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

Name	
Role	NHS Professional
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	After following NICE and Novartis criteria we only administer Omalizumab to those appropriate patients. We have seen a marked reduction in hospital admissions, courses of Prednisolone and a signifdicant improvement in quality of life. We monitor spirometry, QoL and ACT at every visit during the 16 week trial alongside the number of admissions/courses of Prednisolone. After the 16 weeks if the patient is to continue we record these measures every 3-4 months. As we all know the severe asthma population accounts for approximately 10% of the whole asthma population. We are only looking at a small proportion of these that are atopic. We have a small number of patients receiving Omalizumab and the overall outcome has been extremely positive.
Section 2 (Clinical need and practice)	As above. Patients do not want to have to take Prednisolone regularly and encounter all the potential side effects that go along with them. Patients have found a new independance and confidence that enable them to continue working.This not only impacts on the patients but the whole family. As things stand we are actively trying to reduce the number of hospital admissions. I fear that if we stop Omaslizumab in our patients we will see the number of hospital admissions increase adding to an already overburdened NHS.
Section 3 (The technology)	Would there not be some way that NOvartis could make the drug more affordable?
Section 5 (Implementation)	Ethically how can we stop a drug that is clearly benefiting patients in such a profound way.

Name	
Role	Patient
Location	England
Conflict	no
Notes	I am currently a student nurse.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe that Omalizumab has a life changing effect on severe asthmatics and should still be available for trial in extreme cases.
Section 2 (Clinical need and practice)	Before being put on Omalizumab I was on 40mg of prednisolone daily and 1g of Methylprednisolone IV for 3 days every month and had on average 2 hospital admissions a month. I was only able to attend school for 50% of the year and had no quality of life. Since starting Omalizumab I haven't had a hospital admission, I?m on 15mg of prednisolone with no IV

	treatment and am now in my final year of university training as a student nurse. It has changed my life completely.
Section 3 (The technology)	The treatment is very expensive, however, the cost of the hospital admissions, HDU and intensive care beds and emergency treatment I received over the years would equate to more than this. I was also receiving Disability Living Allowance and no longer need this to support my living.
Section 4 (Evidence and interpretation)	The long-term efficacy of omalizumab: My FEV1 has improved dramatically since starting on omalizumab and I haven't had a hospital admission either. My quality of life has improved and I am now giving back to society as I am training to be a paediatric nurse. The corticosteroid-sparing effect of omalizumab: My steroid treatment has reduced from 40mg prednisolone oral daily and 1g of methylprednisolone IV for 3 days each month (maintenance). I am now on 15mg prednisolone oral and I am still reducing this. Adverse effects of oral corticosteroids: I had gained weight, had a 'moon face', had concerns over the health of my teeth and bones and thinning skin, this all had a terrible effect on my self-esteem and quality of life as I didn't want to go out with friends. Now I am reducing the steroids I am much happier and there no concerns at present about the health of my bones, and things are looking positive for eventually coming off the steroids completely.
Section 7 Proposed date for review of guidance)	I believe that the information provided by patients and staff administering omalizumab treatment, should be highly considered as we are able talk honestly and from personal experience.

Name	
Role	Patient
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	As a patient with very severe allergic asthma, who has been on omalizumab since March 2011, I would like to inform NICE that it has changed my life in terms of my allergic asthma symptoms. Since being on the drug I have been able to partake in events outside, be it BBQ's, family parties or holidays. Until I started treatment I had to miss out totally, or view from inside or through photos. Now I can be outside without having to be scared of trees, flowers or grasses. So successful was my summer that I actually got sun burnt for the first time in years (ok so that is not so good). By no-longer recommending omalizumab NICE is potentially preventing other patients from enjoying these benefits
Section 2 (Clinical need and practice)	There is a definite need for an additional or alternative treatment to oral corticosteroids. One which addresses the root causes of asthma, the triggers, rather than simply treating the symptoms which is what the BTS 5 Step Process does. Also one which does not appear to invoke the debilitating side-affects that corticosteroids do.

Section 3 (The technology)	There is already a 16 week trial process in place to look at the effectiveness of Omalizumaub, after which those not experiencing any benefit can cease treatment. The manufacturers also, in some areas, have offered a money back scheme to the NHS trusts for those for whom it is not a useful treatment at 16 weeks. It is acknowledged that it is an expensive treatment long-term however this cost should be addressed in relation to the cost of treating steroid side-affects and the hoped for reduction in hospitalisation costs of asthma
Section 4 (Evidence and interpretation)	- Cost effectiveness of omalizumab in relation to reduced oral steroid usage is a utilitarian measure as it does not take into consideration the increases in QALYs experienced even though the steroid dose may not have decreased. - 4.4.14 The committee co
Section 5 (Implementation)	The technology used in the development and production of omalizumab should be available for future usage, and by withdrawing the NICE recommendation for the drugs use, the further development of this technology could be hampered as the manufacturer would have no incentive to carry on development of this treatment method.

Name	
Role	Patient
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I have been on this clinical trial for over 18 months and it has radially improved my life. . This drug should be made readily available throughout the UK to any asthma sufferer that meets the criteria for this drug. It has saved my life.

Name	
Role	Patient
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Omalizumab has really helped in my management of Asthma and believe it should still be recommended. My hospital admissions have reduced and so has my need to take oral steroids.
Section 2 (Clinical need and practice)	My asthma has been much more controlled since starting on Omalizumab. I missed a great deal of school and college and at one point my school did not want me there as they felt they could not cope. I am now studying towards a nursing degree and hardly miss any time of university. If I did not have the opportunity to be on Omalizumab I do not believe this would be possible and this was discussed with my Consultant and Nurse specialist prior to starting on Omalizumab.
Section 3 (The technology)	Before starting on Omalizumab I struggled to even provide a lung function due to becoming wheezy and it was constantly lower than predicted. I took many different inhalers and tablets and was still waking many times at night and had frequesnt

	symptoms during the day. I had many hospital admissions and ambulances were often called into school causing me to miss time.
Section 4 (Evidence and interpretation)	My lung function improved even after the initial 16 weeks on Omalizumab. My attendence rate at college dramatically increased and I am now only taking short courses of oral steroids as before starting Omalizumab I was taking them for most of the year. In my opinion Omalizumab has changed my life I am able to do much more than before and I am needing a less amount of courses of oral steroids which I am happy about considering their side effects. I am sleeping much better at night wheras before I would be woken several times per night due to asthma symptoms.
Section 5 (Implementation)	Even though Omalizumab is expensive I do believe it has been worth it in my case. I used to have an ambulance to school/college approximatley twice per week and most of these times went up to A&E. I had a perscription for oral steroids most months and had several hospital admissions. All of these have reduced massively since starting on Omalizumab.

Name	
Role	NHS Professional
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am responding to the above consultation document on behalf of the Regional Difficult Airways Disease Service that we provide at Southampton. Our Service currently supervises the care of over 500 patients with Difficult Asthma. We currently treat 26 patients at Southampton with Omalizumab (Xolair). As a group that specialises in managing patients with Difficult Asthma we would urge the committee to retain access to Omalizumab for carefully selected patients who have been thoroughly assessed in a Specialist Clinic.The alternative is to deny patients an effective treatment and continue to expose them to the harmful side-effects of less effective treatments like maintenance oral steroid.
Section 2 (Clinical need and practice)	Our experience with Omalizumab is that it offers an invaluable tool that enables a small proportion of patients with Difficult Asthma to attain much better asthma control when all other treatment options have been exhausted.Our experience is that in carefully selected patients, Omalizumab therapy can have transformational improvements in their levels of asthma control, their quality of life and have had significant reductions in oral steroid dependence, exacerbation frequency and severity. They have also experienced marked reductions in Hospital admissions and in level of Hospital Care required in the event of admission (eg reduction in Intensive Care admission).
Section 3 (The technology)	In our experience, Omalizumab has been very well tolerated.
Section 4 (Evidence and interpretation)	We feel that the NICE appraisal removes an invaluable tool from the Difficult Asthma Clinic which has a potentially dramatic benefit in carefully characterised and selected patients. Put

	simply, without future access to Omalizumab, there are patients living with severe asthma today who will die of their disease in years to come. When an effective treatment is available, that is not acceptable.

