Name	[redacted]
Organisation	«Organisation»
Role	Patient
Job title	Medical Student with Crohns Disease
Location	Wales
Conflict	N/A
Disclosure	«Disclosure»
Comment ID	675
Comment Type	General
Comments	As a sufferer of crohns for whom anti tnf therapy is currently failing to have another option for drug therapy would be something I would love. I am 22 and in university. I study medicine and I know how debilitating this disease can become. I am currently living a nightmare whereby anti tnf is failing and options are becoming more and more limited. To have the chance to try vedolizumab in the future would be of massive benefit to many people like me who strive to maintain normality and want to do anything possible to avoid surgery. It could mean sitting my finals with minimal interruption and being able to carry on and delay surgical intervention until the last possible moment.
Submission date	2015 01 09

Name	[redacted]
Organisation	«Organisation»
Role	«Role»«Organisation»
Job title	«Job_Title»
Location	«England
Conflict	« N/A
Disclosure	«Disclosure»
Comment ID	678
Comment Type	General
Comments	I am commenting as a patient with severe Crohn's. I have tried all the biologics available and although each have worked for a limited time, I have lost responsiveness. The science behind this makes a lot of sense and it's a glimmer of hope that there is something that could work. I am now facing surgery but have been holding off as I want to try this drug. I don't like the idea of spending the rest of my life with a stoma when there is an alternative that could work for many.
Submission date	2015 01 09

Name	[redacted]
Organisation	«Organisation»
Role	Patient
Job title	
Location	«England
Conflict	« N/A
Disclosure	«Disclosure»
Comment ID	678
Comment Type	
Comments	To recommend this drug for Ulcerative Colitis, but not Crohns, is nonsensical, if anything it should be the other way round. UC can be effectively 'cured' by removal of the large bowel as it only occurs there, no amount of surgery can remove Crohns due to it's ability to occur anywhere in the GI tract, in fact surgery tends to make matters worse as sections repeatedly get removed till you end up with lifelong symptoms, and expenses involved in treatment, caused by a shortage of bowel. It's on this basis I believe no drug, especially ones with a relative success rate as this, should be off the table, even if only used in a small number of cases. To do so condemns large numbers of people to a life of unremitting pain, illness and life limiting symptoms. And I say that as someone who is in that situation, and have been for 15 years - had two major surgeries and had every drug available, yet still the illness persists. My outlook at present is to be condemned to never working again, having no social life, depression and having a diet limited to less than ten food items. I know drugs are expensive, but that is not the patients fault and it's unfair to penalise those of us for whom every available drug has failed. And I doubt the cost of treatment of this drug would exceed my current intake of 16,376 tablets and 30 injections every year, which will just roll over year after year after year unless a new drug treatment is successful. So please reconsider your preliminary decision on this drug's usage for Crohns disease. And thank you for reading..
Submission date	2015 01 09

Name	[redacted]
Organisation	«Organisation»
Role	Patient

Job title	Artist, researcher, consultant.
Location	«England
Conflict	« N/A
Disclosure	I may inadvertently by an investor in the company that makes vedolizumab as my pension funds include investments in a number of biotechnology funds.
Comment ID	683
Comment Type	General
Comments	«Comment_Id» I understand that there are issues around this drug, particularly with relation to Crohn's Disease (CD), and this is something I do not have the expertise to comment on. I comment more generally about the need for new treatments for patients such as myself who have reached the end of all existing medical interventions. I have had CD for almost 40 years, including a number of life-threatening crises and innumerable surgeries. Further surgical intervention is no longer considered an option for me because of the very high degree of scar tissue and the fact that my body tends simply to create new areas of disease once 'old' areas are cut out. I have tried all the medical treatments available. Many have been successful for a time, but ultimately rejected by my body: I have not tolerated either of the available anti-TNF treatments, and after almost a decade on high-dose immunosupressants my white blood count began to fall to dangerous levels. I have no options left. I am currently on the last available medical intervention - methotrexate - but not responding particularly well. The jury seems to be out about the efficacy of vedolizumab, and in particular its efficacy:toxicity ratio. However, for some of us (I'm only 58, and have some time to go!), the threat of toxicity must be weighed against having no remaining treatment options.
Submission date	«2015 01 10

Name	[redacted]
Organisation	
Role	Patient
Job title	
Location	«England
Conflict	« N/A
Disclosure	I may inadvertently by an investor in the company that

	makes vedolizumab as my pension funds include investments in a number of biotechnology funds.
Comment set ID	364
Comment Type	General
Comments	The option of using this treatment for people who have exhausted all other medicinal treatment options and now face surgery must be established. Its not acceptable to push these people into costly and risk-laden surgery when a potential medicinal treatment option could be provided.

