training to establish a career. To be taken off a vital drug they need would tragically impair their future chances in life. Where is there any evidence that the Committee should be concerned about the long-term effects of the drugs that they should be withdrawn after 12 months? I am most concerned about the whole disasterous view of the Committee based on a 12 month time-factor termination of Adalimumab, for no valid reason, when the drug enables patients to continue full and rewarding lives in society. Unbelievable!
Section 5 (implementation)	
Section 6	

(proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	02/12/2009 14:11

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no evidence that anti-TNF treatment causes increased harm to patients after 12 months. Patients are monitored when taking these drugs and should be able to decide as to whether to continue, given the risks involved.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	It is inapproriate to impose an arbitrary 12-month time limit when treating severely ill patients - regular monitoring by a consultant and other tests such as colonoscopy should be used to determine whether it is appropriate to continue treatment. It is not clear that the Committee has sought evidence from elsewhere in the world regarding the effects of withdrawal and restarting anti-TNF drugs. It is possible that complications may arise when patients re-start 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)	
Date	02/12/2009 09:08

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The proposals would have an adverse impact on young sufferers (particulary those with a severe form of the disease) due to the disruption caused to their education, training or careers.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	It seems that the Committee remains unaware that patients with severe active Crohns disease have problems pursuing educational courses or careers, or taking part in social activities. It seems that the social cost to society (sufferers remaining on benefits who could otherwise pursue careers, pay taxes etc.) has been ignored.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	02/12/2009 08:21

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

Role	Public
Other role	
Location	US
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	These proposals would have a severely negative impact on Crohns patients, especially those who are young adults, still adjusting to their diagnosis, while simultaneously trying to cope with extremely rigorous and stressful academic and career development requirements. It is especially vital that these younger patients be involved in the active management of their disease. Disruption through being taken off an effective drug and being required to be ill is likely to adversely impact their life chances
Section 2 (clinical need and practice)	Why is there no estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	While treatments for Crohn?s disease never prove to be uniformly effective, it is important to have a range of treatments available, particularly for those with severe Crohn?s disease. Time limits are an inappropriate way of treating severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is inhumane medical treatment. Is there similar pressure on medical professionals to remove drugs that are effectively controlling a chronic health condition such as diabetes, epilepsy or high blood pressure ?to see what will happen, such as a coma, brain damage or a stroke? Patients with severe active Crohn?s disease find it difficult to successfully pursue a course of study, hold down a job or take part in most normal community activities. The social cost to society is completely ignored. Clinical judgment is and ought to be the single determining factor in assessing the outcomes and consequent treatment regime.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	02/12/2009 00:24

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Why was 12 months chosen as a cutoff point - it seems totally arbitrary and not something that is used anywhere else in the world for these totally life changing drugs. Has any consideration been given to the immense stress caused to a patient who has been told that he/she will have to stop effective treatment and will only be able to resume the drug once the symptoms have flared up again. What happens after the two periods of twelve months?- there is no mention of further courses of treatment being made available.Has anyone considered the considerable disruption to a young sufferers education and career prospects? Being without the drug would necessitate long periods off school/university or work with obviously negative results.If one of the enforced periods without access to the drug occurs when he/she should be doing exams then their whole future could be blighted. The cost to the taxpayer of paying benefits to the Crohns sufferer if unable to work (and obviously the fact that the sufferer will not be paying tax themselves if unable to hold down a job)and possible mental health issues (depression is common)should also be taken into consideration.
Section 2 (clinical need and practice)	Successful treatment focuses on inducing and maintaining clinical remission - why then is NICE proposing to withhold effective treatment after 12 months? This is not maintaining remission!Does anyone at NICE actually realise just what a sufferer of severe Crohns has to live with?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Adalimumab falls within NICE guidelines for cost effectiveness and therefore the decision to continue the treatment should rest only with the clinician and patient.The cost of providing the drug is probably far less than the cost of hospital admissions, other drug treatments and possible social security benefits paid to the sufferer if unable to work - and there is also the loss of tax and national insurance contributions that the patient would pay if able to hold down a job. Why is Crohns disease being treated differently to other chronic health condition? I dont believe that NICE would suggest stopping insulin to diabetics after 12 months to see what the reaction is! Half of sufferers are diagnosed as children or young adults, when education and early career progression is vital - for them as well as society in general. The stress and disruption caused to the whole family can be immeasurable. Not every treatment will be equally effective for every patient and it is vital to have a range available. For those with severe

	disease it is important that if a drug works to keep it under control, then surely that drug should be made available without time limits or disruptions.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	01/12/2009 19:03