Name	
Role	Public
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	As someone who suffers from asthma,I am concerned that if my condition worsens that this treatment will not be available to me. As I understand it, the only viable alternative is large doses of steroids. This is a concern.
Section 2 (Clinical need and practice)	The above is rather too technical for a layman such as myself, but I am still concerned at the proposed withdrawal of omalizumab.
Section 3 (The technology)	I am very concerned that the removal of omalizumab is driven by cost rather than by any clinical findings. If it is a good treatment for severe asthma it should be retained if it maintains the users quality of life.
Section 4 (Evidence and interpretation)	Again, too technical for a layperson. The removal of this treatment should not be driven by financial findings.
Section 5 (Implementation)	No comment.

Name	
Role	NHS Professional
Other role	Asthma interested Consultant Physician
Location	Wales
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	All patients who have responded will be extremely keen to continue. I do not think it is fair to prevent further patients to be offered a similar chance to improve their asthma control and overall quality of life.
Section 4 (Evidence and interpretation)	There remain a group of highly symptomatic asthmatic patients, who have been exposed to high levels of systemic corticosteroids and multiple admissions despite significant efforts to optimise their "standard" asthma medication. A number of these patients, carefully selected, will respond dramatically to Omalizumab, with a dramatic improvement in their quality of life and health status. If we are not allowed to start any new patients on omalizumab, a number of these will be deprived of effective, life changing therapy. Also, in terms of duration of therapeutic effect, two of my young asthmatic ladies have had good response to omalizumab which has maintained over several years until they became pregant (one had reported that improvements in her breathing had allowed her to become sexually active with her term husband

	after she had been too short of breath for years). Both patients suffered a significant loss of asthma control during their pregnancy, when Omalizumab had been withdrawn. One of these patient had a further life threatening attack. Both needed big increases in oral steriods while off xolair and improved again once restarted after the baby's birth.

Name	
Role	Patient
Location	England
Conflict	no
Notes	am a patient currently receiving Xolair treatment, and have been doing so now for approximately 4 years. I have found that my standard of living has improved enormously since beginning this treatment. Firstly, I no longer require prednisolone tablets. Prior to Xolair, I had been on a course of the same, continuously, for approximately 5 years. I have found that, since beginning this treatment, my inhalers are now enough to control any symptoms I may have, including tightness in my chest and coughing. I have had no hospital admissions during this time. I have also found whilst receiving the treatment, I have not had a chest infection. This, I feel, is a major achievement, as previously, once I get a chest infection, which is usually around autumn time, I suffer with this almost continuously until the spring time. I have also been able to take up running in my spare time, which before Xolair, would have been impossible. My hayfever symptoms also seem to have improved, and I no longer require antihistamines throughout the year. I have found this treatment has made a huge impact on my life during the time I have been receiving it, and my health has improved more that I thought it possibly could. I am sure that the withdrawal of Xolair would be detrimental to my health.
Comments on individual sections of the ACD:	
Section 4 (Evidence and interpretation)	I am a patient currently receiving Xolair treatment, and have been doing so now for approx 4 years. I have found that my standard of living has improved enormously since beginning this treatment. I no longer require prednisolone tablets. Prior to Xolair, I had been on a course of the same, continuously, for approx 5 years. I have found that since beginning this treatment my inhalers are now enough to control any symptoms I may have, including tightness in my chest and coughing. I have had no hospital admissions during this time. I have also found whilst receiving the treatment, I have not had a chest infection. This, I feel, is a major achievement, as previously, once I get a chest infection, which is usually around autumn time, I suffer with this almost continuously until the spring time. I have also been able to take up running in my spare time, which before Xolair would have been impossible. My hayfever symptoms also seem to have improved, and I no longer require antihistamines throughout the year. I have found this treatment has made a

	huge impact on my life during the time I have been receiving it and my health has improved more that I thought it possibly could.

Name	
Role	Public
Other role	Carer for Wife
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Incorrect, why wife is a chronic asthamtic and has been on the drug for 5 years. The results have been amazing and have dramatically reduced her admission to hospital and have improved her quality of life
Section 2 (Clinical need and practice)	Your fail to identify that by using the drug on a regular treatment plan which is periodically review, chronic asthma suffers infact do reduce the amount of medication that they have to take
Section 3 (The technology)	Sure the cost of the injection is minimal when compared to the actual cost of a person being admitted and kept in an NHS hospital. Perhaps if you looks at both side of the coin you would have a realised appreciation of the cost Injection cost vs likely hospital admission and treatment for an asthma attack
Section 5 (Implementation)	Whilst from you "clinical" trial you say its benefits are limited. Try looking at some of the patients whom have been using the drug since it was first trialed in the UK. Also, it is a know fact that childen do grow ou of asthma, but adults whom develop asthma only get worst as they get older. NICE need to give guidance on it use. Its not a drug that will help all but the most chronic asthmatics
Section 7 Proposed date for review of guidance)	When this is review, I would suggest that factal information is gained from adults with chronice asthma

Name	
Role	NHS Professional
Location	England
Conflict	no
Notes	SpR in Respiratory Medicine with interest in severe asthma
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	My perception as a clinician is that removal of approval for this drug will result in harm to patients with increased risks including risks of worsening asthma (hospitalisations and ITU admissions) and increased risk from drug side effects of other therapies such as high dose oral steroids side effects. I think both these factors will have effects on QALY of patients with severe persistant asthma and increased costs to the health service in the medium to long term.
Section 2 (Clinical need and practice)	Omalizumab is an important Step 5 therapy which canreduce exacerbations and reduce side effects from high dose oral steroids

Section 3 (The technology)	It is good that patients are only continued on this drug if there are clinical responders to the drug. Therefore we are potentially removing a drug from patients that we know are effective. I think this needs to be considered when assessing impact on QALY and the impact of the new guidance on existing patients on this drug.

Name	
Role	Patient
Other role	Also a consultanbt anaesthetist and intensive car edoctor.
Location	England
Conflict	no
Notes	I am a 49 year old Consultant Anaesthestetist and Intensive Care Physician with asthma. I have been receiving omalizunab for approximately 18 months Prior to this I was on aminophylline, montelukast, inhaled budesonide 800mg/d steroid, nasal steroid, seretide 25/250 4 puffs bd and long term itraconazole. In addition I was requiring a course of natibiotics about every 8 weeks and a 5-7 day course of oral sterioids around every 6 weeks. With this regimen I was able to work but with some difficulty and considerable tiredness. I was able to walk up two flights of stairs but often had to rest at the toip before continuing. My health was worsening and was a concern. Within a few weeks of starting anti-iGE treatment my health was transfornmed. I was considrably better in my function, QOL and medication needs. I have been able to drop all my medicines except the montelucast, nasal steriod and inhalers (now at much lower doses). I have needed no oral steriods or antibiotics in the last 16 months. I am back running.My objective measures of lung function have dramatically improved too. Overall a massive success.

