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

Role	NHS Professional
Other role	
Location	England
Conflict	yes
Notes	[redacted]
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am very disappointed with NICE preliminary recommendations. I am very concerned that the patients with multiple sclerosis will be denied this effective and well tolerated disease modyfing therapy.
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	"Best supportive care" which is recommended by NICE as a comparison (in paragraph 3.18) simply does not reflect the clinical practice and the standard of care provided in the UK for patients with relapsing remitting multiple sclerosis and ongoing relapses.
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/30/2011 12:27:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	I am very dissapointed by this draft decision from NICE. I am a patient currently participating in the Fingolimod trail and have been taking the drug since December 2010. I had suffered 3 relapses in the 18 months prior to starting the trail but since the trail has commenced I have been relapse free and this makes a huge difference to my quality of life. Whilst I appreciate there are alternative treatments available for MS there are some things to be considered from a patient viewpoint that I do not believe are currently being taken into

	account correctly. The drug is taken in tablet form rather than an injection. From the patient perspective taking a tablet is far more socially acceptable then having to inject yourself, it also makes managing your illness less psychologically demanding therefore putting less stress on your body as mentally you are in a better place and we know with MS putting less stress both mentally and physically on the body is better. The overall issue is that too much is being placed on the cost of the drug rather than on patient wellbeing and care and this is not acceptable. I urge you to look at this decision again and come to a positive conclusion that truly is in the best interest of the patient.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am very dissapointed by this draft decision from NICE. I am a patient currently participating in the Fingolimod trail and have been taking the drug since December 2010. I had suffered 3 relapses in the 18 months prior to starting the trail but since the trail has commenced I have been relapse free and this makes a huge difference to my quality of life. Whilst I appreciate there are alternative treatments available for MS there are some things to be considered from a patient prospective that I do not believe are currently being taken into account correctly. The drug is taken in tablet form rather than an injection. From the patient perspective taking a tablet is far more socially acceptable then having to inject yourself, it also makes managing your illness less psychologically demanding therefore putting less stress on your body as mentally you are in a better place and we know with MS putting less stress both mentally and physically on the body is better. The overall issue is that too much is being placed on the cost of the drug rather than on patient wellbeing and care and this is not acceptable. I urge you to look at this decision again and come to a positive conclusion
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	

Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/29/2011 11:51:00 PM

Role	other
Other role	Patient and Bioscience Researcher
Location	England
Conflict	no
Notes	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I have MS. I have recently stopped using Rebif because of severe side effects (depression and flu symptoms), after switching from Copaxone because it wasnt effective. Fingolimod is my only chance to stop my worsening: stay at work and have a life.
Section 2 (The technology)	It seems very effective and easy for the patient
Section 3 (The manufacturer's submission)	no comment
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	The drug should be made available to everyone who needs it in the UK
Section 6 (Proposed recommendations for further research)	Yes to future research but use it now
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/29/2011 4:59:00 PM

Role	NHS Professional
Other role	Trust Clinical Lead of Multiple Sclerosis service and Clinical Director of Neurosciences
Location	England
Conflict	yes
Notes	[redacted]
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Appraisal Committes decision is inconsistent with the precedent standard of practice in NICE technology appraisal of a competing product (natalizumab/Tysabri: manufactured by Biogen Idec) and is not appropriately balanced by existing evidence.
Section	The technology is based on an objective and well-defined patient

2 (The technology)	population and the treatment carries no significant risks or fatality. The cost of therapy is less than the competing product (Natalizumab/Tysabri) which has significantly higher risk of fatal adverse events (upto 4%)due to progressive multifocal leukoencephalopathy (PML) in certain high risk patient groups with actively relapsing multiple sclerosis(positive JC virus serostatus,prior history of immunosuppression and a duration of therapy in excess of 2 years). Fingolimod is not an immunosuppressive drug and reactivation of opportunistic infection has not yet been reported with its use in multiple sclerosis or post-transplant population (clinical trial data).
Section 3 (The manufacturer's submission)	There are no established criteria of what constitutes "best supportive care" in disease-specific therapy of patients with relapsing-remitting multiple sclerosis. There is lack of complelling evidence from double blind randomised trials that Rebif 44 is superior to Avonex this isnt a view that NICE or national clinical guidelines have recommended for implementation in current practice. If NICE advocates superiority of Rebif 44 over Avonex as the best supportive care for relapsing-remiiting multiple sclerosis, then it would become imperative for NICE to issue guidelines favouring Rebif 44 as the treatment of choice as a first-line therapy and NICE would be required to re-appraise existing recommendation for natalizumab (Tysabri) where Avonex was used as the comparator and no trial has since been conducted to compare efficacy of Tysabri with Rebif 44. The assumption of constant and continued treatment effect of disease-modifying therapy forms the basis of current practice with first line agents (beta-interferons and glatiramer) and natalizumab. If this assumption is being scrutinised, then it would be only appropriate to extend the scrutiny to all current therapeutic agents.
Section 4 (Consideration of the evidence)	In considering the evidence, the committee has overlooked certain facts which could potentially compromise patient care. 1. Multiple sclerosis patients with high disease activity who either do not tolerate or respond (eg. neutralising antibody to beta-interferons) to existing first line agents and are either unwilling to consider natalizumab (Tysabri) for safety concerns (risk of PML) or are unsuitable because they do no meet the NICE recommended criteria (at least 2 relapses in a year and one Gadolinium enhancing lesion). These patients are likely to experience rapidly progressive disability without fingolimod. 2. Patients with active disease who have positive JC virus serostatus and have higher than average risk of PML on natalizumab (Tysabri). They have no alternative treatment option at present and are likely to be exposed to the risk of a potentially fatal disease (PML) or progressive disability from using a less effective therapy (beta interferon) without fingolimod. For these groups of patients, oral fingolimod would be a highly suitable and potentially effective treatment option.
Section 5 (Implementation)	There should be an agreed protocol of using fingolimod. A protocol has already been developed locally and it has been agreed at the North East London Medicine Management group for use by designated hospital specialists.
Section 6 (Proposed recommendations for further research)	The NICE should consider the wider remit of appraising the effectiveness of disease modifying therapy in multiple sclerosis with a view to set current guidelines to identify suitable patients who are most likely to benefit from high cost therapy to replace existing standards of practice.
Section 7 (Related	

NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/26/2011 5:37:00 PM

Role	other
Other role	Friend of patient on fingolimod trial
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	It is disappointing that the recommendations are not positive. I have see my friend have an improvement in her whole well being since being on this trial. I also have seen another friend who could have benefited from this kind of treatment early in her diagnosis.
Section 2 (The technology)	I have seen no adverse side effects in my friend. If anything, her quality of life has improved.
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	This clearly is effective and cannot be limited to just one person also, it is unlikely that this response is unique. To have evidence of someone who, having had 2 relapses in quick succession then not have any in a prolonged period of time is testament. Add to that a fear of needles which is very common and this surely seems the right way forward, treatment obviously needs to be administered early as with all treatments. This should be no different.
Section 5 (Implementation)	To combat this potentially horrific disease, implementation should be country wide. The repercussion of someone not being given the option because of the health authority that serves them does not sit well with anyones conscience. It would be unethical to remove treatment from those that are already responding well and if you remove the human side, what of the future cost?
Section 6 (Proposed recommendations for further research)	If there are uncertainties, surely further trials are the sensible way forward with expanded patient numbers.
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	The review is too far in advance. This disease can progress at alarming rates for some and 3 years is just not satisfactory.
Date	8/26/2011 4:56:00 PM

Role	NHS Professional
Other role	
Location	England

Conflict	yes
Notes	Our NHS Department has been involved in the clinical trials of this product. I have also received travel grants to attend Academic meetings with this company.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I, along with a number of Consultant colleagues working in the field of MS, am very surprised and disappointed that Fingolimod has not been recommended as a potential treatment for patients with RRMS. I do feel it has a place in the therapeuic armorary, but appreciate the cost may prohibit widespread generalised use.
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	Comments. Yes Avonex is deemed slightly less effective than other interferons with Rebif 44 thought most efficacious. Fingolimod patients would be seen possibly even slightly more in the first year compared with the interferons. Current thinking is that if you do reduce relapse rates (the earlier the better), thought indicative of an affect on the inflammatory component of the disease, you will have an effect on reducing the risk of developing progressive disease.
Section 4 (Consideration of the evidence)	In the real world, patients in group 1B on Avonex (or any first line DMT) would not have there therapy stopped for just best supportive care. Changes between therapies would be attempted eg interferon to copaxone etc. Or certainly nowadays switching to Nataluzimab (especially if JCV ab negative and with no previous immunosuppressants. However, there are occasions were Fingolimod would be certainly considered or be desired. For instance, patients in 1B or 2 who develope an anaphlactic reaction to Tysabri. They require the next most efficacious treatment and that currently would be Fingolimod. Likewise for extremely needle phobic patients (I have one)who will not have Tysabri (or any 1st line DMTs). Therefore, in my opinion, there is a definite and obvious risk of early (and resulting in longterm) neurological damage from unchecked aggressive inflammatory disease in a restricted group of patients that would be best treated with Fingolimod.
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/26/2011 4:18:00 PM

Role	Patient
Other role	
Location	England
Conflict	no

Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Being an individual with MS, I have been on Disease Modifying Treatments for nearly 5 years, I have had 2 different types and have now been informed from my Neurologist that my disease is now progressing as shown on recent MRI scans, and therefore I have been advised to change my treatment. The only other available is an Infusion, which carries in my eyes a great deal of risk. I am a mother of two and the having the infusion would carry a great deal of emotional strain on both my Family and myself, I would need someone to be with me to assist with travel arrangements and support. For a person who meets the Criteria and would be a good candidate for Fingolimod I feel that NICE should look at the bigger picture as to peoples personal rights and also of those who are affected by the disease as I feel that this is also a contributing factor as the person suffering from the illness would require less assistance from the NHS if they remain relapse free for longer periods of time. Please think about the decision carefully as this is people?s lives.
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/26/2011 2:16:00 PM

Role	Patient
Other role	Healthcare Professional (within NHS)
Location	England
Conflict	no
Notes	I submit these comments in response to the invitation from Dr Longson to interested parties to contribute to the development of this guidance. I have been diagnosed with MS for 7 years. I received interferons and high doses of steroids in largely unsuccessful attempts to control my highly active disease. In 2007 I qualified for natalizumab as approved by NICE for those of us with particularly aggressive disease. For over 4 years, I have been lucky enough to receive this disease modifying therapy within the NHS. I work as an NHS consultant, full-time, specialising in cancer

