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

Patient England I have had diagnosed Ulcerative Colitis for 10+ years at this point. To date, Infliximab has been the only medication that has actually kept me out of being admitted to hospital for the period of more than a year and that was just the initial 3 dose induction. I have been fighting to receive the treatment again, as I am into another flare-up, but am having such difficulty in receiving the help that I desperately need.	As a woman who is 45, with 3 children at home ranging from 6 to 16, Colectomy is not an option for me. I have not responded to normal treatment and the disease also appears to be steroid dependent. Infliximab was difficult for me to finally receive, but after 8+ years, I finally received the induction treatment, which worked fantastically well for me. I feel that people sitting on the panel do not understand the people that this illness effects. It has a massive impact on my daily life, particularly when I am in a flare-up. I have trouble traveling on public transport, based on the illness. I cannot commit to work, as my illness can see me sometimes hospitalised for periods of two weeks, no employer wants that. It puts pressure on my partner and children. I think that Infliximab and drugs of this nature, with such a high price should be considered on a case by case basis, rather than a broad sweeping generalisation. I know of someone personally who was diagnosed with Crohn's disease and had the surgery to remove the ill portion and has not had a flare-up since the operation, yet was approved for a year's course of Infliximab. This to me makes no sense, but they were given that simply because they have Crohn's disease. I think that was NHS money that was misappropriated. There are people with Ulcerative Colitis that urgently NEED this treatment, but for the fact that it is not Crohn's disease, cannot receive the treatment. I find this very wrong.

NHS Professional England I have contributed to ad boards for MSD, Abbvie and also delivered lectures regarding biological therapies to IBD Nurses at Bradford University.	Most patients are diagnosed in their late teens, early twenties before they are settled in a career, university or within a relationship. The unpredictability of the disease blights their career prospects, university attendance and causes self-esteem problems that make it difficult to establish a settled relationship. Faecal incontinance is common.
NHS Professional England I have contributed to ad boards for MSD, Abbvie and also delivered lectures regarding biological therapies to IBD Nurses at Bradford University.	Steroids are not recommended as a long term treatment for Ulcerative Colitis.
NHS Professional England I have contributed to ad boards for MSD, Abbvie and also delivered lectures regarding biological therapies to IBD Nurses at Bradford University.	Surgery can be complex and may result in a permanent ileostomy which has it's own financial and emotional costs. Poor pouch function following surgey affects 10% of patients with a pouch. Fertility can be affected and most women are advised to complete their family prior to opting for pouch surgery.
NHS Professional	For those patients who either refuse surgery or are not suitable due to other co-morbidities, long term steroid use often results in osteoparosis, diabetes and hypertension increasing the risk of strokes and

England I have contributed to ad boards for MSD, Abbvie and also delivered lectures regarding biological therapies to IBD Nurses at Bradford University.	cardiac events.
NHS Professional Wales	This is an incredibly dissapointing and short sighted decision on behalf of NICE. My working day is taken up with caring for these patients, many of whom have a very poor quality of life. This decision means there is nothing else to offer them when Aza/6MP fail/are intollerant too. This results in either risking their health on long term steroids or major surgery, and for some this last option is the worst possible scenario. I implore you to put the patient at the heart of the decision and to consider the effect your decision will have, by taking away a potentially life changing treatment option from them.
Patient England	As someone who has had Ulcerative Colitis for 23 years without drugs like Infliximab I would have had to have surgery a long time ago. As I really don't want to go down this road yet these type of drugs are the only way I can have some semblance of a life. I really hope you give the go ahead for the use of the rest of the drugs as it is a great lifeline to those of us who would like to put off surgery for as long as possible. I can not stress enough how miserable my life would be without the help of these drug, I would be virtually housebound.

Patient England	As a patient I have been treated with aggressive Steroid treatment, Mesalazine and Azathioprine with little impact on management and maintenance of my condition. In 2001, while in my early 20's I was struggling to attend University, was in considerable pain and had never successfully achieved remission of my illness. By the age of 21 I had already been diagnosed with Osteoporosis and had developed a severe allergy to Azathioprine, with severe trauma and scarring in my lower colon I had very few medical options open to me when I was first given Infliximab as IV treatment. I was initially given a one off dose with a further dose to follow several weeks later followed by a third and final dose a few weeks after that. The treatment changed the course of my condition, I was initially able to return to my degree studies and engage with normal life, however this remission period lasted only a few months before the symptoms returned, my Specialist arranged for a further dose of Infliximab, my symptoms subsided and I was able to return to studies and normal life. It became clear I was living in a cycle of sustained well-ness followed by sudden on-slaught of symptoms 3 - 4 months later. By the time the effectiveness of the Infliximab was wearing out I had returned home from University, I was unable to arrange care with a suitable GP at the other end of the country or make the journey back to see my regular Specialist. Finally in agony from pain, heavy blood loss and lack of energy I was admitted to my local hospital, unable to treat me with Infliximab they returned to emergency Steroid treatment to get my symptoms under control. Having spent many years heavily dependent on steroids I was terrified and traumatised about the psychological impact and physical and mental dependency that steroid treatment would induce. By the time I was well enough to return to where I had knowledgable, Specialist treatment I had missed my University exams and deadlines. I was forced to drop out of University, however I also faced the situation that I had no-where to live in the area without my University accommodation, and without my place at University I was not allowed to stay in the accommodation, I could not return home because they could only treat me with steroids or surgery. I felt trapped in a city 300 miles away from family, no place to live, money or support, however I did have a Specialist who enabled me access to a medication that gave me a life rather than just an existence. My Specialist continued to offer me Infliximab, with cautions in 2002 that it was a new medication and I could not know the long term prognosis. Within a few months my symptoms were again under control, they did however feel like they were beginning to return 3 - 4 months after treatment. My Specialist put forward the case that as alternative treatments had not been successful with me that I should be allowed to have Infliximab on a regular basis, I commenced an outpatient treatment program, receiving IV infusions every 8 - 12 weeks. In 2004 I eventually completed my degree, I previously had big ambitions to travel the world and to live and work in London, however I knew that that life style was not open to me to be able to successfully manage my condition at the same time. I felt compelled to shape my life and career in York where I had been at University as I was terrified of what would happen if I was no longer able to have access to the medical expertise or treatment that had given me an opportunity to have a life.

	My treatment continued, visiting the local Out Patient clinic at the hospital every 12 weeks to receive Infliximab infusions. After I had completed my degree I was able to start searching for professional employment, I was able to attend evening classes to gain further qualifications. I learnt to live within the parameters of my condition and learned how to manage it to ensure I could live a fulfilled life despite it's limitations.
Patient England	In 2008, after 6 years of treatment with Infliximab I suffered a sudden and un-explained reaction to the treatment within a few minutes of the infusion starting. My treatment was altered to Adalimumab injections that I would manage and administer myself. By this point in my career I was close to reaching 30, I was in a settled relationship, but did not feel I could consider having children due to the strength and dependency on medication, I was working hard to develop a career, working full time, studying a Masters and undertaking Freelance work as well. I was living a socially active and full-filled life, the injections gave me a greater freedom to consider further options and opportunities and encouraged me to consider how I could take some of the chances that were previously closed to me. In 2009 I started developing my own business, my symptoms had been un-seen for nearly 2 years and I felt healthier than I had ever felt previously. I had felt previously that the fear of being unwell in the future meant that I should maintain employment with a large public sector organisation for my own protection. I was well enough that I decided I would take a chance and launch into my business full time, without depending on the security that public sector employment afforded me. At the same point I was conscious that at the age of 30 my choices for life and my future might be limited because of 15 years of continual medication and unknown side effects. I was keen to try and live a healthier life and without the need for drugs. The scarring in my lower colon continued to act like a barometer for my general health, but I was showing less symptoms in general. Feeling at optimum health I started to leave longer periods between my injections. It has now been over 4 years since I last had any treatment, I have lived drug free since that time. I still run my own business, but have since opened a cafe/shop and employ 20 members of staff. I have learned to live with the limitations of my condition, but I have also learned how to manage it to ensure that it does not manage me, this discipline has allowed me to embrace challenges and ambitions I had felt previously were not open to me. My Specialist now considers me to be free from illness and has taken continual tests to corroborate this theory. My scarring continues to act as a barometer, which I dutifully read to ensure I can effectively manage my own health. I have no doubt that the struggles with illness, access to medication, managing treatments, symptoms and demanding access to effective healthcare have prepared me for the stressful demands of running a business, however I am equally certain that these treatments that I received have changed my prognosis and outlook from almost certain surgery and unfulfilled ambitions to being a contributor to the local

	economy. I will forever be grateful to my Specialist and the difference that these drugs made to what in my mid-twenties seemed an impossible dream.
Patient England	I've had crohn's/uc for 6 years now, it took 4 years of using conventional drug treatment before I was given infliximab, during those four years my life totally changed, I was a confident, outdoor person who was always doing things, when uc hit I couldn't be further than 20 feet from the toilet, I would need to go 15+ times a day and was always in pain, in order to work I would take Imodium everyday, which didn't always work. On two occasions I soiled myself at work, not good when you are a teacher in front of teenagers. Steroids and other chemical based drugs have hardly worked for me. Even while on steroids I still have an urgent rush to the toilet at least 6 times a day. The illness is unpredictable which means you can never plan a day out or trip, relationships are difficult to say the least, how do you explain to a new partner the flatulance and constant running to the toilet? Luckily for me my pct put me on humira 3 years ago. This was AMAZING! I can not explain what it's like to get some part of your life back, to be able to go to the cinema and not have to worry where the toilet is, or to plan and go for a meal with friends. Without humira I would of had to give up work and with out a doubt would suffer from depression. Unfortunately after a year of humira I suffered from a reaction and thankfully I was put on infliximab, I'm still crossing my thingers that this will work long term for me. If the biological medicines get taken away from us crohn's and uc sufferers it will undoubtedly cost more, I could not cope with a colostomy bag, would be suffering depression, have to give up teaching and work and have to sign on. Please, please, please, think about the patient and not just the money, I can not explain how much a difference the biological treatments mean to us and help us try to live a normal life. Kind regards [redacted]
Public England	I have lived with Crohn's Disease for the past 20 years and I can speak from experience about the life-changing effect of starting Infliximab treatment. I had been on and off other medications including prednisolone and azathiaprine, but had not been consistently well for more than a year. I had come to accept that I would always have to live with my symptoms; never knowing what the future would hold. I didn't know if I would be able to work or have a family and I was extremely private and embarrassed about my illness. After starting infliximab treatment in 2005 my whole life changed and I have been symptom free for the past 9 years. I now work full time as a teacher, am planning to start a family soon and I am so grateful that I have never had to have any surgery. Having experienced this personally I want others to be able to have same chances of recovery. It may not be as effective for everybody but as Crohn's and

	ulcerative colitis are so similar there may be a chance, and I believe everybody should be given that chance.
Patient England	I am an ulcerative colitis patient and I have read this paper. Not all of it makes sense to me however I have had infliximab. I now have 2 small children and have had a many flare ups. However between my first dose of infliximab in nov 2011 - April 2014 (2nd baby born feb 2014) I had no problems and went to the toilet once a day. In 2011 I couldn't pick up my daughter from the cot because I was so weak from going to the toilet with virtually no warning around 20-30 days. I have literally just had another flare up this week and have been told to get infliximab I have to come into hospital for a few days to have hydrocortisone first to see if that works. But I can't cos I can't leave my children. When hydrocortisone has never worked for me in the past. I don't understand why I can't just go in for the day to have infliximab and then go home to my 4 year old and 7 month old. This drug gives people their life back and should be given at any cost.
Patient England	I have suffered from UC for over 35 years and Infliximab is the first treatment that has kept me in remission for an extended period of time. In 2009, I had a major flare up which saw me hospitalised as an emergency case. Following the hospital admission my consultant decided to try Infliximab as an ongoing treatment (I have previously been prescribed azathioprine and mercaptopurine but both have caused liver problems). I had my first three treatments of Infliximab, which other than psoriasis (which is much more preferable than UC symptoms) caused no other effects which affect my daily life. I continued with Infliximab for another 9 months thanks to the efforts of my consultant but funding was then withdrawn. Within two months I had another flare up which immediately started to affect my everyday life and actually resulted in me having to leave my full time employment. My consultant managed to get me back on the Infliximab which I have now been receiving every 8 weeks for the he past three years. It is the most effective treatment I have had in the past thirty years. It is the only treatment I now have as I have been able to come off all other medication. I have two children and since I have been receiving Infliximab I have not had to worry about everyday activities - I have been able to go out and enjoy mine and my children's lives without the worry. I only wish this treatment had been around earlier. It is effective without life affecting side effects and has now kept me in remission for over three years.

Patient England	I have suffered with moderate to severe ulcerative colitis for about eight years. Unfortunately I am one of those patients who don’t respond well to conventional therapy. I have been hospitalised with acute UC on a number of occasions and each time have been able (with some difficulty) to get Infliximab. Each time I have had it my bodyâ€™s response has been dramatic. The symptoms of UC go within a day or so and I begin to feel well again. I have been allowed 3 doses of Infliximab in accordance with the NICE guidelines for treating an acute flare but have been unable to obtain maintenance doses. This results in remission for about 6 months and then the symptoms of UC start to come back and I start to decline until ultimately I go back in hospital as an acute case. The decline puts a lot of stress on me and my family and it's hard to work (although I do). All the consultants I have seen agree that I would make a very good candidate for maintenance dose therapy of Infliximab but we have yet to get approval. The cost to the NHS of me being hospitalised, not to mention increased visits to see consultants, blood tests etc. must far out way the benefits and cost of maintenance dose therapy. I have seen consultants at Barts and in Harlow we have even consulted Professor Alistair Forbes (an eminent gastroenterologist) who have all agreed that Infliximab would be the best course of treatment for me. It is hard for me as a patient to put up with such suffering when I know that there is a drug that gives me my life back and makes me feel normal again. Last year my UC manifested itself as pyoderma gangrenosum and arthritis again the dermatologists and rheumatologists wanted to use Infliximab but were denied, resulting in a huge amount of pain and a very scarred leg. Instead of going to see consultants and them tell me how sorry they feel for me but they canâ€™t help (as happened a week ago at Barts in London and many times in the past) it would be great to get the therapy that gives me my health back and enables me to live a full and happy life.
Patient England	I'm a patient with moderate to severe Ulcerative Colitis. I can not take any conventional therapy as I am intolerant. Azathiropine was affective until repeated pancreatitis forced me to stop taking it. At that stage I had to have Infliximab privately and it was a miracle treatment for me. I was out of hospital within days and felt normal for the first time in years. Unfortunately my private medical insurance didn't cover ongoing treatment so I couldn't take it past 3 doses. At this stage the NHS had nothing to offer me as they would not continue Infliximab for me. I am left now on an experimental treatment â€“ Tioguanine â€“ that I know of no other patient taking and is not even licenced for Ulcerative Colitis. This has some very nasty side effects and poses a risk to my health but I was left with no choice. I'd say I was at 90% full health with Infliximab and maybe 50% with Tioguanine but it's better than I would be after surgery.

	I'm now having blood tests monthly, MRI scans on my liver and possibly a liver biopsy to hopefully catch any side effects of Tioguanine before they become too serious. Tioguanine is not a viable long term solution. I need Infliximab for maintenance of my condition. Your ruling just seems insane for people like me who have no other choice. I no longer have private medical insurance so should I get ill again I don't know how I will afford Infliximab but if I get ill again I will need it. I believe that Infliximab should be used to keep patients like me in remission. I have no other licenced choice and surgery is not a treatment.
NHS Professional England	The impact on a patients quality of life of active Ulcerative colitis should not be underestimated, often the severe urgency resulting in incontinence and severe fatigue result in patients living a hermits existence. many will do badly in GCSEs and A levels detrimentally affecting the rest of their careers, they may not go to university as planned as a result and suffer huge loss of potential earnings. Many will have to give up work and do not leave the house and so have no social life often resulting in depression. The impact of these costs on the person involved and on the economy in general must not be underestimated.
NHS Professional England	For those who will not consider colectomy, or in whom it is contraindicated due to co-morbidities or extent of disease (i.e. proctitis) long term steroids are often the only option. These have major potential health implications such as osteoporosis, glaucoma and diabetes all of which have major cost implications.
NHS Professional England	I would ask the committee to put themselves in the patients shoes, can they imagine being told in your teenage years or early twenties that you need to have major surgery and a colostomy bag. These patients are just embarking on education, work life and building relationships. They are just discovering who they are as a person and building their self esteem, body image and self confidence. For many the idea of a colostomy is an unthinkable scenario and they cannot imagine how they would function or meet new people with a colostomy in situ.
NHS Professional England	I am concerned that patients who fail conventional treatment will be denied bio logics which do have evidence for their effectiveness. tHis could lead to patients becoming dependant on steroids, increasing their risk of long term side effects such as diabetes and osteoporosis which will Impact on the health economy. they will have to endure poor health, poor quality of life, and be unable to work. Patients will require more hospital follow ups. There will probably be an increase in patients requiring colectomy, which is mutilating surgery for this group of patients who are generally of a younger age, there will most likely be an increase in patients requesting ileoanal pouch reconstruction, therefore more investment into centres that provide this surgery will be required. There will also be an massive increase in the individual funding

	requests to the clinical commissioning groups, adding extra work load to the clinicians involved with these patients.
NHS Professional England	As a health professional and a sufferer of UC I am saddened to read this document and the conclusions. As a health professional I have seen numerous UC patients improve and thrive on these biologics, not only in regards to their medical health but also their QOL. From a personal point of view I have received Infliximab and adalimumab which have provided me with an excellent QOL and enabled me to continue my working role in the NHS. I received 4 infusions of Infliximab 4 years ago and remained in remission until a surveillance colonoscopy triggered a moderate to severe flare this year. I was very fortunate to be enrolled on a humira trial for 6 months this year and the response was immediate. I am now in remission and did not miss 1 day of work, avoided a hospital admission and avoided an increase in my medications. I did not need to see my GP nor consultant about my UC during the trial and only saw the trial doctor as per trial protocol. Surgery is not an option for me, ever. I find it hard to believe in todayâ€™s medical world that biologics are not the most cost effective way forward. As a health professional with an interest in IBD I have read numerous international papers demonstrating a medical benefit, cost benefit and QOL benefit. From my case alone I have proved how cost effective it can be which compares well with what research is demonstrating. This is a very sad step backwards for IBD patients and to see NICE choosing to restrict UC patients to surgery (or at best 3 infusions of Infliximab) if second line treatment fails is very upsetting and prejudice to this group of patients. This will lead to poorer patient-doctor relationship and increased stress in this patient group due to the limited options available. Yes, I know that side effects are expected with most drugs. However the 1st and 2nd line treatments for UC are not without their own devastating side effects which impact upon QOL e.g. steroids and their known negative impact on bone health as well as development of diabetes in some patients both of which are also costly for the NHS. To conclude, I am immensely disappointed in NICE from both a patient perspective but also as a health professional who strives to first do no harm, puts patients first and takes on board patient choice and overall well being. This proposed guidance will do harm, does not put patients first, removes patient choice and will lead to reduce QOL and well being. It is in short shameful.
Patient Wales	As someone who has UC, currently in remission and taking azathioprine, I would be extremely concerned if surgery was the only option left to me if my current medication did not work. Biological drugs such as infliximab give us another - vitally important - chance of controlling our decision medically and living normal lives, rather than have to undergo invasive and emotionally humiliating surgery. Please reconsider this decision and don't treat UC patients unfairly!

Patient N. Ireland	I am a 30 year old Female who was diagnosed with Ulcerative Colitis in Oct 2011. Since then i have been hospitalised 6 times due to severe flare ups. UC has a debilitating effect on my entire life from work to personal to social. I strive to lead as normal a life as possible but its not always an option. Last year i was given infliximab (only 3 doese) and i felt the effects within days. For the first time in two years i felt like a 'normal human' again. I was in remission for 12 months and in that time i took up exercise, got a promotion at work and got married. I finally felt i was turning a corner. I even felt i could start to think about planning a family with my new husband. Unfortunately in Sept 2014 i had another sudden flare. I truly believe if i had been given the infliximab as maintenance i would still be in remission and would not have had this flare. I feel like i have fallen back to the reclusive, demotivated, sick individual i was before the infliximab. I have been given the oppertunity to have another 3 doses of infliximab but its sad that i have to get so sick in order to get it rather than having it as a preventative measure. Infliximab could give me and i am sure many others the chance of a normal life again.
Patient Wales	Whilst I appreciate the cost implications of having these treatments made available to sufferers of ulcerative Colitis, having the condition myself and having many family members who suffer both from Colitis and Crohns, I also know how important it is for patients to have this treatment option. Obviously these types of treatments would be used when all else fails, if this treatment option is taken away from sufferers of ulcerative Colitis then their only other option in many cases would be to have to undergo surgery, which although both treatments come with risks and long term effects, I hope you would agree that surgery is much more damaging, especially psychologically. I hope you take my views into consideration, at present I'm lucky enough to be in remission from this debilitating disease, but it would be nice to think that if I ever needed these biological treatments in the future that I would be able to. Many thanks [redacted]
Patient England	I have suffered from UC for 6 years, I have been on as asacol, azathioprine, prednisalone and predfoam, all of which helped me for a short time. Despite these drugs flare ups were frequent and debilitating. I was unable to work due to fatigue and I was going to the loo up 30 times a day. As a last ditch attempt to get my life back I was put on weekly humeria injections. I had read a lot of positive things about infliximab and adalimumab but I was sceptical about the treatment as nothing else had managed to keep my UC at bay. I have now been in remission for 1year and I can honestly say it has changed my life. I'm able to do all the normal things that I used to do without being in constant pain, needing the toilet every 15 minutes and without being exhausted all the time. I don't take a single day for granted and I am so unbelievably grateful

	that I was lucky enough to have this treatment. The fact that this treatment exists but may not have been available to me is a harrowing and saddening thought as the only other alternative would have been life changing surgery. Humeria has been an absolute miracle cure for me and I really hope it's able to help other people who are suffering like I was.
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Patient Wales	I am 19 years old and have had UC since 2012. During this time, I have had 2 courses of steroids and been on azathioprine and asacol for almost 2 years. I take vitamins and probiotics and eat a healthy diet but struggle to maintain my weight and am underweight for my height. I have tried alternative medicine and treatments, seen a gastro dietician and have excluded different food groups but to date nothing has reduced my symptoms. To date I have not been in remission. This has negatively affected my studies and meant I am unable to work. I rarely leave the house as my life revolves around having ready access to the toilet. I do not have a social life as a result and my personal relationships are affected. The only time I leave the house is for medical appointments. I am aware of people whose symptoms have increased greatly after having infliximab. To date I have not received this treatment due to the cost of the treatment. My consultant believes I would benefit from infliximab but has advised this is a financial decision. I feel strongly this treatment should be available for patients who need this.

Patient Scotland	Infliximab is the only medication which has been able to keep my ulcerative colitis under control. At the age of 16 I started to feel poorly. At 17 was diagnosed, tried five different kinds of medication which all meant I had to restart my prednisolone and became dependant on it, was hospitalised for two week and it was only infliximab that saved me from having an emergency operation to remove my large intestine. Infliximab is literally liquid gold for me. I am now 18 and thanks to infliximab can finally go to uni, socialise with friends and lead a completely normal life all thanks to infliximab. I no longer have to take 18 tablets a day and time them and take them whilst in school which I found embarrassing. I can now leave the house without fear that I will need to rush to find a toilet. I no longer have to deal with having panic attacks and not wanting to leave the house because I was simply a mess.Please don't take infliximab off the nhs, UC is a serious condition which affects mostly young people and anything that can help them sustain a normal life should be used. I have finally gained my life back, please don't take that away from me.
Patient England	I was suffering from a very severe flare up of UC in 2010. I was unable to work and had 2 options left after steroids, cyclosporine, azathioprine and asacol had failed to get my condition at a manageable level. They were surgery to have my full bowel removed or infliximab. I chose infliximab and after 1 year my condition was what can only be described as normal. I am working again full time and have also been able to become a father, neither of which would not have been possible without trying infliximab.

Patient England	Infliximab has changed my life completely.before I started on imfliximab I couldn't go on holiday....I couldn't go shopping....all i did was sleep...poo....and just about hold a job. All three I did very poorly. I had to have a toilet blocked off specificly for my use...because I wouldn't be able to wait..my life was a living hell. I was in constant plain My diet was limited to bananas ,Chips and chicken and rice. On my time away from work I would sleep. I never had time to spend with my son as I would either be sleeping or sitting on the toilet. Then my specialist introduced me to infliximab. I now only go to the toilet three times a day. I sleep for nine hours. I can play with my son and my granddaughter...I can go out of the house and I can go shopping. I don't think you can understand how valuable these drugs are until you have been in the awful situation that us user have been in. They gave completely changed our lives. The thought of having to stop these life line of drugs is depressing and I don't know how I will cope. I will have to give up my job... I won't like other users will end up in a living hell... We won't be able to work and will end up pooing in a bag... This is not the course I want my future oath to take. Please do not stop this service If u wish to speak to me please call or email me...