Name	
Role	NHS Professional
Other role	Respiratory Consultant
Location	England
Conflict	no
Notes	Although this is anecdotal, I am very concerned that Omalizumab should be withdrawn from NICE recommendation. I have had four patients on Omalizumab. All of whom have made excellent clinical response. I have anonimysed this letter, but it gives a clear message as to the dramatic improvement in a patient with severe asthma. This lady has had an outstanding response to the Omalizumab. She had her first dose on the 20th September and fourth trial dose on the 19th December. Following her trial she made a definite improvement and has now been established on this

	drug long term. From a clinical perspective she is much better with dramatically improved exercise tolerance. Interestingly she reported that she can now put on perfume which she had been unable to do for many years. Her peak flow has increased from 209 to 307 and spirometry from 0.86/1.31in August to 1.38/2.43 today. These current values give a ratio of 57% and 67% and 98% predicted respectively. She stopped using her Salbutamol inhaler and has required her nebuliser only twice when she had a chest infection. She has reduced her Symbicort to 1 puff twice a day when previously she was using it every 4-6 hours. She has also come off her Aminophyllin and Cetirizine. This is a very pleasing response. She is due for follow-up at the Royal Brompton Hospital in March. We will see her in three months? time with repeat spirometry. Please consider quality of life and steroid reduction when taking into account the decision concerning NICE approval. Best wishes, Consultant Chest Physician, Bath
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Although this is anecdotal, I am very concerned that Omalizumab should be withdrawn from NICE recommendation. I have had four patients on Omalizumab. All of whom have made excellent clinical response. I have anonimysed this letter, but it gives a clear message as to the dramatic improvement in a patient with severe asthma.
Section 2 (Clinical need and practice)	See anonimised recent letter, "This lady has had an outstanding response to the Omalizumab. She had her first dose on the 20th September and fourth trial dose on the 19th December. Following her trial she made a definite improvement and has now been established on this drug long term. From a clinical perspective she is much better with dramatically improved exercise tolerance. Interestingly she reported that she can now put on perfume which she had been unable to do for many years. Her peak flow has increased from 209 to 307 and spirometry from 0.86/1.31in August to 1.38/2.43 today. These current values give a ratio of 57% and 67% and 98% predicted respectively. She stopped using her Salbutamol inhaler and has required her nebuliser only twice when she had a chest infection. She has reduced her Symbicort to 1 puff twice a day when previously she was using it every 4-6 hours."

Name	
Role	NHS Professional
Other role	NPPG Information Officer
Location	Wales
Conflict	no

Notes	I am responding to this consultation on behalf of the Neonatal and Paediatric Pharmacists Group (NPPG)
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	We are disappointed by the recommendation that omalizumab is not recommended for use in any age group.We consider that withdrawal of NICE recommendations on using this drug would have impact on the health of the existing patients already established on therapy. This will in turn cause problems with funding pathways. We are also disppointed that again, its use is not recommended in younger children due to the significant risks associated with the altenative therapies for severe asthma and the impact on their lives.
Section 2 (Clinical need and practice)	It is important to consider the role for omalizumab in that it allows the reduction of use of systemic corticosteroids and other immunosupressants in view of the significant adverse effects of these agents (as mentioned above). This is of particular concern in children.
Section 3 (The technology)	omalizumab is the first advance in asthma management in recent years with clear benefits shown to symptoms in practice with individual patients (approximately 80% of those tried on it in one local specialist centre) having seen benefits. Since the last NICE TA 201 there has been a change in cost and administration details. The practicality of this means that the number of hospital appointments has been reduced which has an impact on nursing time and will affect costing models. In addition, in practice, spacialist centres will only continue therapy in those patients who benefit from omalizumab. THis also affects costing models.
Section 4 (Evidence and interpretation)	We agree that in UK practice the population for which omalizumab would be considered is smaller than that covered by the marketing authorisation.The previous NICE recommendations requiring hospitalisation as a pre-requisite for treatment does provide a perverse incentive to let the condition worsen and in clinical practice Paediatricians have tried to identify other markers for use such as daytime symptoms or night-time awakening, or a full trial of alternatives at step 4/5 of BTS Guidelines. The lack of information on which to identify the subgroups of patients for whom omalizumab represents a cost-effective use of resources is of concern. We consider that the risks and benefits of removing access to omalizumab needs further discussion. This should also take into account the needs of patients under the age of 12 who were not covered by the NICE TA 133 and in NICE TA 201 were recommended not to have the drug made available. Further work is required to look at the cost-effectiveness models based on clinical use of the drug and not just the marketing authorisation. Perhaps such data could be obtained from centres already using the drug.
Section 5 (Implementation)	Withdrawal of NICE recommendations on this drug will compromise access to omalizumab for patients who are currently receiving it. This will cause funding difficulties and will impact on the newly formed CCGs in England.
Section 7 Proposed date for review of guidance)	It is disapponting to see that if omalizumab is not recommended, the decision will not be reviewed again for over

	3 years.

Name	
Role	Patient
Location	England
Conflict	no
Notes	No
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The treatment should be given to new patients who show signs of allergic asthma. It is a drug which is very very productive. I started this drug 5 years ago and it has changed my life. I was always in and out of hospital and now can say I only have been admitted twice since starting.
Section 2 (Clinical need and practice)	The need for this drug should be increased. It is clear that there are morre asthmatic s who suffer from allergy triggers and thus this drug helps immensely. Also for me my steroids have reduced from approx. 60mg per day to just 10mg per day. This is great as the lifetime symptom of taking steroids is awful.
Section 3 (The technology)	I take zolair every four weeks and for have a headaches for 24 hrs and sleep for about 18 hrs. These are the only side effects and compared to how bad my asthma can be without it l don't mind them.
Section 4 (Evidence and interpretation)	Maybe the committee needs to look at some analysis of people who are now on long term zolair. I think they would find that there is a huge cost benefit. I know for me I do not require as much hospital treatment,or mmedicine or seen by gp or consultant. It means professional people can see others and I can enjoy my life without worrying as to what I will be like later in the day.
Section 7 Proposed date for review of guidance)	I am dumbfounded that this drug is being reviewed. Why take awayan option of a lifeline for a asthmatic. Severe asthmatic are not highly recognised as to their serious illness. Every day we are glad that we are able to breathe. If it means a drug helps us then that's what should be offered unless there is a cure.

Name	
Role	Patient
Location	England
Conflict	no
Notes	No
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The treatment should be given to new patients who show signs of allergic asthma. It is a drug which is very very productive. I started this drug 5 years ago and it has changed my life. I was always in and out of hospital and now can say I only have been admitted twice since starting.
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Section 3 (The technology)	I take zolair every four weeks and for have a headaches for 24 hrs and sleep for about 18 hrs. These are the only side effects and compared to how bad my asthma can be without it I don't mind them.
Section 4 (Evidence and interpretation)	Maybe the committee needs to look at some analysis of people who are now on long term zolair. I think they would find that there is a huge cost benefit. I know for me I do not require as much hospital treatment,or mmedicine or seen by gp or consultant. It means professional people can see others and I can enjoy my life without worrying as to what I will be like later in the day.
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Name	
Role	NHS Professional
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I strongly reject point 1.1. I have approximately 25 patients on Omalizunab in the North Essex area. For many of these patients the drug has been simply life transforming. Putting aside the reduction in critical care admissions I have seen in these patients as well as other health care utilisation events, these is an unrecognised improvement in employment and social impact with the use of the drug. One of my patients is a worker at a well known high street DIY store and her job was constantly under review due to her high Bradford score. Omalizumab has revolutionised her asthma management she has increased her hours and come off income support. The costs of such things is not accounted for in conventional QALY assessments. NICE have clearly made an error of judgement on this occasion. I sincerely hope that NICE reverse this decision as soon as possible. This does not reflect the available evidence which strongly would support more widespread use of Omalizumab at stage 4 of the guidelines rather than removing recommendation.
Section 2 (Clinical need and practice)	The recommendation recognises the long term side effects of corticosteroids but does not recognise that Omalizumab can be successfully used to reduce steroid dose and therefore side effects. NICE also fails to mention that the SIGN guidelines already recognise this.
Section 4 (Evidence and interpretation)	In the exhaustive review NICE comments on some weakness in some of the double blind studies because oof lack of power, It does not recognise the ethical problems of performing double blind studies in such severe patients with such an effective treatment. In conjunction with others I have published data in the form of an audit of patients on the drug in my practise. We found that Health care utiliastion dropped from 165 days in the 43 patients to 12 following initiation of treatment. This included

	Critical care and Hospital days. There was also a reduction in GP visits. NICE have not included this data as it vis not double blind without acknowledging the ethical problems in performing double blind studies in these patients with the knowledge base we have now. We also showed significant improvement in ACT scores and AQLQ in this subset of patients. NICE have not included any bof this data which is a serious omission. It is vital that NICE includes all data availble before coming to a decision.