	diagnosis and care, working with my local Cancer Network and as Staff Governor for my hospital.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The preliminary negative recommendation from NICE is deeply disappointing for many people with MS, their families, carers, nurses and doctors. It is out of step with responses from other authorities, such as FDA and EMA, potentially leaving the NHS in England and Wales behind in its care of people affected by MS. There is un met need for treatments that can reduce illness experienced and slow neurodegeneration in MS. This could be a better time to be diagnosed with MS, than in the past. There are new medicines, like Fingolimod, coming to market which use different mechanisms to reduce the effects of the illness, which could help more people to stay in work and involved with their families and communities. But if not approved by NICE, people will be denied effective treatment that is available in other countries. This does seem to continue the idiosyncratically negative attitude in the UK towards medicines for chronic illnesses that is in such sharp distinction to the attitude towards many drugs for cancers, such as herceptin. It is as if, having one therapy for a chronic condition, no other therapy is thought necessary, even although the first therapy does not help all patients.
Section 2 (The technology)	I am not clear that the Committee understood the significance of these statements from a patients perspective : 2.2 When considering the adverse effects of treatment with Fingolimod, it seems appropriate to compare these with side-effects of treatments for similar severity of MS. Natalizumab is the only approved medication in the UK for rapidly evolving severe relapsing remitting MS. A significant side-effect of natalizumab is progressive multifocal leucoencephalopathy (PML), which carries a 20% mortality, with survivors often severely disabled. Overall the risk is about 1:1000. Recent work has identified risk factors and that risks rise with duration of treatment (my risk is 1:385). Known risks associated with Fingolimod are not this serious. 2.3 In those with highly active disease, being able to move straight from what has probably been an ineffective medicine, without a period without treatment, is important. During any time without effective therapy, the disease continues to damage the nervous system. This damage may not be reversible. The possibility of an immediate switch to Fingolimod is likely to be hugely valued by a patient and their family
Section 3 (The manufacturer's submission)	I do not know enough to address much in this section, however : 3.4 A drug that reduces the number of relapses from 0.40 to 0.18 is wonderful in terms of days not lost from work and normal life. Similarly, reducing the proportion of patients with worsening disability is very significant.

	3.5 A drug that is this effective, which has a safety profile comparable with placebo is remarkable (see comment 2.2). 3.6 Less deterioration in ability to perform daily activities is of huge benefit in terms of continued dignity, self-respect and employment. 3.18 It is almost unthinkable that a person with highly active MS should languish on best supportive care, so this is not an appropriate comparator. Any trial using this as a control group would probably be considered unethical. 3.24 EDSS, however flawed, is the accepted standard for assessing MS. No patient with EDSS 6 would receive Fingolimod. So estimates for EDSS scores 7-10 seem irrelevant. 3.29 I do not think that this argument is valid. There is no evidence for waning of the effects of disease modifying therapies (DMTs) in MS. In other countries, patients who respond have been on interferons for over 20 years.
Section 4 (Consideration of the evidence)	This consultation does not show that the Committee has understood the heterogeneity of the disease between patients. There is no mention of research showing numerous genetic abnormalities affecting multiple pathways for immunologically mediated degradation of the nervous system in MS, offering multiple possible sites of action for drugs, suggesting that different patients will need different drugs for optimal treatment. There is no discussion of the un-met need for DMTs for non-responders to interferons, for whom drugs using different pathways offer hope of effective therapy. The fact that best supportive care is given as a potential comparator suggests little understanding of the object of therapy in the early stages of MS when DMTs are used to prolong the period without significant disability and reduce the amount of illness experienced. Natalizumab is mentioned, but without mention of PML and the need to give it in a hospital setting. Unlicensed alternatives to natalizumab, have major side-effects and if used prior to natalizumab significantly increase the risk of developing PML. Whilst Fingolimod is not known to have any such serious adverse effects and is a daily tablet.
Section 5 (Implementation)	No comment.
Section 6 (Proposed recommendations for further research)	No comment.
Section 7 (Related NICE guidance)	No comment.
Section 8 (Proposed date of review of guidance)	No comment about this paragraph. However, I am surprised that NICE should act to restrict what can be said so drastically. As an individual giving feedback on this consultation, I do not feel that I have been given a fair mechanism for my comments, with entries restricted to 1200 characters in relation to large sections of the consultation. I very much hope that more important interested parties will be given a more reasonable chance to respond more fully.

Date	8/26/2011 12:45:00 AM

Role	other
Other role	Brother of patient on fingolimod trial
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	In the past, treatment for MS has been very poor my father has had MS for some considerable time and now my sister has been recently diagnosed. The difference with my sister is that she is taking part in the Fingolimod trials and this has enabled her to continue working and lead an almost normal life.
Section 2 (The technology)	My sister does have a phobia regarding needles so this oral form of treatment is more beneficial for her than injections. She has not had any adverse reaction to this drug and has not had a relapse during the trials.
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	My sisters? trials are still continuing so I am not sure whether the information that was reported on is now out of date and surely the decision should have been made at the end of the trial.
Section 5 (Implementation)	The National Health Service is just that a service available to all patients that require it nationally across the country ? not a postcode lottery.
Section 6 (Proposed recommendations for further research)	Research is vital to combat this debilitating condition it is not pleasant seeing a parent go through this, and now my sister has also been diagnosed with R-R MS. This is really difficult for her to cope with, watching our father deteriorate with this condition ? my sister has not reached anywhere near this stage of disability to date and further research must continue to help her and others in a similar situation.
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	Why did NICE specify January 2015 as by then, more people could be affected, my sister in particular could have deteriorated as no oral form of treatment would have been sanctioned. I wonder whether anyone that took the decision to leave it to 2015 actually has close relatives affected by this progressive condition.
Date	8/25/2011 11:39:00 PM

Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary	Hopefully, with some more information this decision will change as there are notmany opportunities to make a differnce to the

recommendations)	life of a person with MS and an oral agent is one of them. not all of thos einjecting themselves, day after day or less frequently aremore often than not, troubled by injection site reactions, particularly over long-term and other side effects that need managing.
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	please review this asap
Date	8/25/2011 3:37:00 PM

Role	NHS Professional
Other role	
Location	England
Conflict	yes
Notes	i am a consultant neurologist with an interest in MS that currently participate in a fingolimod trial. i just wanted to note that no patient in the UK with continuing relapses (failing interferon treatment) is treated with the "best supportive care". I understand that no cost comparisons have been made with natalizumab , but cyrrently the majority of patients that continue to have relapses despite interferon receive IV natalizumab.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	3.18 best supportive care is never used with active MS patients in the UK or any other developed country. patients are treated with natalizumab.
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8	