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Nowhere else in the developed world uses an arbitrary cut-off point when using these drugs. Where is the evidence to show that it would benefit the patient health? There is no evidence that anti-TNF treatment increases harm to the patient after 12 months.All patients are monitored regularly while on these drugs and should be able to make informed decisions as to whether to continue, given the balance of risks.The new document has removed all clinical input to continuing treatment at the end of 12 months , It appears to be an arbitary cut off point.What account has been taken of the stress of being made to be ill again before being eligible for a further course of treatment?The proposals adversely impact on young Crohns patients who face having further education/careers etc severely disrupted due to the nature of severe Crohns disease.
Section 2 (clinical need and practice)	Why has the Committee not given an estimate of the likely numbers of people with severe Crohns who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The important thing is to have a range of treatments available for all sufferers. Treatments never prove to be uniformly effective.Time limits are an inappropiate way of treating severely ill patients. The effect on society seems to be ignored as patients find it difficult to hold down a job/course of study etc.Adalimumab appears to fall within NICE guidelines for cost effectiveness.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	01/12/2009 17:25

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

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 the consultant should make the decision about whether or not a patient should continue on these drugs, rather than having a defined period of time. All other chronic conditions are controlled by continuous use of drugs where appropriate eg diabetes
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	I think the drug adalumimab has been shown to be clinically and cost effective for severely ill people. I do not understand the additional limitations.Where is the evidence that patients are so concerned about long term safety that they do not want to remain on this drug?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	01/12/2009 16:13

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	12 month enforced withdrawal of treatment seems completely arbitrary. The new document has removed all clinical input to continuing treatment at the end of 12 months. Withdrawal after 12 months does not take into account the different levels of successful response, some not leading to full remission (ie not a complete response). The evidence regarding long-term safety of the drug does not seem to merit this enforced withdrawal, since the effects are regularly monitored by clinicians. Experience of the drugs in the USA seems to indicate that there is a potential for complications when re-starting treatment after a break. Has the committee considered this at all?
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Section 4.3.10 highlights the fact that it may be reasonable to try withdrawing treatment in people whose disease demonstrated a complete response, however there is no distinction between people who have a complete response and people who have a response where the disease is controlled, but not in 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	01/12/2009 11:58

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I would like to question the clarity of reasoning behind the changing of recommendations to a 12 month cut off.
Section 2 (clinical need and practice)	Why is there not an estimate from the Committee of the number of Crohns sufferers who are eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	In 4.3.10 the committee acknowledge the limitations of the concept of withdrawing treatment in sufferers who had responded well, and yet the Committee has decided to withdraw treatment and ignore the evidently noted risks.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/11/2009 23:52

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

Role	Public
Other role	
Location	Scotland
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	12 month enforced withdrawal of treatment seems completely arbitrary. The new document has removed all clinical input to continuing treatment at the end of 12 months. Withdrawal after 12 months does not take into account the different levels of successful response, some not leading to full remission (ie not a complete response). The evidence regarding long-term safety of the drug does not seem to merit this enforced withdrawal, since the effects are regularly monitored by clinicians. Experience of the drugs in the USA seems to indicate that there is a potential for complications when re-starting treatment after a break. Has the committee considered this at all?
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Section 4.3.10 highlights the fact that it may be reasonable to try withdrawing treatment in people whose disease demonstrated a complete response, however there is no distinction between people who have a complete response and people who have a response where the disease is controlled, but not in remission. Since the committee has decided that maintenance treatment is clinically and cost effective, suddenly stopping it after 12 months seems ridiculous.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/11/2009 19:17

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I think both the timing of the initial treatment and the 12-month cut off need to be looked at. After my last surgery for small-bowel Crohns in 2005, I was treated with Azathioprine and Pentasa as my gastroenterologist expected (from previous experience) that my Crohns would return. It did - despite 2 courses of steroids and an increase in both Azathioprine and Pentasa I ended up 18 months later very unwell, the chance to try infliximab and a referral back to surgeon if it didnt work. The infliximab has worked very well. However, the damage caused by 18 months of active Crohns has left me still very incapacitated. The social cost of not putting me on infliximab after surgery or - at least - as my symptoms returned cannot be understated. I have now been on infliximab for 3 years and, although not having been entirely symptom-free, it has held off the need for surgery and given me back some of my life. The thought of stopping after 12 months and starting again when I get ill scares the living daylights out of me. The infliximab has given me back some control of my life and helped me manage my Crohns better - the 12 month idea gives control back to my Crohns..
Section 2 (clinical need and practice)	So, does this mean that between 50 and 80% of people with Crohns disease should be receiving TNF inhibitors to avoid unnecessary surgery?
Section 3 (The technology)	Having just spent a year living in France, I know the French health care system do things a little differently. I was given Infliximab only after assessment on the day by a gastroenterologist. If I was having a flare, I was given 10mg/kg - which worked quickly and effectively, without the side effects of steroids. Infusion were also always given after an initial infusion of a small dose of steroids and antihistamine. Also, I received my infusions exactly 8 weekly to the day. In the UK my infusions were supposed to be 8 weekly, but the range was 8-12 weeks, with an average of about 10 weeks. This seems to have improved, however.
Section 4 (Evidence and interpretation)	Should TNF inhibitors not be used as an early intervention (and maintenance) to prevent people from developing severe Crohns disease? If I has been treated with TNF inhibitors 12 years ago, I would, most likely, have avoided 4 operations and the loss of most of my small bowel. I would also, most likely, still be working full-time as a specialist nurse in the NHS - a true waste of my training costs.
Section 5 (implementation)	