Name	
Role	Carer
Location	England
Conflict	no
Notes	My daughter is only 2 and suffering with severe Asthma, she is already not living a normal life and if this is due to Allergies this could change her life in the future.

Name	
Role	Patient
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	as a patient recieving 2 weekly injections i have seen an amazing improvement to the quality of my life although still restricted i'm not having 2 weekly emergency admissions to hospital, i feel as its only approx 4000 people the medication applys to its grossly unfair to not allow this amazing medication bieng offered to new patients. the only other options are huge doses of other medication which have more damaging health aspects for patients
Section 2 (Clinical need and practice)	i was on all this medication and more and still had 2 weekly admission to hospital, surley the cost of admissions plus extra medication cancels out the cost of Zolair to the Nhs, plus long term health effects that i still suffer from with the medication regim proposed needs to be addressed.
Section 3 (The technology)	Â£26;000 is surley a small price to pay to give a person thier life back compared to the cost of repeat admissions to high dependency wards and extra monitoring by health care professionals
Section 4 (Evidence and interpretation)	your figures speak for themselves inimal savings to be made, i personally would prefer not to have to travel 70 miles to my nearest clinic for 4 injections every 2 weeks but its worth it to be able to climb stairs again and to able to bathe unassisted

Name	
Role	NHS Professional
Other role	Research Ethics expert
Location	England
Conflict	no
Notes	30 years experience and interest in managing complex and

	severe asthma
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I find this a perverse interpretation of the data alluded to within the guideline which refers to current practice of careful assessment of these difficult to manage patients many of whom are at risk of premature death and hospitalisation within specialist high intensity care facilities within an already compromised and limited service provision. This guidance as it stands will prevent the assessment and potential clinical benefit to a small but severely disabled group of patients. The continuing premature deaths from asthma in the UK is evidence of continuing need to provide this therapy. The clinical services providing assessment and therapy already restrict and stop ineffective therapeutic intervention. Current refund schemes in place to local providers seem to have been ignored.
Section 2 (Clinical need and practice)	This is a good summary. Perhaps it understates the excessive number of deaths and complications of current alternative therapies such as LABAs, steroids, leukotriene receptor antagonists, anticholinergics and steroid sparing strategies.
Section 4 (Evidence and interpretation)	This guidance has failed to adequately assess and assay the already extensive clinical experience in the use of this therapy in the UK. Interpretation based simply on controlled trials fails to identify the real clinical benefit which in my experience can often occasionally be almost miraculous in result. It has failed to recognise the true extent in terms of economic and clinical suffering experienced by these severely disabled patients, frequently young and in the prime of life.

Name	
Role	Patient
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 4 (Evidence and interpretation)	I am a severe Asthma patient at The Respiratory Centre at Southampton General Hospital under [redacted] my consultant. Having the chance of what I can only describe as a miracle drug for me personally, Omalizumab has given me the gift of life back. It makes my life bearable and gives me reprieve of such high and constant steroid use as I was always on 40mg of Prednisolone steroids daily for weeks/months at a time, over numerous years on steroids {25yrs} I couldn?t sleep, breath and being on such high doses of steroids has led now onto other serious health issues. My mobility is poor and my health has suffered greatly as a result of my Asthma. Please, as a patient on Omalizumab please do not take away a life line to me as it has given me back my independence and the chance of living again. I have been admitted to hospital numerous times in the past for my Asthma and since starting Omalizumab I have had no admissions at all in the past 18 months, I owe this I am sure to Omalizumab.

Name	
Role	Public
Other role	Sales
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	As an asthma sufferer, if anything is available at whatever cost to ease the chance of an attack, then the cost to the NHS should not be the deciding factor. Many sufferers like myself would be happy to contribute if it is solely a cost factor.
Section 2 (Clinical need and practice)	As this is something I was born with, I object to the amounts of support offered to people with self inflicted problems i.e. smokers, heavy drinkers, drug users etc.
Section 3 (The technology)	Sufferers should be able to have the choice and be given all the options to them, regardless of cost to the NHS. That's is what I see as a function of the NHS, I pay a lot of tax and NI every month and would like to think it contributes in some way to something I suffer with and others like me.
Section 4 (Evidence and interpretation)	All this to basically say its not cost effective, what about the fact it could save lives or vastly improve some peoples lives. It's about patient choice and offering the best care possible surely.
Section 7 Proposed date for review of guidance)	That's a lot of time to make a decision,

Name	
Role	other
Other role	Sales manager
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Not really stated why not to continue treatment
Section 3 (The technology)	Treatment for severe asthma should never be about cost, asthma is not a choice it is something you have to live with. it should be about the quality of life to that person. In an age where we support obesity, smoking and alcohol abuse I think cost for something people cannot do anything about should be irrelevant. I also do not understand why we do not negotiate with manufacturers of life saving drugs.
Section 4 (Evidence and interpretation)	There is no evidence to say it shouldn't be recommended for the treatment of severe asthma, it is purely cost related.
Section 5 (Implementation)	Would you work the same templates for an obese person? Or someone on drugs? Or alcohol? People with asthma can't change there circumstance. Should it be about cost.

Name	
Role	Patient
Location	England
Conflict	no

Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Firstly, I am extremely gratified to see the effort and attention to detail that goes into making these decisions. While I may personally be disappointed with the result in this case, having read the consultation document it seems to be carefully researched and well presented (despite the technical nature of the content). I don't expect my anecdotal case will sway the committee, but I include it nonetheless in comments on section 2. I only have a couple of technical criticisms which are presented in comments on sections 3 and 4 (and of which I am unsure myself).
Section 2 (Clinical need and practice)	My condition (severe adult onset asthma at age 30) resulted in 5 admittances from A&E in the year prior to my starting xol-air. Subsequently I have had none, although we have found in my case that a combination of methotrexate and xol-air is necessary to control the condition (we have experimented with each individually - methotrexate alone prior to starting xol-air, and xol-air alone since starting it, but individually they were insufficient). In the 2nd year before I started xol-air I had taken a significant number of oral steroid courses (12) which contributed to osteoporosis of the lumbar vertebrae (>3 SDs below normal density). Since starting xol-air I have needed significantly fewer steroid doses (3-4 per year) and with the intervention of alendronic acid and calcium supplements my spine is now considerably better (1 SD below normal density). I can only imagine the cost to the NHS if my vertebrae were to suffer serious damage as a result of osteoporosis. A final note is that since starting xol-air I've taken no more than 1 week per year off ill from full-time work - considerably fewer than in the years prior to starting xol-air.
Section 3 (The technology)	I note that everything in the report is carefully quantified and properly sourced with one exception: what is the source of the 30,000 per QALY limitation referenced in various paragraphs of section 4.2? All other figures seem calculated, and perhaps this one is too, but its neat rounded nature seems to suggest it is the result of someone sticking their finger in the air. I don't dispute that some cut-off is required (especially in a state-run institution like the NHS), but I'd be more persuaded by this case if I could see that the same dilligence had gone into the calculation of the cut-off as had gone into the quantification of the cost of gaining a QALY.
Section 4 (Evidence and interpretation)	In S4.2.16 the assessment group use a discount rate of 3.5% from the NICE reference case. As a recently developed drug produced by a single provider I assume that xol-air is patented. I assume (possibly incorrectly) that at the end of the life of such a patent (which may well be outside the 10 year range that the assessment group were modelling) that there would be a considerable one-off decrease in the cost of the drug as other manufacturers step in and provide competition. Do we know when the patent(s) applicable to xol-air (if any - although I'd be rather surprised if there were none) expire? If it is within the 10 year range considered by the committee, is it possible to model this?
Section 5 (Implementation)	I sincerely hope that either Novartis will reduce the cost of the

	drug (extending their period of investment recoup for example), or that further evidence may come to light convincing the committee of the economic case for xol-air as, at least in my case, it seems to have been extremely beneficial and I suspect that over the long term it may save the NHS from greater costs (not to mention allowing me to continue to pay my taxes to fund this extraordinary institution!). Of course, I must allow for the fact that my evidence is anecdotal and cannot replace the rigour of the properly conducted trials that the committee considered. I would be interested in knowing what events or timescales are grounds for re-examination of the subject by the committee (major price drops? new trial data?). In the meantime I am at least impressed that such decisions are not taken lightly and that considerable care and work has obviously gone into this decision.