Name	[redacted]
Organisation	«Organisation»
Role	«Role»«Organisation»
Job title	«Family Group Conference Co-ordinatorJob_Title»
Location	«England
Conflict	« N/A
Disclosure	
Comment set ID	365
Comment Type	General
Comments	I am a Crohn's Disease sufferer. Currently I have infliximab infusions to stabilise my symptoms. It is however regrettable that the effectiveness of this treatment will one day become ineffective. Accordingly it is essential at this time there an alternative treatment. Without this treatment my health will deteriorate resulting in the need for regular hospital attention. Undoubtedly such continued medical intervention will affect my day to day life greatly and my ability to continue to work. This would mean a greater drain on the NHS and a poor quality of life.
Submission date	2015 01 11

Name	[redacted]
Organisation	«Orga
Role	Patient
Job title	«Job
Location	«England
Conflict	« N/A
Disclosure	
Comment set ID	368
Comment Type	General

Comments	» I am very disappointed to read that NICE are currently considering not approving the use of vedolizumab in patients with Crohn's disease who have lost response to other biological treatments. I have been fortunate enough to have enjoyed 5 years of good Crohn's disease control on adalimumab. This has meant I have been able to work full time in a very demanding profession, start a new family, and enjoy life as someone in their 20s and 30s would hope. None of these would have been possible without the adalimumab. Before treatment with this, I had a treacherous time through A-Levels and university, battling symptoms that made my life miserable. Unfortunately, over the last year, my response to adalimumab has started to wane. I have had to have 2 courses of steroids this year and, on finishing these, my symptoms are still not manageable - I fear my disease will flare to the point where more drastic measures are required. I worry particularly about having to take extended periods of time off work due to uncontrolled symptoms, and, ultimately, I fear most that I may need to have surgery - which, as you will be aware, is often futile with Crohn's disease and would in itself require extensive time off work. The prospect of having a new biological agent with a novel mode of action is incredibly exciting and I would be devastated if NICE did not allow this to be used by patients in my situation. Keeping young people productive and in work is hugely cost effective for society and biological therapies are an effective way of achieving this. I sincerely hope that this will be re-considered at your review and would be more than willing to be approached for any further information that would help with your decision making. With many thanks for taking my views into consideration. [redacted]
Submission date	2015 01 13

Name	[redacted]
Organisation	«
Role	Patient
Job title	«Job_Title»

Location	«England
Conflict	« N/A
Disclosure	«Disclosure»
Comment set ID	369
Comment type	General
Comments	There are a great many sufferers of Crohn's Disease who, like myself, are desperately hoping that Vedolizumab becomes available to them. My situation is unusual, although not rare. My Crohn's disease has always reacted positively to anti-TNF drugs like Infliximab and Adalimumab. However, within a year or two, the efficacy of these drugs has tailed off and I have had to return to courses of steroids, other immunosuppressants, and always, eventually, surgery. My next bowel resection will be my sixth. My only hope is that a new medical treatment becomes available which can keep my health at a level which will allow me to lead a relatively normal life. Perhaps this new treatment will work for me long term, perhaps it will just put off my next bowel resection by a couple of years. Either way it is an incredibly important option. The worse my disease gets, the worse the pain is. The more surgical procedures I have, the greater the risk of psychological and general health problems. A new medical treatment for Crohn's gives people like me a lot more hope. The existing drugs no longer work and unless new drugs come along, there really is no where else for me to turn.
Submission date	2015 01 14

Name	[redacted]
Organisation	
Role	Patient
Job title	
Location	«England
Conflict	« N/A
Disclosure	«Disclosure»
Comment set ID	375
Comment type	General
Comments	«Comment_Id» I am very disappointed to see that NICE are not recommending the use of vedolizumab. I have had CD for over 20 years. In the last two years, I have had severe flare ups of my Crohn's and have been hospitalised twice for PN feeding. I have lost response to inflixamab and am

	currently on humira. I have an NG tube for feeding and have not eaten properly for about 2 years.. My disease is too extensive and complicated for surgery. The humira has helped but certainly not put me in remission. My consultant believes I am now losing repose to humira. This would leave me nowhere to go. Vedolizumab looks like my only option. If I can't get access to it then my quality of life, as well as my family's, will continue to be difficult. I have a two-year-old who hasn't seen me eat properly. I've had to be away from him in hospital for several months. If I have to go back in for another flare, he's now at an age where he would miss me greatly. On a day to day basis, It's hard to explain to him why I can't come out of the loo and why I'm in there for 20 minutes at a time. The fatigue that comes with the flare ups also makes it difficult to function as a family, as do the symptoms- trips out or plans to visit people have to be changed or cancelled. It's also had a big impact on a job I love. I can't always be sure I'll be able to go in and having been off long- sick there are always fears about redundancy. And there's the emotional and financial pressure on my husband to carry everything. He was basically a single parent for 4 months. Not to mention the emotional impact on myself. I would plead with NICE to rethink its decision for people like myself who have run out of options. I just want my life back.
Submission date	2015 01 14