Section 6 (proposed recommendations for further research)	All excellent suggestions.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/11/2009 17:14

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

Role	Public
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)	- All patients are monitored regularly when on these drugs, and should be able to make informed decisions as to whether to continue, given the balance of risks. They should not be considered unable to make these choices. - It appears to be an arbitrary c
Section 2 (clinical need and practice)	The Committee should take into account the likely number of people with severe Crohn?s who would be eligible for treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	- Treatments for Crohn?s disease never prove to be uniformly effective. The important thing is to have a range of treatments available, particularly for those with severe Crohn?s disease. - Time limits are an inappropriate way of treating severely ill p
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/11/2009 16:36

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

Role	Public
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)	- All patients are monitored regularly when on these drugs, and should be able to make informed decisions as to whether to continue, given the balance of risks. They should not be considered unable to make these choices. - It appears to be an arbitrary c
Section 2 (clinical need and practice)	The Committee should take into account the likely number of people with severe Crohn?s who would be eligible for treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	- Treatments for Crohn?s disease never prove to be uniformly effective. The important thing is to have a range of treatments available, particularly for those with severe Crohn?s disease. - Time limits are an inappropriate way of treating severely ill pa
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/11/2009 16:33

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

Role	other
Other role	Friend of sufferer
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Withdrawal after 12 months does not take into account the different levels of successful response, some not leading to full remission (ie not a complete response).
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Section 4.3.10 highlights the fact that it may be reasonable to try withdrawing treatment in people whose disease demonstrated a complete response, however there is no distinction between people who have a complete response and people who have a response where the disease is controlled, but not in 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	30/11/2009 16:33

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

Role	Public
Other role	
Location	Scotland
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The withdrawal of infliximab after twelve months (when the treatment has not failed) seems totally arbitrary. Why must the sufferer have to wait to become ill again before being approved for another course of the drug? What a stressful and upsetting wait it must be for people who have finished their first lot of twelve months and know that they are likely to become ill again. Has it been shown that twelve months of treatment is a period which usually sends the disease into remission? Is the sufferer likely to experience adverse symptoms when resuming the treatment after a break?
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	With regard to section 4.3.10, what constitutes a complete result?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/11/2009 15:55

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I would like to question the limitations of only using either drug for 12 months, as there is no provision for those who need continuation of treatment after this period, as they may still have active Crohns disease despite a lack of symptoms due to the drug. Also this removes the clinicians input on deciding when a patient is suitable to be removed from this drug, as every Crohns patient is very different. I do not understand the reasoning behind this 12 month limit, as it was not mentioned before and has no scientific reasoning behind it, as none of the cited studies show results after being taken off the treatment, and whether it is effective if given again.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	When addressing cost effectiveness of treatment, I feel that the issue that you have failed to adress is that with an illness like Crohns many are non-responsive to current treatments, and so comparing the two is null, if the first does not work. This means that the fact that a Crohns sufferer who could not hold down a steady job under usual treatment could work, when maintained on one of these drugs. This makes the cost effectiveness more complex, and this has not been taken into account. The comittees conclusion to only allow 12 months treatment seems unaware, as only those that consultants have seen to have multiple relapses would be prescribed these drugs, and as adalimumab appears to fall within the NICE guidelines for cost effectiveness, it seems that NICE are attempting the consultants job.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	There should be research on the effects of removing people from these drugs, and if they are subsequently less or more responsive to these drugs.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/11/2009 15:50

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	close friend of a patient suffering from Crohns who is presently on adalimumab
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	seems that there is no suggested treatment for a patient once he has had 2 courses of the drug. Also, has the effects of being sick been considered ...why wait for someone to become sick when you can stop them becoming sick? What is the reason for this change of heart? Are you suggesting there would be nenefits? or is it purely financial? Would it not be cheaper to keep someone well rather than risk someone beciming sick because they are no longer on the drug?
Section 2 (clinical need and practice)	How many people would be eligible?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Surely, the best course of action would be to have a range of treatments available rather than such a stringent method. Why has the committee changed their minds? What is the experience of other patients in other countries? has the committee considered the social cost of having so many Crohns patients unnecessarily sick going in and out of hospital and unable to hold down a job or be a productive member of society?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/11/2009 15:35