Name	
Role	NHS Professional
Location	England
Conflict	no
Notes	I am a consultant running a difficult asthma service that covers a large area of South Yorkshire, and the co-lead of the Yorkshire and Humber Severe Asthma Network
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I believe 1.1 to be the wrong recommendation. I treat patients from across South Yorkshire with severe asthma. I am an effective gatekeeper for this expensive treatment. I have initiated about 30 patients on it over the last few years, with about 25 remaining on it, 20 of whom remain under my supervision (the others stopped because of lack of efficacy). In the treated group, responses have frequently been life-changing. It has become routine to see patients weaned off oral steroids, with very marked improvements in symptom burden, quality of life, and exacerbation rates. Patients have got back to work who were having attendance difficulties, and have a much better outlook in terms of long term morbidity from asthma and asthma medications such as steroids. The current NICE guidance for omalizumab use already applies a stringent set of tests patients must pass before treatment is initiated. We do not continue it unless benefits are evident and marked. This is a life-changing treatment that both provides immediate quality of life benefits and marked long term decreased risk of morbidity, mortality, and drug-related complications (e.g. through reductions in steroids).
Section 4 (Evidence and interpretation)	I have patients who have started on omalizumab and gone from daily severe symptoms and long term oral steroid dependance with frequent A&E attendances, admissions, and other episodes of unscheduled care to being stable on standard inhaled medication without admissions, with well-controlled and predictable symptoms, and much better able to engage at work and at home in the ordinary activities of living. This drug can

	genuinely transform the day to day life and long term care of a group of people who are highly disabled by their disease, where other options are unappealing because of side effects (high dose oral steroids). In parallel, I have many patients who have been crippled or had their lives shortened by long term steroid side effects (diabetes, osteoporosis, heart disease). I use this drug with care and caution, and in well-selected patients it changes lives. In patients in whom it does not work, it is discontinued. Careful patient selection and agreed stop criteria in those in whom improvements are not seen is a much better way forward.

Name	
Role	NHS Professional
Location	England
Notes	I am a consultant respiratory physician and I have a major interest in asthma and run a specialised asthma clinic in conjunction with regional centres in Sheffield and Leeds. I have several patients who have had a very significant response to Xolair, with a major impact on their quality of life and reduction in admissions, hospital attendances etc. Some have been able to return to their previous employment. I have no doubt that, using the NICE criteria for assessment, and discontinuing the drug when defined objectives are not achieved, it is a very cost-effective intervention for a small number of well selected patients. I do not understand why you are considering a nagative asessment, unless there is new scientific evidence that I am not aware of.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I have a major interest in asthma and run a specialised asthma clinic in conjunction with regional centres in Sheffield and Leeds. I have several patients who have had a very significant response to Xolair, with a major impact on their quality of life and reduction in admissions, hospital attendances etc. Some have been able to return to their previous employment. I have no doubt that, using the NICE criteria for assessment, and discontinuing the drug when defined objectives are not achieved, it is a very cost-effective intervention for a small number of well selected patients. I do not understand why you are considering a negative asessment, unless there is new scientific evidence that I am not aware of.
Section 2 (Clinical need and practice)	I agree with this asssessment. Xolair allows some patients to reduce their dependence on oral steroids
Section 3 (The technology)	I agree with this assessment
Section 4 (Evidence and interpretation)	I am a consultant respiratory physician and I have a major interest in asthma and run a specialised asthma clinic in conjunction with regional centres in Sheffield and Leeds. I have several patients who have had a very significant response to Xolair, with a major impact on their quality of life and reduction in admissions, hospital attendances etc. Some have been able to return to their previous employment. I have no doubt that, using the NICE criteria for assessment, and discontinuing the

	drug when defined objectives are not achieved, it is a very cost-effective intervention for a small number of well selected patients. I do not understand why you are considering a nagative asessment, unless there is new scientific evidence that I am not aware of.
Section 5 (Implementation)	I cannot see why we should not continue to work with NICE's current guidance which limits use to appropriate cases
Section 6 (Related NICE guidance)	I agree with the other NICE appraisals, including the 2007 guidance on omalizimab

Name	
Role	NHS Professional
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Real life data on the effectiveness of Omalizumab in severe persistent allergic asthma is currently underway and various other other abstracts presented at international meetings have not been considered. Omalizumab when used in selected patients significantly reduces healthcare utilisation costs and improves quality of asthma control. One cannot blindly recommend for it not to be used in these patients.

Name	
Role	Patient
Location	England
Conflict	no
Notes	I have been on omalizumab now for around 3 years, after being on a short trial that was highly successful. Omalizumab has made such a difference to the quality of my life and has relieved my symptoms to a bearable level. Prior to taking omalizumab my asthma had caused me to become hospitalised on several occasions, almost monthly with stays of no shorter than 10 days. Again prior to omalizumab no medication that i was offered made as much difference to the quality of my life as omalizumab has done. I would really like NICE to consider, at the very least, offering this treatment to people such as myself, that omalizumab has made such a difference to. Without this treatment i fear that i will again become a regular patient at my local NHS hospital, and thus costing the NHS more funds that my current treatment does. Now i feel that you have found a treatment that works well, i think in my case and other similar cases, it would not make sense to try and find another treatment that works as well, when

	you have already established a course of treatments that works very well. If you would like any more details from me, please contact me and i will be happy to provide you any information i can. Best Regards.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I would like my treatment of omalizumab to continue as it works very well for me and i have severe persistent allergic asthma.

Name	
Role	Carer
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	It would be silly to stop his treatment for severe asthma . How much does a visit to A&E cost ? All of these people would visit it several times a month so there is no cost saving if they don't have zolair they e Will cost the Nhs more ! There is a major improvement in my wife's condition she can nearly lead a normal life ! You are just looking at this through a narrow perspective , yes there is a cost 8k year ,
Section 2 (Clinical need and practice)	Not too sure about section 2 it's very medical ?
Section 3 (The technology)	But what a difference in the quality of life ! Need to focus on this ,
Section 5 (Implementation)	Too complex !
Section 7 Proposed date for review of guidance)	Do not let money come before health ! Do not implement the proposed guidance for zolair ! Talk to the area lung clinics [redacted] ! He will advise best

Name	
Role	other
Other role	Relative of asthma sufferer
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I strongly urge the Committee to reconsider its decision. Omalizumab is transformatory for those with severe asthma. Without it, patients and their families are left devastated and with severely curtailed quality of life.
Section 2 (Clinical need and practice)	Corticosteroids as a long-term treatment for severe/brittle asthmatics is suboptimal when compared with Omalizumab.
Section 4 (Evidence and interpretation)	Cost of drug wins out against proven (in-vivo) life-changing impact. Interesting. I urge the committee to reconsider and to continue to make Omalizumab available. Thank you for your

	consideration.