Name	[redacted]
Organisation	«Organisation»
Role	Carer
Job title	«Director
Location	«England
Conflict	« N/A
Disclosure	
Comment set ID	376
Comment type	General
Comments	I write to ask NICE to reconsider the decision not to recommend the use of vedolizumab in patients with moderate to severe Crohn's Disease for whom other anti-TFN drugs have failed or lost efficacy. I can do no other than cite the case of my son. Simon (not his real name) was diagnosed with moderate-severe Crohn's at the age of ten. At fifteen his entire colon was removed. Successive surgical operations removed all but

	the last 60 centimetres of his small intestine. He is now thirty. [redacted] has had many years on azathioprine, lengthy courses of steroids, methotrexate and many other drugs including repeat courses of anti-biotics such as ciprofloxacin and augmentin. He has had lengthy courses of infliximab and adulimumab. Both these drugs were effective for a number of years but lost efficacy. He is dependent for life on Total Parenteral Nutrition. We have long awaited the next anti-TFN drug. Vedolizumab offers [redacted] the chance of continuing life - and quality of life. His doctors - who assuredly know more about this than anyone - are keen to start him on it as soon as possible. Our ultimate hope is that it will be possible for Simon to have a transplant of engineered bowel but it will be several more years until this is available. Vedolizumab offers [redacted] the chance of some years of reasonable quality of life until then. When he developed anti-bodies to the adalimumab there was nothing left for him but yet another course of high dose steroids. That is where we are now. Without the vedolizumab there is nothing else to give him. He cannot have any more surgery if there is to be any hope of, ultimately, a transplant. When his Crohn's is active and severe - as it always is when he is not on drugs that control it - Simon is in constant pain. He can eat nothing. He suffers high fevers, is susceptible to opportunistic infections which - if his feeding line is involved - can quickly become life-threatening. Controlling the Crohn's as effectively as possible is essential for not just his quality of life, but his life. A word about [redacted]. He is a highly intelligent, resourceful young man. He is engaged to be married. He was the founding Chair of the Patient Panel at his hospital, has been re-elected - without competition - as the Chair, in each successive year, although he would be more than happy to step down. He has, for the last three years, organised a conference on IBD which now draws people from all over the world. This in spite of his dependency on the TPN and the fact that his intake of actual food is minimal. He has everything to live for and everything to give. It is the opinion of his doctors that vedolizumab is the vital

	next step in giving him that chance.
Submission date	2015 01 23

Name	[redacted]
Organisation	«Organisation»
Role	Patient
Job title	NHS Patient with Crohn's Disease
Location	«England
Conflict	« N/A
Disclosure	
Comment set ID	377
Comment type	General
Comments	I am extremely concerned to hear that NICE is currently not recommending Vedolizumab as a treatment for the management of moderate to severely active Crohnâ€™s Disease, since my consultant gastroenterologist judges that the drug could be of considerable benefit to me. If we cannot try it, we will never know. Crohn Disease is an incurable and relapsing condition, which blights my life. I am an experienced professional teacher and a trustee of a local charity but my ability to contribute to my community, to wider society, and to pay my taxes, is limited by the impact of the disease. It forces me to work part-time when I would otherwise work full-time and I have regular episodes of sick-leave, roughly every 12 - 18 months. The latest period of sick-leave will last six weeks, which is a burden on my employers. The impact on my family and social life is huge. I havenâ€™t been able to travel abroad for over two years. Long-term use of aminosalicylates and immunosuppressants gives me only partial remission: the disease is currently absent from my colon (where it has been in the past) but remains severely active in my terminal ileum and caecum. The symptoms of the active disease are very debilitating: explosive diarrhoea, excruciating abdominal pain, severe nausea, projectile vomiting and extreme fatigue. At crisis points I have been treated with steroids and antibiotics, which calm things down for a while but cannot be used long term. I have been on an exclusive liquid diet for the last two months and I will shortly be having surgery: an ileo-caecal resection. I hope this will give me a few years of respite but Crohnâ€™s Disease has a habit of returning to the site of a bowel resection.