Carer England	My daughter is 7 years old and was diagnosed with UC two years ago, she started off with mild to moderate colitis and in the past two years has tried all the medications available...some of which she had a bad reaction to and some of which she is still taking. Following a recent scope, we have been advised that her condition is now severe. We have no alternative but to start Infliximab. The only alternative would be surgery. We are counting on this medication to help her colon to start healing, she is leading a normal life, not missing school and looks perfectly healthy, no one could imagine what her insides are going through, its impossible to tell without a scope. We do not want to have to put her through surgery as it really seems unneccessary so we are really relying on the infliximab. From my point of view, it would obsurd to rule this option out so I plead with you not to withdraw this hope from our lives.
Patient England	I am alarmed at the suggestion that Adalimumab may not be a cost effective treatment for moderate to severe Ulcerative Colitis and Crohns Disease. In my personal experience it has been extremely effective in treating my condition. I was first diagnosed with Crohn's disease when I was 18 in 1979. I was treated with a strong course of steroids and Sulphasalazine. This seed the condition but occasional flare ups continued culminating in a severe case which required an emergency Hemicolectomy in 1987. My medication was changed to Azathioprine. I had a period of several years of remission but flare-ups returned and my life style become significantly affected. I had to be extremely cautious with my diet avoiding any high fibrous foods, too much sugar or eggs all of which would either leave me in extreme pain or with serious bouts of diarrhoea. Whilst I am very aware that my condition was relatively mild compared to many sufferers it was none the less extremely debilitating, I was unable to enjoy the freedom to enjoy life as I wanted, I felt unable to venture far from home, was off work many times and had a number of hospital stays. In 2010 the decision was taken to attempt a bowel resection as the scaring around the surgery site from the 80's was contributing to my condition. I was admitted to High Wycombe Hospital in September of that year. Unfortunately the surgery was far more complex than originally considered, I needed a second operation within a week of the first and culled with a number of other complications I was seriously ill. As I needed more specialist care I was transferred to The John Radcliffe hospital in Oxford under the care of [redacted] one of the most eminent consultants in the field. [redacted] prescribed Adalibamab which I continue to take every 14 days. Since my final discharge from hospital I have experienced a complete transformation in my health. I visit Dr Travis every six months and have had a Flexible Sigmoidoscopy every year to check

	the condition surrounding the surgery site in my bowel. There has been no sign of a reoccurrence of Crohns. My lifestyle is now as close to normal as it could possibly be, I can eat whatever I like, I have freedom to travel, I play tennis and enjoy my work. I have not had a single day off work through ill health since returning after my surgery. I am in no doubt that my medication and in particular Adalibamab has made a huge contribution to maintaining my health. The degree of surgery I have had means that I cannot possibly contemplate loosing any more of my bowel, the only options open to me should my Crohns return would be more costly hospital visits, surgery and a Collostomy thus severely restricting my quality of life. I have complete confidence that Dr Travis has made a very informed decision to prescribe Adalibamab to treat my condition and that on balance it is a cost effective treatment given the huge outlay that hospitalisation incurs. I sincerely hope that you will reconsider advising against the use of these drugs to treat UC and Crohn's disease, in my opinion and experience they are a valuable addition to the means for combatting these deeply debilitating conditions.
Patient England	I believe the recommendation that influx iamb and other biological drugs shouldn't be used to treat and maintain ulcerative colitis is frankly quite shameful. From my own experience I have seen first hand the quality of life infliximab have me back and how it was taken away and I suffer now despite being on a high dose of azathioprine and mesalazine. Steroid medication does not work for me and being asked to take it repeatedly when I the side effects have had a catastrophic effect on my well being. I am a young person and cannot understand why I will not be given a medication which in the past has induced and maintained my remission and thus a normal quality of life. I feel who ever wrote the report doesn't understand the debilitating symptoms of ulcerative colitis and how they can destroy relationships and wreck a persons life. My illness has at times become so severe that I have dropped out of university twice and struggled with my studies. Infliximab made me feel normal. I have been hospitalised twice for a period of 8 weeks in total, how can it be cost effective to let my flare ups get so severe that I end up in hospital when regular infliximab infusions would avoid this totally.

	I look forward to hearing from you and hope you reconsider.
Patient N. Ireland	I am an unfortunate patient that has suffered now for 7 years with Ulcerative Colitis. I was seriously ill in 2007 and fortunately with the help of cyclosporine I bounced back. However since that I have been on many various tablets. Many of them however did not agree with me or the side affects were so bad I couldn't cope. At the moment I am taking Mercaptopurine 50mg and Balasalazide 750mg. In June 2012 I got infliximab which worked fantastically well. I couldn't believe my luck until Christmas past when things started to go down hill again. I received Infliximab again in April 2014 past and again to my delight the bleeding has stopped again. However, the point I wish to make is: When receiving Infliximab the first time there was a lady in the same ward with Chrohns that was receiving Infliximab on a regular basis but said it wasn't helping at all. Why then were they giving it to her? I also spoke briefly to a lady in April past and she also stated the same thing. Again why give it to those it doesn't work for? And yet argue with people like myself who it does work for? I just don't get it! Also if you were living with this condition you would feel differently about trying to cut it from the NHS!
Patient England i was not followed up and when i said i thought my condition had got worse because of the infusion i got no reply	i was diagnosed with micrscopic cologenous colitis and was recommended to have infliximab to help with condition and rheumatoid arthritis after only two days of the first infusion i became ill with shingles and could not have the second infusion . i have had 5 bouts of shingles and been really ill for 12mths and no improvement on my condition..

Patient England	This product (infliximab) has been vital for me as a UC sufferer - it enabled me to come off prednisolone and get control of a flare which hospitalised me 3 times in 9 months and required me to receive blood transusions etc. Azathiaprine would not work on its own for me and this drug allowed me to rebuild my life and return to work and look after my son properly. This year i felt normal again, regained weight, was able to sleep and was much less anxious. The thought of surgery makes me anxious and depressed and have suicidal thoughts - it is not a cure for the condition and surely must cost more in the long term - surgery would be inevitable for me if biologics were removed. Even if biologics only gave me a few additional years without surgery at least my son would be older and it would be easier to explain to him why he can't jump on me or why i can't face taking him swimming. This drug is vital to my physical and mental health. Please reconsider withdrawing this - we would be the only country in Europe not to offer this apparently if this proposal goes ahead.
Patient England	I can't pretend to understand all the medical information contained here as I am not a medical practitioner. I am writing as a patient who has been on infliximab for 18 months. I have to tell you that it was an overnight cure of UC for me - mine was severe and was impacting badly on my life. I was facing having to give up work (I was only 47 when diagnosed), I had to go to the loo several times a night so never had a good nights sleep, my joints were beginning to ache as I never absorbed the right nutrients from what little food I could eat, I was just a terrible mess. After one dose of inflix, I was fine. I stayed in remission all the time I was on inflix and for 6 months following the withdrawal of the drug. I am now 8 months from that date and sadly deteriorating. I am not as bad as I was but each month I get slightly worse. And I never eat more than 1 meal a day - sometimes I don' t eat any meals at all - because I can't, it makes me feel worse. And then I can't work. And if I can't work, I can't pay my national insurance and then that will impact on funding for the NHS. It is simply unfair and not morally correct to withdraw a treatment that helps people

Patient England	Hi there. I am a UC suffer and have tired all the tablets and conventional medicines. None of them helped. In fact 6MP and Aztoprhine made me very ill. My joints all ceased up and I could hardly walk after less than a week using both of them. I could not stay on them. I did know what I was going to do. Mt consultant advised me to try Infliximab which I did earlier this year. After only 4 treatments it is making a big different to my life and my health. I do not know what I would do without it now. I am only 35 years old so I have a long way to go in life if infliximab was taken away. I think other treatments, flare up and investigations would me more costly in the long run for the NHS.
Carer	It is clear from ulceratis colitis forums and personal accounts that a range of biologic drugs have the capability of delivering a good solution to living with an incredibly nasty disease. It is surely better that such people benefit from a better quality of living and, moreover, are kept from getting even more ill and subsequently ending up in hospital where they will require even more costly methods of treatment and use up hospital beds and staff that could have been used by another patient. Before such drugs are suddenly withdrawn from people who desperately need them, what exactly is being offered in their place?

Patient	I think it is extremely important that this drug is available to severe sufferers of Ulcerative Colitis. Although it does not work for all UC sufferers, it works extremely well for some and can save them from needing surgery as this is their last option prior to it. It can also put many sufferers in remission for at least a year.
Patient England	I have had a two year battle with my Ulcerative Colitis, until this point I had successfully managed to control my symptoms & lead a relatively normal life. Over the last two years I have had various obstacles in the path of good health and I am desperate to try a new treatment to enable me to get my life back. I am currently waiting a referral to a hospital where I can seek further help and advice on treatments available as I feel I am no longer getting the care and support I need at my current hospital, they seem to be pushing me towards surgery but I strongly feel that this is such a drastic measure, I haven't yet exhausted all my options and if I'm entirely honest I do not clearly know what all my options are. I just know that surgery will not be an end to all my problems having conducted my own research and seeked advice from fellow suffers. It seems that Infliximab and the like have proven to be very effective in some cases of UC, granted not all but for some this has proven to be the saving grace before surgery. I want the chance I deserve, I want to be me again. Please don't take my hope away from me as it is all I have.

Public England	UC affects a great many young people, who are trying to establish themselves through education/training, and in the early stages of a career. UC can have really debilitating impact on the young person's ability to establish themselves in the work of their choice. If cheaper treatments fail, and the biological drugs work, this has a massive positive impact on their life. Although these drugs are expensive, the cost of a young person not being able to work , plus the potential added problems of depression that are very likely to occur should be taken into consideration. This drug can transform the young person's life. My comments are based on seeing a young person who had to take time out of his education, due to his UC, who is now well and working in the financial world because he is well. I fully appreciate that these drugs are not going to be appropriate for everyone, but I feel the decision should rest with the patient's consultant - and not subject to an absolute rule. UC is very variable, and the individual's response to the drugs also seems to be very variable.
Carer England	My son was diagnosed with Ulcerative Colitis when he was 10 years old and needless to say it was devastating for the whole family including two teenage sisters. The convential treatment of steroids had zero success and my son suffered from the side affects of the steroids during this 14 month period to the extent that he changed from being a very successful performance sports person (Kent no 2 in tennis and in Crystal Palace advance centre for sport in an age group above his age) with a strong social life and self confidence to almost being a social recluse. He had to give up tennis. He had a moon face and put on weight and developed facial and body hair clearly beyond his age. His school work suffered and my wife and I nearly ended up with divorce as we simply could not cope with the pressure of seeing our sons decline in this way. I remember once my son asking me why me daddy why me. What have I done wrong which left me in tears and feeling helpless and useless as if I could not care for my son. Our consultant then suggested trying infliximab and explained the advantages and disadvantages. Surgery was not really an alternative as the whole colon would need to be removed. This was absolutely not an option for a 10-11 year old without first trying every other option possible as it would destroy my sons already non existent self confidence and would have ended his sporting life, one thing that he valued above all else. So we started infiximab treatment after about 14 months of sheer hell. AND WHAT A DIFFERENCE HAS THIS MIRACLE DRUG MADE. He has had no side effects and His condition has been in remission since. He is now once again into his sport and has just been picked to play for ENGLAND in u16 Hockey. He is once again self confident and enjoying his school life to full. Our family is once again enjoying a NORMAL life and the only thing that reminds us of his condition are the antiflamatory tablets he takes daily and the 8 weekly visits to hospital for the infliximab infusion at our local

	NHS hospital. Clearly if this treatment was not offered under NHS this would be devastating for our son and the rest of our family as we could not afford to continue with it privately. So my final plea to those who are looking at this purely from a financial view point is please I beg you as a father and on behalf of my son do not stop this treatment as it would ruin the lives of so many people that depend on it.
Patient England	Dear Sirs In February 2010 I was diagnosed with Ulcerative Colitis. At the time I was not very concerned as I did not release the impact it would have on me for the rest of my life. I was rushing to the toilet up to 25 times a day with nothing but blood coming out of my bottom. I was also in an unbearable amount of pain. I was prescribed to take steroids which had nothing but negative effects on me. Within a few months I was reduced from being a happy competitive sportsman to a chubby moonfaced child and severely depressed. My parents were also very depressed but they always tried their best and searched all over the world to help me. During this period I was also going to school everyday in a large amount of pain and was hopping to and fro from lesson to toilet. We tried many alternative medications but none had a long term helpful effect. When we were introduced to infliximab it was like a miracle. I stopped bleeding very shortly after my first few infusions. I then also began to lose weight and slowly built myself back into sportsman shape. I am now playing for England hockey and in the best shape I have ever been. My short story just goes to show that this miracle drug can help so many other people all around the world and get them back to their normal lives. I urge you to please keep infliximab on the NHS as I really do not want to re-live what I went through before I had this treatment.

Carer England	Dear Sirs In early 2010 my son was diagnosed with Ulcerative Colitis. After many weeks of losing blood and the GPs not being much help we ended up at GOSH. Our first year of diagnoses was spent watching our son go from a bright confident super fit performance sports player to a young chubby depressed boy with no confidence and all he seemed to be doing was taking tablets & eating . He became angry and did not understand what had happened so quickly to change his life. He was a top tennis player for the South of England at the time & now he couldn't possibly play in any tournaments because he needed to go toilet every 10 minutes or so. Our whole family life had changed and I am sure we did not laugh for a whole year. My husband and I were discussing divorce because we couldn't handel the pressure on our family. Then after a year the consultant mentioned 'infliimab' we were desperate and would have tried anything . It was a mirical we had been praying for. From the first infusion (after bleeding for 14 months) the bleeding stopped. Although it was too late to go back to the top level at tennis my son started playing team sports and it was not long before he was selected for the Arsenal Development center of football excellence and last week we had the fantastic news of him being selected for England Hockey. We have a very happy confident young man - he takes his medication religiously and never complains about the amount of blood tests and colonoscopys he has to have. Infliimab made it possible for him to attend full time school and he is doing very well academically and hoping to study law in the future. We cannot face life the way it was without infliimab. Please do not take my sons and I am sure many other children's lives away by not making it available on the NHS. Thank you
Carer England	As a parent with a child who in the past relied heavily on infliximab, I would like to say how stressed and upset I am that it is being suggested that certain drugs will not be made available to patients when they have relapses. My child has been very ill over the years and missed so much school and life in general. Imagine not being able to do the normal day to day things we all take for granted, school, going out to see friends, family, leaving the house is not an option sometimes. My child tried many drugs to help get the condition under control. Steroids, methotrexate, mesalazine, azathioprine and foam enemas. When in a state of relapse none of the above drugs worked. Eventually my child was given infliximab, the effect was almost immediate. My child stayed on this drug for 2 years. Recently my child came off of it after responding very well. My child did not experience any side effects from this drug. Very quickly my child was able to go back to school and lead a very normal life. To think that this drug would not be an option again in the future, should a relapse occur, is very scary and it makes me extremely upset. Life for people suffering

	with this chronic condition is hard enough. Knowing that there is a drug that works for you when you become ill is very comforting. What should my child do then if this drug is no longer available? How much time can my child take off school before it effects studies, the future. Should my child stay in school for extra years to get exams to enable a decent job and support oneself in the future? My child could go on benefits if too much school is missed and exams are failed would that help the welfare state? My child is a bright and deserves a future. This drug could help my child stay well again in the future should she become sick. My child doesn't want surgery, why should one have invasive treatment at a young age? I would urge those making the decision to deny patients with chronic conditions to think about how they would feel if this were their own child. It is unacceptable to deny anyone the drugs that they need to help them lead normal lives.
Patient England Just that we are so very concerned that the only effective treatment I receive (Humira) could not be available to me after paying into the state system all my life and will also contact my Parliamentary MP regarding this cost cutting by NICE especially as other treatments are funded for people who have in a lot of cases brought on their own medical conditions as detailed above.	I was diagnosed with Ulcerative Colitis in 2012 and had to be admitted to hospital where with excellent care I recovered enough to be sent home. The Colitis was treated with all conventional treatments that failed and only Humira has given me stability of which is a chronic life long condition (unless a cure is found) Living with UC is difficult with occasional flare ups and all the associated symptoms that are well known including fatigue and toilet habits but Humira has greatly improved my life since it was offered to me and to date I have had no side effects from taking it. In the past I have had surgery for other problems and after surgery you are never the same again and of course it is irreversible and I still live with issues from those other past operations (not for UC) So I view surgery only as a very last resort. I have also paid into the state system with all my taxes (40 years) to be able to use the NHS and all treatments available and if Humari was refused to me as a treatment then my quality of life would be effected and sure human rights will enter this somewhere as this treatment is holding me together. Myself and family and friends are very concerned that NICE considers this treatment not to be cost effective on the NHS especially as I did not ask for this condition whereby money is easily found for people with conditions brought on by their own life styles to be treated on the NHS ie drug. alcohol . over weight people and even cosmetic surgery all in most cases supported by NICE (see examples below) Gay and lesbian couples and women over 40 could be offered free IVF treatment under new Government proposals published today. Same sex couples should be given the same rights as heterosexual couples according to a consultation document released by the National Institute for Health and Clinical Excellence (NICE). Those carrying an infectious disease, such as Hepatitis B or HIV, could also be offered IVF under proposals by NICE.

	http://www.mirror.co.uk/news/uk-news/gay-couples-to-get-free-ivf-treatment-Mirror on Facebook
Patient England Just that we are so very concerned that the only effective treatment I receive (Humira) could not be available to me after paying into the state system all my life and will also contact my Parliamentary MP regarding this cost cutting by NICE especially as other treatments are funded for people who have in a lot of cases brought on their own medical conditions as detailed above.	
Patient England	I really can not believe this is even up for discussion!!! NICE ARE YOU SERIOUS? I pray to GOD that one day you are a loved one does not have the unfortunate life changing diagmoses of Colitis or Crohns. I have tried surgery, Azathorprine, Budesonide, Azacol, Steriods, herbal, alternative..you name it I have tried it and the only thing that works is Humira. It allows me to work, look after my two sons and have a almost normal life. You take that away and I cannot work (pay tax) look after my family and pretty much be a depressed walking disaster. I urge and implore you not to take away the only salvation I had to cling to.

Concerned Parent England	Before Humira we had a very sick child. We spent a year and a half in and out of hospital either referred by the hospital or our own GP, emergency admission via A&E and once via a direct 999 call on flashing lights & sirens. He was diagnosed after a very short period initially with UC and quickly exhausted the normal drugs. Following a Colonoscopy, biopsy and endoscopy the diagnosis was modified to indeterminate colitis/Crohns. We are very concerned that with such a diagnosis He could be excluded from the only drug that is keeping his disease under control. Below is a summary of Hissâ€™s condition, treatments and outcome. At 15yrs old in early 2009 after a stomach bug He had continuous bloody diarrhoea for about 2 weeks. Following a doctors appointment he was initially given Cocodamol to treat the diarrhoea and pain he was now in. We were not happy with this diagnosis and via the NHS help line we gave them the details i.e. loss of blood, loss of weight and pain. The computer said admit him via A&E. Thatâ€™s what we did. He was put on Mesalamine, Which failed to work. A course of steroids followed again with limited success and over the long period He was on and off them has reduced his bone density and has left him with stretch marks. By this point He had lost over 2 Stone and was a little over 5 stone. All drugs were stopped and Hissâ€™s condition improved for a short time before relapsing. He was then put on Azathioprine, which looked promising for about a week when we had to dial 999 as he was in acute pain. He had developed Pancreatitis and Azathioprine was stopped immediately another course of steroids commenced. After several months Steroids and a different 5-ASA drug were proving to be ineffective and following a regular blood test He was admitted coincidentally by the Hospital and our Doctor on the same day via separate phone calls. Again all drugs were stopped and He was given infliximab. Almost immediately his condition improved. This was short lived as following the second infusion He went into Anaphylactic shock, his lips turned blue etc. Steroids were immediately administered and He recovered. In 2010 He was put on Humira which changed his life completely. He has had one or two small blips but no hospital admissions for 4 years. After 4 years He is now 8 Â½ Stone, he has been put onto several other forms of the 5-ASA type drugs. On every occasion he has severe abdominal pain and his condition worsens and immediately returns to normal when stopped. His medical records show he is no longer to be prescribed 5 ASA drugs, Azathioprine or Infliximab. Even during Diagnosis and Treatment He managed Multiple A* GCSEs, Multiple A grade A levels, Part sponsorship for his Masters Degree at Cardiff university, Part Sponsorship by the UK electronics skills foundation, a paid year out at a large communications firm and with the continued success of his treatment is looking at a paid PhD. Would NICE like to comment on the options He would have if Humira was no longer available? Based on his history I would suggest multiple hospital admissions, probably surgery and possibly a very sick adult

	claiming benefits. Is this now cost effective?
NHS Professional N. Ireland Received honoraria to speak from MSD.	I am concerned that the models are flawed, the 100-year time horizon is too long and that to condemn all patients who fail to respond to conventional therapy to surgery is grossly unfair.
NHS Professional England I have received honoraria for speaking and served on advisory boards for manufacturers of this technology	I have significant concerns that the recommendations as stated are based upon inappropriate evidence / assumptions and that the previously highlighted issues have not been taken into consideration. As it stands this guidance will cause huge harm to patients with ulcerative colitis and mandate patients with otherwise treatable disease to undergo mutilating surgery which is associated with a significant burden of side effects. These patients are often adolescent / young adults, and the implications for their social and work productivity are immeasurable 1) The model as it stands is unintelligible to most clinicians / patient groups, and the outputs seem to bear no relation to the clinical trial data as I understand it. 2) The patient groups included in the analysis are taken from the clinical trials which include patients who have simply failed a 5ASA. UK practice would be to treat patients with more severe disease (who have more to gain from therapy). 3) The side effects and costs of surgery are underestimated by a significant margin. Patients often have 3 major surgeries after colectomy. Costs of complications post surgery are not adequately considered. Nor are the costs of stoma appliances etc 4) Patients who fail anti TNF therapy do NOT simply go back to conventional therapy â€“ many will undergo surgery and others will remain with chronic un treated disease (and its associated appalling quality of life) in order to avoid this. 5) Patients who respond to anti TNF induction therapy have a much better long term outcome â€“ would it be possible to approve use for patients in the category? I would urge you to re-consider this decision

NHS Professional England	I have read the document in some detail and I am afraid that I believe many of the assumptions made are incorrect such that the conclusions drawn are unsafe. One of the biggest flaws relates to the outcome after failure of anti-TNF. As I understand, it is assumed that the majority of such patients will simply go back onto conventional therapy and that it will work. This is ludicrous. The only remainiing option currently after failure of anti-TNF is surgery. Returning to conventional therapy is not a treatment option in this situation. The fact that some patients choose to refuse surgery at that time prefering to live with chronic ill health, often with ongoing steriod exposure is simply a reflection of tthe unwillingness of patients to undergo surgery. As a treating physician, there is currently no other NICE approved therapy in this situation although if vedolizumab was approved, this would be an apppropriate traement at that time. To suggest that only 1% of this cohort go to surgery is grossly misleading. Again, one could argue that 1100% of such patients should go to surgery - I would imagine that probably 50-70% actually choose surgery within 12 months in this situation.
NHS Professional England	As far as I can tell, the costs of chronic active disease and ongoing steroid dependency in the group mentioned above are not accurately considered. Chronic active disease is associated with an increased risk of malignancy, with very poor quality of life with disease related complications such as poor nutrition, aextraintestinal manifestations, an increased risk of thromboembolism, reduced fertility, osteoporosis etc. In addition, many of these patients will also be steroid dependent increasing the risk of chroinc disease including diabetes, hypertenision, osteoporosis and cataracts. Has this been introduced into the costing model?
NHS Professional England	It would appear that the costs of surgery are not fully considered. Most surgery is done as a 3 stage procedure (occasionaly to stage). But this is not a cure for the disease. Pouchitis is common and often recurrent. Pouch failure occurs. Increased use of fertility treatment as well as treatemnt for erectile dysfunction needs to be considered. Admission with intestinal obstruction also needs to be considered

NHS Professional England	As far as I can tell, no consideration has been given to the possibility of discontinuing thearpy with anti-TNF. In general, as for Crohn's disease, it would not be unreasonable to consider a model in which treatment is reconsidered in patients in remission after 1 year of therapy
NHS Professional England	Ulcerative colitis is a young person's disease. The cost to society of preventing people from reaching their full educational achievement through school and tertiary education as well as work absence cannot be forgotten. Whilst I accept that this may be difficult to model, ignoring this important matter discriminates against young people and people with UC
NHS Professional England	I find it difficult to understand how the ACERs can be so drastically different to Crohn's disease. Whilst the trials are somewhat different, the differences in response and effects on disease activity and quality of life are not in reality so great. This suggests that there must be something wrong with the models
NHS Professional England	Very disappointing. 1: I don't think patients will accept this. 2: The cost of surgery seems to have been vastly underestimated and the assumption made that it is a panacea - what about pouchitis, peristomal hernia, high output problems - all are costly and involve admission to hospital. 3: Finally, the report is written in unintelligible language with the findings hidden in obscure, poorly worded sentences. Since when has 'dominated' been part of the scientific lexicon when considering the efficacy of medicines?
NHS Professional England	We believe that antiTNF biologic therapy should be available to patients with moderate to severe disease, for whom failure of established medical therapy currently mandates colectomy. This is important as there are other novel therapies in development that patients who have conserved their colon might respond to; whereas a colectomy is a finite treatment with risk, following which novel treatments that may be effective and less expensive would not be possible to use.

NHS Professional England	Committee agrees that there is evidence for clinical effectiveness of all three anti TNF agents in this group of patients with moderate to severe UC. Cost analysis is flawed - conventional therapy as a comparitor is fundamentally a flaw as by definition these are patients who are failing on conventional therapy - if the conventional therapy was working they would not need anti-TNF. I understant the committee is not strictly using surgery as a comparitor but would like to state that it must not be seen as an alternative to anti TNF as many patients refuse this and would not consider it, also costs of surgery grossly underestimated (drug cost of zero, single surgery rather that 3 visits (pouch), cost of onging post surgical care (stoma issues, pouchitis etc) not adequately included. I would argue that a subgroup of patients should be allowed anti-tnf - those who refuse surgery and in whom conventional therapy (steroids, mesalasines, thiopurines and sometimes calcineurin inhibitors) have failed to work (on going need for high dose steroids, no mucosal healing with severe symptoms.
NHS Professional England I do not work for the manufacture of these medications but Abvie (adalimumub) do sponsor educational events that I attend and have sponsored meetings at my work place.	"it is difficult to extrapolate from seemingly uniform clinical trials, with rigid inclusion criteria, to assess the impact of TNF-alpha-inhibitor therapy on patientsâ€™ quality of life compared with surgery." Just because it is hard to compare this information it doesn't mean it needs to be unregognised. Instead efforts to find out this information should be sort. I am unsure if you have taken into account the cost of complications due to surgery, cost of possible depression when trying to adapt to body image issues and being unable to face work. I appreciate that unless you have got the condition or work with patients that have the condition it is hard to appreciate the full benefit of having the above medications available instead having to go through major life changing surgery. With this in mind I am also puzzled to the fact that in the titles I would have thought you would have had gastroenterology consultant involvement on the apraisal committee I can not see any gastroenterology consultants listed. In my experience, some patients do choose collectomies, they feel they can deal with a stoma but for others - to take away the chance to retain their body image and gain control of their symptoms by having the stated medication seems wrong.