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	By setting an arbitrary twelve month cut off point for treatment all clinical input to treatment decisions seems to have been removed. If treatment wasnt working the doctor would stop it anyway. What happens after 24 months, the seems to be no provision for the tereatment to be continued after that even if it was working and nothing else did. It seems barbaric to insist that a sufferer has to come off treatment, develope all the adverse syptoms again before being able to be put back on treatment. Surely the treatment would be constantly monitored and if it was working and adverse affects taken into consideration, the treatment should be continued at the discretion of the doctors involved with each individual case.
Section 2 (clinical need and practice)	I cant see any estimate of the number of peeople who might need Infliximab and/or Adalimumab.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	It seems that infliximab and adalimumab have proved to be clinically effective and adalimumab in particular, cost effective for maintenance therapy. Whilst there is a lack of long term data, there is a mass of evidence of the adverse effects of severe Crohns disease. With 50% of people being diagnosed under the age of 30, as much as possible should be done to relieve the symptoms in young people as they study and establish their careers. As mentioned above an arbitrary treatment cut off based on time rather than clinical need seems to be inhuman and then allowing people to get ill again before treatment can be resumed is nothing short of barbaric.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	Consideration should be given to continuing treatment with infliximab and adalimumab beyond twelve and twentyfour months, with careful clinical monitoring.
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/11/2009 14:56

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

Role	Patient
Other role	
Location	England
Conflict	no
Notes	I was an expert patient witness for the consultation.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	In point 1.1 there is the line Treatment with infliximab or adalimumab may be a planned course of treatment until treatment failure (including the need for surgery), or until 12 months after the start of treatment, whichever is shorter. This arbitrary 12 month enforced withdrawal of a treatment which is successfully keeping the disease in check seems completely illogical. It doesnt take into account different levels of non-failure, assuming that all people on whom the drug acts will have a complete response. Additionally, it removes all clinical input by the consultant doctor in regards continued treatment. If its for safety reasons, then surely stipulation for continued monitoring and review by a doctor experienced in anti-TNF treatment (as in the September guidance) would be sufficient, and more ethical, rather than withdrawing treatment that may be necessary for the maintenance of a patients health. In 2.5, you recognise that Crohns disease will often need treatment that suppresses symptoms, since a cure is not possible and remission is also not possible in many cases.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	4.3.10 states that clinical experts felt it may be reasonable to try withdrawing treatment in people whose disease demonstrated a complete response. Since this is the only place in which 12 month period is mentioned, I must assume that this is where the 12 month caveat in 1.1 is from. It looks to me as if you have misinterpreted complete reponse (meaning full remission induced by the drug) for a "non-failure" of the drug (so you believe that anyone who would still be on the drug after 12 months would be in complete remission/have a complete response). This is patently not the case and was made clear at the consultation I attended, by both the patient and clinical experts. In my own case, even after 2 year course of the drugs, where I have had an incredibly successful response, with complete suppression of symptoms, MRI scans taken this July show that the disease is still active, and that removing the drug would result in a full and almost immediate return of the symptoms. It seems that the nature of the disease is not understood - it is individual and so consultant doctors should make the decision with their patient at the end of a period, rather than forced to remove it.
Section 5 (implementation)	
Section 6	

(proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/11/2009 14:14

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I have a friend on adalumimab who has been able to work because it makes him so much better. I cant understand why anyone would stop it.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The evidence seems to show that adalumimab works and is cost effective. I cant understand what the reasons are for not being able to carry on with it. My friend understands the possible dangers is able to make his own mind up.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/11/2009 14:14

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	As the drug is clinically effective, and within NICE cost guidelines I think the decision about coming off adalimumab should be made by the consultant on clinical need
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	In other parts of the world these drugs are not routinely stopped unless the doctors decide. I see no evidence of patients being so concerned about long term effects that they wish to stop 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)	
Date	30/11/2009 14:10

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

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 wrong to remove a drug from a patient when it is working, and when the consultant wants to continue to use it. Their health can be monitored to minimise long term risks.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	NICE accept adalumimab is clinically effective and within cost guidelines for severely ill Crohns patients. The issue of risk should be a matter for the patient and the consultant to discuss and agree on.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/11/2009 14:04