Name	
Role	Patient
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	1.2 - For pre-existing patients on Xolair, does this statement allow for indefinite continuation assuming benefit is maintained? And if not how do you propose patients are withdrawn (which I don't support), personally, as a patient on Xolair for over 10 years (I was in the clinical trial) the only time I have ever needed to be ventilated on ITU was after having my Xolair stopped due to the clinical trial finishing and before Novartis agreed to supply it on a named patient basis until the product was officially launched.
Section 2 (Clinical need and practice)	This is my clinical need, my clinical lifeline, an n=1 trial if you will! I have been on Xolair for over 10 years, I noticed a beneficial effect within 2 weeks of starting the medication, before Xolair I couldn't work, frequent hospital admissions, I was on 60mg of prednisolone all of the time with the associated side effects (including spinal fracture requiring L4-S1 spinal fusion), on hourly nebulisers, I couldn't climb the stairs in my own house and it was a struggle to get to the bathroom, I was on sickness benefit and disability living allowance mobility and middle rate care. Within 2 weeks of being on Xolair I was controlled for the first time in years! I could climb the stairs, I specifically remember not having an attack when my neighbour mowed the lawn and have been able to work ever since, Xolair for me has been life changing, I don't use a nebuliser anymore and have reduced my steroid dose from 60mg daily to 10mg daily, my DEXA scan has normalised and I live life like a normal 36 year old, rather than a 63+ year old with no hospital admissions for asthma during these last ten years!
Section 3 (The technology)	My IgE before starting Xolair 10 years ago was over 700, I was assigned to the highest maximum dose (at that time) during the clinical trial - 300mg fortnightly. The effects were noticeable within the first two weeks - it was that dramatic. My asthma is purely allergic and Xolair works wonders for me. This is what NICE should focus on, I have been on this drug for ages, I have seen many others on this drug and I have thought to myself why are they still on it - it's not working, why was it even started, if someone has an Ige of <200 is it really going to make a difference? The people I have met who appear to do well on it are people like myself whose IgE is really high, and maybe instead of blocking it for all adults perhaps NICE should restrict it for adults whose IgE is above a certain level who may actually get some benefit from it. Also the recommended dosing strategy is different now, my weight has stayed the same in the last 10 years but if I was dosed now the regime is doubled to 600mg fortnightly, twice the price when 300mg fortnightly works wonders for me!
Section 4	I have been concerned for a number of years that something

(Evidence and interpretation)	like this would happen and I urge you to rethink your decision, I am not the only one whose life has been turned around by Xolair, but our dramatic improvement is being diluted by the inappropriate use of Xolair in patients whose asthma does not have an allergic cause or is multifactorial, and in these patient groups all the positive cost benefits of this drug for example reduction in hospital admissions and corticosteroid burden with their associated side effects cannot come to fruition because blocking the allergic response in these patients doesn't solve the problem, compared to someone like me whose asthma is purely allergic and who does feel cured and controlled by this medication.

Name	
Role	Patient
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I suffer from severe allergic asthma and firmly believe that without this drug I would be dead by now. If another patient were to be in my situation and starting this treatment was unavailable, it would be tantamount to a death sentence by slow asphyxiation.Â
Section 2 (Clinical need and practice)	In my case the full spectrum of treatment had been tried. The specialists and GPs had used everything to control my condition and I was still deteriorating. Xolair has made a profound difference to my life. Not only for my asthma but all the other aspects of allergy related problems. It has reduced the violent reactions that used to plague my day to day life.
Section 3 (The technology)	The threshold for administration of this drug is set very high. First a patient must have life threatening episodes and have an IgE level that demonstrates that there immune system is seriously malfunctioning. The cost per year at the maximum dosage is dwarfed by the cost of Ambulance, GP, A&E, Specialists, ward, specialist ward costs. I was a patient who drew upon these services on a weekly or monthly basis. There are additional costs to consider. Quality of life, creating a widow, the loss of a parent to a young child. The drug can also be measured by the massive reduction in IgE.
Section 4 (Evidence and interpretation)	In terms of cost effect and measurement I would propose that the IgE levels be used to confirm the effectiveness of the drug. If this is measured at 16 weeks and 32 weeks the amount of placebo effects is removed. The drug only operates on IgE and therefore it can be used to exclude patients for whom the drug is not appropriate. If the drug is withdraw from patients where the IgE is not significantly reduced then there will be a solid basis for control

	of the spread of the drug to non appropriate patients. There could be a yearly blood test to ensure the drugs continued efficacy. The analysis is somewhat floored as it includes patients who do not fit into the very narrow area of the drugs competence. It also excludes the very patients for whom the drug is incredibly valuable as no double blind trials can be used. This being due to the life threatening nature of the illness. In terms of cost, the analysis is flawed again by the inclusion and exclusion of the inappropriate patience. If the drug is more closely controlled and administered only where IgE levels are high, and that the trial 16 weeks shows a statistically significant improvement, then cost benefit analysis would show a far higher gain.
Section 5 (Implementation)	The implementation guidelines are correct. The only flaw is the conclusion of the benefits of the treatment. It remains a powerful and effective drug for a section of the severe ahstma population.
Section 7 Proposed date for review of guidance)	It is hard to describe the feeling of utter dread that accompanied the discovery of this proposal. I am certain that I would be dead now if it was not for this drug. I understand that NICE must consider the cost befit analysis of this drug, however I would like to advocate on behalf of the other men, women and children who have my particular allergic problems and have not yet been exposed to this drug. Dying from anaphylaxis or a severe asthma attack is an horrific way to end a life. I can speak to this as before being placed on the drug I had been resuscitated on four separate occasions. I called an ambulance monthly, Sometimes twice in a week and had almost no quality of life. This has been completely changed by the drug. This drug works. Its effects are easily verified by monitoring IgE and can give a much higher cost benefit ratio if the patients that do not have the appropriate levels and response are removed. Please, and I ask this as a father who only wishes to see his daughter grow up, do not remove this clinical option from the armoury of the specialists who battle to keep us going.

Name	
Role	NHS Professional
Location	England
Conflict	no
Notes	YOU WILL RECEIVE LOTS OF SCIENTIFIC DATA FROM MANY MEDICAL PRACTITIONER, I AM SURE BUT I AM GOING TO TELL YOU ABOUT THE PERSONAL SIDE I HAVE WITNESSED. I HAVE BEEN USING OMALIZUMAB WITH PAEDIATRIC PATIENTS FOR OVER 6 YEARS.

	ON THE CORRECTLY ASSESSED PATIENTS, IT HAS CHANGED NOT ONLY THEIR LIVES BUT THEIR FAMILIES AS WELL. THIS IS A PHRASE THAT MAY WELL BE OVER USED BUT THESE CHILDREN SUFFER FROM SEVERE, DIFFICULT TO CONTROL ASTHMA WITH HIGH DOSES OF DRUGS SUCH AS ORAL STEROIDS AND METHOTREXATE AND LIFE IS VERY LIMITED FOR THE WHOLE FAMILY. IN MOST OF THE CHILDREN BY THE END OF THE TRIAL THEY HAVE STOPPED OR DRAMATICALLY REDUCED THEIR REGULAR LONG TERM STEROIDS AND OVER THE FOLLOWING MONTHS OR YEAR AFTER STARTING IT, SOME OF THEIR OTHER DRUGS AS WELL.(LESS SIDE EFFECTS AS WELL AS REDUCED GP AND HOSPITAL USEAGE). THEY HAVE GONE ON TO IMPROVE THEIR SCHOOL ATTENDANCE (A GOVERNMENT TARGET) PLUS TAKE UP SPORTS SUCH AS ATHLETICS, RUGBY, BOXING, MANY TO A HIGH STANDARD WITH ONE BOY TO COUNTY LEVEL (ANOTHER GOVERNMENT TARGET TO FIGHT OBESITY). BUT MORE THAN THAT, I HAVE SEEN CHILDREN ELATED WHEN THEY COME INTO CLINIC AND ONLY BECAUSE THEIR PARENTS HAVE ALLOWED THEM TO STAY OUT OVER NIGHT AT FRIENDS OR GO SHOPPING WITH JUST FRIENDS FOR THE FIRST TIME IN THEIR LIVES AND THYE SAY THEY NOW FEEL NORMAL AND ALL BECAUSE THE PARENTS FOR THE FIRST TIME FEEL CONFIDENT TO LEAVE THEM OR EVEN LET THEM OUT OF THEIR SIGHT. THIS HAS BEEN BECAUSE OF OMALIZUMAB. THESE ARE NORMAL EVERY DAY OCCURRENCES FOR MOST CHILDREN AND THESE SIMPLE GOALS SHOULD NOT BE DEIGNED THEM. PLEASE DO NOT DO THAT TO THEM. THANK YOU FOR LISTENING AND PLEASE COME SEE OUR PATIENTS IF YOU CAN AND FIND OUT FOR YOURSELVES.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	1.1 do not agree 1.2 agree
Section 2 (Clinical need and practice)	we work to these standards already
Section 3 (The technology)	agree
Section 4 (Evidence and interpretation)	this drug is costly but if the what price can you put on educate, parents in work and the patient getting work, a family functioning or death? if patients are correctly assessed to ensure that regular BTS treatment is followed but found to not be effective, or that there aren't any other obvious factors driving the condition before commencement on Omalizumab, the difference for the correct