NHS Professional England I do not work for the manufacture of these medications but Abvie (adalimumub) do sponsor educational events that I attend and have sponsored meetings at my work place.	
Carer England	My daughter has been on Humira for a month and it has made a great difference to her life she is the best she has been for over 8 years if she did not have this she would go back to how she was before spending days in bed unable to do anything except go to the toilet
Patient England Please reconsider to let me and others to have the meds	Hi I have suffered with ulcerative colitis since I was 18 and now I'm 44 , I have took allot of meds over the years ranging from asacol to steroids and enemas ,over the last couple of years I have had several flare ups taking more meds trying to control it but now the consultant as suggested I have the infliximab which should help with my situation, and make my life a bit easier and now I have heard you are considering not to let patients with ulcerative colitis have this ,would please consider to let patients have this as it would make day to day life better and to cope with. Thank you
Patient England	I am horrified at the potential removal of these drugs for the treatment of Colitis - when all other drug treatment has been unsuccessful. I am a member of a patient panel and also a hugely popular forum for people with Crohns and Colitis. There are many people I have spoken to, for whom these drugs have been a godsend and the only therapy which helps them. I, if I am not responding to traditional NSAID and Steroid Therapies, want the option of using these drugs. Remember they do not have to be used long term, once the flare is over I could go back to using the more traditional methods to manage the disease. I think that removing this option and forcing the only other alternative - Surgery with all of its complications and ongoing maintenance of having a stoma, which is likely to become permanent is not acceptable. The

	mental and physical implications of having an ileostomy are huge. Removing the patient wellbeing, and quality of life from the equation, I cannot believe that the removal of these drugs is cost effective. I would like to see what due diligence has been done on the business case and cost benefit analysis. The ongoing costs to the NHS must be significant and on the same level, if you include all of the real costs. The ongoing maintenance of a stoma, all products, likely delivered at and sold at a premium. The stoma nurses and follow ups for complications. This is without considering the patients quality of life which needs to have a large weighting when making this decision. I expect you to "do the right thing" rather than look for quick reengineering saves, which are likely flawed.
Patient England	the removal of vital medicidne would have a large impact on the lives of thousands of ulcerative colitis sufferers. This life log disease which is currently incurable takes over your life and makes every day tasks impossible as a 31 year old I have been at worse diagnosed with moderate sevre ulcerative colitis in November 2010 whilst in hospital. The pain both emotionally and physically when you have a flare up is unbearable and anything that eases this paid should be made available to sufferers. some of the problems you face include diarehea, blood stools, excruitating stomach and abonminal pain, fainting, sickness, nausesa, migraines, inability to control your bowels and weight loos, malnutritution, embrassment, depression, accieents with going to the toilet in public, conspitation and flu like sypmtoms like fealing week. To not be offered medicine which for thousands of people works when nothing else does will impact their daily life and stop you from having a normal quality of life - at times you feel like someone in their 80s or a baby as you have no control over your body. this illness makes it impossible to work ,even holding a conversation is impossible. I please ask you to reconsider your decisions and make medicine that keeps this illness in remission available to everyone all over the country as the knock on affects of ibd is greater than you can realise only when you have it do you realise just how awful it really is. I believe we should all be treated equally and that this disease is as serious as cancer for example as there is NO CURE

Patient England	I have suffered with Crohns since 1995 and I never had remission for years until I started using humira. It's changed my life I'm like a new woman. I can lead a normal ish life and work. If I wasn't able to have humira is become very ill very quickly and spend long periods in hospital I also cud lose the rest of my bowel. My quality of life Wud worsen 50% and I don't think I'd get the chance to become a mother. Please please please don't stop us having humira on the NHS I cudnt cope without it.
Carer England	My son was diagnosed with Ulcerative Colitis in 2013 at 28yrs, he had never been to a GP before this event. He has had 2 flare ups both of which have required hospital admission where he failed to respond to initial medication., lost 2 stone in 3 weeks and endured severe pain. He received 3 infusions of infliximab which achieved remission for him. This condition is one of the worst things I have experienced as a nurse in terms of chronic symtoms, to withdraw these drugs would be devastating to sufferers and I believe would result in much more use of GP time , prolonged inpatient stays and surgery. I recognise that our experience is only ours but I would plead for these drugs to remain a lifeline for IBD patients
Carer England	I have a 15 year old daughter who relies on her medication to get her through the day.Having this medication it enables her to lead a normal as possible life as a teenager. At the moment she can eat and socialise with her peers and without it it would prevent this and make life for her a lot more difficult. Without the drugs it would mean she would need a dietician and for her school to provide who with a special diet which all costs money and may negate any savings from not giving the drug. [redacted]

Patient England You will take hope and life from a million people by taking these drugs off of the free nhs and u should be ashamed for even thinking of doing so .... what would happen if one of ur family members came down with crohn's disease you'd soon change your minds then	I was diagnosed with crohn's disease and colitis 10 years ago and I've on ever medication there is and also had a resection operation and I'm still suffering up until my consultant [redacted] at barnsley hospital south Yorkshire put me on humira 2 weeks ago and I now have my life back ... humira was my last chance to be able to get my quality of life back ... before 2 weeks ago I couldn't work , I had to be close to a toilet at all times goin for a bm 20 to 30 times a day and in constant pain that made me cry it was so bad, I was in and out of hospital every couple of weeks , I couldn't go out and see friend or family I had no future of having a family of my own , but since I started humira 2 weeks ago with in 2 days I felt what I suppose healthy people call human , I can go out with out worrying that I might have an accident n not make it to a toilet and I'm looking into goin back to work , my pain has gone and my bm are down to 8 ish a day , if you make humira and the other drugs not available on the nhs I will not be able to continue on them because of the price which will mean ill be back to how I was before and to be honest I might as well be dead because it's not a way to live a life it's not a life and many people rely on these treatments just to be able to live a normal life .... If I could give one person who wants to take these drugs off of the nhs my crohn's disease for one day before I started humira they would soon change there mind , humira is a miracle drug for people like me that other drugs haven't worked on and to take them off of the nhs would cause many of us to live a life in hospital constantly and would end up costing you all more than leaving drugs on free nhs

Patient England You will take hope and life from a million people by taking these drugs off of the free nhs and u should be ashamed for even thinking of doing so .... what would happen if one of ur family members came down with crohn's disease you'd soon change your minds then	
Patient England	I was diagnosed with uc this time last year, I have been flare up free for the last 3 months after starting a course of azathioprine in janurary. I was told if this didn't work that the next option would have been surgery as sterdoid treatment had been the only thing to have previously worked. The though of having to under go surgery when there were still treatments available but that they were deemed to expensive sickened me as I knew there were other less life impacting options still available. Part of me even felt as is dying would have been a better option. I couldn't feel more strongly about this being available for everyone who suffers

Patient England	I have just read that NICE are looking for evidence of success while using Infliximab for Ulcerative Colitis. I had severe UC which was not responding to conventional treatments. Over the years I have had pentassa, steroids, metronidazole, azathioprine and methotrexate. My consultant suggested surgery was the only option. However, I refused surgery and begged for an alternative. I eventually received Infliximab infusions and responded well following my first infusion. It was like a light switch and I finally had my life back. I had three infusions. Prior to this treatment I was constantly unwell, had numerous hospital stays, miscarried three children and was fearful of socialising for fear of accidents. I now have two children, work part time and it never crosses my mind that I couldn't go somewhere because of toilet issues. I would be devastated to learn this treatment would not be available again should I relapse. It has literally been a wonder drug for me. Many thanks for reading [redacted]

Patient England	After having various drugs for UC fail, my options are already getting less. The removal if these drugs is just unfair (and if due to money, morally an issue). I would like options to improve the quality if my life, not panic that I have no other avenues to go down.
Patient England Please save our last hope before resorting to surgery automatically	Having spent 1 month in hospital in May 2013 where azathioprine and IV steriods max dose did not touch my severe colitis, the rescue drug INFLIXIMAB saved me from needing surgery. If you remove this option, I believe that the costs to NHS for surgery, stoma care will far outweigh the costs of infliximab. It certainly was my life saver and improved my then quality of life enormously. Apart from the physical benefits of being able to use these biologics, the physiological benefit is just as great if not greater, my wellbeing has been transformed. It may well be that surgery is needed along the line, but surely if I can avoid surgery and maintain a good quality of life by using this drug either as rescue or maintenance it must be a preferred option? Please listen to the people who have had this drug, the proof lays in the success rate of this drug. Put yourself in their shoes, you have this condition, you only get offered surgery /ileostomy when standard treatment fails, and you know there is a chance this will rescue you, how would you REALLY feel? Be honest
Patient England Please save our last hope before resorting to surgery automatically	

Patient	I am greatly concerned at NICE's preliminary decision to prevent individuals with moderate/severe ulcerative colitis to use these invaluable biologic drugs as a stable form of treatment. After presenting with a severe flare up and being hospitalised for about a month the only medication which finally caused my symptoms to subside was Infliximab. It took many tests for my consultant to decide that my IBD unspecified was severe ulcerative colitis (90-95% sure). I am currently being managed on Infliximab along with other medications after intravenous steroids failed to stabilise my condition. Infliximab has genuinely propelled me from being in an incredibly weak and chronically ill individual to a normal functioning adult again. I am aware that in this document NICE explain that biologics such as infliximab remain as an option for these acute circumstances but I am appalled that NICE are considering pulling it as a long-term treatment. But you already know how effective these treatments are for patients, let me quote back key conclusions from this document: 4.60 "The Committee concluded that patients and clinicians considered TNF-alpha inhibitors to be a valuable option that could offer long-term remission to some patients with moderately to severely active ulcerative colitis." You also know that crohns and colitis are incredibly similar and you have been advised by experts to treat the diseases the same: 4,61 "The Committee noted that, in the clinical expertâ€™s opinion, the benefit of TNF-alpha-inhibitor therapy for moderately to severely active ulcerative colitis will be similar to that for Crohnâ€™s disease for which there is positive NICE guidance for using TNF-alpha inhibitors." Despite expert advice from both patients and medical professionals NICE has chosen to pin it's final conclusion on the Assessment Group's Model. I understand that this model is comprehensive and needs to be taken seriously. However, as the limitations in section 4.57 make clear, this model only considers the data of one year in the life of someone with this disabling chronic disease. Ulcerative Colitis is for life. I am 24 and I will hopefully have at least 50 years of having to cope with and manage this incredibly variable and unpredictable disease. The biologic medications have clearly been life-changing for individuals and I really do not believe that the Assessment Group's Model can truly reflect cost-effectiveness for a disease which is life-long. I would also like to highlight that biologics are still a new form of treatment and it is noted within this document that adalimumab and golimumab are lacking in clinical trials. The story of how these life-altering medications and how they can play a major role in the life-long maintenance of severe/moderate

	Ulcerative Colitis is still in their infancy. Please, do not take such a massive step backward in the treatment of this condition and deny thousands of patients the right to a normal life and the ability to contribute to society. I believe that withdrawing the access to infliximab, adalimumab and golimumab as a treatment for moderate/severe ulcerative colitis will genuinely result in patients suffering until they are so ill that hospitalisation and emergency surgery are considered. Do not allow this suffering, waste of NHS money and valuable time; keep people well. Keep these effective medications as a long-term treatment option.
Patient England	I strongly believe that these drugs should continue to be used for patients with UC. I've just been offered Infliximab after having allergic reactions to most conventional drugs, other than steroids which are no longer as effective for me. I'm very grateful for the opportunity to have Infliximab, I wouldn't want anyone to have to suffer without suitable treatment, especially if conventional drugs have not been effective.

Patient England	I am a 23 year female. I was diagnosed with ulcerative colitis in April 2014. At the time of my diagnosis I had fairly mild symptoms, I would have around 4-6 stools per day, often with blood. I was originally treated with topical steroid foam enemas. However my UC has progressed over the past 6 months. I have been treated with oral Prednisolone, this then became ineffective. Therefore I required IV steroids. At first the IV steroids controlled my symptoms, and I returned to using oral Prednisolone. Unfortunately as I tapered my dose of Prednisolone down my symptoms returned. I was readmitted to hospital for further IV steroids. Unfortunately the steroids have had no affect on my disease and I now pass around 12 stools a day with a large amount of blood. I am currently in hospital, this is my fourth admission since April 2014. I have recently started azathiaprine, however this will take 3-6 months to take effect. In the meanwhile I find it increasing difficult to have any quality of life. I am scared to leave the house as I have sudden urges to use the toilet, and it can be difficult to find somewhere in public. I also suffer from fatigue. I feel that the fatigue is worsened by steroids as they cause me insomnia. On a more personal level I got married on 1st October 2014. I spent my wedding day in agony and in fear of soiling myself. This was very embarrassing and upsetting. Since my wedding I have been readmitted, my consultant suggested that the next course of action may be to give me a course of infliximab. I hope that this treatment will allow me to have a new lease of life. Of course I am aware that it may not be compatible with me, but for NICE guidelines to take this option away would be great loss. If my steroid and azathiaprine treatment fails my only option would be surgery. Surgery is not an option I wish to contemplate whilst I'm still so young. I've yet to have children and I fear that surgery could pose a risk to my fertility. There is clinical evidence that infliximab is a effective treatment for ulcerative colitis, funding is not an issue for those with Crohn's. Why take a viable option away from patients with ulcerative colitis. The decision to prevent patients with UC accessing infliximab on the sole basis of funding is punitive.
worried mother England	My son has had Crohns and uc for 10 years. He is having some success with the medication you are planning to withdraw. It will cost the ns much more in surgery if his options are withdrawn
Patient England	It saddens me greatly that you are considering withdrawing these drugs from use by the NHS as they are of great use to many people and by withdrawing them you are condemning then to a life of pain and misery as there may not be any other drugs that work to the extent that these do.When I was first diagnosed with UC it was some time before a drug was found that relieved and stopped the disease in its tracks,I have to continue taking these drugs until a cure is found(in my lifetime I hope)or that another drug has to be used because of the side-effects of the current regime(as you are aware all drugs have side-effects).

	Sometimes when one hears that NICE are withdrawing/ not allowing a drug to be used by the NHS it seems ,from this side of the fence that for all your professional expertise that you are on a different planet to the one that patients(whose life is on hold or their life is restricted) are on. Please do not withdraw these drugs as it is a great comfort for myself and others that they are there if we need them in the future and that patients already using them can continue to do so. I am sure you are aware of the impact of UC on a person who when experiencing a flare -up that it severely restricts their social life and indeed their whole life and if these drugs are withdrawn there will probable be more hospital admissions and and time spent treating the patients whose drugs have been changed.
Patient	As a patient with Crohns who's life has been completely turned around by Infliximab I cannot stress enough how important this medication is! I went from 4 rectal operations, being one step away from a colostomy bag, permenently half blind in one eye and in a wheelchair with chronic peripheral arthritis to returning to teaching dance, being able to lift, play with & have the energy for my little girl and having a life. I have a close friend who has a crossover diagnosis of both Crohns & UC I am shocked that if her future diagnosis swings towards UC this medication will no longer be available to her. Infliximab is the way forward in medicine & I am fully aware that the so called 'secrets' behind it have now been opened up to everyone in the medicine world so that it no longer costs so much. I have a friend who works in Pharmaceuticals who was at the conference when this was announced so for heavens sake why withdraw a drug that A. works so well & B. Is now cheaper? PLEASE consider this. Thank you.
Parent England	I am writing as parent - my son has ulcerative colitis and I am horrified at the prospect of the withdrawal of infliximab treatment. Earlier this year my son was hospitalised with severe UC. Leading up to this point UC had a devastating impact upon his life and I feel very few people understand the horrendous nature of this condition. He had had months of rushing to the toilet 20- 30 times a day and having accidents on a regular basis, no sleep, lost so much weight, was malnourished and feeling very unwell with fevers and was unable to leave the house. So infliximab was recommended and has totally transformed his life back to normality. He had already tried other drugs but these had not worked and had dreadful side effects. Looking at the bigger picture and costs, I feel that UC patients will end up hospitalised and needing surgery without the infliximab treatment and this would be far more costly in the long run- not to mention the distress and disruption for the patient We are a very hardworking family who pay into the system and feel it would be just so unfair. I sincerely hope that you decide to 'do the right thing' rather than go for the quick money saving fix. Please, please, please do not withdraw infliximab for UC patients. Thank you. [redacted]

Public England	Hello, My name is [redacted], I live in Nottingham and am also a member of the [redacted] . I've had 7 Infliximab treatment infusions since last July 2013. And it has really worked for me. My UC is in remission now and my quality of life has improved immensely. I'm so grateful for this drug & all the help received from the IBD nurses, colitis consultant & gastroenterologist at Circle & QMC. I'm off infusions now for almost 3 months and have been on Marcaptopurine tablets since last year. Hope this feedback helps! And if you need further info then please don't hesitate to contact me. Kind regards [redacted]

NHS Professional Scotland I have received an educational grant to attend European Gastroenterology week this year from Abbvie	I have been a Consultant Gastroenterologist for over 12 years and working in a unit with a large population of patients with UC have dealt with many cases of moderate to severe UC. It is perhaps difficult to articulate the distress and disruption that this condition causes to people. Education is interrupted, employers lose patience and patients lose employment, relationships with friends and families are stretched to breaking point. Thankfully, nowadays, very few people die as a consequence of their disease but many many lives are adversely affected and many days of useful employment are lost. While for many individuals a colectomy with or without subsequent restorative (pouch) surgery is a good option when conventional therapy fails or isn't tolerated, this seldom results in restoration of normal physiological function and further inmpairment of quality of life and educational and employment potential results. Many colectomised patients are deeply traumatised by their surgery and would have given anything for the opportunity to avoid it. It is simplistic to see colectomy as an end point especially when looking at long term health related QoL. The effects of surgery on days off work, impaired social functioning continue well beyond the immediate post operative recovery period. Gretaer emphasis needs to be given to the deleterious effects of surgery on long term QoL
NHS Professional Scotland I have received an educational grant to attend European Gastroenterology week this year from Abbvie	It is deeply iniquitous to deny access to a group of highly effective drugs to UK patients when experience of their use and utility continues to build up in other civilised countries in Europe, North America and beyond
NHS Professional Scotland I have received an educational grant to attend European Gastroenterology week this year from Abbvie	Already we are seeing a situation where patients from other EU countries are coming to live and work in the UK already established on anti TNF therapy for their UC

NHS Professional Scotland I have received an educational grant to attend European Gastroenterology week this year from Abbvie	Many patients have struggled on with ineffective conventional therapy, putting up with unpredictable, frequenct loose stools, abdominal pain and incontinence, running the risk of chronic poor health, reduced social functioning and the risk of bowel cancer because of the absence of any middle ground between conventional therapy and surgery. I will be deeply disappointed to have to spend the next few years of my working life dealing with these problems in the knowledge that such an alternative exists but cannot be used in the UK because of an economic model which does not take account of all the factors involved in this illness
NHS Professional England	within our trust we do not use maintenance therapy for our UC patients. the acute and sub acute follow the same pathway. 2 doses of Infliximab, a repeat sigmoidoscopy then +/- a 3rd dose. if no improvement after 2nd dose they are then referred to the surgeons. Bridging with Infliximab for sub acute patietns allows us to introduce immunosuppressent therapy which can take up to 12/52 to have full effect. patients feel better faster and can return faster to their work/school or homelife. we undertook a prospective study looking at our UC patients that had been treated with Infliximab and the results were as follows: Efficacy of infliximab therapy in acute and sub-acute ulcerative colitis: A single centre retrospective study Cheema D, Harrison E, Nizamuddin M, Slater J, Wood L, Ishaq S, Cooper SC, de Silva S Abstract: Background: Ulcerative colitis (UC) is a chronic relapsing and remitting disease with almost a third of acute severe cases needing rescue therapy. Infliximab is NICE approved in the UK for treating acute severe UC and moderate to severely active UC that is non-responsive to conventional therapy, however limited data exists with respect to long term outcomes. Methods: We conducted a single centre retrospective review of patients with UC who received infliximab between July 2006 August 2013. Patients were grouped according to whether they had received infliximab for either an acute or sub-acute exacerbation. Data gathered included all treatment, colectomy rates, CRP and platelets at presentation and smoking status. Fisherâ€™s exact or Mann-Whitney U analyses were performed. Results: 50 patients received 1-6 doses of infliximab in the 85 month period studied, 23 for acute and 27 for sub-acute UC. 70% received 3 loading doses only, then up to 3 further maintenance doses if indicated. In the acute group 15 patients (65%) avoided colectomy, with a median follow-up of 38 months. 73% of the acute patients who avoided colectomy were immuno-naive. In the sub-acute group 21 patients (78%) avoided colectomy, with median follow-up of 29 months. All patients in the sub-acute group had previously been exposed to immunomodulators.

	Conclusions: Infliximab has potential benefits in the treatment of both acute and sub-acute UC. Immuno-naive patients with acute ulcerative colitis are more likely to benefit from infliximab than those patients previously exposed to immunomodulator therapy (p=0.04). This supports the use of infliximab in these groups of patients with UC. this study is continuous so more data has been collated and currently being written up. admitting every patient to hospital for inflxiimab is not cost effective for the Trust due to pressures on beds but also for the impact on the patients loss of earnings/education and social life all of which can have longer term implications. loss of education can lead to reduced capacity to get a job and so they may become more financially dependent upon society. for those patietns who do not wish to have a colectomy this could have long term consequences on their disease activity, increased disease activity and being diagnosed at a young age can both lead to an increased risk of colon cancer.
NHS Professional England	
Carer England	My daughter was diagnosed with moderate ulcerative colitis more than two years ago, and had symptoms for at least two years prior to the diagnosis being made. As the disease developed, she was given various medications to help manage her condition. Until May this year (2014) the medication she was taking did not really work. With constant flare ups of her disease and effective control through azathiaprine, asacol and steroids not working, my daughter at the age of 15 - just before her GCSE exams - was offered infliximab as her ulcerative colitis had become steroid dependent. The centre where my daughter is receiving treatment did not enter into this course of action without assessing the chances of success, and having carried out their analysis, it was deemed that my daughter was a good candidate for having infliximab which would continue to be effective after a year of use. Since having regular infusions of infliximab the impact on my daughters day to day living has been a revalation. Not only does she now look more normal as she doesnt have the side effects from the steroids, she has stabilised her weight and has been able to attend school regularly. Prior to her infliximab infusions she had extended periods of time away from school which isolated her from her peer group and had a very negative impact on her self esteem and her ability to maximize her potential in her school work. My daughter was a very sporty child before diagnosis, however, since her diagnosis her engagement in sporting activity has been hugely reduced - that is until now and since she has been on infliximab. My daughter is now able to participate in sport like any other child at her school, and this has had a very

	positive effect on her. Now my daughter comes home from school tired because she has been active, not because she is exhausted from just having her disease. There are also other benefits of having infliximab, which includes the potential healing properties of this biologic medication. It is clear to me that the possibility of healing is worth the price regardless of the cost at present. I am aware that infliximab (Remicade) is soon to come out of patent, and as this is the case the cost will become significantly cheaper as biosimilars will be made available. At present the cost is high, but this will change. NICE could decide to allow this drug to be prescribed on the NHS, or they could settle for a cost over quality of life decision and push my daughter towards a life away from school, away from work, needing unplanned hospital admissions, the potential for huge cost to the NHS and potentially other government departments for decades to come. Without infliximab there will be a direct impact on the quality of life for my daughter and for me as a parent. I have also had to take extended time off work to care for my daughter, but since she has been on the infliximab the only time I needed to take off are when she has a pre-planned hospital appointment. Discussions have been had between my daughter, consultant and me as a parent about the possibility of surgery. Due to the nature of my daughters particular ulcerative colitis, any surgery would involve complete removal of her rectum and would result in her lifelong need for an ostomy bag. Surgery is NOT the answer for everyone, and presently as the use of infliximab has been so effective, my daughter and family were devastated by the news that infliximab may be withdrawn for her to use. I sincerely hope that you reverse your decision and continue to allow this life changing drug to be made available to patients through the NHS when it is appropriate to have it prescribed.

Patient England	I was diagnosis with UC late in life and tried on two different drugs one being Mercaptopurine which disagreed with me to the point of spending 6 days in hospital on all sorts of antibiotics. I have been on Inflixamab for nearly three years and my quality of life has changed to very good. Not so many visits to my GP and feeling confident to lead a normal life. I would be back to square one if taken off this drug.
Patient England	My name is [redacted] & I have suffered with Ulcerative Colitis for many years. My mother also had the condition, but, it was never made clear. whether she had Crohn's Disease or Ulcerative Colitis, or a combination of both. She had an Ileostomy Procedure in 1964 & I nursed her for many years prior to her death in 1990. It was a degrading & embarassing condition for both of us. I was officially diagnosed in 2006 after decades of misery. My life was on a permanent hold, as I could not leave the house for any length of time, or go any place, without knowing that a toilet was available. In the early days, my GP did not pay too much attention to my problem & was told on numerous occasions that it was just one of those things I had to live with. In 2013, my condition got so bad, that a friend forced me to go & see my GP, which I did on 19 August 2013, & I was admitted to The Royal County Hospital Winchester, where I was hospitalised for 8 days. I underwent intensive tests, & it was decided that after 5 days of Intravenous Prednisolone, they would try Remicade/Infliximab Infusion. Some of the Doctors were unhappy that I was been given this treatment, & it was actually stated that I was "too old". One of the Consultants stated that my colon was scarred from top to bottom, which indicated that I had, had this condition for decades. Within 8 hours of receiving the Infliximab infusion, it was unbelievable the change that took place. In my opinion, " a miracle had happened." I had visions of having to have a Colostomy, & at the then age of 70, this is not what I wanted to be subjected to, for the rest of my life I have now been on Infliximab for 14 months, & sometimes I find it hard to believe, how much my life has improved. Realising the best years of my life, had been on hold , due to lack of interest or caring by the Medical Profession. I attend The Royal County Hospital Winchester every 8 weeks, where the ward staff are absolutely fantastic. These are truly wonderful caring individuals.

	[redacted]
Carer Wales I urge you to reconsider- this is a decision to remove treatment that I will continue to fight- for my son,his future and that of others for whom they have been given their lives back.	I am the parent of a young man who had a diagnosis of UC in his late 20's. This followed a period of extreme illness, hospital admission for pancreatitis and general worry about deteriorating health. The investigations towards his diagnosis were done privately through his work health scheme. He was struggling to maintain a healthy weight, was constantly feeling sick, rushing to the toilet and in pain and missing a great deal of his work at a stage in his career(post Masters) that was very important to him. It was awful to see my son almost disappearing before my eyes. He was unable to continue his sport and his social life was negligible. He had to take medication to digest his food and this was a very dark time for him. Then following many invasive tests and deteriorating health he finally got a diagnosis. By this time it was at crisis point and he admitted himself to hospital. Once in the NHS system the staff have been very caring and supportive and Crohn's and UC UK have been a lifeline. It has been extremely hard to come to terms with the enormity of this condition alongside the fact that we were learning, whilst watching him deteriorate in hospital. A really fit active young man who now could not even walk down the ward and who had to suffer the ignominy of discussing his "poo" with all and sundry. Despite corticosteriods, azathioprine and others drugs, nothing was working. The steroids caused him great distress and made him very difficult company, as his girl friend would have said. Even when he was out of hospital the drugs were not helping at all and trying to work was a nightmare. He experienced crushing fatigue. Until he went onto Infliximab that nothing would improve it. He was becoming very stressed as there were great expectations on him in work (Renewable and sustainable energy for Wales Govt). He spend more time in the toilet and even had an interview feeling violently sick and rushing from time to time to the toilet mid interview. We were really proud of his determination, but had to stand by and watch him suffer. He keenly felt the impending doom of surgery and researched this in depth, as a young man in the field of science would do. As a family we were aware of the advances in this auto-immune type of disease and looked for answers that did not involve finality of surgery. His fear of this in the future has meant that his relationship did not survive, and I feel this has contributed to him being single now- not wanting someone to have to look after him. A colostomy was planned as nothing else had any effect. He was still in hospital when a trial from Swansea university was mentioned by the medics. He had to choose A or B as a random choice and was accepted on the trial.