	If the Crohnâ€™s does return after the surgery, my consultantâ€™s options are very limited. I am intolerant of Azathioprine and 6-Mercaptopurine. I have been on Methotrexate for four years. If I develop dangerous side effects from the latter, I will be in trouble. I cannot be given Infliximab or Adalimumab because they both carry significant cancer risks for me. I had breast cancer four years ago and later learned that I carry the BRCA2 genetic mutation. My gastroenterologist therefore concludes that using anti-TNF drugs in my case would be too dangerous. At the moment, Vedolizumab looks like the only other viable option for my further treatment. I am sure that I am not the only patient for whom anti-TNF treatment is not suitable. PLEASE give us the opportunity to access Vedolizumab.
Submission date	2015 01 23

Name	[redacted]
Organisation	«Orga
Role	Partner of Crohn's sufferer
Job title	«Job_Title»
Location	«England
Conflict	« N/A
Disclosure	
Comment set ID	379
Comment type	General
Comments	My fiance is a Crohnâ€™s sufferer and I have seen first-hand the physical and emotional toll this disease can have. Over the past 15 years or so, he has undergone numerous resections and now has a very small section of small bowel remaining (he has been on TPN for the past 5-6 years). Infliximab and, more recently, adalimumab have also failed to bring his symptoms under control despite an initial positive response to both drugs. My fiancÃ© recently turned 30 and we would like to start a family in the next few years, which means that keeping him as healthy as he can be is our priority. For us, this means salvaging and maintaining in a vaguely healthy state what little small intestine he has remaining; further surgery has to be the last possible resort (this would leave

	him with little or no remaining small intestine). If there is a possibility that the use of Vedolizumab could avoid or postpone the day when further surgery becomes necessary for my fiance or for others in a similar situation, this would then I would urge NICE to recommend its use for Crohnâ€™s patients. It is no exaggeration to say that Crohnâ€™s touches on every aspect of our lives. My fiancÃ© is extremely restricted in terms of what he is able to eat, which means that meals out are never a simple affair and travelling requires meticulous planning to ensure we donâ€™t leave home without a crucial bit of kit (which has happened many times!). Over the years, we have experienced the disappointment of treatments not working or not working as well as they should. More importantly, the fear that treatment options are â€œrunning outâ€• for us is one we face constantly. Approving another treatment option would give a huge psychological boost to those Crohnâ€™s patients who are most severely affected and to their families.
Submission date	2015 01 26

Name	[redacted]
Organisation	«Organisation»
Role	Patient
Job title	NHS Professional
Location	«England
Conflict	« N/A
Disclosure	I am both a doctor and Crohn's sufferer.
Comment set ID	380
Comment type	General
Comments	"I write as both a doctor who has treated IBD patients and seen the effects it has on their lives, and as a Crohnâ€™s sufferer myself. I cannot stress enough the detrimental impact of IBD on sufferers, and the need for as many treatment options as possible both to avoid surgery, but also to allow sufferers to maintain good health and thus economic activity for as long as possible. From a personal perspective, I was diagnosed with Crohnâ€™s around 4 years ago. This has taken a huge

	physical and mental toll on me. Obviously, day to day symptoms have seriously affected my activities of daily living given the number of times I need to go to the toilet, the arthritic and myalgic symptoms and general feeling of being unwell. Even worse is the mental effect from loss of self-confidence and depressive symptoms which have only been compounded by being able to work only intermittently since diagnosis. Having failed to maintain remission on Budesonide, Mesalamine or 6 Mercaptopurine, I finally found relief from starting Humira (adalimumab) and was able to return to work around a year and a half ago. However, as with other patients, I have become resistant to this and am now faced with switching to infliximab or adding in methotrexate, and am again faced with being economically inactive. Whichever treatment option I eventually choose, it is more than frightening to realise that these options are running out. Knowing this forms what I can only describe as a psychological shadow over my daily life given that it may be thrown upside down at any moment with the prospect of debilitating surgery on the near horizon. Accordingly, on first being informed about the possibility of a new drug, vedolizumab, possibly becoming available, I was both happy and relieved. It is deeply disappointing to find out that the drug is likely to be denied funding. Separate to the treatment possibility that this drug holds, I would question the health economics of removing this option from sufferers who are thus likely to be economically inactive for longer if / when their disease flares and they are out of all other options. Should you wish for any further information, please do not hesitate to contact me using the details provided. "
Submission date	2015 01 26