	patients is priceless. Reduced hospital admission, GP visits, prescriptions, side effects and the treatment there of must be considered.
Section 5 (Implementation)	agree Every patients should be treated following the BTS guidelines and monitored by appropriately trained staff to ensure education is given to the patient . May reduce inappropriate use of Omalizumab
Section 6 (Related NICE guidance)	
Section 7 Proposed date for review of guidance)	Is there anyone on the committee who is actually involved in prescribing this drug or administering it to patients? I cannot see any paediatric clinical nurse or a specialist respiratory paediatrician who uses omalizumab on the committee. I can only see paediatrician and he is PICU.

Name	
Role	Public
Location	England
Conflict	no
Notes	My dear friend is on this drug - it has transformed her life and prevented her from having such severe attacks that she was hopitalised on a very regular basis. She actually died and was brought back to life once too. This drug has given her a life as well as continually saving it. Stopping this drug would quite literally be a death sentence hanging over her head. The costs in her intensive care stays were more than the preventative costs of her being on this drug. Have a heart not an accountant's mind and keep her living.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	My dear friend is on this drug - it has transformed her life and prevented her from having such severe attacks that she was hopitalised on a very regular basis. She actually died and was brought back to life once too. This drug has given her a life as well as continually saving it. Stopping this drug would quite literally be a death sentence hanging over her head. The costs in her intensive care stays were more than the preventative costs of her being on this drug. Have a heart not an accountants mind and keep her living.

Name	
Role	NHS Professional
Location	England
Conflict	yes
Notes	Novartis are an industrial partner in the IMI-funded UBIOPRED project, for which I am the Manchester PI
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	After 2-5 yrs of treatment we usually consider a trial of omalizumab withdrawal, on the basis that we do not yet have long term safety data. In the current proposal would we then be able to restart it if the patient deteriorated on withdrawal?. If not we are less likely to try stopping it when there is no safety net.

Name	
Role	Patient
Location	England
Conflict	no
Notes	I am 32 years old & was born with asthma. As I got older, my asthma got worse. 18 months a go I was approved for Omalizumab injections; 2 injections every 2 weeks. Within 2 months my symptoms had improved greatly. 18 months on Omalizumab & my quality of life has improved dramatically. Before starting my treatment I was being treated monthly for recurring chest infesctions and was on oral steriods for 2 years. Since starting my treatment I haven't had any chest infections, antibiotics or steroids. Before the injections I was having to take a huge amount of sick time off work due to my asthma. In the past 12 months I haven't had 1 day off sick with my asthma. Even my dr's are impressed with how clear my chest now sounds.

Name	
Role	Patient
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	As someone who has recently begun regular Xolair injections, start date June 2012, I am dismayed at the possible decision to restrict usage. I am already feeling the benefits of the drug after several years of suffering from severe asthma and being dependent on high levels of steroids. Whilst the recommendation is for clinicians and patients to decide on its continuation this will undoubtedly put increased pressure on funding.
Section 2 (Clinical need and practice)	My condition has led to repeated hospital admissions and disruption to my working life as a nurse. The regular use of steroids has contributed to increasingly negative self esteem and stress which has had a detrimental effect on my life and well being. The course of Xolair injections is finally enabling me to reduce steroid usage and I fell more confident as a result of this. If Xolair was I available I cannot imagine what alternative there would be.
Section 3 (The technology)	A simple injection has changed my life and other than some minor side effects e.g. Nausea, headache it is a straightforward process which does not interfere with my day to day life.

Name	
Role	Public
Location	England
Conflict	no
Notes	Asthma sufferers rely on this type of treatment, i therefore believe it would be ludacris to withdraw it.

Name	
Role	Public
Location	England
Conflict	no
Notes	I think it will be detrimental to asthma sufferers if this treatment is withdrawn

Name	
Role	Patient
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Yes I agree
Section 2 (Clinical need and practice)	Serve asthma suffers should be referred to specialist care and have the opportunity to receive existing or new treatments to help controlled and improve their asthma and general life.
Section 3 (The technology)	The cost of Xolair is out weighed by the cost of treating serve allergic asthma with long term steriods inhalers antibiotics and possible hospital treatments. If Xolair is successful for a patient then the above costs will be reduced as the patient will not require them as much if not at all.
Section 4 (Evidence and interpretation)	Each patient is different and you cannot know if the treatment will or will not be successful until they have conpleted a 16week trial. Xolair treatment should not be stopped because only 4 out of 10 patients respond to the treatment.

Name	
Role	Patient
Location	England
Conflict	no
Notes	I am a severe astmatic under the care of The Royal Bromton Hospital. I have been receiving the Xolair treatment at the hospital every fortnight sice 2007 - when my local PCT funded the drug for me. My symptoms improved dramatically with the drug and it gave me my life back. Unfortunately, over the last few months I have become quite poorly again with my asthma, and my consultant DR Andrew Menzies-Gow has decided to try a different drug regime to get over this episode. He has taken me off the Xolair - with a view to me going back on it in around 6 months time. My worry is if NICE is to withdraw Xolair as a treatment - will I be unable to resume using it??? I'm VERY concerned and worried - this has been a WONDER drug for me - and to have it withdrawn depresses and worries me no end! Please advise!
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	This treatment should NOT be withdrawn from patients - it has been a WONDER drug for many of them, me included,and to deny them it is cruel - this medicine is a vital tool in combating

	A&E admissions - much more expensive than the drug!
Section 2 (Clinical need and practice)	I already take HUGE amounts of steriods - am I expected to use these as my lifeline- with all the side effects - just as is is a cheaper alternative??? How cruel!
Section 3 (The technology)	Surely you can not put a price on life! My, and my families lives were dramatically improved when I was granted the Xolair drug.
Section 4 (Evidence and interpretation)	I disagree - the pros of this drug for severe asthatics far outweigh the cons - it is just a way of saving money - and it is denying life saving drugs from the most vulnerable.
Section 5 (Implementation)	So.....if I move to Scotland I can have Xolair - GREAT - thanks really helpful!
Section 6 (Related NICE guidance)	I expect to be using the A&E dept at my local hospital a lot more over the next few months - using MORE & MORE of the NHS reduced resoures - and I'm sure I won't be alone!
Section 7 Proposed date for review of guidance)	Let's hope I can get my health back on track and get Xolair again before the deadline - but I pity all the poor asthma sufferers out there who will be denied it.