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	? This proposal has removed all clinical input to continuing treatment at the end of 12 months. It appears to be an arbitrary cut off point. If the treatment proves clinically ineffective, the clinician will stop treatment anyway. If it is working, why stop it? ? There seems to be no provision to continue treatment after two periods of 12 months ? What account has been taken of the stress of being ?made? to be ill again before being eligible for a further course of treatment? ? It seems unclear what the reasons are for changing the preliminary recommendations to a cut off of 12 months. ? Nowhere else in the developed world uses an arbitrary cut-off point when using these drugs. Where is the evidence to show this would benefit patient health?
Section 2 (clinical need and practice)	This review is focused on those patients who are critically ill with Crohns - why havent you estimated the likely number who are going to receive this treatment? You cant estimate costs without knowing the reality of the likely levels of prescrition.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	? Time limits are an inappropriate way of treating severely ill patients. An annual review, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is inhumane. Other chronic health condition such as diabetes, epilepsy or high blood pressure dont have time limitations on treatment ? Research shows there is potential for complications when patients stop and re-start these drugs. As they are a "last resort" this is a careless judgment. ? As well as "failure" and "remission" these drugs also control active Crohns disease, enabling sufferers to life a normal lifestyle.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	I understand your concerns about obtaining further information, but why impose trails on sick people when the information you seek is available via trials in other countries with comparable or better medical research facilities. There is no need to replicate such research for the sake of it (either in cost or humane terms). I would also urge that a gastroenterologist is appointed to the review committee as they would have the necessary knowledge to comment on some of the stranger areas of the discussion in which the committee seems to have indulged.
Section 7	

(related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/11/2009 12:15

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no evidence that anti-TNF treatment increases harm to the patient after 12 months. Patients are monitored regularly and should be able to make informed decisions. They should not be considered unable to make these choices. The new document has removed all clinical input to continuing treatment at the end of 12 months. It appears to be an arbitrary cut off point. If the treatment proves clinically ineffective, the clinician will stop treatment anyway. There seems to be no provision to continue treatment after two periods of 12 months if proving clinically effective? What account has been taken of the stress of being ?made? to be ill again before being eligible for a further course of treatment? The proposals adversely impact on young Crohn?s patients who face having further education/professional training/early careers severely disrupted due to the nature of severe Crohn?s disease. The reasons for changing the preliminary recommendations to a cut off of 12 months are unclear. The term ?planned course of treatment? is not a clarification for patients, who understand the terms ?episodic? and ?maintenance? therapy in respect of these drugs.
Section 2 (clinical need and practice)	Why has the Committee not given an estimate of the likely numbers of people with severe Crohn?s who would be eligible for treatment?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	The committee seems to have paid little attention to the fact that 50% of the newly diagnosed are under age 30. For those people it is crucial that they can complete their studies/professional training/establish a career. Disruption through being taken off an effective drug and being required to be ill is likely to adversely impact their life chances. Has the Committee looked for evidence elsewhere in the world regarding the withdrawal and restarting of these drugs? There is a potential for complications when patients re-start anti-TNF drugs. The Committee states in 4.3.10 the limitations of the evidence suggesting that it may be reasonable to try withdrawing treatment in people who demonstrated a complete response, yet has concluded to do just that. Has the Committee received evidence from Patients that they are so concerned about the long term effects of these drugs that the drugs should be withdrawn after 12 months? Is the recommendation of two planned courses of treatment designed to take relevant patients through to the next proposed review by the Guidance Executive?
Section 5	

(implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/11/2009 11:56

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The new document has removed all clinical input to continuing treatment at the end of 12 months. It appears to be an arbitrary cut off point. If the treatment proves clinically ineffective, the clinician will stop treatment anyway. There seems to be no provision to continue treatment after two periods of 12 months if proving clinically effective? What account has been taken of the stress of being ?made? to be ill again before being eligible for a further course of treatment? The proposals adversely impact on young Crohn?s patients who face having further education/ professional training/ early careers severely disrupted due to the nature of severe Crohn?s disease. It seems unclear what the reasons are for changing the preliminary recommendations to a cut off of 12 months. The term ?planned course of treatment? is not a clarification for patients, who understand the terms ?episodic? and ?maintenance? therapy in respect of these drugs. Nowhere else in the developed world uses an arbitrary cut-off point when using these drugs. Where is the evidence to show this would benefit patient health?
Section 2 (clinical need and practice)	The Committee does not give an estimate of the likely numbers of people with severe Crohns who would be eligible for treatment. Why not? Has this been considered?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Treatments for Crohn?s disease never prove to be uniformly effective. The important thing is to have a range of treatments available, particularly for those with severe Crohn?s disease. Time limits are an inappropriate way of treating severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is inhumane medical treatment. Is there similar pressure on medical professionals to remove drugs that are effectively controlling a chronic health condition such as diabetes, epilepsy or high blood pressure ?to see what will happen, such as a coma, brain damage or a stroke?