Carer Wales I urge you to reconsider- this is a decision to remove treatment that I will continue to fight- for my son,his future and that of others for whom they have been given their lives back.	This is where he began to get his life back. They explained that all other avenues had been tried and all that was left was surgery and the team came in the explain the procedure. I cannot fully share with how devastating it was for me, as a mother of a lad who; is not yet married, not fully enjoyed the fruits of his extremely hard work in school, university and subsequent Masters, being told about having to come to terms with the finality of surgery. Any future progress in research will be useless to him as he would have no lower bowel. The trial began and slowly he began to improve. He has an infusion every two months in hospital here, having a chance to have some emotional support and time to be with others in the same boat. His work accept he has to have this, and he works from home in the afternoons of the infusion. Even the steroids he has to take a few days before the infusion make him feel unwell, but this is a small price to pay. The only real side effects he has are cold sores- but as he was prone to these before, he has learned to manage them. He is now a happy, healthy young man who is training in the gym three times a week, working on his strength to maximise his health. He eats well and healthily, watches his alcohol intake and has again been able to travel. We no longer discuss "poo". He has ditched the special key to toilets and can drive to North Wales for his job without being scared to even go to town on the bus. He has not had to have any invasive tests. Watching him have tubes down his throat, up his bottom and swallow disposable cameras was so stressful to me that I spent many a night in tears. Infliximab has been a life line to him, and for us as a family we have been able to breathe again . His sisters and brother do not have to keep asking him how he is, and sometimes I even forget two months has gone by. He does not seem to have been more prone to illness than anybody else. Any flu like bugs have usually come after a period of stress- working too hard, but many people experience this so I do not think it is linked- To watch him now is a joy- he has put on weight (never was easy for him to do this) is strong and healthy looking- before he looked like someone from Belsen. He even had to come home to live for a while as he was unable to look after himself. Now he just comes home for a chat and a meal! He has loads of energy and lives a fully fulfilling life. With regard to work- he is on top form and has been promoted, and now feels confident enough to apply for a job in another town. He was not able to do this before as he was worried about losing the care he has received at his hospital..All of the previous treatments had unpleasant side effects, but the main issue was that they were not allowing him into remission. He has had NO flair-ups since being on Infliximab, no hospital admissions and no more tests. Towards the end of the time before he has his transfusion he occasionally begins to feel some discomfort, but again after the transfusion all is well again.

	I would ask the question of anybody sitting on the panel that makes this decision would you be able to look at your son or daughter who is healthy and a valuable part of society, who is no burden on any state system, rather a positive contributor to it, and say surgery is the best option when they have a drug that is giving the best quality of life possible? Would you want to teach them how to manage a colostomy bag before they have established a long term relationship, before they have had children and whilst they are a burden on nobody and well? It makes no sense and I will fight this until the end.
Carer Wales I urge you to reconsider- this is a decision to remove treatment that I will continue to fight- for my son,his future and that of others for whom they have been given their lives back.	Certainly some do not respond as well to this treatment as with any drug, but it seems criminal to even discuss the withdrawal of a drug that has worked so well. This is not an end of life drug that gives a few more months- it is a drug that has given a young man his life back. Removing the problem(colostomy) is not a final solution as there are many concerns that arise from it and the need for further surgical/medical interventions so it is not a final solution- maybe just a more convenient one? Surgery would be a massive emotional and psychological barrier for our son at this stage in his life- his career is one where there is constant development and to be out of this for a while would be disastrous. Any break in service would mean he could not keep his home and mortgage so would be far more of a burden on society- how can this be the right way to proceed. We do not know how his disease will progress in the future BUT as drug treatments develop all the time and he is VERY well we have hope. I hope that this case has shown how valuable the drug is and how it should be given to both sufferers of Crohn's and UC where it is appropriate to do so. It is such a private part of a person's body that to have a colostomy where there is an alternative cannot be good for either their physical, emotional, psychological or physical life. My son's step grandfather had a colostomy following an operation to remove a cancerous growth. He came close to suicide and had to be rescued a 'couple of times' , miraculously the cancer died and the colostomy was reversed. My husband and I have worked nearly all our working lives in Special Education and we have seen firsthand the trauma a colostomy impacts on the lives of the recipient and their families. I urge NICE to reconsider this-It is our son's future and the futures of many others which will be affected.
Carer Wales I urge you to reconsider- this is a decision to remove treatment that I will continue to fight- for my son,his future and that of others for whom they have been given their lives back.	

Patient England	Over Christmas of this year I was admitted into my local hospital after months of being bed bound. I was taken through A & E and after a series of test I was diagnosed with U.C. At the time I naively thought that after treatment I could continue my studies at University and my normal life. However after strong steroid treatments and conventional medications the pain didn't stop. I spent numerous days bound to my bed in pain with regular visits to my A & E department. When suffering the pain did not allow me to study at University and I was simply unable to socialise. It began to affect more of my life than I had ever expected, my health was deteriorating rapidly. I had several appointments with my specialist who suggested the use of Infiximab every eight weeks. When first being put on the treatment my apprehension was obvious but as I saw people within the ward I began to feel more comfortable with the situation. But the pain didn't stop there as the disease continued I was unable to continue working, I was absent on many occasions and felt that my body would not allow it any longer. I felt unable to continue working and consequently gave up my job. Infiximab treatment has now become more frequent receiving it every 4 weeks. I now have my disease at a bearable level where I am able to attend University an acceptable amount to continue my studies. The treatment has made me feel mentally and physically stronger and more positive about my situation. My pain is constant and I live with it every day, my life has been altered and nothing is the same as before. My specialist has given me the option to undergo an operation which I have not yet taken up. As a student I will have no income for the time in which I will be unable to work and I will not be able to complete my studies. What strikes me is the inability to know if this major operation will work and allow me to live a normal life which I desire. By taking away this treatment you are removing my life line, I will no longer be able to study and ultimately complete my degree. My physical and mental health will deteriorate to the state I was once in and struggled to recover from the first time. I hope that you will reconsider taking into account the life changing negative impact this will make on thousands of patients like myself.
Patient England	I am on adalimumab and have been for 2.5 years. I have moderate UC and also ankylosing spondylitis - the medication is known to be effective in both conditions. I have tried various medications prior to going on adalimumab, which were not effective. I was working full time but finding it increasingly hard to remain doing so due to the UC messing with my internals and the AS causing me considerable joint pain. I practically begged my UC and AS specialists to put me on adalimumab, I had reached desperation point. Having to inject myself was a minor inconvenience compared to the benefits I hoped for. Within approximately 2 months I was feeling far better with both my UC and AS. I used to walk with 2 sticks and was in pain all the time, I could not walk far without them. As the UC was under control I have been able to eat foods such as fruit and vegetables which upset the condition, which means I have been able to lose

	weight. Over the last 1.5 years I have lost a total of 6 stone and this is due to being on adalimumab - I am sure I would not have been able to eat healthier and therefore lose weight if not for the medication. As a bonus effect I hardly need my sticks now thanks to the weight loss as my joints are also less painful. I would not ever want to stop taking adalimumab as I know my UC and AS would return, meaning I couldn't eat healthily because the foods would upset the UC. I beg you please do not remove the availability of adalimumab for those with moderate UC. Thank you.
Patient N. Ireland	I was diagnosed with Ulcerative Colitis in December 2011. Due to the symptoms of this disease I have been unable to work leading to major financial difficulties and unneeded stress. The disease has affected every single aspect of my life. I no longer have a social life and have been left a recluse as I have been unable to leave my house. I have lost friends and it has had a major impact and put strain on my marriage. I have experienced regular flares of the disease since diagnosis. I was first prescribed Asacol MR 800mg tablets. I continued to flare and was admitted to hospital for IV steroids and discharged with 50mg of prednisolone. I flared following tapering of the drug and was continuously 're admitted to hospital. I was prescribed 2 further courses of prednisolone and then prescribed Azathioprine. At present I have not reached long term remission with any of the prescribed drugs. This is having a major impact on my quality of life. It is making my life not worth living if I am being totally honest. My Gastroenterologist is going to prescribe Infliximab as my next course of treatment. This has caused further anxiety as I will only receive 3 infusions. If this drug improves my quality of life long term why can I only receive 3 infusions? I have spoken with patients with Ulcerative Colitis that have received long term Infliximab infusions and have described it as their "wonder drug" which has given them their life back. I will be denied the possibility of a better quality of life if the use of Infliximab is restricted for the use with Ulcerative Colitis. I can't help but feel cheated by your strict guidelines. I am now faces with surgery and life with a stoma if this is not approved. I am terrified at the thought of surgery and wonder what a stoma will do to my body image and confidence. I want to avoid surgery at all costs. Removal of the colon has been described as q cure for Ulcerative Colitis. This is certainly not the case as surgery can lead to further complications, lead to a poor quality of life , and even death.

	This is actually disgusting; you and your organization have the power in your hands to possibly give me back my life. If I was your daughter would you consider the same decision and deny me this treatment? Please reconsider your decision and save my life!
Patient N. Ireland	
Senior Lecturer in Sociology England	I am an academic and have written a PhD on the Quality of Life and Coping in Children and Adolescents with IBD (2006). I am absolutely devastated to hear of the suggestion by NICE to no longer offer the above medication on the NHS. The purpose of my PhD was to explore the various social and cultural impact of having IBD on those diagnosed. Part of this focused on various medication and their diverse social consequences. For the children who had been through the various other forms of treatments, Infliximab in particular offered a huge alleviation of their symptoms which in turn improved their quality of life. With an increase in quality of life of course such patients become less likely to access services such as family counselling or other forms of therapy. I urge you to reconsider your proposals and make a decision to allow these to remain on the NHS list of treatments. It is a matter of allowing these group of people with IBD to live a more comfortable and productive life.

Patient England	I am a 25 year old, diagnosed with Crohn's Disease in 2007. Crohn's disease really effected my late teen years and while on Pentasa and Azathioprine, I was extremely ill, which had huge social, mental and ofcourse physical impact on me. It wasn't until I began taking Humira 18 months ago that achieved remission for the first time since being diagnosed. Since, I have managed to successfully push on in my career and social life - Humira has enabled me to have a normal life., which was simply not possible on Pentasa (which didn't really work) and Aziathioprine (which made me much more ill). best, [redacted]
Patient England	Infliximab- my success story I was diagnosed with Ulcerative Colitis in January 2008. I was prescribed the usual drugs, progressing through Balsalazide, and, and other drugs of the same family and when these were no longer sufficient I moved onto Prenisolone & Budesonide I was then tried with Azathioprine but within 3 weeks this treatment had to be stopped I was very ill with hepatitis and pancreatitis, caused by the 6MP drug. In 2012 my UC was very severe and had become steroid resistant. I lost my job, one I had held for over 30 years as I was spending more time off sick than at work. Even when I tried to work the bone crushing fatigue and the toilet visits meant I was no longer a productive member of staff. As a last line of attack, it was recommended by my specialist that I try Infliximab, it was my last hope and I was put onto 6 weekly infusions. Within days the bleeding stopped, the pain was less and my 20+ toilet visits per day were down into single figures. Within 6 weeks I was normal! I had a colonoscopy 3 months later and my colon looked normal! I was in remission. I have stayed in remission ever since. I have received 7-8 weekly infusions now for 2 years Simply put, if I

	have an Infliximab infusion every 7 weeks I don't have Ulcerative Colitis. Importantly, I have not had one single reaction or experienced one single side effect to Infliximab Infliximab has given me my life back. My world before I was given Infliximab was my bed, my sofa and my toilet. I even had to sit or lie with the door to the room open, and the toilet door open, day and night, so I could get to the toilet as quickly as possible, but I still had accidents which were totally demoralising and upsetting. I was also in constant pain from stomach cramps and back pain and acute arthropathy (joint pain) I lost my job, I had no social life, and my husband was greatly effected. It was a very depressing existence. At one stage I was taking up to 25 tablets per day to try and control my UC, but nothing worked. I don't want this disease. It is not lifestyle driven. I havenâ€™t, smoked, drank or eaten my way to this. In fact Iâ€™m a very trim 105lbs I donâ€™t eat junk food and Iâ€™ve never smoked. I canâ€™t do anything to prevent it happening. If I could I would! I don't like NICE thinking of me as not a good use of public funds,• however if you look at it from an overall cost to the country if you take Infliximab away with nothing in its place there are going to be more people unable to work, and more hospital admissions, even a rise in Colon cancer. Please donâ€™t assume that surgery is the great solution to this disease. It is obvious that NICE are thinking along these lines as Infliximab isnâ€™t being withdrawn for Crohnâ€™s patients, only UC. Surgery for UC a major operation with a high number of people going on to develop further complications, further hospital admissions and further costs. Feel free to review CCUK, Ulcerative Colitis Awareness, United for Colitis and any other number of support groups and web pages available. Surgery to take out your Colon to so call â€œcureâ€• UC is quite frankly like curing an in growing toe nail by amputating the foot! Per say it isnâ€™t my colon thatâ€™s the problem, UC is an auto immune disease. Infliximab isnâ€™t a drug that may just improve the patientsâ€™ condition a little, or may give you a few extra weeks or months. It either works or it doesnâ€™t. It becomes obvious almost immediately if itâ€™s going to work and if it doesnâ€™t then the treatment isnâ€™t continued so there is no further financial outlay. For us it does work for, Infliximab is nothing less than a miracle drug and enables us to be full functioning productive members of the community. Rethink your recommendations NICE. Please donâ€™t take away this successful treatment. INFLIXIMAB

	WORKS It is a good use of funds to those it works for and to the overall cost to the country. Yours faithfully [redacted]

Patient and a health care professional (Dietitian) England	As a health professional and a sufferer of UC I am saddened to read this document and the conclusions. As a health professional I have seen numerous UC patients improve and thrive on these biologics, not only in regards to their medical health but also their QOL. From a personal point of view I have received Infliximab and adalimumab which have provided me with an excellent QOL and enabled me to continue my working role in the NHS. I received 4 infusions of Infliximab 4 years ago and remained in remission until a surveillance colonoscopy triggered a moderate to severe flare this year. I was very fortunate to be enrolled on a humira trial for 6 months this year and the response was immediate. I am now in remission and did not miss 1 day of work, avoided a hospital admission and avoided an increase in my medications. I did not need to see my GP nor consultant about my UC during the trial and only saw the trial doctor as per trial protocol. Surgery is not an option for me, ever. I find it hard to believe in todayâ€™s medical world that biologics are not the most cost effective way forward. As a health professional with an interest in IBD I have read numerous international papers demonstrating a medical benefit, cost benefit and QOL benefit. From my case alone I have proved how cost effective it can be which compares well with what research is demonstrating. This is a very sad step backwards for IBD patients and to see NICE choosing to restrict UC patients to surgery (or at best 3 infusions of Infliximab) if second line treatment fails is very upsetting and prejudice to this group of patients. This will lead to poorer patient-doctor relationship and increased stress in this patient group due to the limited options available. Yes, I know that side effects are expected with most drugs. However the 1st and 2nd line treatments for UC are not without their own devastating side effects which impact upon QOL e.g. steroids and their known negative impact on bone health as well as development of diabetes in some patients both of which are also costly for the NHS. To conclude, I am immensely disappointed in NICE from both a patient perspective but also as a health professional who strives to first do no harm, puts patients first and takes on board patient choice and overall well being. This proposed guidance will do harm, does not put patients first, removes patient choice and will lead to reduce QOL and well being. It is in short shameful.

Patient England	I have personal experience of treatment with Infliximab to treat a severe flare up of UC. I was being treated with a maintenance regime of Azathioprine and Mezavant when this flare up started. I was passing blood up to 20 times a day and was in constant pain. Treatment with prednisolone failed to have any effect. I was hospitalised and given intravenous steroids as well as blood transfusions. The intravenous steroids also failed and I was getting thinner and weaker. I was advised that surgical removal of my large intestine was under consideration. However a 3 infusion course of infliximab was agreed. The treatment was miraculous and put me back into remission in a matter of weeks. 5 years later I am still healthy and did not require intestinal surgery. In my case infliximab was a wonder drug treatment. It should remain an option for consultants where they feel it appropriate.
Patient England	I had severe UC, diagnosed in December 2012 (but symptomatic for many years before then). The only treatment that seemed to work was a high dose of steroids (Prednisolone, 30-40mg per day). I had Infliximab for 4 months but my consultant said it wasn't making any difference so I had surgery in the end. As a driving instructor, I couldn't live with the symptoms of UC long-term, but I had the flexibility to take a day off when I needed to be in hospital for the injection. I had gone through 2 years of hell before being prescribed Infliximab, and having spoken to other UC patients I had high hopes for the treatment. Unfortunately, it had very little effect on my colitis. I had surgery to remove my colon last April and everyone who knows me has said they can't remember me looking so healthy! Surgery should always be a last resort, but for me it was the best choice I ever made. Living with a stoma has taken a bit of getting used to, and I can understand why it would be a nightmare for someone who cares a lot about their appearance, but my quality of life is infinitely better than it was pre-surgery!

Patient England	As a sufferer of Ulcerative Colitis, I am very dismayed to see this being put forward. I know the health service is being somewhat strangled by the current Government, but this is certainly not a good answer to people who suffer from UC and other, similar diseases. When I was turning 24 I was first diagnosed with severe, acute UC and was in hospital for a number of weeks. Steroids did not do a thing for me, and the case was so severe that surgery was being discussed as a necessity. As a 24 year old man, a life-changing surgery is absolutely not something I wanted to deal with in my life. The last chance was an infliximab infusion, which I had and which put me on the road to recovery. It completely saved the need for surgery and everything that goes with it, and gave me my life back. Now, at 28, I live with this condition and while I have good days and bad, I manage to live a fairly normal life. It is a blessing to me to know that if it got very bad again, an infliximab infusion would be there as an option for me so that I can live as normal life as can be offered. To take this away from myself and so many others is immoral, and will have a severe negative impact on thousands who suffer from this condition. I cannot stress enough how much I am against taking away infliximab as an option for IBD sufferers, and what is an absolutely horrible illness will become so much worse for so many people all in the name of saving a bit of money. Should you go through with this, just know that you have decided to take away a very useful treatment from a disease with no cure that thousands struggle to live with every day.
Patient England	I am a sufferer of both crohns & ulcerative colitis, and my life is hell so I implore you not to make these drugs unavailable to us sufferers. I was on infliximab a few years ago and had a reaction to it and I had to come off the drug it was very upsetting as this drug gave me back some sort of life. I am on methatrexate at the moment but it is not working making my life hell just been on holiday it was torture,I am also a front line ambulance worker so you can imagine how difficult that is. They are going to try me on a simular drug to ifliximab called humara and they think it will be as good as infliximab. So I am begging you not to take this life line away from so many people that it sets free from there medical internment.

Public England	Whilst I appreciate that this range of drugs/treatments is high in cost the undoubted quality of life that is offers patients including my daughter must be considered against the long term costs of removing the colon not least the real cost of the operation and ongoing treatment. The phycological effect must also be considered in the cost analysis as this operation would have a devastating effect on the patients confidence for many years, many of these patients are young with busy lives as workers, parents and partners so the effect of surgery goes far farther than just the patient. The value of this treatment cannot and must not be under appreciated due to cost
Public England	I provide support for my partner who suffers from severe ulcerative colitis. When this condition first appeared it was a very stressful time for her, with the thought of surgery vastly increasing this stress. A number of treatments were attempted that didn't ease the condition but with infliximab the improvements have been dramatic. Her quality of life returned to normal and without the threat of what is life altering survey hanging over her a massive weight was lifted. I believe that these treatments are an essential part of the health service. Due to life long effects that surgery for this condition would have it should only be seen as a last resort rather than a quick fix for the health service. A patients well being and mental state should always be top priority and if a non surgical procedure is able to alleviate this condition then it should be every patients right to be offered this

Patient England	Dear Sirs, I am the [redacted] of the IBD patient panel at UCLH, a [redacted] with the Disability Benefits Service at Crohn's and Colitis UK , and an ulcerative colitis sufferer. These are my comments in relation to the draft guidelines on the use of infliximab, andalimumab and golimumab. I am currently in receipt of exceptional case funding from my CCG for infliximab treatment for my UC. I have been receiving infliximab treatment for the last eighteen months. I am extremely disappointed and concerned that NICE are not recommending biologic treatments for moderate to severe ulcerative colitis. I feel that a number of very important factors are missing from your considerations of the cost effectiveness of these treatments. The number of treatments currently available for UC in the UK is extremely limited. I have suffered from UC for three years and within approximately one year of diagnosis I had already exhausted all conventional treatment options. This is not uncommon. The first line of treatment for UC is corticosteroids. I note that in your draft guidelines there is no mention of the well known complications of long term steroid use, including osteoporosis, cataracts, diabetes, suppressed adrenal gland hormone production, etc. The reality is that the majority of UC patients are left with no choice but long term steroid use because maintenance treatment options for UC are so limited and poorly tolerated. The costs of long term damage and increased use of NHS resources to treat these complications do not appear to have been considered in your reasoning. Biologic treatment enables patients to stop using steroids and therefore avoid these complications as well as the day to day side effects of steroid use (weight gain, poor sleep, anxiety or euphoria, acne etc). The cost of hospital admission for intravenous steroid treatment should also have been considered.
Patient England	Other treatment options for UC are mesalazine, which is often ineffective in moderate to severe UC, or immunosupressants such as azathioprine, methotrexate or mercaptopurine. (which is essentially the same drug as azathioprine). These medications have significant side effects but can also be ineffective. Azathioprine caused my white cell count to drop. Methotrexate was completely ineffective and mercaptopurine was not even offered to me since it is the same as azathioprine. After nine months of being extremely unwell with UC, up to ten bloody bowel movements per night, extreme fatigue, temperature, weight loss, anaemia, I was eventually admitted to hospital and treated with infliximab. I cannot express

	how much this treatment has improved my quality of life. I had to fight extremely hard to access the treatment that I needed, both with my hospital and my local CCG. If I had Crohn's disease no questions would have been asked. Thanks to infliximab I was able to stay in work, pursue a career, avoid hospital admissions and consider starting a family. To be told that my quality of life is not worth Â£210 per month is despairing.
Patient England	There appears to be an assumption that surgery is an easy and cheaper option to treat UC. The costs of surgery have not been properly considered in this appraisal. The cost of hospital admission for up to three complex surgeries, the cost of stoma care, the cost of treating complications arising from surgery (including biologic treatment for severe pouchitis in certain cases) have not been properly considered in this appraisal. There also appears to be an assumption that most patients treated with biologics will have surgery within two to three years anyway. This is not accepted. Some patients do lose response to a biologic within three years of starting this, however a switch to another biologic would be an option if all three treatments were approved. These treatments could therefore provide up to nine years of remission to patients, or indeed the possibility of avoiding surgery altogether if mucosal healing is achieved. Surgery is not an acceptable option for me as a UC sufferer because this would mean around nine months out of work, a significant impact on my career, risk to my fertility as well as a delay to starting a family, and there is no guarantee that surgery will result in an improvement in my health and quality of life. Infliximab on the other hand has resulted in a huge improvement in both my health and my quality of life. If NICE requires further information on cost effectiveness and comparison with other treatments and surgery then a delay should be sought in the publications of these guidelines in order for this information to be collected. These treatments should not be rejected without this information being available. I very much hope, on behalf of the 120,000 UC sufferers in the UK, that you will reconsider your decision to reject these treatments.
Patient England	infliximab did not force my colitis into remission, it did however significantly reduce the symptoms for several weeks after each infusion. i have since had surgery after a year of infliximab, but have met other patients who have had their lives transformed by the treatment. As this condition may be genetic, it is on behalf of my family, and future children to ask that this treatment is continued for colitis sufferers as it may help them in the future. NICE should consider investing

	consider using their influence to push for new drugs and treatments with the view to adoption of more effective drugs prior to the withdrawal of infliximab. kind regards
Carer England	Dear Sirs, My daughter who lives in [redacted] found out she had ulcerative colitis around 7 years ago and although treated with various drugs including steroids her condition deteriorated to the point where we thought she would die and she has been in hospital a number of times. The second time she was in hospital they treated her with Infliximab which consisted on 3 infusions followed by a follow-up infusion two months later. This alleviated all her symptoms and she was able to have a normal life. This was 4 years ago. Unfortunately, she was not prescribed a maintenance dose and after about 12-18 months her condition deteriorated again until everything in her seemed to shut down and she had to go to hospital as an emergency where she was again given Infliximab and all her symptoms and illness went away. There was, however, a warning on her hospital notes that if she was to be admitted to hospital again she was not to be given Infliximab. Since then she has developed pyoderma gangrenosum on her leg which no-one at her local Harlow hospital had seen before as it was quite rare and she went through some excruciating treatment and huge amounts of steroids to try to combat this lesion. The lesion was stabilised and she was referred to [redacted]. But as the lesion was stabilised she was not given Infliximab. Also he has since written to her saying he thought a colostomy might not be the answer to her condition. She is once again ill and trying to keep down a job at the same time. The only way she can survive at work is not to eat anything. Unfortunately as her condition gets worse this time she will again have to be admitted to hospital (usually for around 2 weeks) and it looks as if she will lose her job. My daughter because of circumstances left school at 16 and has worked hard to carve out a career for herself. [redacted] None of our family has ever been a burden on the State. [redacted] Daily we hear about innovations with drugs which can heal all kinds of sicknesses and prolong life. But what is the use if those drugs are only available to the few who can afford them. The rest of us are fobbed off with cheaper options which neither cure nor help us live a useful life. If you counted out the number of days off sick, the hospital time and the various specialists, such as dermatologists, rheumatologists, haemotologists and gastroenterologists â€“ all with their hands tied as they cannot prescribe the drugs that are needed â€“surely just a waste of time and money plus the sacrifice of a life. Here is a list of GPs and specialists she has consulted most frequently. [redacted]

	[redacted]
Patient England	Dear Sir/Madam As a sufferer of IBD I am horrified to hear that NICE does not think that Infliximab is a cost effective treatment. Having tried almost all the other treatments available, two of which put me in hospital, namely Azathioprine and Mercaptopurine, and none have worked for me. I am finding that Infliximab is working and keeping me clear of any symptoms. If this treatment were to be stopped on the NHS I, for one, would not be able to afford it privately (and I'm sure there are many other sufferers currently on Infliximab that would not be able to afford it either). This would, most likely, mean that I would be likely to have a relapse and end up back in hospital which would, I would have thought, cost the NHS substantially more in treatment. Given the number of sufferers of all ages, stopping Infliximab being available on the NHS would, in my opinion, end up costing the NHS a lot more and not only put our hospitals under even more pressure than they already are, but would cost the country a lot more in working time lost. PLEASE BE 'NICE' AND DO NOT RECOMMEND THE STOPPING OF TREATMENT OF THIS DRUG UNDER THE NHS.