Name	
Role	Patient
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I strongly urge NICE not to deny new patients access to this treatment, which could prove life changing for many. I suffer from Allergic Bronchopulmonary Aspergillosis. For this condition I have been on a treatment of steroids for the last three years. You may believe this to be a satisfactory treatment but it come with it?s own problems. Because of long-term use of steroids I now suffer from the following: Low bone density in my hips, the emergence of cataracts in both eyes, irregular menstrual cycle, facial hair, weak muscles, high blood sugars, insufficient Adrenal function. All this at just age 36. Xolair was my only hope to stop using steroid treatment. If you decide to take it off of the NHS my hopes will be sunk and my problems will continue. The fact that you will allow patients who are already taking Xolair to continue to do so only enforces the fact that you can see it has medical merit. Therefore your decision to remove it from the NHS makes this a cost-cutting venture that is highly immoral. It is being used successfully in Scotland and the USA; they do not come to the same conclusions you do. Once again ? do not put lives of so many Asthma patients at risk with your decision.

Name	
Role	Patient
Location	N Ireland
Conflict	no

Notes	I am a 43 year old woman who suffers from allergic BPA and Bronchiectasis. I have been receiving Xolair injections for the past 2 years. I get 4 injections every fortnight. I live in Bushmills and I have to travel to Belfast, taking unpaid leave from my job as a teacher in order to do this, but I can honestly say, I could not live without them. Xolair(and the supberb care given to me by [redacted] and his staff at Belfast's city Hosp) has dramatically improved my life. Up until this point I was unable to function without high dose oral steroids which adversley affected how I lived my life. I was unable to work, and was on the cusp of being medically retired at 40. Since taking Xolair, I have not missed a days teaching through illness in almost 2 years. I am able to enjoy a life that I had been robbed of for years and for that I am eternally grateful. My husband has a wife and my children have a mother that is not confined to the sofa, overweight and volitile through heavy duty steroid use. My visits to A an E and Hospital admissions are a thing of the past. I know it is inconvenient, tying and expensive to administer, but there isnt a day goes by that I dont thank God, [redacted] and the NHS for Xolair!

Name	
Role	Patient
Location	England
Conflict	no
Notes	Iv had asthma all my life, then I turned 12 and it went downhill dramitically. I was suffering really bad attacks and then when I was 13 I had an attack, needed to be recusitated and was put on a ventilator for a week... This happened again two months later.. Then after that my health went seriously downhill, my adrenal glands had failured, I was on medication, especially high dose of steroids daily which caused further problems. Eg, sickness, dizziness, missing school, complete end to my social life. I was spending so much time in bed in pain and suffering with my asthma, I needed to use a wheelchair on the odd occasions I went out. The doctors told my mum there was nothing more they could do and they didn't no how long I had left. At this point we heard about xolair but had to fight to get it as I didn't feel ready to go yet. I eventually started this and within a couple months I managed to reduce my steroids and I noticed I could do more in my life, the change was amazing, I lost weight and started my social life again..... And I feel very strongly about this drug and will fight for other people till the end,, people deserve a chance like I got.. And if the reason is cost then it deeply upsets and sickens me that NICE would prefer to loose many lifes.. And compare this cost to the hospital stays etc..
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	This is deeply saddening that you would decide to stop new people starting it. It saves people and completely changes some poeples life around. Asthma is not taken seriously but if anyone had the life I had would changed their views in a second. I feel eventually the drug would be stopped all together

	and this would be devastating for the people and their families.
Section 2 (Clinical need and practice)	Long term steroids have a serious effect on people. I developed adrenal failure, massive weight gain, dizziness, sickness, muscle weakness and many more. Then I started xolair and the dosage was dramatically reduced, now I'm on a dose that would not cause an effect on the body. But I would not be here if it wasn't for xolair.
Section 3 (The technology)	If we are looking at my sitiuation before I was on xolair and add up costs of- weekly admission to hospital for asthma and the treatment to help control it and the stays in hospital, being in intensive care on ventilator, consultations, doctors appointments, other admissions and appointments for further probs caused from medication, mri, ct and other investigations that was needed.. And that is not even the half of what I needed from nhs... Then now look at cost of not needing all these... Its so saddening and very discriminatory against asthmatics to basically decide that they would rather lose lifes and devistate families just because the cost!!!!
Section 4 (Evidence and interpretation)	The evidence that xolair works is that I am sitting here writing this.. If it wasn't for xolair I would not be here not fighting for people to have the right to their life.
Section 5 (Implementation)	Yes this guidance is important.. But what's more important is speaking to people like me and visiting the seriously ill that will have no other option if xolair is taking away.

Name	
Role	Public
Other role	
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	People should be able to take Omalizumab for as long as it improves their quality of life not until you run out of funding
Section 2 (Clinical need and practice)	I have watched a young girl in her 20's struggle with her breathing, have to give up her running and reduce her quality of life. This treatment is the only positive thing she has had available to her that gives her the opportunity to be normal again.
Section 5 (Implementation)	The right for a person to have a good quality of life should not depend on the cost of the treatment they need. People who have received positive results from this treatment should have the right to continue having their life quality improved and not have to spend their time fighting to be able to live their lives like the rest of us.

Name	
Role	other
Other role	spouse of patient and prnciple carer
Location	England
Conflict	no

Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Im concerned that the announcement of the review may send mixed messages to cash-strapped NHS prescriber's who may withdraw funding for their existing patients.
Section 4 (Evidence and interpretation)	In our own experience, my wife a patient receiving Xolair, in the 1st half of this year she had three acute admissions to our local hospitals via ambulance, A&E and resus, in one admission needing an Intensive Care admission for a short spell. Since starting Xolair injections, she hasnt needed to visit A&E at all in the 2nd half of this year. That represents a considerable saving to the acute hospital sector.
Section 7 Proposed date for review of guidance)	Announcing the review on November 9th and inviting comments by the 30th is quite short notice for the public to be alerted and submit their comments.

Name	
Role	Public
Other role	
Location	England
Conflict	no
Notes	My friend is using the treatment at moment and seems to be doing great, she has been using for the past 2 .5 years, she feels great , please dont stop this.

Name	
Role	other
Other role	Parent of asthma sufferer
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	My daughter aged 19 has severe persistant allergic asthma. She has has the drug injected for the last few months. It has made a dramatic difference to her lifestyle and therefore appears to recommend itself for use on sufferers of spaa, regardless of what is in its marketing authorisation.
Section 2 (Clinical need and practice)	Before receiving Xolair my daughter had been on oral coricosteroids and injected steroids [Kenalog] and has suffered severe side effects. She has had so many courses of steroids and emergency admissions to hospital I have lost count.
Section 3 (The technology)	Although Xolair is not the cheapest drug, it has made such a difference to my daughter's lifestyle. She is able to live away at uni and study /work as a student nurse.m

Name	
Notes	Please may I forward my comments on the above, please find detailed below my concerns which I hope may be taken into consideration for the appraisal committee meeting on the 22nd January 2013. My daughter was diagnosed with asthma when she was 18

	months old, over the years numerous doctors have tried a variety of different medications none of which prevented frequent asthma attacks which resulted in either steroid administration or hospitalisation or a mix of both. For 19 years I have strove to get her the help she needed, a GP even said if it did not get it under control, due to the frequency of the attacks, by the time she was 40 her lungs would not function as they should. Since she was referred and accepted for the xolair treatment her life has changed dramatically, the change in her breathing and the amount of times she had to take salbutamol were noticeable within a few weeks and she has not had to use steroids or attend hospital since she has been on this treatment. Prior to the treatment she took salbutamol on average 8 times per day and it still did not fully stop her wheezing or coughing this is the only medication to give her a normal day to day life. She has never smoked or been around smokers and as a family we try to manage her surroundings to minimalise any influences that may affect her but season changes and the weather have a huge influence of her condition which we cannot control. When I think of the quality of life she had prior to this treatment and the years we struggled to find something that could help her and then the relief and hope we have had since she began the treatment I cannot comprehend that if this medication is no longer available for her that we may have to go back to the quality of life as it was before. I hope that the bigger picture will be taken into consideration when considering the future of this treatment as surely the cost out ways the costs of the numerous GP visits and hospital visits that would become necessary should the treatment be stopped as well as the quality of life of my daughter.