	The committee still seems unaware that patients with severe active Crohn?s disease find it difficult to successfully pursue a course of study, hold down a job or take part in most normal community activities. The social cost to society is completely ignored. Adalimumab appears to fall within NICE guidelines for cost effectiveness for maintenance therapy. It seems wrong to remove the decision whether to continue on the drug from the clinician and patient.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/11/2009 11:49

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	12 month enforced withdrawal of treatment seems completely arbitrary. The new document has removed all clinical input to continuing treatment at the end of 12 months. Withdrawal after 12 months does not take into account the different levels of successful response, some not leading to full remission (ie not a complete response). The evidence regarding long-term safety of the drug does not seem to merit this enforced withdrawal, since the effects are regularly monitored by clinicians. Experience of the drugs in the USA seems to indicate that there is a potential for complications when re-starting treatment after a break. Has the committee considered this at all?
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Section 4.3.10 highlights the fact that it may be reasonable to try withdrawing treatment in people whose disease demonstrated a complete response, however there is no distinction between people who have a complete response and people who have a response where the disease is controlled, but not in remission. Since the committee has decided that maintenance treatment is clinically and cost effective, suddenly stopping it after 12 months seems ridiculous.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/11/2009 10:41

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Experience of the drugs in the USA seems to indicate that there is a potential for complications when re-starting treatment after a break. Has the committee considered this at all?
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Section 4.3.10 highlights the fact that it may be reasonable to try withdrawing treatment in people whose disease demonstrated a complete response, however there is no distinction between people who have a complete response and people who have a response where the disease is controlled, but not in remission. Since the committee has decided that maintenance treatment is clinically and cost effective, suddenly stopping it after 12 months seems ridiculous.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/11/2009 08:15

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

Role	other
Other role	Member of the public
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	There is no evidence that anti-TNF treatment increases harm to the patient after 12 months. All patients are monitored regularly when on these drugs, and should be able to make informed decisions as to whether to continue, given the balance of risks. They should not be considered unable to make these choices. There seems to be no provision to continue treatment after two periods of 12 months if proving clinically effective?
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Adalimumab appears to fall within NICE guidelines for cost effectiveness for maintenance therapy. It seems wrong to remove the decision whether to continue on the drug from the clinician and patient. Has the Committee looked for evidence elsewhere in the world regarding the withdrawal and restarting of these drugs? There is a potential for complications when patients re-start anti-TNF drugs. Time limits are an inappropriate way of treating severely ill patients. An annual review with a consultant, an MRI or colonoscopy are all reasonable requirements to determine whether continued treatment is appropriate, but a 12 month cut off is inhumane medical treatment. Is there similar pressure on medical professionals to remove drugs that are effectively controlling a chronic health condition such as diabetes, epilepsy or high blood pressure ?to see what will happen, such as a coma, brain damage or a stroke?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	30/11/2009 07:51

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

Role	Public
Other role	
Location	US
Conflict	no
Notes	An English friend of mine with Crohns greatly benefits from the continued availability of the drug. Also, experience of the drugs in the USA seems to indicate that there is a potential for complications when re-starting treatment after a break - has the committee considered this at all?
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	30/11/2009 03:42

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Withdrawal after 12 months does not take into account the different levels of successful response, some not leading to full remission (ie not a complete response). The 12 month enforced withdrawal of treatment seems completely arbitrary and removes all clinical input regarding the success of each case.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Section 4.3.10 highlights the fact that it may be reasonable to try withdrawing treatment in people whose disease demonstrated a complete response, however there is no distinction between people who have a complete response and people who have a response where the disease is controlled, but not in 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	30/11/2009 00:18

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

Role	Public
Other role	
Location	Scotland
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 4.3.10 highlights the fact that it may be reasonable to try withdrawing treatment in people whose disease demonstrated a complete response, however there is no distinction between people who have a complete response and people who have a response where the disease is controlled, but not in remission. Since the committee has decided that maintenance treatment is clinically and cost effective, suddenly stopping it after 12 months seems ridiculous.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	29/11/2009 23:56

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

Role	Public
Other role	
Location	Scotland
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The new document has removed all clinical input to continuing treatment at the end of 12 months. Withdrawal after 12 months does not take into account the different levels of successful response, some not leading to full remission (ie not a complete response). The evidence regarding long-term safety of the drug does not seem to merit this enforced withdrawal, since the effects are regularly monitored by clinicians. Experience of the drugs in the USA seems to indicate that there is a potential for complications when re-starting treatment after a break. Has the committee considered this at all?
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Section 4.3.10 highlights the fact that it may be reasonable to try withdrawing treatment in people whose disease demonstrated a complete response, however there is no distinction between people who have a complete response and people who have a response where the disease is controlled, but not in remission. Since the committee has decided that maintenance treatment is clinically and cost effective, suddenly stopping it after 12 months seems ridiculous.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	29/11/2009 23:53

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

Role	Public
Other role	Medical Student
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Withdrawal of effective treatment after 12 months seems illogical and arbitrary given little evidence showing concern with the drugs long term safety. Furthermore, despite the complete response termed by the appraisal committee, the nature of Crohns mean that relapse is probable and US trials have demonstrated a higher risk from re-starting this treatment than continued treatment.
Section 2 (clinical need and practice)	
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Section 4.3.10 is particularly flawed due to its poor distinction between complete response and the mere suppression of symptoms by an effective treatment. Complete response suggests a cure, which has at no point been shown to be the case. Withdrawal of treatment based on this allegory is a poor justification.
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	29/11/2009 23:50