Patient England	Good afternoon, My name is [redacted] I am 21 years old and I am a patient with Ulcerative Colitis, who was diagnosed in September 2012 at the beginning of my second year of University. My first big flare up was when i received a diagnosis, treated with steroids, i was put into a remission for the remainder of my second year at university. Beginning my 3rd year of university then saw the start of continual flare ups and courses of steroids. I was also experiencing Joint problems and Psoriasis, as well as the extreme fatigue, blood loss and diarrhea. This severely affected my quality of life and i struggled to complete my degree, there were many late submissions and I didn't attend more than 3 lectures during the second semester. Fortunately the uni were very supportive and i still managed to get a 2;1 degree. However every time i was reducing off a course of steroids the symptoms would again become worse and worse. Once my degree had finished and the stress was over my biggest flare up of that period began. Even a 9 week course of steroids couldn't settle this flare. At the beginning of this course my Consultant decided that i was becoming steroid dependent and that i had already been having so many courses (without a good response) it was time for something else to be done. I then tried suppositories, enemas and other various types of medications with no relief from my symptoms. This flare up had also presented itself with intense stomach pain which caused me to have to give up work and move home with my parents. The flare up was ongoing for 3 months and involved a hospital admission, before the pharmacy would accept my application for infliximab. After my first infusion I saw a dramatic difference in both my joints and psoriasis. I was experiencing no problems with either of these any more. With the next two infusions the stomach pain decreased and the amount of blood and bowel movements a day also dramatically decreased. Infliximab has given me the chance to start back at work, begin working in a school before I enroll on a course to become a teacher and has allowed me to become a cub scout leader. This is a dramatic change from the 3 months before my first infusion where every day was spent on the sofa curled up in pain. Without infliximab I would have had to consider surgery or other drugs that can cause more harm then good. I feel that if surgery is needed i would like it to be my decision and my choice. It is my life and if I had been told i would need surgery before i got the chance to try infliximab I would have been furious that there is a well known drug that has good benefits that i wasn't allowed to try. For me and many others surgery is a last resort. Infliximab not only sorted my colitis, but also my psoriasis and joint problems. For me, it has been a life line, a chance to keep my colon and lead almost a normal life.

NHS Professional England	I am extremely concerned that NICE have once again taken the decision to deny anti-TNF drugs to patients with moderate-severe ulcerative colitis (UC). Not only is this is out of step with European and American practice it is also against UK clinical experience with these drugs in this setting. In essence anti-TNF drugs are being compared against colectomy which is not a fair or valid comparison. Many patients who have UC which is not responsive to so called conventional therapy or who are unable to tolerate these drugs very reasonably do not want to have a colectomy especially when knowing that they might derive significant benefit from an anti-TNF agent. Indeed some will refuse colectomy and carry on with debilitating symptoms, more frequent hospital contact, absence from work and ongoing steroid use with all the associated long term side effects. This is an intolerable and cruel situation when drugs are available from which some of these patients will derive life-changing benefit. The decision from NICE appears to be based on cost-benefit modelling, not lack of efficacy. Consequently patients who have ongoing symptomatic disease, unresponsive to currently â€˜recommendedâ€™ treatments, have to be told, in the clinic, that while there are drugs available that might literally transform their lives and allow them to keep their colons NICE have said that they canâ€™t have them because itâ€™s apparently cheaper, based on a mathematical model, to offer a colectomy. Of course not all patients with UC will respond to anti-TNFâ€™s. But some do. Denying these patients a chance of a symptom free, steroid side effect free, life, based on a mathematical model of an unpredictable disease whose course varies enormously between different patients is not only ludicrous but unconscionable.
NHS Professional England nothing to disclose	The overall conclusions seem reasonable, although the continued emphasis on the economic costs of colectomy are disappointing. What seems to be missing in this document, especially related to service provision effects, is the interactions with clinical research networks. As the document states the optimal management for thiopurine non-responding patients is not certain and whilst the ant-TNF drugs are theoretically an option, it must be agreed they are no that effective at all. There are many ongoing clinical trials supported by the Gastroenterology Research network of novel agents, the majority of these seem to be considerably more effective that any of the anti-TNFs in inducing both clinical remission and improvement. The whole point of the NIHR infrastructure was to support clinical research and increase the availability of clinical trials to potential patients. The correct option for the patients surely should not be have anti-TNFs of modest efficacy and great cost, or a colectomy but to enter a clinical trial, which actually offers greater chance of benefit? By not driving a increase in clinical trial participation in this important group, the NICE guideline group are condoning less than optimal practice and disadvantaging the patients. There is already too much reluctance to refer patients elsewhere, perhaps for better care, and certainly insufficient patients are referred to centres recruiting patients to trials. This then clearly creates post-code prescribing: patients in the local area of research active units, get better drugs and better results. Those patients local but not quite local enough, will just get a colectomy.This guidance is very much a missed opportunity to reinforce the benefits of clinical trial participation and involvement in the research network,

	when this will be a clear benefit to individual patients.
Patient England	Diagnosed with uc 6/2010. admitted to hospital 1/2013 with severe uc and came close to having entire colon removed. All standard medical treatment failed including steroids. Received Infliximab and condition improved. I have been prescribed it since and my condition has improved drastically. It has given me my life back and I realise without it my quality of life would be poor again
NHS Professional England My daughter has UC. Biologics have transformed her quality of life	I do not feel that the complications (specifically Surgical Site infection and adhesions) post-surgery have been given enough consideration. Surgical site infections in bowel surgery and are underestimated my national surveillance schemes at approx 9%. These schemes look only at inpatient data and high quality surveillance undertaken as part of research studies put the rate at 27% (Tanner J, Khan D, Aplin C, Ball J, Thomas M, Bankart J. Post-discharge surveillance to identify colorectal surgical site infection rates and related costs. Journal of Hospital Infection. 2009;72(3):243-50.) The cost associated with these SSIs was Â£ 10, 523 per case. The cost associated with abdominal pain and adhesions requiring further surgery also should be considered.
NHS Professional England My daughter has UC. Biologics have transformed her quality of life	

Patient Wales	I encountered my first symptoms of Ulcerative Colitis 5 years ago, which initially manifested itself as an attack of acute pancreatitis. After 1 month in hospital recovering from the pancreatitis I was released and it took a further 12 months of symptoms before I was diagnosed via colonoscopy. At this stage the disease appeared to be relatively mild, although present throughout my entire large bowel. I was frequently in pain and suffered from bleeding, but still managed to hold a relatively normal life. I was given prednisolone which put me quickly put me into remission. I took the steroids for the length of time stated by the doctor and also placed on asacol as maintenance. Unfortunately the remission last 2 months and from this point onwards my disease progressed quickly and became more severe. I was given steroids a second time and these failed to work. I suffered for approximately 12 months with repeated trips to the doctor and was told to continue taking the steroids, at a higher dose. Azathioprine was mentioned as a potential option, but my consultant was extremely hesitant to give it to me due to my previous history of acute pancreatitis. My condition got rapidly worse over the coming months and can only be described as a living hell. I could not leave the house and had to be signed off on long-term sick leave. My bowel movements increased in frequency with each passing week. Each bowel movement was accompanied by a large amount of blood followed by crippling stomach pains that would leave me unable to move or function for prolonged periods of time. I became withdrawn and lost a large amount of weight (I am 6â€™6â€™ and weighed 74kgs at my lightest). During my final few days before being admitted to hospital, I could barely leave the bathroom. I was experiencing 15-20BMâ€™s per day with approximately 50% of these being almost entirely blood. The stomach cramps were debilitating and I frequently threw up due to pain. I was admitted to hospital during easter 2012 and spent a total of 4 weeks as an in-patient. I was immediately put on IV corticosteroids which resulted in a very minor improvement in symptoms. Immediately after tapering off, the symptoms returned. I was diagnosed as having severe pancolitis and was told if my symptoms got any worse and could not be controlled, then I would have to undergo surgery and having my entire colon removed. The first time this was even mentioned was an option was when the surgical team came to assess me. I was given a leaflet on life with a stoma and that night I wept for the first time in years. I asked desperately about any option other than surgery. Again, the consultant mentioned azathioprine but was extremely concerned about using it due to the pancreatitis and there appeared to be no options left. On day 26 I was approved for a medical trial testing the effectiveness of infliximab vs cyclosporine. And received my first infusion that morning. Within 3 days I was discharged having achieved a dramatic reduction in symptoms and returned to work 6 days after being discharged. This is a very brief description of my disease progression and is as accurate as possible considering the pain I was in.

	Before being admitted to hospital I was a shell of my former self. I stopped playing sport and going to the gym (previously I had been extremely active playing sports for multiple clubs and weight training daily), my social life was non-existent as I could not be certain I would not soil myself getting between locations with toilets (this did happen on 2 occasions). I had to be placed on long-term sick as my job requires frequent travel and public speaking, which I was not able to do. My relationship broke down due to depression at my condition. I did not want to speak to my family or friends at all due to a mixture of shame and relentless fatigue. cont on comment 2...
Patient Wales	cont from comment 1 - This was not only damaging to myself but to my loved ones who had witnessed my descent from being happy, active and successful, to painfully underweight and withdrawn. In short, I felt everything worth living for had been taken away and at times I did not see a reason to go on living. I suffered badly with fatigue and at times slept for prolonged periods, only getting out of bed to use the toilet and eat enough to not be hungry. I was in a fragile emotional and physical state, which was made worse by being admitted to hospital for a month. The doctors, nurses and general care I received were excellent, but prolonged stays in hospital present difficulties for most patients and I did not handle it well. After suffering for close to 2 years in almost daily pain, the speed and effectiveness of infliximab was nothing short of miraculous. Everything in my life turned around within 24 hours of receiving my first infusion. The first thing I noticed was a dramatic reduction in pain after a bowel movement. I could not remember what a pain free bowel movement felt like but felt compelled to tell everyone that I knew (which seems absurd now, but at the time I was elated). My appetite returned and steadily over the next 3 days by bowel movements reduced in frequency and severity (a distinct reduction in bleeding). Although still very weak, I felt like a giant fog had been lifted and I began to remember what it was like to not be in constant pain and had energy I did not know it was possible to possess. For the next few months I made steady improvements, I gained weight from a starting point of 74kgs up to 80kgs and finally after 2 years I have reached 85kgs, which is the weight I was before my first symptoms. At this point I feel like I owe my entire life to the drug. Everything I do on a daily basis is down to the treatment I receive every 8 weeks. I have a happy and fulfilling life that was not possible with the effects of severe ulcerative colitis. I still have occasional symptoms at the end of my 8 week cycle, so often look forward to my infusion date as that grants me another 8 weeks of happy life. I do not generally plan anything beyond 8 weeks as I rely on it so much to be healthy.

	I am now aware of the surgical option for ulcerative colitis and I am aware that I have very few treatment options left if infliximab fails to continue working or is withdrawn by my doctors. It has taken a long time, but I am finally mentally ready for this as an option and have spent a long time talking to people with ostomies, colostomy bags and j-pouches about their life after surgery. But facing that surgery in the fragile mental state I was in after being admitted to hospital would have been nothing less than devastating. I was not in a healthy state of mind and facing life with a colostomy bag was blown out of all proportion in my head. I had not had a chance to educate myself about the implications. Looking back I am very concerned that I may have taken drastic action. cont on comment 3...
Patient Wales	cont from comment 2. This is the point I extremely concerned about NICEâ€™s proposal to withdraw infliximab as a treatment option for severe UC. I believe infliximab is essential for people with severe UC to give them time to understand their condition, and face the fact that they may require surgery in the future. I believe it should remain as an option for people on their first admission to hospital, where all treatment options have failed and they are facing imminent colectomy. This should ideally be provided with counselling to help them understand the future implications of surgery and help them prepare. This major surgery also has wider implications for people in their lives. Now that I have been given time, I am able to plan a career break should I need one. Due to the nature of my work I am now on fixed term contracts and self employed. Having time to plan for surgery means I can save money and make arrangements to cover my mortgage and bills whilst recovering from surgery. Unplanned hospital admission and surgery could have even more devastating effects on patients who do not have sufficient savings to cover their bills. I would be extremely close to defaulting on my mortgage if I was not prepared. As I am still relatively young, I would like to continue on infliximab as long as possible to enjoy my life without a colostomy bag. I am still extremely concerned about having the surgery especially as I know of people who have struggle with blockages, pouchitis and erectile function post surgery. I am still single after my relationship broke down due to my severe flare up and would like the chance to form a stable and lasting relationship before I undergo such a life changing operation. I would also like other people to have the same opportunities I had to receive this drug and make the necessary adjustments. However, the surgery would be in no way as devastating as if it had happened two years ago and that, more than

	anything, is why I believe it should remain as a treatment option for people with severe UC. Thank you for your time.
Patient England	I was given infliximab after 2 weeks of IV steroids which did not work. I'd been having 30+ bowel movements a day. The day after my infusion I had 4 bowel movements. I was discharged 2 days later. I had 2 follow up infusions and was in remission for a year. A year later I have flared up again and have been in and out of the doctors and hospital for outpatients appointments. I am taking pentasa both orally and anally and mercaptopurine and have been on prednisone but it still won't settle for more than a few weeks. In terms of my health, infliximab helped immediately and unequivocally. In terms of Value For Money - It would undoubtably be better to nip a flare up in the bud with infliximab rather than going back and forth to the doctors. Not only do we as taxpayers pay for the useless drugs which fail to improve my health, the taxpayer also pays for the doctor's and receptionists time and my time (as I take paid leave off work for these appointments). I work for the civil service, so my paid leave directly costs the taxpayer money. This is just for appointments, not to mention the cost of lost working hours (both mine and those who take compassionate leave to visit me in hospital) not to mention the direct cost to the NHS if I had to go back to hospital. I am sure that the cost of infliximab infusions is less than the costs mentioned above.

NHS Professional England	6th October 2014 Dear NICE Today we had a meeting of the British Society of Gastroenterology Inflammatory Bowel Disease (IBD) Clinical Research Group. At the end of the meeting many opinion-leading IBD gastroenterologists [redacted] X€™s, London]) expressed substantial concern at the draft NICE guidance relating to the use of anti-TNF therapy in ulcerative colitis. In particular was concern at the complexity and tangential relevance of the modelling used to interrogate costs and benefits (making the analysis all but impenetrable even to experts in IBD management highly familiar with the literature on this topic) and the flawed assumptions on which it seems to be based, seemingly failing to recognise that: 1. The patients included in the published studies of anti-TNF therapy were NOT representative of the patients who would be considered for this treatment in the UK [ie mild disease refractory just to mesalazine treatment vs â€˜end of the lineâ€™ patients often refractory to steroid and azathioprine and in whom surgery is the only remaining option] 2. A smarter treatment algorithm could be implemented, for example allowing patients an induction course of anti-TNF therapy and only allowing maintenance in those who clearly make a complete response â€“ having a dramatic impact on the cost-benefit analysis 3. The arrival of bio-similars in Q2 2015 will inevitably reduce the costs associated with anti-TNF therapy and substantially alter assumptions made in the current cost-benefit analysis 4. Critically, many patients who undergo colectomy for ulcerative colitis are NOT cured and do NOT return to a normal quality of life. 39%1 are incontinent of faeces overnight and 26% suffer some daytime incontinence2. 20% suffer from sexual dysfunction3 with only 56% being able to conceive at 2 years4. 20% of patients have on-going problems relating to inflammation in the pouch at 1 year5. Many of these are managed with anti-TNF therapy and 13% require further surgery to remove the pouch2. Thus the evidence from the literature and the large collective experience of our panel is that the traditional assumption â€˜colectomy = cureâ€™ is deeply flawed, and that a modelled dysutility value for post surgery of 0.75 based on the paper by Woehl presents a hugely optimistic assessment. Accurate assessments of the costs and morbidity associated with post-surgical complications and care must be included in the model. We would strongly urge your committee to reconsider its analysis and the details of its modelling, and further engage experts in the gastroenterology and IBD community to input into the process. Otherwise we

	fear a grave injustice being done to this predominantly young and economically active patient group which would put UK practise at variance with the rest of Europe and North America, and which risks undermining confidence in the undoubted strengths of NICE. Thank you for taking these views into consideration Yours truly [redacted] 1. de Buck van Overstraeten A, Wolthuis AM, et al. Long-term functional outcome after ileal pouch anal anastomosis in 191 patients with ulcerative colitis J Crohns Colitis. 2014 Oct 1;8(10):1261- 2. Wheeler JM, Banerjee A, Ahuja N, Jewell DP, Mortensen NJ. Long-term function after restorative proctocolectomy. Dis Colon Rectum. 2005 May;48(5):946-51. 3. Chapman JR, Larson DW, Wolff BG, Dozois EJ, Cima RR, Pemberton JH, et al. Ileal pouch-anal anastomosis: does age at the time of surgery affect outcome? Arch Surg 2005;140(6):534â€”9

NHS Professional England	4. Hueting WE, Gooszen HG, van Laarhoven CJ. Sexual function and continence after ileo pouch anal anastomosis: a comparison between a meta-analysis and a questionnaire survey. Int J Colorectal Dis 2004;19(3):215â€”8. 5. Hahnloser D, Pemberton JH, Wolff BG, Larson DR, Crownhart BS, Dozois RR. Results at up to 20 years after ileal pouch anal anastomosis for chronic ulcerative colitis. Br J Surg2007;94(3):333â€”40.
Patient England	Dear Sir i would like NICE to appreciate just what a lifesaver treatment with infliximab is to patients who respond well to this drug. I was diagnosed with UC in 2009 and did not respond to any of the conventional drugs: steroids, mercaptopurine, anti-inflammatories. For different reasons I was unable to tolerate any of them, so was put on to infliximab. This was quite miraculous - from the first dose I started to recover from a horribly distressing flare-up of UC, where I was unable to work, eat, sleep, look after the family. I felt my life had come to an end. Without infliximab I would have gone straight to a colectomy and living with a stoma, with all the difficulties associated with major surgery, both physical and psychological. With infliximab I was able to get back to my job and start living again; it really did give me my life back both at work and with the family. I felt so lucky to have it, as I know some patients can't access this drug. I have never experienced any health problems with infliximab, either during the infusions or during periods between infusions. Apart from 8-weekly infusions I haven't needed any further medical interventions, hospital stays, etc, for 5 years; surely this would make treatment with infliximab a viable treatment financially from this point of view. I would urge NICE to allow treatment with this drug for patients with UC who can't tolerate the usual drugs for UC. I understand infliximab is coming off patent so surely this would make it cheaper for the NHS.

Patient England	I am an Ulcerative Colitis patient who received treatment with infliximab. The classification of severe UC is more than 6 bowel movements a day. During my last flare-up (2009), I was having a bowel movement at least once an hour, and required a blood transfusion. I was in extreme pain, and my parents returned from living abroad, so serious was my condition. I was taking steroids (orally and topically) and also azathioprine. I remember having my first dose of infliximab on a Saturday afternoon. By the Monday afterwards, there was a dramatic improvement in my condition - the relief for myself and my family was immense. I then had a second treatment several weeks afterwards. As time passed after this treatment, my symptoms returned, even though the azathioprine should have kicked in and suppressed my immune system. I was back to living in extreme pain, waking every 30-60 minutes in the night to use the bathroom, and losing control of my bowels - at one point while driving on the motorway. I felt like my life had been reduced to nothing more than battling my illness. Surgery was discussed with me, but this was an option I wanted to avoid at all costs. In your reports this may be a more cost effective option, but you don't have to factor in the same things as I do - such as having to carry around a 'nappy bag' of stoma supplies as if I have a baby, how to manage the bag when I am running, or doing martial arts, and being sat in a meeting at work and effectively starting to defecate in a room full of my colleagues or customers - and possibly still suffering UC-related symptoms anyway. Then I began a 12 month course of treatment with infliximab. Again, from the first treatment there was a marked improvement within days. Only at this point did I start to rebuild my life. I gradually walked longer distances, and eventually I was able to start running again, 30 seconds at a time. I was able to rekindle the travel plans that I had given up my job and left my previous life to begin - I had to abandon these completely when I flared up, as my visa application then was refused. My life had been changed completely during the course of my flare-up, and only infliximab gave me the health and the hope to rebuild it. At first I used to feel the symptoms creeping back as my treatments became due, but by the end of the year I felt healthy all the time, and my health has been maintained using 'cost effective' conventional therapies for four years (I note in your report you question whether the effects of these treatments extend past the first year). If the recommendation of NICE is to withhold these treatments from UC patients, then my heart will break. I dread the onset of my next flare-up, and to know that new and effective treatments are being developed, but won't be available to me, will make it harder than ever to deal with.

Patient N. Ireland	As a patient I received 5asa and various steroid based medications as far back as 2006. After 2 years of fairly ill health and with my symptoms showing no signs of improvement (bloody bowel movements 15 times per day) I was admitted to hospital where I required a blood transfusion. I spent almost a month in hospital and was started on IV steroids as well as azathioprine. At this point the steroids besides causing chronic insomnia were doing nothing for my symptoms. I received an Infliximab infusion on day 26 and immediately noticed a positive response. For the first time in two years the bleeding and frequency of bowel movements reduced. A few days later I was discharged feeling extremely lucky to have escaped collectomy surgery and having had the chance to receive this therapy. Over the next 8 weeks I received 2 more Infliximab infusions and by around week 7 my symptoms were almost entirely gone. The positive outcome enabled me to regain something closer to a normal routine and to get my life back having had to leave work in 2007 and being pretty much house bound 24/7 and unable to make it beyond the bedroom or bathroom for 3 months. The full remission lasted for approximately 6 months and then slowly the symptoms started to return. I was again started on steroids but they had no effect so after another couple of months of slipping back down and increasing my Azathioprine dose I was offered another does of infliximab. As with the first time, my symptoms were completely gone. In short. Infliximab enabled me to enjoy something approaching a normal life again. I was able to return to work and to make plans that looked further ahead than just one day. I have not experienced any ill effects from using this medication. UC can be an extremely debilitating disease. Surgical options are far from ideal in my opinion, especially for people who do physical jobs. While I appreciate that Biologics will not work for all IBD patients I feel that their use is invaluable in saving a proportion of UC patients from surgery and all of the baggage that comes with that.

NHS Professional England	I write as a gastroenterologist caring for patients with UC for over 30 years, as [redacted] as a previous expert adviser to NICE and as a clinical researcher in the treatment of IBD. I'm afraid I share the extreme concern of many other individual clinicians, professional groups and patient organisations about the proposed guidance on the use of antiTNF therapy in UC. I fully support the feedback sent to you by the British Society of Gastroenterology (though I haven't contributed to it) and will not reiterate their highly justified criticisms of the conclusions NICE has reached and the assumptions and methods it has used in so doing. (I should add that I have not contributed to, or seen the response from Crohn's and Colitis UK). I would like to make, however, just a few points: 1. The alternative treatment proposed by NICE, surgery, is not, unfortunately, a perfect solution. The procedure is a major one, and even with the best results, leaves patients with either an ileostomy or an ileoanal pouch necessitating defecation of liquid stool 4-6 times daily and often in the night. Up to 50% of patients with pouches may develop pouchitis, itself a very unpleasant inflammatory condition for which there is limited medical treatment. It is unsurprising that most patients and their doctors opt for medications that can prevent or defer for as long as possible this irreversible and unsatisfactory procedure. 2. AntiTNF therapy does not of course help all patients with UC. In some, however, it completely transforms their lives, often converting them from steroid-dependent sick people unable to leave their homes, to fully functioning and working members of society. 3. Because antiTNF therapy is not effective in every patient, its use should be carefully monitored. One approach, used currently by us, is to undertake flexible sigmoidoscopy before and at 2-3 months after initiation of treatment to ensure that there has been an objective mucosal response. Patients not showing a good mucosal response, as well as those whose symptoms have not improved, have their antiTNF stopped. For them, surgery is very regrettably the only current alternative. For patients who respond clinically and sigmoidoscopically, treatment continues until, just as in Crohn's disease, a formal re-evaluation at one year, with a view to withdrawing the antiTNF in those in complete remission. Has NICE considered this approach? 4. Many patients who respond to it want/need antiTNF therapy only for a limited time anyway, eg to get them through exams at school or university, to tide them over marriage and conception (which may itself be threatened by surgery). In these patients, there is a particularly clear social endpoint, as well as need, for use of antiTNFs. 5. Early colectomy in patients presenting for the first time, but who fail to respond to conventional therapy, is a huge psychological as well as social and physical hurdle. Delaying surgery through use of antiTNF therapy can be enormously helpful.