(Proposed date of review of guidance)	
Date	8/25/2011 3:25:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	I started on the Fingolimod trial in March 2011, previously I had tried Rebif and Avonex. Both of the previous drugs gave me horrible side affects-abscesses where injecting, very sore patches/lumps on my legs, overwhelming hot spells which were very unpleasant and had a considerable effect on my day to day life, horrible flu like symptoms when starting both drugs and during the time I took them these symptoms would reoccur at different times, again affecting my day to day life. Since I have started taking Fingolimod I have had none of the above problems linked with the Rebif and Avonex-it is not just the easiness of taking a tablet every day (which is of course fantastic) it is the ability to plan normal day to day activities such as lunch with friends without worrying if this was the day I would feel fluey or generally lousy as a result of the Rebif and Avonex. I have mentally felt so much better since taking Fingolimod I am able to go swimming, walk and am generally more active with my children and husband which I was unable to do on the other drugs. The drug being in the form of a tablet has made my life so much easier, there are more than enough hurdles to deal with when you have MS and the Fingolimod has meant that I have had no relapses since being on the drug, surely it is better for the NHS to pay for a drug that will improve my quality of life and health other than placing me back on a drug such as Avonex which caused more health problems than it cured, in the long run costing the NHS more money with MS nurse and G P appointments along with consultant appintments and hospital treatments. I feel that my MS is under as much control as possible with Fingolimod which is surely a good thing as stress worrying about my MS can cause a relapse whereas I am relaxed while taking Fingolimod as I know this drug works! I am very happy to be on the Fingolimod and would find it unbelievable difficult to have to contemplate not being on it, this drug works - I feel so much better on it and have a better quality of life as a direct result of taking the drug-please allow other people and myself the opportunity to continue taking this tablet as it is makes a real difference to MS sufferers - all the trials have proven this and surely somebodys health and well being is the most important factor when deciding whether or not to approve this tablet for use in the UK.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3	

(The manufacturer's submission)	
Section 4 (Consideration of the evidence)	I started the Fingolimod trial in March 2011, previously I had tried Rebif and Avonex. Both drugs gave me horrible side affects-abscesses where injecting, very sore patches/lumps on my legs, overwhelming hot spells which had a considerable effect on my day to day life, horrible flu like symptoms which would reoccur at different times, again affecting my day to day life. Since starting Fingolimod I have had none of the above problems-it is not just the easiness of taking a tablet every day (which is of course fantastic) I have mentally and physically felt so much better since taking Fingolimod I am able to swim, walk and be more active.The drug has made life much easier,there are more than enough hurdles to deal with when you have MS and the Fingolimod has meant that I have had no relapses since being on the drug, surely it is better for the NHS to pay for a drug that will improve my quality of life and health other than placing me back on a drug such as Avonex which caused more health problems than it cured, thus costing NHS more in the long run. I am very happy to be on the Fingolimod and would find it unbelievable difficult to have to contemplate not being on it, this drug works!
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/25/2011 1:56:00 PM

Role	Public
Other role	Step parent ot ms sufferer
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I found this news disappointing as my understanding is that as medical knowlage advances this will be of advance to the sufferes of severely disabling ilnesses. This should be espically true of non reversable symptoms such as the nerve damage such as this drug is designed to prevent.
Section 2 (The technology)	I have a relative who is on a trial of this drug and hve been pleasently suprised on the positive effect that this drug has had on their quality of life, general demeanour and outlook on life. This is espically true as it does not involve the use of needles and there have been no side effects.
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the	As test results cannot be predicted and there are still major tests still in progress that are not due to end for at lease another

evidence)	12 months, I cannot see how NICE can pass comment on the effectivness of the drug. A negative answer from NICE will make use of the drug a postcode lottery which is inherently unfair and unethical. The most important consideration should be the dignity, quality of life, mental health and future of the patients.
Section 5 (Implementation)	Implementation should be across the whole NHS as it would be inappropriate and unethical to create a postcode lottery and wqholly wrong to remove it from patients who are responding to the new treatment
Section 6 (Proposed recommendations for further research)	It would appear sensible to continue the tests and progress research on the drug for the benifit of excisting patients and trialists
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	2015 is too far away for guidence, surely the correct time for guidence is when the present trials have been completed and the results analyised. This would give sufferes a dateline to plan for and enable them to continue with a near normal standard of living
Date	8/25/2011 8:32:00 AM

Role	Patient
Other role	Full time teacher at the moment
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I have written to my MP about this drug and the decision against it, so I have attached a copy of the letter that I have written. Hi Karen, I need Pauls help. I dont know if he can help, but both my neurologist and my head teacher have suggested that I ask him. As you know, I have multiple sclerosis. I was diagnosed two and a half years ago and I have varying degrees of nerve and muscle damage to my right leg, for which I take a medley of drugs. I suffer with fatigue dreadfully. My memory loss is frustrating as I could always pride myself on an excellent memory. I have tremors in my arms, I have balance problems, I have fisculations throughout my body which resemble a scene from Alien! I am also hot twenty four seven. Its sometimes Utophfs phenonomon, but basically I am boiling hot all of the time which also has a knock on effect to the fatigue. Some days, I walk with a limp, but I spend most of my days pretending to be normal, because I look it. This is my life now, on a daily basis. But thats excluding the relapses. Two and a half years ago, I was told that I had approximately fifteen years before I was wheelchair bound, (that was by the original neurologist who I swapped for a much nicer one!) It took me and my family a long time to come to terms with it, and I will never accept it, simply because I never signed up for