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

Role	Public
Other role	
Location	Wales
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	If the person is eligible for a further course of treatment or the treatment has worked well on them, why put them under the stress of being ill again?
Section 2 (clinical need and practice)	There is no estimate of the likely number of people that would need treatment. If this treatment can stop people from needing surgery, why not produce the drug to save on surgery costs?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	There seems to have been an oversight of the fact that 50% of people newly diagnosed are under 30 these people will need to complete professional training or degrees or in many cases even finish a basic education. If the drug is working for these people and enabling them to have a normal life, why take them off 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)	
Date	29/11/2009 19:42

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

Role	Public
Other role	Health Professional private sector
Location	England
Conflict	no
Notes	How awful that it hasnt been considered what the effect would be to be taken off the drug, feel ill again, before being eligable for treatment. The young person we know with Crohns has had his life given back by the medication
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The following are comments, not questions really: Why has the arbitary cut off point been put at 12 months? What are the reasons? Does this happen anywhere else in the world?
Section 2 (clinical need and practice)	There is no evidence that anti-TNF treatment increases harm to the patient after 12months
Section 3 (The technology)	Surely surgery would cost more to the NHS?
Section 4 (Evidence and interpretation)	Young people as well as older ones are diagnosed with Crohns disease. The disease is disruptive enough to their careers and life, without taking them off treatmment that works. Is there a greater danger when restarting these drugs? Isnt the possibility of expensive surgery an even worse spectre?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	29/11/2009 19:04

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	These proposals are sickening, cutting people of a drug that gives them a quality of life after an arbitrary 12 months is appalling and tantamount to deliberate cruelty both physical and psychological as they begin to fear the deadline. The date that their treatment will be withheld from them. I notice that the NHS spends thousands of pounds giving unnecessary IVF to women having trouble conceiving. Altho this has absolutely nothing to do with health only happiness. Yet on the other hand it witholds treatment from people with a terrible disease like Crohns because theyve been receiving treatment for a year? So quality of life is important for 1 group of healthy patients but not important to people suffering from Crohns disease. Its disgusting. In the US there is evidence that people who stop and start this treatment can suffer from complications because of this . Also, where is the distinction between patients with a complete response and someone whos disease has gone into remission?
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	29/11/2009 18:51

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The proposals adversley impact on young Crohns patients who face having further education / professional / early careers severly disrupted due to the nature of severe Crohns disease
Section 2 (clinical need and practice)	Why has the committee not given an estimate of the likely numbers of people with severe Crohns who would be eligible for treatment ?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Has the committee looked for evidence elsewhere in the world regarding the withdrawal and restarting of these drugs ? There is a potential for complications when patients re-start 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)	
Date	29/11/2009 17:26

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

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	What is the point in ceasing treatment which is working well just because a set time of 12 months has been reached? It is senseless and cruel to withdraw the drug and allow a person to return to ill health along with the accompanying misery and disruption this would bring to the sufferer and their family.
Section 2 (clinical need and practice)	There is no mention of how many people with severe Crohns would be elibible for treatment.
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	I fail to understand why a 12 month cut off period for treatment has been suggested. This would not be recommended for treatment of other chronic illnesses e.g. diabetes, high blood sugar. Many of the newly diagnosed Crohns sufferers are young people under 30 who are still in full time education, tertiary education or trying to establish careers. What cost to them and the state to inhibit them in their goals, enforcing them to become dependent on benefits because they are too ill 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	29/11/2009 16:59

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

Role	Public
Other role	Mother of child with Ulcerative Colitis
Location	England
Conflict	no
Notes	Member of NACC
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I know a young man with severe Crohns who is currently receiving adalimumab and it has transformed the quality of his life, enabling him to take up a place at university and educate himself for the benefit of himself and wider society. If he were arbitrarily taken off the treatment just because the time limit had expired ie 12 months - his quality of life would be severely disrupted and it is unikely he would be able to continue his studies. His need for care would increase dramatically and he would require a great deal of help, care, attention etc from the NHS. How can NICE be sure that it is cost effective to arbitrarily cease treatment? What evidence is there to support the concern that long term use of the drug is harmful to patients? I understand that patients in other countries who respond to this drug are not under threat of having the successful treatment randomly terminated just because its considered to be too expensive. Is NICE treating this as a purely economic excercise? If so, what about the social economic cost? Surely it is better to have these young people (as many Crohns sufferers are diagnosed under the age of 30) in education or in work??
Section 2 (clinical need and practice)	Are you aware of how many patients with severe Crohns would be eligible for treatment ie has a survey been conducted?
Section 3 (The technology)	
Section 4 (Evidence and interpretation)	Patients who suffer with Crohns respond differently to different treatments therefore it is preferable to have a range of treatments on offer to ensure that the greatest number of patients can be successfully treated. Removing this treatment as a long-term option, means there will be patients who continue to suffer despite the existence of a drug to relieve this suffering - this seems to be morally irresponsible as well as economically irresponisble as severe Crohns sufferers are less likely to be able to make positive contributions to the social economy through education or work if they are constantly ill. It is not acceptable to treat human beings so arbitrarily and to withdraw their successful treatment after 12 months. This is a severe medical condition and it should be a decision made with the expert consent and knowledge of the clinicians treating the patient. Crohns patients have a right to expect best possible care and treatment surely - just as any patient would. This condition is exacerbated by stress and the stress of knowing that your successful treatment will only last for a certain period of time before it is stopped will only aggravate stress for the patient.

Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	29/11/2009 09:24

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

Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Please include the need to use Harvey-Bradshaw scores to determine severity of CD and response (severe CD H-B score of 8 or more). CDAI scores generally require the patient to return to clinic adter 1 week. H-B scores can be calculated easily and in a more timely manner. H-B score reductions idemtify responders to 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	26/11/2009 13:22

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

Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Does the resumption of treatment for a further 12 months in people whose disease relapses after the planned course of infliximab only apply to adults- can I presume this is not pertinent to paediatric population as no mention in section 1.4 about this aspect of treatment though product license for use in paedS does mention use of 8 weekly maintenance.
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	24/11/2009 16:59

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

Role	NHS Professional
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)	Does this preliminary guidance support the use of dose escalation of infliximab to 10mg/kg in those who have lost response-implied but not explicitly stated.
Section 4 (Evidence and interpretation)	Was sequential use of TNF blockers in those intolerant of- or lose response to-one of the agents considered?
Section 5 (implementation)	
Section 6 (proposed recommendations for further research)	
Section 7 (related NICE guidance)	
Section 8 (proposed date of review of guidance)	
Date	24/11/2009 11:04

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

Role	Patient
Other role	Carer of disabled mother/Honorary lecturer (PHD)
Location	England
Conflict	no
Notes	My comments are made as a patient who has started a recent course of infliximab at Leeds. I think, on the whole, the effects have been quite good but still have symptoms etc especially loose motions. I have a stricture in the small bowel deemed severe and other symptom areas (oral etc). The infliximab has really a very significant effect in terms of revitalizing and counteracting what was a very difficult disease with worsening symptoms/avoiding surgery. My view is that a potential cut off point (unless avoidable at 12months) would mean that re-occurrence was a more probably feature. Prevention of re-occurence rather than awaiting its inevitable appearance is needful in my view and what will happen is that individuals will revert to steroids when their symptoms re-occur - they will not await the imminent destruction of their bowels by a revitalized disease (if this were to occur).
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I thought I had submitted these formerly - I explained I was a person with Chrons and on infliximab. I felt a problem existed with a cut-off point of 12 months and it would result in a case of persons reverting to steroids or being put into surgery etc.
Section 2 (clinical need and practice)	I add my comments to that made formerly - an error is present here. Chrons disease is unpredictable in its effects and at times, its course, but it can be highly predictable in terms of its likliehood of persisting. That is why maintenance is sought by patients as an ongoing therapy. Patients do not like to wait around for the pattern of inevitable re-occurrence to re-assert itself in whatever form it may do so(SGSheard@aol.com)
Section 3 (The technology)	I understand the arguments re cost but consider the cost to the person of the disease and those around them. I for instance am a carer - what is the cost of potentially placing my cared for mother in a nursing home if my health fails. The situation is not linear but complex and relates to the context of patients not the isolable features of cost of a drug. Granted that is how you seem to do things. Consider also the cost of surgery and the problems when individuals have had enough surgery or are rapidly losing bowel to have removed (SGSheard@aol.com)
Section 4 (Evidence and interpretation)	
Section 5 (implementation)	Please note my comments are made as a person experiencing Chrons and not as a profesional but they have a value in their appropriate context as being from a person on infliximab.
Section 6 (proposed recommendations for further research)	Yes, but trials are trials and you need to get it right for the mass - many of whom are reliant for their good health on the continuance of a drug. What also happens after two years if the patient does not remit (having had successive courses perhaps after a relapse). Have you given it any thought? Does it fall in

	the catch all category of 1.7. Surely more clarity ought to be given as regards 1.7 and also to express leeway for surgical discretion to prevent re-occurence for example in individuals with limited possibilities for surgery and/or in case of contraindications like the case in which steroids have effect but are to some extent contra-indicated?
Section 7 (related NICE guidance)	Comments concluded.
Section 8 (proposed date of review of guidance)	Comments concluded as educated layperson with personal experience of the condition writing.
Date	22/11/2009 20:27