	6. A likely outcome of a proportion of patients refused antiTNF treatment is that they will refuse surgery and battle on with obsolete and dangerous longterm steroid therapy, with resultant (expensive) complications. 7. A decision by NICE, despite the accumulated evidence, to prevent the selective and carefully monitored use of antiTNFs for people with UC will be a dreadful one: it will be considered inexplicable and extraordinary by patients and gastroenterologists not only in the UK but all over the world. For me, it would entirely undermine the credibility of NICE and its decision-making processes.
Patient England	With regard to the committee preliminary findings of not recommending â€œthe use of adalimumab to treat adults who have moderately to severely active ulcerative colitis that has responded inadequately to conventional therapy including corticosteroids and mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapiesâ€• I object to your findings and would urge you to reconsider your recommendations for the following reasons: 1) I was diagnosed with UC during the 90â€™s. Initially my condition was under control with the use of Messalazine. However, as the year progresses, I have regular relapsed and the use of corticosteroids helped but not for long. The condition continues to deteriorate and in 2005, I had a severe relapsed and ended up in hospital three times despite the use of corticosteroids. I was unable to work and had extremely poor quality of life. 2) My consultant prescribed mercaptipurine to me and I nearly die from the side effect as I have no white blood cell left in me. I lost all my hair in 2 weeks and I ended up in an isolation ward due to the fact that my immune system has collapsed. I was in hospital for two weeks and this must have been cost NHS a lot of money. 3) I was then prescribed infliximab; however, the drug did not work for me as I was still relapsing. In addition to that, I face was swollen like anâ€• elephant manâ€• due to the reaction to infliximab. As a result my consultant stopped the treatment. 4) My consultant finally prescribed adalimumab to me and this has changed my life. I noticed the change very quickly and I am now able to resume a normal life. I am in remission and I fear that if this is withdraw then my quality of life with be reduced to an intolerable level. 5) I can confirm that adalimumab is an effective treatment that prevented symptoms from recurring and helped me maintain a good health state for long periods. I noticed my symptoms of ulcerative coliltis returned (with my bowel opening many times with loose and bloody stools) when I had to stop my injection of adalimumab for two weeks due to my chest infection. As soon as I return to my normal injection, my UC symptoms gone away. 6) In concluding, I would like to bring your attention to the following: a. Adalimimab has given my self-confidence back. This is priceless for any individual.

	b. With the use of the TNF-alpha inhibitors, the symptoms of ulcerative colitis had stopped and I felt â€˜normalâ€™ again and able to work and lead a normal life. c. The TNF-alpha inhibitors is a valuable option to many patients, (I am a living example) that could offer long-term remission to patients with active ulcerative colitis. d. With regard to the cost effectiveness of the Adalimimab, it is very cost effective as patients with their Ulcerative Colitis condition under control will not require constant hospitalisation and going to see the GP or the consultant therefore it reduces the NHS treatment costs. e. I urge you to factor into the NHS cost of taking care of patients who relapsed due to not being able to access the TNF-alpha inhibitors drug and the cost to the UK economy.
Patient England	Introduction I suffer from Ulcerative Colitis and I receive Infliximab to control the condition, successfully. My Ulcerative Colitis was diagnosed in 1977, though I had a history of diarrhoea for the 10 years prior. Since 1987 my condition worsened and had been chronically active. It was defined as moderately-severe and debilitating. Conventional drugs had failed to control symptoms of the disease, I was hospitalised, and in addition I suffered the adverse effects of drug treatments. Surgery was considered. In 2005 I was offered a trial administration of Infliximab. I responded positively, and entered remission that has lasted most of the time since 2005 (except in 2008 when we tried to switch to Adalimumab). My life changed for the better. I was saved from a major risky operation.

Patient England	My condition when I was very ill 1987 â€“ 2005 I was most of the time ill, bed ridden, with frequent flares of chronic symptoms and few very brief periods of remission (longest 4 months). My condition was defined medically as refractory Ulcerative Colitis, moderately-severe and potentially debilitating. Due to the unpredictability of my illness, I was unable to plan for work and social life. I constantly lived in fear of the illness and potential operation. My condition was defined. Symptoms: Physically: I was very ill, chronic, urgent, frequent, watery explosive diarrhoea (up to 16+ times daily), incontinence (diarrhoea leaking), a lot of blood and mucous, blood splattering all around the toilet seat, wind, bloating, stomach pains, intestinal cramps, weakness, fatigue, tiredness, dizziness, dehydration, loss of appetite, loss of weight, malnutrition, anaemia. I also suffered side effects from the drugs. In addition, the disease has had extra-intestinal manifestations: I had Pars Planitis which necessitated steroid treatment (drops and eye injections) and left me with scars on the retina and Hypopigmentation and therefore susceptible to Age Related Macular Degeneration. I also suffer from Ankylosing Spondolitis. My intestines seemed to react to the majority of food items. So I eliminated them, which resulted in a very strict and limited diet, which nutritionally is imbalanced. Emotionally: depression, desperation, fear of leaving the house (urgent diarrhoea), travelling, developing cancer, of the operation. Family: I was afraid of travelling and therefore could not see some of my family frequently. I was unable to travel to help my daughter when her new born was critically ill and she desperately needed my help. Socially: I was isolated. I could not go out (for fear of the urge of diarrhoea), I could not pursue my hobbies of country walking, dancing. I felt miserable, stayed in bed a lot of the time. Economic: there were times I crawled on all four to get to work, as I feared losing it. And finally due to long absence, I gave up work. In 1999 I left my employment due to ill health. I started to work from home as self-employed. When I was ill, I found it hard and at one time had to drop clients, as I could not cope. That resulted in loss of income. Quality of life: None. Treatment â€¢ Anti-inflammatories: steroids both enemas and suppositories â€¢ Immune-suppressants: methotrexate, azathioprine â€¢ Amino salicylates: Salazopyrin, followed by Mesalazine. â€¢ At the end of 1999 I was hospitalised and given intravenous hydrocortisone and prednisone enemas.

	In the years 2003 â€“ 2007 (4 years) I was on a high dose of steroids, most of the time 40mg daily. My disease proved corticosteroid resistant. Once I started on Infliximab, I cut down the steroids. But it took me a long time to wean myself off it completely. During that period I suffered side effects: Salazopyrin â€“ enlarged blood cells. Methotrexate â€“ inflamed liver (after 5 years). Azathioprine â€“ liver inflammation (after 6 weeks). Steroids - osteopenia (I still suffer from it), muscle weakness, moon face, weight gain, candida, my nervous system reacted to the drug: rapid mood swings, anger and rage, severe insomnia, tachycardia, To combat the insomnia, I took 200mg Amitriptyline and 7.5 mg Zopiclone nightly for several years. It took me a long time to wean myself off the latter, but have not managed yet to come off the former completely. In 2005, it was clear that my condition was not responding to conventional therapies. The consultant tried me on Infliximab. I responded well and my symptoms were alleviated. Initially it was prescribed episodically, and later when this was not sufficient, as maintenance.
Patient England	The impact that Infliximab has had on my health and life As a result of being on Infliximab, I have been benefitting from good health long term. Infliximab has prevented symptoms from recurring and saved me from an operation. Clinically: I entered clinical remission, and inflamed tissues were healed. Physically: I feel healthy, energetic, and free of most symptoms. I undertake less clinical appointments, less colonoscopies, less medications, put less pressure on clinical staff. I can do country walking, exercising (to combat osteopenia). I can eat most things, and have a varied healthy diet. Emotionally: I am happy, feel confident, enjoying life. Economically: I can work. Socially: I can socialise, go out for meals with friends, dance, travel to see my family in Devon, France, Indonesia, USA, Israel. My quality of life improved dramatically. Side effects from Infliximab: occasional sore throats, very mild skin allergy on my upper lip.

Patient England	What will happen if I stop taking Infliximab? Stopping the Infliximab will mean returning to where I was up to 2005, with frequent episodes of illness that take their toll on me physically, mentally, emotionally and economically. This is potentially life threatening. There will be an increased risk of bowel cancer and other complications of the disease (perforated colon, toxic megacolon and more). The potential loss of work will mean more reliance on State Benefits (sickness, income, incapacity). I will have no option but to agree to surgery. Will that be cost effective?
Patient England	The impact and cost of surgery The operation: An operation means one MAJOR operation to remove the whole of the colon, joining the small intestines to the anus, creating a reservoir near the anus (out of the small intestines), creating drainage (stoma). After 3 months they do a second operation (minor) to close the stoma. Theoretically so long as the reservoir works, I can recover. But in practice, most people develop complications which have further implications for the patient and the NHS. It is an expensive double operation. It is life threatening (as Mr George the Colorectal surgeon told me) and bears major risks: Heart attack, breathing problems, blood clots in legs and lungs, bleeding, injury to other organs, blood vessels, small intestines, the ureter and the urinary bladder, a leak form the connection between the two ends of the intestine, tears (anastomosis) in the sutures that reconnect the remaining parts of the digestive system â€“ all can be life threatening, scar tissue and adhesions in the intestines that cause a blockages, wound may break open, wound infections, abscess, fistula, and more. Other complications: Pouchitis, anal muscles not being strong enough and therefore severe incontinence â€“ then they have to reverse the operation and make the stoma a permanent feature. For those who survive the operation, potential complications may mean a future with multiple operations and multiple hospital admissions. How much could developing these complications having these operations and hospitalisations cost the NHS? Patients are often left disabled, unable to work and in need State support (incapacity benefits, care,

	unemployment benefits, income benefit, pension credit, counselling and more). How much could all that cost the State? Quality of life will be dramatically reduced. Limited food intake. I will be miserable. Mental health: decline (depression). I would need counselling to support me in my daily life. By saving pounds in stopping the treatment, the costs could dramatically spiral upwards. Here is an example: my friend, Tanya, suffers from Ulcerative colitis. She had undergone the surgery 7 years ago. Since then she has been in and out of hospital many times. Some of her admissions lasted months (she suffered pneumonia after one the operations). People that she had come across during her prolonged hospital stays, have been in and out of hospital several times, having one operation, then reversing it due to complications, then repeating it etc. One woman was in hospital 2 years!!! Is that economy? No, it is false economy.
Patient England	Conclusion Infliximab has saved me from surgery for the past 9 years. It has been a miracle cure. I re-gained my life. In my view, replacing Infliximab with surgery is a very short-sighted view. An operation is not a cheap option, therefore, stopping Infliximab is not a cheap option.
Patient England	Two years ago my UC was diagnosed & treatments escalated over several months without success. I was admitted to hospital & eventually given Infliximab in the CONSTRUCT trial. For me it was a miracle drug & my symptoms improved within 24 hours. The PHCT would not approve maintenance doses for me (I can't have azathioprine -dropped my wbc & neutrophils) & I have flared twice since; one through almost my entire pregnancy. By way of costs I had two weeks in hospital, IV steroids (with horrendous side effects), 3 endoscopy procedures & since then numerous bloods tests, consultations, prescriptions & time off work.

	There are also emotional costs -it was extremely stressful being refused the inflixamab by the PHCT as I felt it would keep me well and someone else deciding that was too costly is very difficult to come to terms with. And flaring in my pregnancy was very difficult in a time that should be enjoyable. I understand budgeting constraints & its a shame the drug companies make it so expensive. If it works for the individual it will change the quality of peoples lives and save further costs in medication, endoscopies, blood tests, hospital stays and surgery. UC is a hidden disease that has an affect on all elements of life -an effective treatment can change that.
NHS Professional England	Whilst we endorse that surgery is an essential treatment in patients failing medical therapy as surgeons there are a number of concerns that we have with the conclusions drawn from the evidence synthesis. Some points worthy of consideration include: The psychological and social impact of surgery The true impact of surgery for colitis has to incorporate the full social and psychological implications of such treatment. Many UC patients who come to surgery live with an ileostomy either temporarily or permanently. Whilst most patients accommodate to this change to the mostly young population involved this can have profound deleterious effects on work and relationship progression. In certain circumstances use of medical therapies to defer surgery until physiological, social or psychological circumstances have improved is necessary. The implications of surgery Many medical trials fail to fully detail and categorize surgical treatment failure. Throughout the document â€˜colectomyâ€™ is referred to. Colectomy (or subtotal colectomy)is the acute procedure undertaken in colitic patients not responding to medical therapy. This patient group do however frequently progress for further complex pelvic surgery for either restorative proctocolectomy (ileal pouch) or completion proctectomy. In ileal pouch procedures a temporary ileostomy is generally used â€“ requiring reversal at a later date. As such, colectomy is often the start of a surgical journey taking 12-24 months to complete. This represents a significant punctuation point in young adultsâ€™ lives. In addition, the treatment failures associated with ileal pouch surgery require due consideration. Certainly, much of the published literature reflects the outcome from expert centres and it is likely that outcome is worse when the national perspective is taken. In addition to the above, it is established that female fertility is reduced substantially in ileal pouch surgery. Furthermore, approximately 10% of patients undergoing pouch surgery suffer such bad complications or outcome that they either never have their stoma reversed or they require further surgery to revert back to a stoma.

	The economic costs of surgery The direct cost comparison of surgery and biological therapy assumes equivalence of outcome. As stated above, the full cost of the surgical treatment journey requires inclusion. In addition, the outcome of surgery - either a permanent stoma or an ileal pouch, are unlikely to represent to patients an equivalent outcome.
Patient England	I have been diagnosed with ulcerative colitis for 19 months. I have been admitted to hospital twice. For we stays whilst they try to get it under control. It never goes away for any longer then 6 weeks max. I no longer take predisolone as I have had to many courses of them. I am now on azathioprine along with asacol tablets and asacol enemas and calcium and vitamin d tablets and iron tablets. Azaiathioprine I have been on for 5 months and it is not having an impact. I have been clinging onto the hope that all is not lost as they could still try infliximab. During my last hospital stay I was going to the toilet 30 plus times a day. My hands wrinkle like I am sat in a bath from the dehydration and I resemble an 80 year old lady bent over in pain and a wrinkled face when it gets to its worst. I work full time and have a you young family to look after. I am 32. Sometimes it's hard to stay positive as I feel so exhausted though the thought of infliximab still being there as ann option has helped me hold on and keep going. If it's not available on the nhs i don't know what the answer is. I guess I should just start planning on next step loosibg my colon which I hoped would never come. I really hope this is reconsidered as he effect of removingbir from the nhs would have on myself and other ulcerative colitis suffered more negatives and no positives that I am aware of.

NHS Professional England	What appears not remotely considered is the fact that colectomy with ileostomy or with ileo-anal pouch formation are profoundly debilitating surgical procedures. The obvious debilitation caused by an ileostomy aside, colectomy with ileoanal pouch - at its best - leads to a frequency of bowel openings comparable to moderate UC, and - at its worst - to pouchitis (up to 20%) that is frequently treatment-refractory with extent of symptoms often indistinguishable from active UC. This assessment does not even take into account the risk for immediate surgical complications including those on the reproductive tract in mostly young patients. There is no way such surgical therapy could possibly be considered 'curative'. UC has clearly become a well medically treatable disease. Clinical trial data on short-term and long-term clinical efficacy of anti-TNF, especially infliximab and golimumab, are overwhelming, and corroborated by even better data from 'real-life' analyses from a variety of healthcare settings (the latter is not entirely irrelevant given the risk for recruitment bias in randomised controlled trials in chronic diseases where a set of therapeutic options is available). Consequence of that is the wide adoption of anti-TNF in clinical practice in all European, North American, and the Australian healthcare systems; e.g. I am not aware of a publicly funded healthcare system in Europe that would not pay for anti-TNF in UC. This includes low-medium income southern and eastern European countries with a fraction of the economic prowess of the UK. This leads to the obvious question whether withholding an effective, ~20 yr old treatment such as anti-TNF from the UK UC patient population, at a time when infliximab has even already come off patent and is reasonably priced (especially for a biologic, and compared to recently introduced medications in other indications), would need to be considered negligent. This fundamental question aside, evidence from other healthcare systems that have adopted (indeed widespread) use of anti-TNF in both CD and UC (making it a standard treatment option for both diseases) suggests that the economic burden of IBD has actually not increased, but has led to a shift of spending from in-patient and surgical procedures towards medications (see e.g. van der Valk et al, Gut 2014). I would argue that these data derived from a real UC patient cohort is substantially more robust than the projections underpinning the cost-effectiveness analysis provided in this consultation document. I have been lead author of one of the early anti-TNF pilot studies in UC (published 13 years ago in 2001!), have contributed to the pivotal trials, and have widely used anti-TNF for the treatment of UC up to my recruitment to the University of Cambridge / Cambridge University Hospitals NHS Foundation Trust in 2011, and hence have had the opportunity to gain broad clinical experience with these therapeutics. These therapies, though not yet perfect, can make a massive difference in the lives of patients suffering from UC, and I am adamant that we can no longer afford to actively withhold this type of treatment from our patients.

European Crohnâ€™s and Colitis Organisation Europe	The European Crohnâ€™s & Colitis Organisation (ECCO) would like to express substantial concern that the Appraisal Consultation Document considering the role of biological treatment of ulcerative colitis (MTA UC - revTA140, revTA262, golimumab (2nd line) [ID695]) would uniquely disadvantage patients in the UK compared to other European countries where such treatment is made available. The Governing Board of ECCO (www.ecco-ibd.eu), which is the largest forum for specialists in inflammatory bowel disease in the world, does not consider that NICE has taken account of all the relevant evidence, nor made a reasonable interpretation of the clinical and cost-effectiveness evidence, nor proposed sound recommendations. The reasons are: â€¢ The dominant impact of treatment-refractory ulcerative colitis on young people is ignored, although this is the group most likely to benefit from anti-TNF therapy since they have disease of shorter duration and are most adversely affected by surgery â€¢ The trial populations do not represent UK or indeed current widespread European practice, which reserves anti-TNF therapy for patients with objective evidence of disease activity. Such patients are more likely to respond â€¢ The limited alternatives â€“ other than colectomy â€“ may not fully have been understood. The majority of patients with moderate or severe UC that fail conventional therapy would undergo surgery, and not be maintained under conventional therapy as the model has assumed. â€¢ Avoiding colectomy is one of the highest priority issues for patients with UC â€¢ Cost and quality of life data following total colectomy, ileo-anal pouch operation, or permanent ileostomy have been appreciably underestimated and are quite distinct (for instance) from segmental resection for Crohnâ€™s â€¢ The results of surgery are suboptimal. The estimated dysfunction of permanent stomas or pouch surgery indicate a dysfunction affecting QoL in one third of individuals. However all these results come from highly experienced units; the proportion of patients with poor quality of life after surgery is higher if operations performed in all centers are considered â€¢ Reduced fertility is observed in 30% of female patients have not started or finalized their family planning and impotence in around 2% of men following pouch surgery. This has not been taken into account in the QoL modelling â€¢ The pouch failure rate after surgery (25% at 25 years) has been ignored. â€¢ A diagnostic approach, including flexible sigmoidoscopy, biopsy and clinic visits and treatment of acute and chronic pouchitis is frequently needed (up to 40% of patients) resulting in additional costs

	â€¢ Concern about an increased risk of dysplasia and malignancy have been observed in the cuff or pouch means that surveillance programmes after pouch surgery are comparable to those patients with longstanding UC and no surgery â€¢ Patients with distal colitis or proctitis, have not been considered separately, although it is in this group that anti-TNF therapy may be most appropriate. This is not because there are any data to suggest greater efficacy, but because removing the colon (a large part of which will be normal) is a really radical step when there is potentially effective treatment untried. â€¢ An inappropriately high ICER for anti-TNF therapy has been applied, because the ScHARR model used by NICE does not reflect the use of these drugs in clinical practice. Furthermore, achieving deep remission (mucosal healing and clinical remission off steroids) identifies a group of patient in whom it may be possible to stop anti-TNF therapy, which has not been considered in the model.
European Crohnâ€™s and Colitis Organisation Europe	â€¢ Primary treatment failures and those who lose response (who would stop treatment after a defined period and resort to experimental therapy or colectomy) have not been considered in the model. Furthermore, the pricing mechanism (for instance, reimbursement of golimumab costs for primary failures) appears not to have been factored in â€¢ Applying strict stopping rules not only at 1 year for those in remission, but at week 12 â€“ 14 for non-responders should contain costs â€¢ It would be surprising if the ICER for using anti-TNF treatment for ulcerative colitis was so widely different to Crohnâ€™s disease, especially because colectomy would be far more common for treatment-refractory disease than surgical resection for Crohnâ€™s. â€¢ Disallowing treatment of UC with anti-TNF agents in spite of randomized-controlled trials and postmarketing experience that have shown improved quality of life and avoidance of colectomy would make the UK an absolute outlier in Europe â€¢ ECCO, as a society, is closely concerned that patients with this chronic, debilitating disease get the same access to health care cross Europe: if NICE confirms its current position in the ACD, effectively denying access for UC, this will heavily discriminate against patients in the UK We sincerely hope that NICE will re-evaluate their guidance. ECCO is happy to contribute constructive comments on further iterations of the guidance. [redacted]

	[redacted]
Carer No	My 15 year old son has suffered his whole life with epilepsy & mild autism and when he was first diagnosed with ulcerated colitis this was further aggravated by the stress he suffers due to his underlying health problems. His ulcerated colitis is now acute and is not only in his bowel, but also in his stomach and esophagus too. Great Ormond Street hospital has recommended treatment with the use of infliximab as a last resort, and the consultant believes that this has a high possibility of alleviating my son's symptoms, the only other option would be to have colostomy bag. My son has been through enough during his short life, with the other medications provided (steroids, Salofalk, Imuran) giving him so many side effects, and he is now losing his hair He has the most miserable of existencies when he is suffering a flare up of his symptoms, (which occur whenever he's not on steroids) and he deserves the chance to have as normal life as is possible. If the infliximab treatment successfully treats the symptoms then he should have every entitlement to continued treatment once he can no longer be seen at Great Ormond Street (when he's 16 ?). It is a disgrace that the NHS do not intend to support this treatment on account of the cost, especially since they do so for Chron's disease where the symptons are identical and as life changing as those suffered by my poor son. I would urge you to rethink. Thank you.

NHS Professional England	I belive the CEA modelling is flawed. Colectomy has signficant morbidity and complications (including psychological and fertility) and most of my patients have ongoing problems. This is not reflected in the model, and certainly requires a reduced QALY
Carer N. Ireland	I am the father of a 9 year old boy, [redacted], who suffers from severe Ulcerative Colitis. We spent 2 very worrying months, July/August 2013, in and out of hospital trying to get his condition under control. Then another month early this year dealing with a severe flare-up. With UC there is not definitive 'fix' to get the condition into remission and in the case of my son the use of infliximab is key to his continuing remission. Without infliximab the only alternative would be irreversible surgery, an ileostomy, which would be devastating for a 9 year old and severely affect his quality of life. We need to keep our son well, so that his body can grow naturally and we don't have to resort to an irreversible treatment, when a better treatment may be discovered round the corner.

Patient England	As someone who has Ulcerative colitis I struggle already and I'm taking the maximum dosage of Azathioprine that's safe for my weight. If that option fails me and these new rules come into effect I might as well go kill myself because there won't be any other options left but to have my insides removed, why should I have to go through that at just the age of 25, not when they're are other options out there?
Patient England	I am a former u.c sufferer whose case was taken to the board on a recommendation for infliximab. My condition was so severe I was housebound, made at least 50 trips to the toilet per day and had constant pain that could not be controlled. I was granted permission to trial the drug for my condition. It gave me temporary relief of all symptoms and allowed me to travel abroad on a family holiday. Unfortunately in my case it did not cure my symptoms on a long term basis and left with no viable options I had surgery (sub total colectomy with ileostomy) although infliximab didn't work for me it did give me my life back for a brief amount of time and it allowed me to be pain free and to feel normal. U.C sufferers should be allowed a chance to trial a drug that could save them the pain and misery of this terrible disease and the physical and psychological problems that can stem from surgery.
Patient England	I am currently receiving Infliximab treatment for my colitis at St Richard's Hospital. I have this treatment every 6 weeks, and for me the treatment works after about a week helping to reduce my symptoms and give me a better quality of life. I am also a university student in my final year, and personally infliximab is crucial to help me to feel well enough to complete my work. I do not understand why you are even contemplating taking away a drug that clearly has such a huge impact on people's lives. I cannot afford to waste time in trying out new drugs that may not even be as half affective as Infliximab is, and end up failing my degree due to not being well enough. I understand that it is expensive but then so is this review wasting precious time and money on a matter that has greater benefits than drawbacks. I cannot stress to you enough that this is added stress and fear of the unknown as to what may happen to our treatment, will not do sufferers of ulcerative colitis any good, personally stress is a major trigger of flare ups, and what with it being my final year at university, and now the uncertainty of my medication and treatment, I am guaranteed to feel the effects. All I ask is for you to put yourself in our shoes, have the fear shoved in your face out the blue, have vital options and choices taken away from you for what? You're happy to help people who are obese, or smokers who now have ill health because of their life choices. We did not choose to have a chronic illness, we feel we get treated unfairly? I have always had very healthy lifestyle I try eat a good balanced diet. I just hope that yourself or any of your loved ones never have to suffer with this chronic illness and become dependent on vital medication such as infliximab.
Patient England	I am a sufferer of relatively severe Crohns and Ulcerative Colitis. I am currently in a remission period thanks to treatment with Infliximab and Azathioprine. Previously I was treated with Steroids in the short term, followed by Azathioprine to maintain remission,

	however a series of flare-ups have demonstrated that Azathioprine on it's own will not control my symptoms, and as a result my condition has worsened. Having been placed on a course of Infliximab, my health has returned to normal and my condition is stable. I have no notable side-effects from the treatment and can live a totally normal life without concern for diet or lifestyle in relation to my condition. Without this treatment, my quality of life, my business and my family are all seriously affected detrimentally. I would urge NICE to recommend the continuation of this treatment through the NHS as it provides the difference, for me and many others, between a normal life and one of significant pain and misery. In fact without this treatment, or a very similar form of treatment, both my consultant and I feel that my condition could potentially prove fatal. You hold the quality of my life in your hands - please make the right choice and retain these treatments so people can live normal lives despite this horrific condition. Thank you.