	this, but I decided live now. I bought a sports car. Cant really fit a wheelchair in one and at fifty Im more likely to be looking for suped up scooters! I got in touch with Access to Work, and they came into my work place, assessed what I needed, and provided some of the funding for a specialist chair etc. They also provided funding for an assistant. I get twenty hours of support, and after a year of working with her, I know that I couldnt do my job without her now. I am trying to work full-time for as long as is physically possible. I am an art teacher at Baines in Poulton Le Fylde, and I have worked there for eleven years. I love my job. I love working with the kids. The staff know about my condition and my head teacher has been incredibly supportive. I have to have adjustments to my timetable, for example, I cant physically teach five hours back to back anymore. Its hard for every teacher, but with MS its impossible. So I have someone come and cover a lesson for me on one of those days, so that I can collapse in a heap in my cupboard! Yes, a cupboard! Its a walk in, storage cupboard, and I have a very comfortable camping chair in there, so I can rest for an hour. I am having to tell some of my older pupils now, as my fatigue is harder to hide somedays and my tremors are worsening. Its a progressive disease after all. Ive had two relapses this year within the space of six months. To be honest, I dont think that my body really fully recovered from the first because I worked through it. I also worked through the second. With all the cuts that are happening in education, I dont want to add a supply bill to the school if I can cope. I know now that I should have asked my boss for a couple of weeks rest back in May, I that could have prevented the second relapse, but thats the problem with relapses. You dont know youre having one until you are! I do have an early warning system-bit bizarre, like the disease! I get really bad toothache. The nerve in one of my teeth will flare up. The pain is excruciating-the type where pliers are very tempting! This happened in January, ten days later I woke up to Optic Neuritis. It had only effected the peripheral vision in my right eye, so I could still see. Bright lights hurt like hell, so I wore sunglasses for a couple of months. I worked through it. Mid may, same tooth, same pain. This time my fisculations became unbearable again and for the first time I experienced an MS Hug. Then the nerves in the base of my neck began screaming in pain. I googled, and I realised that this meant that Id had a flare up of the spinal cord-new lesion. Second relapse in six months. Google also informed me that diazepam would help lessen the symptoms. (This was about the time I contacted you about my lovely doctors receptionists! Ive spoken to the Practice Manager since then, and things seem to have settled a bit-until the next relapse!) I saw my neurologist last Monday and he confirmed a second relapse. The diazepam did the trick. The symptoms abated, and I was

	able to con my body in to carrying on working. Right up until 22nd July. The only problem was, there was no way that I could drive, so I got in touch with Access to Work, and they provided me with taxis to and from work and I put some money towards each journey. They have also just funded two air conditioning units to help keep my classroom at a more ambient temperature and hopefully help with the fatigue. I am also to continue with the taxis until the October half term, as to go from relapse, to rest, to full blown teaching again is going to be particularly hard this time round. So, as you can see, Im doing everything I can to stay as normal as possible, for as long as possible. I am also a single parent with a nineteen year old daughter hopefully about to embark on a degree in September, so I cant afford to work part time. Nitty gritty time. Sorry if Ive waffled, but I needed to be able to put Paul in the picture a bit. I need to go on disease modifying drugs. I had an MRI in February that showed at least four more lesions in my brain, and I know first hand that I have a second in my spine. I am needle phobic. So injections have never been an option. Plus, the side effects are so horrible, that I couldnt possibly work as I am able to do now. The reduction in relapse rate is only 30%, and what you have to endure for that little help, the side effects make it nonnegotiable. Two years ago, my neurologist told me about a drug that they were trialing that would be ideal for patients like myself. It has a 50% reduction rate and none of the nasty daily side effects. It isnt without risks, liver damage, skin cancer etc. but these were low risk. Day to day, no extra fatigue making it impossible for me to function, no hair falling out, no muscle pain and damage from the injection sights, no flu like ache and pains, to name but a few lovely examples that I wouldnt have to endure on top of everything else. The drug was passed by the FDA in February, but then it had to go in front of NICE, and they made it clear that they would take their time. Weve only been waiting two years, whats a few more months. Yesterday, they decided against it. Its too expensive. It would cost approximately Â£18,000 a year as opposed to Â£6,000 for the injections. Forget quality of life, forget how poorly the other drugs make you, forget working, forget living. None of them must suffer with MS. Im pretty sure that it would cost more than Â£18,000 a year to cover me for supply lessons, for additional medications to make me better from the nasty things inflicted through the jabs etc. For me to have to stop working. So I am at a standstill. The drug that could enable me to carry on living, working and functioning has been turned down. But Ive had two relapses in six months, so I know the disease is progressing and I need to slow it down.

	Cuts are everywhere, weve lost eleven members of staff that are not going to be replaced. I cant afford to take time off work but I also know that I cant afford to work through the relapses anymore. This last one has proven that. Im still not over it yet. My head teacher is prepared to write a letter on my behalf, my neurologist has about fifteen patients that he desperately wants on the drug, myself included. If it can be funded through the PCTs or somehow???? I think there can be exceptions. Its available everywhere else in the world. The drug company have the patent for the next ten years, but there are others in the pipeline in the USA that may come on the Market in a few years time. My other, cheaper option is a drug that they give to transplant patients. It kills off your White blood cells and effectively wipes out what is left of an already shot at immune system. Teacher, children, germs, bugs, snotty noses? Dont quite see how that one could really work, do you? So, Ive written to my MP. The drug in question is called Gileyna or the Novartis MS pill. I dont know what else to do or who else to turn to. Kind regards, [redacted]
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/25/2011 12:50:00 AM

Role	other
Other role	Mother of patient on fingolimod trial
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I have experience that the treatment for MS is very poor in England. Fingolimod has given hope to my daughter during the trial and has enabled her to continue working. The MHRA gave their backing to this drug for patient choice.