Patient England	I have suffered from UC for 3 years. I am 33 years old and have two young children. Since my diagnosis I have struggled to achieve remission. I have had more than 8 courses of steroids over the last three years and azathioprine has failed to help. I was hospitalised from May to August of this year suffering from a nasty flare up, I was malnourished, neutropenic and very very unwell. Infliximab has dramatically helped and finally after my fourth dose just two weeks ago I am getting my life back. Steroids have huge negative side effects for me including mania, insomnia and acne. Infliximab does make me tired for a day after the infusion but I can not speak more highly of it and urge you to recognise how much of a life changing medication it can be. I have been unable to work due to my colitis but am now hopeful I can return to work in the near future.
Patient N. Ireland N/A	My name is [redacted] and I am aged 24. I was diagnosed with Ulcerative Colitis (UC) in September 2010. Since January 2010 I was stricken with the associated symptoms of Ulcerative Colitis and was on a waiting list for investigations, since at the time it was a new presentation and no diagnosis was yet made. When September 2010 came I still had not had the investigations and by that time I had lost almost 3 stone in weight, my haemoglobin count was around 6.0 and I was unable to get out of bed and care for myself. This was in addition to the usual symptoms of UC, with which, I was visiting the bathroom up to twenty times a day and during each visit I was suffering from diarrhoea, bleeding and vomiting, constantly. I was pretty out of reality and was taken to the Emergency Department (ED) at Craigavon Area Hospital (CAH) by my parents. At that time I was seen immediately in Resus. The next day I was sent for investigations and was diagnosed with UC. During my stay in hospital there were numerous complications and due to the seriousness of the illness I experienced cardiac events due to the extremely low haemoglobin level. I was started on treatment and after a few weeks it began to settle whilst I was an inpatient but it took me months to recover. Having said that, I have never fully recovered. UC has changed my life. For the following year I was in and out of CAH ED like a frequent flyer, being admitted for each presentation. I was put on oral steroids, IV steroids, IV antibiotics to name but a few. Often I was taking up to ten tablets a day. My UC is extensive which affects the entire of my colon, from one end to the other. None of the many medications I was being pumped with were working. Yes, they sometimes worked at the beginning but as they were tapered off the UC came raging back. I was commenced on Azathioprine which did help to keep the UC in remission for longer but unfortunately I developed Pancreatitis due to it and therefore had to discontinue it. In the Summer of 2011 I was started on a three dose regimen of Infliximab at CAH as an inpatient for the first dose and as a day patient for the subsequent two doses. It immediately worked. I was in remission for over a

	year. This was the first time I felt some sort of normality. I could actually go about my business like a normal person again without having to plan my day out around toilets. In addition I actually had the energy to do basic daily activities without them draining the life force out of me. The period of remission eventually came to an end and low and behold the UC came back. I received a second set of three doses of Infliximab and yet again it worked immediately. At the time of diagnosis I was in second year of a BSc (Hons) degree in Biomedical Science at Queens University Belfast (QUB). I was absolutely determined to finish the degree and thankfully was able to but at a great cost to myself. There were many periods I was unable to attend university as I was an invalid in bed and unable to care for myself due to the sheer systemic effects UC had on me, namely severe fatigue due to anaemia. I always pushed myself to return to class as soon as possible and was thankfully able to complete the degree but with great difficulty. I achieved a high scoring 2.1 Hons degree but my tutors believe had I not been stricken with UC I would have achieved a 1st class Hons degree. After QUB I became a Healthcare Assistant in the Royal Victoria Hospital (RVH) for two years mainly working on the Endocrine Ward but moonlighting in the ED as well. During that employment and previous employment I have had to take weeks at a time off work due to flareups, yet because I was determined not to let the UC control my life I continued to fight it and held my employment positions. Whilst I did fight, there were many times where I near gave up. I simply cannot stress the effects UC has on oneâ€™s life. *Continuation in comment 2*

Patient N. Ireland N/A	*Continued from comment 1* As I mentioned above, it is not just the associated symptoms of UC that affect one, it is the systemic issues as well. I believe a lot of healthcare professionals and researchers forget about this or perhaps donâ€™t even realise it. UC is a crippling illness. Even the medication that one takes to combat UC causes serious detrimental effects on the body. I have been on high dose steroids for far longer than I should have, simply because nothing else was available or working. Stemming from this I have a number of side effects from the steroids. Against all the odds I am now following my dream. I have since moved on from RVH and am now in first year medicine at Trinity College Dublin (TCD). It has been sometime since my last flareup but I am constantly (every day) afraid that it is going to come back. Sorry, I should rephrase that since I know for a fact it will come back, itâ€™s simply a matter of when. Most often it starts during times of increased pressure and stress such as at examinations. I am terrified I wonâ€™t be able to follow my dream of completing medical school and becoming a doctor. Although I am well and â€œin remission,â€• I use that term loosely, I still am not myself. I have never been myself since this first began. During remission when I am â€œwellâ€• I still lack energy. I still visit the bathroom up to 10 times a day. I still feel nauseated. I still experience abdominal cramping. I sometimes still feel like giving up. Having said that, Iâ€™ve got used to the daily pain but I simply cannot get used to the fatigue because it is the main thing stopping me from achieving my full potential. Often many times I come back from classes and simply crawl into bed because I am so exhausted. I constantly tell my friends that I cannot come out. I have to prioritise my life, my medical degree comes first and whilst I know the importance of extracurricular activities and socialising, most of the time this simply has to be forgotten about because otherwise I wouldn't be fit for another day of study. Having a hand in the medical field I am aware of the financial constraints on the NHS and from working in the RVH I have experienced first hand what doctors, nurses and other healthcare professionals are faced with. I get there is a lack of funds but surely there are other ways to save money than withhold medications that have the potential to change peoplesâ€™ lives. Colectomy was put to me as an option for solving the issue. I was astounded at the start and for a long time I never considered it an option. In fact I still donâ€™t really consider it an option because I know there is a medication out there (Infliximab) that works for me. Having said that, during times of extreme flareups sometimes I just wonder if I should give up and have the surgery? But then I think to myself, why should I undergo major surgery when there is a more effective and appropriate alternative available. Itâ€™s like saying to a patient who has a broken leg, â€œSorry you're leg is broken, we need to cut it off because its much easier for us.â€• I feel that there is a sense of taking the easy way out and the cheapest method. Who cares about the patient who will have to defecate into a bag for the rest of their life and

	probably have continued issues relating to major surgery and ilestomy problems? Certainly those who are in positions of decision making had they experienced what Inflammatory Bowel Disease (IBD) suffers experience I am certain there would be a push towards doing as much as we can for UC sufferers. I know that Infliximab is a huge cost per infusion but if it is a medication that could potentially work for UC patients why not give them the opportunity to try it and avoid the life changing event of colectomy. I also acknowledge that it may not work in every individual but that is also true for many other medications, so why should Infliximab be withheld for UC patients. *Continuation in comment 3*
Patient N. Ireland N/A	*Continued from comment 2* . Surely in the long run if Infliximab was available sooner to UC patients this could potentially save money as there would be less hospital admissions, more free hospital beds, less secondary conditions developing and so on. Surgery is not an option for many and it would seem that Inflixmab might have the potential to alleviate a lot of pressure on the NHS. What also confuses me is the fact that Inflixmab is given to Crohnâ€™s Disease (CD) patients and not UC patients. Yes for the most part, CD and UC can be definite. Yet there is an emerging number of people who are classed as Indeterminite because quite often the symptoms of CD and UC overlap. Granulomas are present in 60% of CD specimens but are never present in UC specimens; therefore, their presence is specific for CD but only in 60% of cases. Therefore someone could actually present with CD but be diagnosed with UC based on this information, provided other factors agree. Aphthous ulceration is considered unique to CD however I am plagued with serious mouth ulcers, particularly during flareups and prior to a flareup starting. These are just two examples, I could go further into the scientific journals to back up my point but I simply do not have the time as 1st year med is proving to be very intensive. Because UC and CD have the potential to be so similar it seems strange that UC patients do not have the potential to access Infliximab. In fact sometimes the medications that are used to treat CD and UC are the same, up until the biologics, and beyond those only CD patients have regular doses of biologics. Yes there is currently the option of three doses of Infliximab for UC patients but it is slightly worrying that UC patients must be acutely unwell before they actually get the three doses. That is quite sad that we allow someone to get so unwell before we give them medication. I believe not enough is being done for UC specifically. IBD is not pleasant, many people donâ€™t want to talk about their toiliting habits and I believe that this is why there is not as much coverage on IBD. There are a lot more expensive treatments available on the NHS and even some cosmetic treatments available, yet for some

	reason UC patients canâ€™t access potential life changing medication. In conclusion, I believe more research needs to be done into UC and possible treatments but I believe that under current knowledge there is the potential for Infliximab and associated biologics to work in UC and if they donâ€™t, thats fine, stop them for that patient but at least give them a go in UC patients instead of just confining us to carry a ilestomy bag for life. I have tried to outline the seriousness of UC, how it is life changing and that it rarely stays in remission for a length of time. I would like to emphasise the point that UC has changed my life and I have never been the same person simply because my flareups are so frequent. UC patients suffer chronically and daily and more needs to be done for us. I genuinely believe from experience and from knowledge gained working in healthcare that Infliximab will work in many UC sufferers.
Patient N. Ireland N/A	I am a member of the IBD patient panel based at [redacted] We campaign for better treatment and care for IBD patients in conjunction with an IBD nurse and relevant medical and nursing staff. We all believe that the current proposal by NICE is unacceptable. Below is a short paragraph from another of our members: I am a IBD patient since 1979 and throughout this time I have received conventional treatments. Over the years it proved difficult to achieve sustained remission and surgery in 1990 resulted in a stoma which has been resited in 1998 and more recently in 2010.I often wonder if my 'journey' could have been very different with the use of biologics. From conversions with others who currently use them and enjoy all the benefits that they bring, I would see the cessation of their use as a backward step and ask that very serious consideration be given to the quality of life of such patients especially in the 15 to 25 age group - [redacted].

Patient	I am writing regarding the proposed NICE review of biologics for Ulcerative Colitis (UC) and wish to put forward the following comments: I was diagnosed with UC in 2007. Since then I have tried various treatments, namely Mesalamine, which I am intolerant to and Azathioprine, which also made me ill. This leaves me with few choices. During hospital consultations, a very limited course of Infliximab was discussed as a possible medication to try, but after this I would not have been offered any more. I did not feel this was sufficient. As my UC is untreated, it has resulted in me suffering from contamination OCD and also severe depression, This and the lack of suitable medications available to treat UC has had a very negative effect on my life being unable work or attend university. If the possibility of being given Infliximab is taken away, I fear the only option left would be surgery. I do not believe this would be a viable option as I am only in my early twenties. As new treatments are being researched all the time, I do not want to live the rest of my life with the results of surgery, especially if this medication could be given to prevent it.
Patient England	I was admitted in to hospital, suffering from sickness, bloody diarrhoea, fatigue and extreme dehydration. I had two flexible sigmoidoscopyâ€™s, the first one showed some mild erythema in the rectum and sigmoid. I was prescribed intravenous steroids, prednisolone and masalazine but my symptoms continued to get worse, passing blood continually. A repeat flexible sigmoidoscopy was done which showed possible sparing in the rectal sigmoid with more significant inflammation higher up resulting in me being diagnosed with severe ulcerative colitis. I was started on a course of 6-mercaptopurine and co-trimoxazole. By this time I had been suffering from symptoms for over a month. I was told that my daily blood results had shown my haemoglobin levels to be very low and the doctors had decided to give me a blood transfusion. However that evening I collapsed and was placed on oxygen. The nurses said I had lost over a litre of blood just from that one visit to the toilet. I continued to experience strong stomach pains and lose blood throughout the night resulting me having a blood transfusion and being looked after by the critical care team. The surgeon gave me the option of surgery or starting the rescue therapy of Infliximab. I did not want surgery under any circumstances and opted for infliximab. I started to improve immediately and a couple of days later my bleeding had virtually stopped and visits to the toilet decreased. I remained symptom to free for some time, managing to gain weight after dropping to 5 half stone and returned to work fulltime. I unfortunately suffered a relapse and once again conventional therapies

	did not work and infliximab did, putting me back into remission again. I am grateful that this review does not involve stopping infliximab as a hospital rescue therapy. However, I have very serious concerns about stopping funding for maintenance therapy. Just looking at all 128,000 people with ulcerative colitis and putting a price on it is very crude and is going to miss out people who donâ€™t fall in between the guidelines. The cost effectiveness review of infliximab does not take into account the circumstances of individual patients and some people are going to suffer. I sincerely hope that NICE will investigate which patients do benefit from infliximab as a maintenance therapy because for many patients it does work effectively. My own experience shows conventional therapies currently available on the NHS to treat ulcerative colitis do not always work and the drug infliximab does work. It was positive and effective in controlling my condition, enabling me to live a normal life again. If this is taken away then what option is left for myself and people in the same situation when conventional therapy fails? I therefore urge NICE to support the use of infliximab has a maintenance therapy and continue to fund the drug on the NHS, enabling to give life back to thousands of ulcerative colitis sufferers like myself.
Parent of a UC sufferer N. Ireland	My sons was diagnosed with severe pan colitis inJuly 2013. He was in hospital for 30 days during that July and August trying to get his condition under control and into remission . He was given I've steroids on two occasions and two different asa s to try which he reacted to so the asa s had to be discontinued. As a final resort his consultant decided to put him on a programme of infliximab infusions which he now receives every two months, the only other option for him at that time would have been to have surgery and therefore have a bag until he was at least sixteen. This would have had a devastating effect on him both emotionally and physically which I believe would have affected him for the rest of his life. Infliximab is the only medication which has kept him well and able to lead a normal life for an outgoing lively fun loving nine year old boy. If this drug was removed I feel he would face surgery which would result in a much poorer quality of life for him, myself, my husband and his twelve year old sister who was an amazing daughter and sister during his time spent in hospital and away from her immediate family. Please consider the quality of life this vital drug can give to UC sufferers, my son is a perfect example of this!!

Patient England	NICE Review of biologics for Ulcerative Colitis Thank you for the opportunity to comment on your draft guidance on the use of biologics for the treatment of moderate/severe Ulcerative Colitis. I am extremely concerned by the draft recommendation that infliximab, adalimumab and golimumab should not be available on the NHS for the treatment of moderate to severe Ulcerative Colitis (UC) where conventional therapy has failed. This is limiting the availability of drug treatment for UC for patients who might benefit greatly from the availability of these drugs and is therefore a step backwards in the care and treatment of UC. Where successful drugs can make a significant difference to the quality of life for patients with UC. For those of us who live with this disease the impact of remission on our lives is significant. When the disease is active a normal life is just a memory - the diarrhoea, pain, blood loss, constant (often urgent) trips to the toilet, disruption to sleep can intrude on all aspects of life. Remission leads to improvements in one's relationships, home life, ability to have a full working life and general well being, not to mention improvements in self esteem. It is difficult for those who do not have IBD to appreciate how debilitating this disease can be, not just from all the symptoms described above but also from the unacceptability by general society of having a bowel disease. Self esteem is often at a low - not only do you have to manage this yourself but also, putting it bluntly, the reactions of others to the urgency, smell and noises associated with UC can be most unhelpful and humiliating. Reducing the options available to treat UC is most definitely a backward step. I have lived with UC for thirty years and if my current conventional drug therapy fails then my options would be further limited. Over the years I have seen new and improved drug treatments for UC, why go backwards? This is particularly true for the treatment of young people with UC, for those at school or college or just starting out on their working life and permanent relationships. Appropriate treatment to enable these young people to complete their education and realise their potential is so very important. It is so important that active UC be brought under control to lessen the risk of developing bowel cancer. Clearly surgery is always an option but this brings with it risks and long term costs, and, particularly for the young, further potential issues with self esteem. This was a very real prospect for me when first diagnosed. At the time I had only just secured my first job in my chosen career , in a new area without friends or family nearby to support me and I do not know what impact that would have had on my mental health. I note that biologics are not currently generally available to patients with UC, requiring exceptional funding. This is in contrast to Crohn's Disease where biologics are widely available for treatment. Whilst it remains that the causes of both diseases remain unknown, they share common genetic factors. I find it inconsistent that treatment available for Crohn's is not available for UC when there is often an overlap between these diseases and their treatment (and diagnosis may change. It has been suggested to me that my UC is more typical of Crohn's). I believe that NICE should give a positive recommendation for NHS funding for these biologic drugs to be

	available for the treatment of moderately or severely active UC after the failure of conventional drugs.
Patient England	I have severe ulcerative colitis and have just managed to get it under control this year with infliximab if this is taken away treatment will stop which seems completely unfair leaving me with no options as have tried everything else!
Patient England	I have had UC for over 3 years now, over time it became evident that my symptoms were getting worse despite the drugs that I had been put on (mainly azathioprine) and it got to the point where I was really quite ill. That's when, after steroids had calmed my symptoms down, I got put onto adalimumab/Humira, pretty much my last chance to avoid surgery. It's still early days for me but in general my symptoms are currently tolerable - whilst the effects of UC are utterly horrendous and have had a significant impact on my life if I can keep going as I am with the help of Humira in my opinion this is a far better option than surgery. For me the main issue with UC is the frequency of toilet visits, I've been lucky enough not to suffer in too many other ways (e.g. pain, fatigue), if I end up having to have the operation(s) it will involve a significant amount of changes to my life, the pain of the surgery and recovery, having to take a long time off work and from what I can gather about life following the surgery (either with a stoma bag or a J-pouch) in my case I'd be no better off in terms of quality of life, in fact it may even be worse - one problem would have been solved (the diseased part of my colon would have been removed) I'd still be left with as many or more than before (such as having to live with a stoma bag, or still having to go to the toilet as often following having a J pouch for example). I'm only 30 and still feel young, from my perspective any drug therapy is preferable to surgery as I still want to feel young and like I can do what I want, the fact that these drugs do work for some people makes them invaluable to them - you cannot understand the impact UC has on someone unless you have it, it is a truly depressing condition, the prospect of being denied a drug that could help you live a life as close to normal as possible in favour of major surgery that isn't exactly a pain free process that works brilliantly would just make things worse. I appreciate that there isn't a bottomless pit of money to pay for expensive drugs for every condition, but to deny UC sufferers the option of using these drugs when other therapies has failed is to basically force those people to have surgery and to put up with the problems and consequences involved - which in some cases will lead to a drastic reduction in that person's quality of life, not for a few months or so but for the rest of their life. For some the surgery is the right thing to do, but for some it isn't unless all other options have been tried first. Please consider that this is a decision that can adversely affect people for the rest of their life, which could be many decades, it's not something that they'll just get over.

NHS Professional England	In our experience, the use of anti-TNF (infliximab) therapy in appropriate patients has improved patient outcomes, quality of care and promotion of safe patient care through:- â€¢ A reduction in the risk of complications and co-morbidities associated with severe ulcerative colitis â€¢ Impacts on health inequalities through equitable treatment access (to people with CD) â€¢ Improves outcomes, quality and/or safety â€¢ Improves patient experience. The treatment can potentially reduce the need for repeated hospital admissions for the patient group in question, thereby improving quality of life and allowing them to be managed in an outpatient setting.
NHS Professional England	1. The appraisal does not address the direct and indirect costs of diagnosis. For example, loss of earnings, loss of education and the longer term socioeconomic effects of these; and it may have underestimated the impact of poorly treated disease on health. As a tertiary centre, we have significant contact with people diagnosed with Inflammatory Bowel Disease (IBD) and raise concerns on behalf of patients with Ulcerative Colitis (UC) who feel their treatment options are unequal to those with Crohnâ€™s disease (CD).

NHS Professional England	2. Review of the current consultation document does not address medical options after failure of conventional therapy. The overarching aim of UC management is to achieve steroid-free remission. The consultation assumes that patients will respond to a re-trial of medications to which they have previously been refractory. Clinical experience tells us this is not the case. Therefore the current document does not provide options for patientsâ€™ refractory to conventional therapy who are unsuitable for, or unwilling to have, surgery. This raises concerns regarding this emphasis within the consultation which appears to advocate prolonged use of steroids in this patient group which contradicts local, national (BSG) and international guidance (ECCO) for the management of UC. It is well documented that the repeated use or long-term exposure to steroids is associated with potentially irreversible complications including osteoporosis, diabetes, hypertension, increased susceptibility to serious infection, adrenal insufficiency and hepatic and ophthalmologic effects. It is not clear that the economic models used have taken these factors, and subsequent costs of managing the long term effects of steroids, into account. The modelling tool also does not appear to have considered the financial impact when patients are unwell such as the loss of earnings, lack of productivity, loss of education and general impact on family life. People with chronically active disease may be unable to work, or work full time due to severity of symptoms, such as urgency, faecal incontinence or fatigue.
NHS Professional England	3. The appraisal document does not seem to realise the impact of pelvic surgery on fertility. The economic model made the presumption that 47.3% and 5% of patients going to colectomy will develop transient or chronic post-surgical complications respectively. With regards to colectomy and Ilea-anal pouch procedure (IAAP), the British society of Gastroenterology Guidelines (2011) state that complication rates can be significant and pouchitis remains a persistent and difficult problem following surgery, therefore incurring on-going costs through complex medical and often surgical management and follow-up. The guidelines go further to state fecundity of young women may be reduced by 40-50% following IAPP, probably as a result of pelvic surgery and subsequent pelvic adhesion and that an exploration of alternative medical or surgical options should be undertaken in women of childbearing potential before IAPP. The European evidenced-based consensus on reproduction in inflammatory bowel disease (2010) report that pelvic surgery may lead to impotence or ejaculatory problems in men and that those who undergo ileoanal pouch surgery for UC, may experience retrograde ejaculation and erectile dysfunction. In addition ECCO guidelines (2010) conclude that the fertility of women with UC was reduced after restorative proctocolectomy, suggesting a a three-fold increased risk of infertility compared to medical management. It is essential that the scope of this document considers surgical management beyond initial colectomy.

Patient England	I am flabbergasted that these drugs are being withdrawn which means I have no effective medication open to me during periods of UC flare up. Please advise how you are to deal with prolonged periods of bleeding, pain, stress, family stability and time away from work that will result. The medical professionals, not NICE, are very much against this approach. You are not considering the wider implications of patient welfare and cost to the nhs overall. You must rethink .
Patient Wales	Having Ulcerative Colitis is a terrifying, not knowing what day of the week you will land up in hospital is no quality of life. Being housebound and afraid of the outside world due to the embarrassing symptoms is bad enough without having the threat of invasive surgery looming over my head! I strongly urge you to continue offering such VIRAL medications that are proven to work!! These medications could one day be a lifeline for me as they are for many others. You are not only taking away my shot at a future you're ultimately forcing me into having MAJOR INVASIVE SURGERY with the possibility I may die or if I am spared I may die from the complications that surgery brings. I can't believe my fate lies in the hands of whether these drugs that are proven to work may not be offered due to cost!! I DID NOT CHOOSE THIS TORTUROUS EXISTENCE unlike many who becomes obese or have breast enlargements, nor am I smoker, alcoholic or diabetic who have complete control over their lives and outcomes. I did not choose this way of life and I guarantee many thousands of people suffering with Ulcerative Colitis have already contemplated suicide...if many contemplate suicide as a better alternative to living with this illness surly that is enough of an example as to the HUGE life changing impact this illness has on an individual. Why take away hope and peoples lifelines, who gives you the right to send thousands to surgery when it could be prevented due to cost. What an absurd idea to even have a debate. As a tax payer of many years I WANT ACCESSIBILITY TO THESE DRUGS WHICH ARE PROVEN TO WORK!!

Patient England	As a patient who has UC and has been treated with Infliximab, all be it privately through health insurance, I'm very concerned that this treatment will not be made available to all suffers who do not respond to conventional medicines as myself. My experience of Infliximab is indeed that it is a wonder drug, one that prevented surgery and effectively brought a normal life back to me. I was diagnosed with UC finally after 2 years of visits to my GP where very little was done, I managed to persuade my GP to refer me to a consultant, [redacted] in August 2012 where the disease was confirmed, after treatment with Asacol, Salofalk, Prednisolone and Azathioprine failed to control the condition over the next 12 months the decision was made for me to begin a course of 3 Infliximab infusions over a 6 week period. There was an improvement a short while after the first infusion, with the condition finally under control by the end of the 6 weeks, and has been in remission since then simply controlled with Asacol and Azathioprine once daily. It is not difficult to relay the difference that Infliximab made to my life, I could return to work on a normal basis, which as it happened was working on Bristolâ€™s new super hospital, rather than pretty much confined to home working, it meant that normal bowel function was returned at a healthy frequency, not the 20 times a day just 6 weeks previous. Infliximab allowed me to have a normal life, enjoy days out and simply not worry anymore, obviously my mental state was so much better as well as my physical state. To take this opportunity away from sufferers of this cruel condition is not acceptable and NICE must acknowledge the amazing benefits this drug can bring to UC patients. To differentiate between UC and Crohnâ€™s patients is also not correct, however why is this not obvious to NICE? Sometimes I wonder if those making decisions for NICE actually know what the acronym means, it is certainly not clinically excellent to deny UC suffers a life changing therapy, one that may prevent major surgery, one that can allow an ongoing normal life to be maintained afterwards by simply taking some very inexpensive medicines.

Patient England	Hello my name is [redacted] I have had ulcerative colitis for 9 yrs, I have 2 jobs 1 as a driving instructor and 1 as a fire fighter and I would like to share my life with you living with uc. At the beginning I had a flare up was put on steroids /azathioprine and pentasa which brought things under control for around 3 yrs and I lived a good life I was left on these drugs for a while but they had stopped working so i was starting to flare more and more the hospital that i was under didnt seem to worried so after lots of visits I went to guys hospital london where my new drugs journey began, Up until this point I had been flaring for nearly 2yrs and life was impossible, I had never taken my little girl to school as in the mornings i would struggle to not be at a toilet every 5/10 minutes I was now having to think about my future as a driving instructor as I just had to cancel so many lessons I was also on long term leave from my job as a fire fighter as I could not be away from the toilet right to the point where I was now becoming house bound which lasted for 3 months I was 32 and now my life was not good I could never go out with my wife or children I would even worry playing in the garden as at many times just running to the toilet and not making it in time was becoming a major issue, I came to London and walked into a&e as I was in a very bad place and just wanted my life to either end or change so it was a last chance for me, I was kept in for 2 weeks and had steroids to bring my to some form of control and my medication was changed to balsalazide, or surgery was happening in the next few days, Surgery for me was never what I wanted as I am a young person and when im well I race motorbikes and being a fire fighter having a bag wouldn't work when exposed to heat etc. The surgeon came to see me we had a long chat with the whole team and the word infliximab was used I asked lots about it and was very excited to give this a last chance. I was sent home to then come back for my infusion. This day changed my life after the infusion I felt million dollars my flare was under control and I took my little girl to school for the 1st time in 3yrs and I had no side affects. I then had 2 further injections of infliximab to then hear the devastating news I could no longer have it due to funding my life changed again back to urgency and lots of toilet visits and no social life, I opted to go into drug trials because it was my only hope of finding something new and I was put on humira which gave me the boost I needed and it was like the infliximab again my body changed I was well again, To then have the trial stop and my humira has been taken away again so what does my future life look like without the help of these wonderful drugs ? from where im sitting I feel sorry for my wife and children because they only have half a dad and husband as me leaving the house is not really an option.

NHS Professional England	The model used is not easily understandable to me, and I am given to understand, not to those who know the data better than I do
NHS Professional England	The UK patient group in whom the therapy would be considered are not the same as the ACT 1/11 patients who had a more mild disease
NHS Professional England	The costs of surgery are significantly underestimated and do not take into account the side effects and complications from pouch surgery
NHS Professional England	In my opinion it is not correct that patients who fail antiTNF therapy simply go back to conventional therapy and continue. They either struggle on in a poor quality of life or they have surgery. 1% surgery per year in this group is far too low an estimate.
NHS Professional England	The costs of antiTNFâ€™s for this group of patients would be lower if non responders discontinued treatment after an attempt at induction AND if consideration was given to stopping patients at one year if they enter complete remission of their ulcerative colitis
NHS Professional England	Withdrawal of this treatment in the NHS in England would have a major negative impact on patients and many would end up having surgery that they would not otherwise need

NHS Professional England	
NHS Professional England	I am concerned regarding the potential impact on children who have Ulcerative Colitis if these drugs are withdrawn. As you are aware without these drugs the medical treatment for this condition would be dramatically reduced, thus having an increase in the number of patients requiring life changing surgery. Having your colon removed and formation of an ileostomy can have major psychological impact on both patients and their families and I feel that this can not be under estimated. We currently have 15 patients beween 8-17years old on infliximab with ulcerative colits and 50% of them have been on it for 1-4 years with some dramatic effects. We are aware that some of these patients may require surgery at some point as are the families, but the benefits gained from these treatments both medically and psychologically, even if that is for a period of 1-4years can have a dramatic effect on a childs wellbeing. I feel that these points have not been properly considered in this consultation
Patient England	I am writing to feedback my experience of infliximab. I have severe pancolitis and have had the three induction doses plus another 4 doses of infliximab since the beginning of December 2013. Before that I had been admitted to hospital almost every two months -5 times in 2013 alone. This pattern has existed since my uc flared in 2010. I have had 3 years of constant flare ups and no remission. I have been hospitalised numerous times and been on every type of medication from a range of enemas, mercaptopurine,Â azathioprine,Â and numerous others- none worked. Over the years I also had to have several courses of prednisolone,Â which I don't need to explain the side effects of. Â Infliximab has kept me out of hospital since the beginning of December 2013, it has given me my life back, I can also work and have a social life, I have gained some confidence in myself and am not constantly worried about urgently needing the toilet. I have not had any bleeding or diarrhea since February and I finally feel like my gut is having a chance to heal. I am only opening my bowels between 2 and 4 times a day. I have energy, my joints and bones are generally better and my hair (which had thinned and fallen out with steroids and other meds) is growing back to its former glory.

Patient England	However, sadly in June i was informed that my CCG would not fund any more treatment as NICE do not recommend it for maintenance of UC.Â My concern is that 1) other CCGS do fund infliximab for patients in my position so why is there a postcode lottery occurring (if some CCGs realise it is worth using infliximab why can't nice? 2) the cost of the 35 days I spent in hospital last year will far out weigh cost of treatment, not including cost of my additional sick days (I work for Local authority), if repeated again,Â 3) I should not have to have surgery which also would cost more (cost of surgery, therapeutic input for the trauma, further surgery if needed, cost of bags amd medication if infection arises) but also it is not my preference (i am still young and wish to have a family so dont want my fertility affected) which brings me onto 4) patient choice! I should not have to have surgery which is likely to mean opening my bowels upto 10 times a day! I don't want to wear a bag on my body, i work with children so leakage would increase chance of infection for them, I still wish to have children so don't want surgery,Â I have a good quality of life on infliximab so would like it to continue! In july i had to fund raise amongst friends and family to ensure I received my treatment on time (I am aware that stopping and starting treatment after aÂ break can lead to becoming resistant to the medication and I didn't want to be resistant to the only treatment that has worked for me), whilst my consultant appealed the decision. Where is the patient equity in this situation? Â

Patient England	I am so happy with infliximab and what it has done for me and so disappointed that NICE guidelines are taken as law by CCGS wanting to save money. Please think about the individual, think about the NHS- infliximab is cheaper than the alternative and is my choice and most importantly it works, I urge NICE to consider this when amending their guidelines!! Â Nice need to recognise that although an evidence based practice is.important, this is dealing with humans and a condition that varies so much that each case must be made on its own merit. If after 4 years of being a guinea pig my consultant has finally found something that works for me, why are nice so strongly against them using it? My final comment relate to what i believe NICE considers as quality of life adjusted years when considering treatments and I am shocked that treatments for cancer that cost Â£120,000 to extend someone's life for 6 month can be approved but infliximab which gives me my life back, allows me to work, gives me hopefully 50 plus years of a better quality of life, gets declined. The reasoning is ludicrous. To just because cancer is a more emotive disease but the impact on quality of life is persistent and severe for UC. Awareness raising needs to take place with the public but i am surprised that nice need to be reminded of equity amongst patients.
Patient England	I don't know if this is what you were hoping for but I hope it has given you some insight into why I think NICE should recommend flexibility with the use of infliximab for maintenance of uc. I am a human being, not a subject in a study, a hospital number or a set of symptoms that people at NICE have decided I should just live with or have my organs pulled out in order to decrease my quality of life in a different way! Please please ensure that CCGs realise that infliximab is a life changing (and saving) medication...without it I may as well not have a life. Nice please do your duty to the patients and recognise that infliximab does work and should be used.

Carer England	My 27 year old daughter was diagnosed with UC this year and spent a month in hospital. At first she was diagnosed with moderate UC and treated accordingly with the conventional treatment of steroids and anti biotics etc. These did not work and her condition worsened to the extent where she collapsed with blood loss, was on oxygen and had to have two blood transfusions. She was re -diagnosed with acute severe UC and was started on the rescue therapy of Infliximab. Her condition improved dramatically and is now on maintenance therapy. She is now virtually symptom free and can get on with her life and work. Unlike UC there are no restrictions on Chrohns disease patients bring prescribed Infliximab but the two conditions are very similar, symptoms can overlap and diagnosis can change from one to the other. I feel that it is counter productive and morally wrong withdrawing anti TNF drugs from UC patients on the grounds of cost. Some patients will be in no mans land between the two options with only the prospect of surgery as the last resort. I urge NICE to positively recommend that NHS funding be available to patients with moderate to severe ulcerative colitis after the failure of conventional therapy.

Patient England	Hi, i Suffer from Ulcerative Colitis, in 2012 i had a bad flare up and wasn't responding to any other treatment, i was in hospital for nearly 3 weeks and then i was started on Infliximab which worked almost instantly and enabled me to get back to work quicker than i would of been able without it. The past 2 years since i took Infliximab have been the best period of Remission i have had since i started with the illness 12 years ago at 18, with no flare ups. I hope you will be able to carry on providing Infliximab for UC sufferers. Thank [redacted]
Patient England	I was diagnosed with Ulcerative Colitis in 1972 and have had numerous â€œflare upsâ€• with extended periods of hospitalisation in 1986, 2003 and 2006. Treatment in hospital was both intravenous and oral. On each occasion I was urged to consider surgery; a suggestion that I have always rejected. At various other times there has been a reoccurrence of ulcerative colitis with severe weight loss [over 30% of body weight], passing blood and severe debilitation. On these occasions treatment has been solely by oral medication. Over this period of time I have been economically inactive for a total of several years and whilst at work my efficiency was impaired. This culminated in me retiring prematurely on ill-health some ten years before state pension age. It appeared that I did not meet the criteria for infliximab treatment when it became available, but a close family member has. She responded extremely well to the course of treatment with no apparent side effects over a comparatively short period of time. In comparison my symptoms were significantly worse and my recovery period considerably longer. As I am now retired it is unlikely that I would meet the existing criteria for Inflixmab were my condition to deteriorate however I would urge NICE to extend the availability of Infliximab for Ulcerative Colitis rather than restrict its use. If that approach is taken then I believe many people with the disease will have an improved quality of life and there will be a net benefit to the economy.

Patient England	I was diagnosed with ulcerative colitis in October 2010 during my second pregnancy. I was initially put on prednisolone but this failed to have any impact on my symptoms, which quickly progressed to acute severe colitis. I was hospitalised as a result and failed to respond to intravenous steroids. On day 3 of my hospital stay, I was entered into the CONSTRUCT trial on infliximab and responded very well. After previously having approximately 20 bloody stools per day I was able to leave hospital 3 days later with comparatively normal bowel movements. I was advised to stop infliximab in the third trimester of my pregnancy. Within weeks of giving birth, I began experiencing symptoms of a flare up. I was put on azathioprine and prednisolone but my symptoms continued to escalate and treatment with infliximab was reinitiated, with azathioprine continuing. Again I responded very well and my symptoms disappeared. I continued to have infliximab infusions every 8 weeks until August 2013, when a colonoscopy revealed full mucosal healing and my consultant advised that I stop infliximab to see if I could manage without (I understand that funding also played a part in this decision). In October 2013 I began having symptoms of a flare up and again this escalated until a flexible sigmoidoscopy in January 2014 revealed continuous inflammation to the extent of the scope, with a UCEIS score of 7. Biopsies showed patchiness and deep inflammation favouring Crohnâ€™s disease. I was immediately hospitalised and again failed to respond to intravenous steroids. Infliximab therapy was reinitiated and I soon left hospital with significantly improved symptoms. A colonoscopy in October 2014 again revealed full mucosal healing thanks to infliximab (I am no longer on azathioprine). In summary, infliximab is the only treatment to have had any impact on my symptoms and it has consistently done so rapidly and effectively. Without infliximab I am unable to lead a normal life; I struggle to leave the house (owing to many urgent toilet trips) and my ability to work is severely affected owing to the debilitating nature of the disease. On infliximab I am able to be economically active and continue my work as a freelance consultant in the pharmaceutical industry. I am able to look after my two young children (taking them back and forth to school and pre-school several times each day, on foot as I do not drive) and continue my voluntary work in the local community. If infliximab treatment was halted, it would seem highly likely that my condition (diagnosis of which is not definitive and which is now regarded as inflammatory bowel disease unclassified) would relapse to an acute severe form and that colectomy may be my only remaining option. As an active 33 year old with two young children, a demanding job and a very busy lifestyle, I simply could not deal with the incapacity that major abdominal surgery would bring. I am self-employed and would likely have my current contract terminated if I

	was unable to work for months at a time. My family life would see huge upheaval and we would incur the significant expense of having to employ someone to look after our children while at the same time experiencing the complete loss of my earnings. The whole situation would bring great distress to our child who has autism spectrum disorder. The knock-on effect of the loss of earnings would be that we would struggle to pay our mortgage and would be forced to minimise expenditure in all aspects of our lives.
Patient England	I also do not wish to take such an extreme measure as surgery when my condition is currently very well managed by infliximab and when treatment options for inflammatory bowel disease are likely to change in the course of my lifetime (I write about pharmaceutical treatments in development as part of my work and have a degree in biochemistry). The outcome of colectomy is also not always favourable and can result in some quite unpleasant after effects (I have spoken to a colorectal surgeon about what this would involve). I simply do not wish to take the significant risks associated with major surgery when I am in excellent health on infliximab. My father has had ulcerative colitis for more than 40 years and has managed to avoid surgery, despite a number of hospital admissions and despite being told that this was his only remaining option. I view surgery as an absolute last resort that I would only consider if my life was at risk. I question the ethics of removing such an effective treatment, without which I am likely to become very ill. Finally, I would like to highlight that when biosimilar versions of infliximab become available for use in the UK, the cost of treatment is likely to fall.

Pharmaceutical Industry England I am the medical director of Hospira UK, a biopharmaceutical company that will be marketing a biosimilar infliximab (Inflectra) after expiry of the patent of the originator infliximab (Remicade).	Hospira wishes to contribute to strengthening the biosimilars content (section 4.74) of NICEs appraisal document, Ulcerative colitis (moderate, severe) infliximab (review TA140), adalimumab (review TA262) & golimumab (2nd line) [ID695]: appraisal consultation document. Hospiraâ€™s biosimilar infliximab, (Inflectra) is licensed as follows in particular for the treatment of: Ulcerative colitis Inflectra (infliximab) is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. Paediatric ulcerative colitis Inflectra (infliximab) is indicated for treatment of severely active ulcerative colitis in children and adolescents aged 6 to 17 years, who have had an inadequate response to conventional therapy including corticosteroids and 6-MP or AZA, or who are intolerant to or have medical contraindications for such therapies. It has been previously noted that NICE concluded that there is currently not enough evidence to prove that Remicade (infliximab) is clinically and cost effective compared with other treatments currently available to ulcerative colitis patients on the NHS. However, I can inform you that Hospiraâ€™s biosimilar Inflectra (infliximab) has a Pharmaceutical Price Regulation Scheme (PPRS) cost of 10% less than the innovator molecule. Real-world costs of biosimilars in the literature are often 15-30% less than the originator prices in the European Union [1], [2]. The assessment of the cost-effectiveness of a biosimilar for reimbursement purposes depends primarily on the relative efficacy, given that a biosimilar is likely to be significantly less expensive than the reference biopharmaceutical. On the basis of these facts, Hospira supports NICEâ€™s reappraisal of the cost effectiveness of infliximab (and other agents) in the context of a soon-to-be available biosimilar infliximab, in the indications under review. A positive appraisal would likely improve access for patients with ulcerative colitis, consistent with the EMA-approved indications, on the NHS to an important biological product, currently only available for the treatment of acute exacerbations of severely active ulcerative colitis in patients in whom ciclosporin is contraindicated or clinically inappropriate. Reference: [1] Declerck PJ, Simeons S. A European perspective on the market accessibility of biosimilars. Biosimilars 2012;2:33-40. [2] Boone N et al. How to select a biosimilar. Eur J Hosp Pharm 2013;20:275-286

Pharmaceutical Industry England I am the medical director of Hospira UK, a biopharmaceutical company that will be marketing a biosimilar infliximab (Inflectra) after expiry of the patent of the originator infliximab (Remicade).	
Patient England	Keeping this basic and simple. I have UC and fistula Crohns. I started infliximab October 2013 after other treatments failed. Since then I am back working full time and for the first time in many many years have felt normal again. My symptoms are very calm allowing me to persue hobbies such as swimming and travel. My quality of life has improved and people have commented to me the change they have seen, not only in my health but appearance too. UC left me crippled and in a lot of pain. Today I'm am living virtually pain free enabling me to work full time. I experience the odd headache side effect but this does not outweigh my initial suffering. Short and sweet, without infliximab my life would be very very different.

Patient England	I have crohns since I was 9. I have had every tablet going all failing to control my condition as I can not absorb them properly. I tried humira which worked for about 1 1/2 years and have now happily been on infliximab for the last 3 1/2 years and have not been unwell and needed a hospital admission in all that time. I would be lost and very unwell without the option of infliximab
Patient N. Ireland	after being diagnosed with ulcerative colitis and conventional therapies failing I am finally finding relief and getting my life back with the help of golimumab and I am distraught at the thought of this lifeline being taken away from me. I have tried Asacol and Azathioprine at various doses with absolutely no impact on this disease. The only time I have had any relief prior to starting golimumab was when i was taking steroids. I was off work longterm due to the symptoms of my disease as I was unable to leave the house due to frequency of toilet visits, pain and fatigue. I relied on friends and family to do shopping for me and visit the bank, I didnt have a social life as I was unable to commit to anything that involve me leaving the house. While on Steroids I suffered the effects of cushing syndrome, I had sever Joint pain, struggling to walk up a flight of stairs, out of breath at the smallest amount of excursion. I am now obese as a result, my hair fell out my face was swollen, I had terrible mood swigs , I suffered from insomnia and my confidence is at rock bottom. I was afraid to leave the house as I physically didnt look like myself. And I was slipping into a depression. In the last 3 months since starting Golimumab I feel I have got some of my life back. I am back at work full time, I have even had a weekend break away. I am starting to organise meeting people again after over a year of being almost a recluse. My joint pain has eased, I have finally lasted more than a few weeks off steroids and am starting to lose the weigh gained while on the steroids. As there is little known about the cause and cures for this disease I am discussed that you are thinking of removing the lifeline that these drugs give to suffers. The thought that my only option would be surgery is not only frightening but unnecessary when these drugs are available and work. To have to undergo major surgery when there are alternatives is an utter disgrace. The though of having to have a body part would mentally be unbearable. I plead with you to allow me to have some sense of life without the need for major surgery and continue to fund these drugs

Public England	As a patient with quite a severe case of UC I think that approving these drugs for continuous use would be incredibly beneficial for myself and other patients. When I was 18 years old I became incredibly ill with my UC and having the 3 induction doses of Infliximab saved me from having to have surgery. Although having a biological drug is a lot to deal with emotionally and mentally as well as physically, I believe it is nothing compared to the emotional and mental adjustments I would have had to have made had I needed to have surgery instead. Having a permanent ileostomy was something I would not have been prepared for at that stage of my disease. I think having this drug also benefitted me physically as it allowed me to recover quicker and get back on track with my studies than had I had surgery. My disease is also progressing fairly quickly and I am currently using methotrexate as a maintainence drug. However just recently I have had to go on a few courses of steroids as my disease has been quite unpredictable and slightly out of control. I think I would feel a lot better knowing that there were other drugs such as Infliximab and other biologics that were approved which I could try before having to undergo surgery to control my disease, as I am currently at university and taking time out for surgery is not only scary but would disrupt my studies and awful lot, not to even mention the process of having to accept an ileostomy. For me knowing that I could have Infliximab as a mantainence drug would be amazing as it has worked very very well for me in the past and I don't want to give up my colon yet!

Patient	I believe the focus is on UC and not Crohn's because UC patients can just have their colon removed and a stoma for life, and stoma supplies are cheaper than biologics. However, there have been a number of cases of UC patients having their whole colon removed to cure them and then developing inflammation in the small intestine - meaning they had crohns all along and not just UC. These patients often end up requiring TPN and having no quality of life as their small intestines become more diseased. This NICE review is short-sighted.
Patient England I work as a doctor	I was diagnosed with ulcerative colitis 4 years ago. I then developed an IBD related arthritis and couldn't walk, write or do anything. My Gastroenterologist started me on Humira (adalimumab). He had great difficulty in getting funding because it is not licenced for use in U.C, although it is used in Crohns disease. Initially the hospital actually funded it for me. It allowed me to walk again, to write, to work as a doctor. I could not have done this without Humira. He had to go through lengthy application forms to prove I was an exceptional case, and that the Humira allowed me to work to contribute to society. Now I have been told that I might have crohn's disease but thankfully I am on the right treatment. I know I couldn't have managed without this drug. More evidence is needed and individual cases need to be considered.
Patient England I work as a doctor	

NHS Professional England Some signaturies have in the past received some money from companies that manufacture anti-TNF drugs to participate in research, but not all.	As one of the largest units in the UK treating children and young people with Ulcerative Colitis, we (the clinicians of the paediatric IBD service at Barts Health) felt compelled to respond to this guidance. We manage 25% of all IBD patients in London under the age of 16 (365 out of 1465 patients), and average approximately 30 new diagnoses of UC in children per year. Historically, the paediatric patients described by this draft guideline would most likely have undergone colectomy. This remains the preferred option for most of our patients in this difficult situation. Indeed, we have only treated 5 paediatric UC patients with anti-TNF therapy. Only one of these patients has required surgery to date. However, there are a variety of reasons why we would advocate supporting the availability of anti-TNF therapy in this group, which have not been fully addressed in the current draft guideline. The economic modeling that was used compares anti-TNF therapy to surgery. Our experience is that many young patients in this circumstance, when faced with surgery as the â€œonlyâ€• sound medical option, often choose to delay or defer this for months or longer. This is invariably due to an understandable reluctance for a teenager (who has been chronically ill for years) to accept the need for a stoma, albeit potentially temporarily. The consequences of delay, with ongoing illness and use of steroid therapy can be disastrous on a young persons growth, development, education and potential employment opportunities, with lifelong consequences. The chronicity of the disease also affects the parentsâ€™ and siblingsâ€™ work and education over this time. At Barts Health we have long experience in running a clinic for young adults with IBD (aged 16-25 years) in conjunction with the adult IBD service. This ongoing relationship gives us particular expertise in understanding the difficult issues that our patients face between paediatric and adult care. The consequences of protracted active disease, prolonged steroid use, or even the complications of surgery, particularly in those with ileo-anal pouches, can be very significant. From our experience, certain patients have benefited enormously from the ability to delay surgery for UC through important years of education. We find it difficult to believe that this can be accurately reflected in any economic modeling. There are many other reasons why we believe that the option of anti-TNF therapy should remain accessible to young people with UC. These issues have been raised in previous submissions by professional and patient groups and we do not wish to repeat them all. Briefly, we acknowledge the limitations in the literature for the use of anti-TNF therapy in children with moderate to severe UC. This relative absence of evidence in not uncommon in paediatrics and while unfortunate, we would support the view that in general, teenagers with UC are likely to experience similar outcomes from these therapies as adults do. However, they are at greater risk

	of long term adverse outcomes in education, employment and development from periods of significant chronic illness. In summary, we would urge the committee refrain from limiting access to these therapies for children and young people with this chronic disease. We believe it is difficult to quantify the effect one or several years of remission without surgery may have on a patient and their family. Yours faithfully, [redacted] [redacted] [redacted]

NHS Professional England No	Surgery can be lifesaving for UC, but carries mortality 2% at least. There are a group of patients with moderate UC who are not controlled by azathiorpine and are not suitable for ciclosporin. We should be able to trial antiTNF therapy for these patients with endpoints to confirm efficacy. Deying these patients a therapeutic trial condemns them to a life of steroid dependant disease or surgery with mortality risk
NHS Professional England I have sat on advisory boards for all the pharmaceutical companies in the area of IBD including the manufacturers.	The ACD here will be a significant retrograde step in the treatment of UC patients. In relation to the questions posed:- The evidence has been taken into account, but the models used and the interpretation of the data have been flawed. The costs of surgery have been under-represented in terms of the fact that most surgical interventions require a minimum of 3 surgical procedures. In addition the way the model is constructed that allows patients who fail biological therapy to simply return to standard of care, which has already failed, is clearly wrong. When this occurs patients are consigned to chronic ill health. The colectomy rates that have been used seem remarkably low, and the populations used are not representative of the patient population in the UK who would need these therapies. This the current recommendations are not a sound and suitable basis for guidance in the NHS, and put the UK completely at odds with almost every other developed country. Whilst the anti-TNF agents do not work in everyone, those patients in whom they are effective often experience a complete revolution in their quality of life, and are able to work and live normally for the first time in months or years. It is clearly important to choose patients for therapy carefully, after having tried conventional therapy, but to consign young adults to surgery rather than try these drugs is a poor choice. The drugs should be available for the small proportion of refractory patients, and should be stopped in patients who do not have a clear response. If the current proposed advice is allowed to stand then UK patients with UC will be consigned to potentially substandard care, out of line with international norms, which will condemn them to chronic ill health or major disfiguring surgery.
NHS Professional England	

I have sat on advisory boards for all the pharmaceutical companies in the area of IBD including the manufacturers.	
Pharmaceutical Industry England	Janssen values the opportunity to comment on the MTAâ€™s appraisal document. Since Janssen does not market Simponi and Remicade in the UK, Janssen limits the focus of its comments to two critical points of particular interest to Janssen
Pharmaceutical Industry England	Janssen agrees with the statement that the meta-analysis from the Assessment Group (AG) does not allow a conclusion to be drawn about the relative effectiveness of TNF-alpha inhibitors. In addition, the statement â€œthe difference for maintenance therapy was not statistically significant except for adalimumab for 1 maintenance outcomeâ€• is misleading, and Janssen agrees with the clinical expertâ€™s opinion that the results from the meta-analysis were not congruent with actual clinical trial data. However, Janssen considered flaws in the methodology in the analysis by the AG: - The AG assessed efficacy in those patients who were deemed in remission in both PBO and TNF groups; however the proportion of patients who achieved response/remission was statistically greater in the TNF group, thus supporting the use of these agents in the treatment of UC. - There is no clear rationale why the AG has chosen the second half of the first year (Weeks 32-52?) as the time horizon for â€œmaintenanceâ€• therapy. The efficacy in this period should consider the efficacy from the preceding periods (from induction or from Week 0 of maintenance through to the desired time points) There is no valid protocol or methodological reason to assess data in this time period alone, and the clinical significance of this analysis is unknown. - It appears through the analysis that the AG was attempting to assess the sustained efficacy of subjects who achieved response/remission from induction. The randomized-withdrawal trial design of PURSUIT(for golimumab) adequately assessed the benefit of maintenance therapy of golimumab instead of an â€˜induction onlyâ€™ treatment strategy. Therefore, it is inappropriate to assume that there is no difference between PBO and TNF blockers.

Pharmaceutical Industry England	The model assumptions in which only patients in the remission or response state continue treatment with TNF alpha inhibitors misrepresents the benefits (and thus QALYs) accrued with TNF-alpha inhibitors, as demonstrated in clinical trials and clinical experience in other countries. - As a result of this model, less than 20% of patients remain on TNF alpha inhibitors at year 2 (in either remission or response), and only very few patients (~10%) remain in remission or response at 3 years of treatment. o This is not in alignment with long-term data of the clinical trials with the TNF alpha inhibitors. Patients did not forego treatment with TNF-alpha inhibitors immediately after non-response, and as a result, significantly more patients were on the active treatment and in the response or remission state in these trials compared to what the model suggests. o Data of real-world cohorts in other Western world countries also demonstrate that significantly more patients stay on therapy than what is suggested by the model. (e.g. Scan Journal of Gastroenterology 2014; 49: 1207-1218) - The definition of response and remission in the infliximab and golimumab trials do not allow the responder and remission rates from these trials to be used for this type of model within the context of decision making. Patients that were remitters or responders based on the Mayo score (or partial Mayo score) were counted as non-responders if they received any (temporary) augmentation of concomitant medication. However, in a clinical practice setting, these patients would not be taken off TNF-alpha inhibitors (as suggested by the model) and continue to benefit from treatment (and consequently accrue QALYs). o In addition, the model used had patients stop therapy immediately after losing response, whereas in real clinical practice, a loss of therapy would likely be assessed over a long period of time where dose titration or concomitant medication use could be used to re-induce response. Given the relapsing-remitting nature of UC, the current model structure has more conservative estimates of QALY gains
NHS Professional England	Dear NICE I express concern at the draft NICE guidance relating to the use of anti-TNF therapy in ulcerative colitis. I am concerned at the flawed assumptions on which it seems to be based: 1. It is modelled that after patients lose response to anti-TNF therapy they may be treated with conventional therapy. Patients are treated with anti-TNF therapy because they fail conventional therapy. 2. Cyclosporine and long-term steroids are given as possible long-term options. This is not modelled but it is alarming that this is seen as current practice. 3. The arrival of bio-similars in Q2 2015 will inevitably reduce the costs associated with anti-TNF therapy and substantially alter assumptions made in the current cost-benefit analysis

	4. Critically, many patients who undergo colectomy for ulcerative colitis are NOT cured and do NOT return to a normal quality of life. 39% are incontinent of faeces overnight. 20% suffer from sexual dysfunction with only 56% being are able to conceive at 2 years. A proportion of patients never returning to work. 20% of patients have on-going problems relating to inflammation in the pouch at 1 year. A significant proportion of these will require anti-TNF therapy or further surgery (15%) to remove the pouch. Removing anti-TNF therapy as a potential option to these patients will invariably increase the number of resections with these described outcomes. I would strongly urge your committee to reconsider the scope of its analysis and the details of its modelling, and further engage experts in the gastroenterology and IBD community to input into the process. Otherwise we fear a grave injustice being done to this predominantly young and economically active patient group which would put UK practise at variance with the rest of Europe and North America, and which risks undermining confidence in the undoubted strengths of NICE. Thank you for taking these views into consideration