Section 2 (The technology)	Oral treatment is more beneficial than injections to patients that have a phobia regarding needles. My daughter has not had any adverse reaction to this drug and has not had a relapse during the trial.
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	How can this be compared with giving no treatment and just letting the illness progress. This suggests that the only criteria that NICE considered was the cost to the PCT and not the hidden cost to the government in disability benefits, hospital admissions, carers allowance etc. There are still trials continuing so I do not understand why the decision has now been taken.
Section 5 (Implementation)	It is inappropriate to make certain drugs only available in a postcode lottery. The NHS was designed to cover all patients.
Section 6 (Proposed recommendations for further research)	Research is vital to find a way to combat this dreadful debilitating condition.
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	Why did NICE specify January 2015. In that time disease progression may advance significantly. There is currently no way to reverse the effects of nerve damage, why would NICE therefore wait to recommend new treatments and update the guidance for best patient care? Time cannot be replaced. Quality of life, ability to work/drive, and dignity are important to daily living, mental health, and ultimately, a future.
Date	8/25/2011 12:15:00 AM

Role	NHS Professional
Other role	
Location	England
Conflict	yes
Notes	[redacted] has received research grant support from Bayer-Schering Healthcare, Biogen-Idec, GW Pharma, Merck-Serono, Merz, Novartis, Teva and Sanofi-Aventis. He has received personal compensation for participating on advisory boards, trial steering committees and trial data and safety monitoring boards from: Bayer-Schering Healthcare, Biogen-Idec, Eisai, Elan, Fiveprime, Genzyme, Genentech, GSK, GW Pharma, Ironwood, Merck-Serono, Novartis, Pfizer, Roche, Sanofi-Aventis, Synthon BV, Teva, UCB Pharma and Vertex Pharmaceuticals.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	The Committee?s conclusion that best supportive care (rather than one of the currently available disease-modifying therapies) is the most appropriate comparator demonstrates a lack of understanding of this specialist disease area. ?Best supportive care? essentially means no disease-modifying therapy. It is inconceivable that patients, who fulfill the EMA?s marketing authorisation for fingolimod, with ?high disease activity despite treatment with beta-interferon? or ?rapidly evolving severe

	relapsing remitting multiple sclerosis? should receive no disease-modifying therapy at all . Progression of disability in these patients is approximately twice as fast as in patients with less active multiple sclerosis.
Section 2 (The technology)	I would suggest NICE advises Novartis such that it would be feasible for the Department of Health to negotiate a price at which fingolimod becomes cost effective for use in the NHS.
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	The appraisal of natalizumab by NICE was based on a comparison against the therapies that are currently available under the Department of Health?s Risk Sharing Scheme. My understanding is therefore that fingolimod has been rejected on the basis of an economic evaluation that used an inadequate comparator, i.e. ?best supportive care?. The clinically correct comparison is with the licensed disease-modifying therapies, which are currently being used for treating people with MS in the UK. This comparison may lead to a different conclusion regarding the cost-effectiveness of fingolimod.
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/24/2011 6:42:00 PM

Role	other
Other role	MS Charity Organisation
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	This is not the result we at MSRC were hoping to hear and for some people with MS this will reduce their treatment options when other options have been exhausted. We hope that Novartis and NICE can discuss this further to talk over why this decision has been reached.
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	

Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/24/2011 4:12:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	To whom it may concern, I find it quite short sighted that the oxymoronic NICE can not see what benefits a drug such as Fingolimod can bring to the overall well being of RERRMS patients. Suffering from MS myself for 11 years, I have tried Copaxone and Rebif but neither worked and in fact caused more problems when taking them as my body does not take kindly to being injected every day. Tysabri is a drug that has shown links to PML and the possibility of death whilst taking it and as such definitely rules it out for lots of people, myself included. I have had 4 relapses in 15 months and for NICE to determine it would not be cost effective to fund the drug is narrow minded considering the support and services I require during those times that I am ill. There are lots of MS patients worse off than myself, but I and others could, unless some sort of treatment is given, rapidly deteriorate to a state where I would need support running into the tens of thousands of pounds and the pressure this would put on my family and local services would be immense. RERRMS is one of the areas where NICE should be looking to push drugs as soon as they are proven (all trials proved conclusive that there is a major slowdown of relapses whilst taking said drug) as lots of these patients will move into the other more aggressive and debilitating forms of the illness unless a stop gap is provided in the near term. Having paid taxes since I was 17 and served my country for 13 years, I am totally taken aback that when I call on my country to help me, NICE, in its ultimate wisdom, says no. Yours, totally disgruntled [redacted]
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	

Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/24/2011 11:37:00 AM

Role	other
Other role	Father
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Having experienced my daughter participating in the fingolimod trial the better quality of life and general well being is very very significant. Previously when taking avonex she was unwell for two to three days with flue like symptons and experienced severe panic attacks on a weekly basis due to the injections. Her general demina and all round better quality of every day living is much improved while taking fingolimod, she requires much less medical supervision and visits to the doctors / hospital have been greatly reduced.
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	Being the parent of a patient and seeing the improvement in the quality of life and the general well being of your daughter nobody would doubt the outstanding results of this drug. The reduction in medical visits and general demand placed on the medical profesion are greatly reduced and from a person point of view my daughter is able to hold down a very demanding job and continue to contribute to society in general.
Section 5 (Implementation)	As a parent of a MS patient I speak from a personal point of view, the demands on the medical profession generaly are much less while taking fingolimod with reduced doctors / nurse / hospital visits. Plus my daughter is much more able to work and contribute back to society which further enhances her well being and makes her feel better.
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/23/2011 7:00:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	Im currently on the trial of CFTY720 and i heard to day that they were going to stop providing the pill. I think this is a very bad idea as myself and the others i know on the trial have benefited majorly from it. I used to have 3 or 4 relapses a year and i havent had one as bad as they were before on this trial, the one i did have while taking the pill was very early on and very mild, i can only say on behalf of myself but i feel better within myself and have enjoyed the fact that i have felt better. I think if this pill was stopped all the research has been wasted and would have been for nothing, i do not want to have to go back to the way thinks were before the trial as i had no quality of life, now i can walk better, make decsions better and alround am a happier person, even my family agree that it has done me the world of good, and they are the ones that were there for me when i was ill, and i do not like having to put them through it., this way if the pill was stopped they will have to look after me all the time and thats not fair on them or me, i should be able o do it myself.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Do not stop the pill, its a waste of research and my time. It seems to me that if your not dying then you dont deserve th ehelp and that money doesnt need to be wasted on us, isnt quality of life what matters?
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/23/2011 5:41:00 PM

Role	Carer
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's	my daughter has been so well since bieng on the trial for fingolimod jan 2011.

preliminary recommendations)	Sh ehas not needed any doctors appointments, which includes 1 x week for avonex as she cannot inject herself and other appointments she has not needed any antibiotics in fact has not been unwell since. This is a ludicrous decision keeping people well and working must be paramount and quality of life. This drug should definately be available as it is in america australia tec. etc.
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	this drug in my small amount of knowledge and people who are on the drug all declare they have been better since recieving the drug
Section 5 (Implementation)	costs must be cheaper than constant doctors visitsd etc
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	far too late we seem to be in a second rate country for healthcare
Date	8/23/2011 3:39:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	I am a patient with rapidly evolving severe relapsing remitting MS. I have started treatment with beta interferon and the side effects are debilitating but I soldier through for a possible reduction in relapses of one third. Hoping I can stave off serious disability for as long as possible. I am still employed full time. This will not last long if I continue to have relapses at the rate I am now or if the side effects of the beta interferon do not abate soon. I want to be able to work. I want to be able to look after myself. Fingolimod offers hope. Not only will taking a tablet be infinitely easier and less stressful for me as I have decreased motor skills but a 50% chance of reducing replaces is an enormous improvement. I have corresponded with people outside the UK who are being treated with Fingolimod and sing its praises. It works and side effects are minor. I am 34 years old. I have no family that will be able to care for me. Please do not take my best chance at staying independent away. Please do not write off thousands of MS sufferers as not valuable enough for treatment. Can you put a price on your independence?
Comments on individual sections of the ACD:	
Section 1	I am a patient with rapidly evolving severe relapsing remitting

(Appraisal Committee's preliminary recommendations)	MS. I have started treatment with beta interferon and the side effects are debilitating but I soldier through for a possible reduction in relapses of one third. Hoping I can stave off serious disability for as long as possible. I am still employed full time. This will not last long if I continue to have relapses at the rate I am now or if the side effects of the beta interferon do not abate soon. I want to be able to work. I want to be able to look after myself. Fingolimod offers hope. Not only will taking a tablet be infinitely easier and less stressful for me as I have decreased motor skills but a 50% chance of reducing replaces is an enormous improvement. I have corresponded with people outside the UK who are being treated with Fingolimod and sing its praises. It works and side effects are minor. I am 34 years old. I have no family that will be able to care for me. Please do not take my best chance at staying independent away. Please do not write off thousands of MS sufferers as not valuable enough for treatment. Can you put a price on your independence?
Section 2 (The technology)	Not only will taking a tablet be infinitely easier and less stressful for me as I have decreased motor skills but a 50% chance of reducing replaces is an enormous improvement. I have corresponded with people outside the UK who are being treated with Fingolimod and sing its praises. It works and side effects are minor in comparison to regular beta interferon drugs.
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/23/2011 11:22:00 AM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3	

(The manufacturer's submission)	
Section 4 (Consideration of the evidence)	I am on the trial of Fingolimod and have been since january. Before this I was on the injection Betainterferon. My life had totally changed.I was Ill once a week on betainterferon, it totally destroyed my immune system,I was constantly Ill,had the flu twice, tonsilitus, another throat infection, my wisdom teeth played up every month and it generally made me feel Ill. It controlled my life having to go to the doctors once a week. I couldnt do it myself so my mum and partner both learned to do it for me but even this was too stressful. I was up until 3am most days trying to pluck up courage but couldnt. Since Fingolimod,my life has changed. I havent had any symptoms or relapses, I havnt been Ill at all with anything for 6 months! And Im not generally down in the dumps anymore. I feel so much mire positive about the future knowing that Im on Fingolimod and how good it is and how much easier it makes your everyday life.Im not controlled by my MS anymore, I control it
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/23/2011 10:04:00 AM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	The people who make these decisions really need to get their heads out of the sand. Why dont you inject the dmd drugs into your bodies and see what they bloody do? Every time there is hope you people just destroy it because its all too expensive. You will only learn the lesson when you have it and then lets see if you wished you had put this drug through. Its a joke and so is nice. Hope you all sleep very well!,
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6	

(Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/22/2011 11:21:00 PM

Role	Private Sector Professional
Other role	
Location	Scotland
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	"the risk of disease progression for Avonex was estimated by indirect comparison to be higher than for placebo." if this statement is correct, then in itself it is surely an indication that fingolimod is worth licensing. "The ERG was concerned by the manufacturer?s approach of using only Avonex as the comparator treatment for population 1b" In my understanding this group is most likely to need a change of DMT. "Rebif-44 was more expensive and less effective than either best supportive care or fingolimod" Best supportive care, ie Methylprednisolone, is not prescribed in an effort to alter relapse rates, this seems an unfair comparison both for the manufacturer and the patient. QALY, def in glossary, dismayed to find, while NICE uphold Equal Opportunities, theyre happy to accept evidence putting cost on QoL for people with disabilities, witholding treatment which is apparently clinically effective & cost effective. MS 1:500 in Scotland affects the individual at a crucial time of life: family, work, financial commitments QALY: priceless in terms of human cost
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	

Section 8 (Proposed date of review of guidance)	
Date	8/22/2011 7:58:00 PM

Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	I have received support for attendance at conferences from Merck Serono, Biogen, GlaxoSmithKline and Teva
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I find it odd that the committee have not recommended fingolimod having previously agreed to natalizumab for highly active MS. If we cannot prescribe it in the UK it will make us the poor relations in Europe and the rest of the world in terms of treatment and research and may result in patients, research and quite likely neurologists going elsewhere.
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	I cannot share the ERG opinion that Avonex was an inappropriate comparator. There is no way that patients with active MS are going to be offered best supportive care. They will in the current clinical climate either be switched to copaxone or natalizumab (or other experimental agents) depending on the degree of activity and presence or absence of interferon antibodies. Treatment is going to be more expensive than best supportive care. The economic model is bound to be open to criticism as economic data have not been the primary endpoints of trials (and I would hope clinical trials will continue to have clinical endpoints). The fact that NICE agreed to natalizumab using a similar model and is now declining fingolimod seems to me to be illogical and inconsistent and will make it very difficult to know what to do with patients on Tysabri who have evidence of previous JC virus infection in whom an alternative treatment is wanted (there is reasonable trial evidence that switching to interferon or copaxone in this situation results in a recrudescence of disease activity). The subgroup analysis (1a,b, 2) does make the data even more difficult to disentangle.
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/22/2011 3:08:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	This is very disappointing news as I am fortunate to currently be taking part in the fingolimod extension trial. I have grown up watching a close relative deteriorate from a similar condition without any treatment. Once the nerves are damaged it cannot be reversed and has long lasting effects on quality of life. This has resulted in considerable years living in a care home at significant cost.
Section 2 (The technology)	I have not experienced adverse side effects nor had a relapse since I started taking fingolimod. This has had a positive effect on daily quality of life and offers hope for the future.
Section 3 (The manufacturer's submission)	The comparison to Avonex and placebo has shown that Fingolimod is more effective than both and less expensive than Avonex. Whilst Natalizumab may not have been included in the comparison there are additional safety concerns and it is more intrusive for a working life. As a person who experienced two mobility relapses in short succession prior to the trial and has a fear of needles, the development of a successful oral medication is a significant and most welcome development.
Section 4 (Consideration of the evidence)	As progression cannot be predicted comparisons are difficult. The absence of EDSS scores could be an omission as such data may show a positive trend relating to a reduction in disability progression. The evidence has proven the effectiveness of fingolimod, therefore resorting to a postcode lottery appears unethical. Limiting treatment on the NHS to those most affected ignores the fact that starting treatment early provides a better prognosis.
Section 5 (Implementation)	Implementation should be made as practical and widely available as possible on the NHS. It would be unethical to remove a treatment from patients who are responding well to a new treatment (unless on medical grounds). It is also inappropriate to deny access to other patients who may benefit, due simply to a postcode lottery.
Section 6 (Proposed recommendations for further research)	If NICE are not certain about the efficacy of fingolimod please encourage Novartis to continue the fingolimod trials with exiting patients and expand the patient pool to enable other comparisons to take place.
Section 7 (Related NICE guidance)	Do NICE plan to compile a guidance document specifically commenting on fingolimod in the near future? It would assist PCTs if NICE do not recommend fingolimod in the short-term.
Section 8 (Proposed date of review of guidance)	January 2015 is too far away. In that time disease progression may advance significantly for patients. There is currently no way to reverse the effects of nerve damage and fingolimod is not thought to be suitable for later stages of the condition. Quality of life, ability to work/drive, and dignity are key drivers to daily living, mental health, and ultimately, a future.
Date	8/21/2011 11:10:00 PM

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I find it incredibly frustrating, that a drug like Fingolimod is being rejected for use on MS patients, despite the fact that it significantly reduces the symptoms and development of this debilitating condition. Surely, if a drug works, it should be used. MS patients could continue to lead a normal life maintaining their jobs and family lives, whilst decreasing their need for future healthcare and professional carers.
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	What does supportive care entail though? Are we talking other drug therapies or are you comparing it to nothing? If the latter, surely this is a completely unjust and unfair comparison. How can a comparison of a drug be compared against nothing!! With this drug, MS patients that qualify could still be working active members of the community. People who can still pay taxes, generate an income for the country and for a longer period of time. Not to mention that these are peoples lives that you hold in your hands their lives and that of their families. Also the model that suggests the drug will reduce its efficiency must be based on an assumption itself. As far as Im aware the manufacturer have stated that the drug will be constant and consistent due to its mode of action. A drug taken daily will continue to act in this way precisely because of this mode of action!
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	A longer term research project on the patients already taking the drug seems a reasonable recommendation. That way, the proposed projections of how the drugs reduced effectiveness can be compared against actual data from MS patients.
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	Thats 4 years time!
Date	8/20/2011 2:14:00 PM

Role	Carer
Other role	
Location	England
Conflict	no
Notes	Its all very well evaluating new treatments and then due to cost denying indivuals with better treatment. I guess If someone close to you suffered from MS you would soon change your mind and approve these vital new medicines as it would then ofcourse benefit you directly. Drug companies spend billions

	and you guys come along and say "thanks but no thanks" What a waste of time!! Use some common sense and think about what this horrid disease does to once beautiful people. Lets hope you sleep well because I dont.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/19/2011 8:51:00 PM

Role	NHS Professional
Other role	
Location	England
Conflict	yes
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	I have been involved with a phase IV study of this treatment involving nine patients. Eight of them were receiving or have received an alternative DMT. Two patients were extremely needle phobic, one was still having three or more relapses on a DMT and the rest were having adverse events associated with the DMTs. The final patient who had not received a DMT had been having continuing relapses for one year. Since commencing Fingolimod in January 2011 not one of my patients has had a relapse, it stopped the relapse of the last patient I mentioned within a week. Most of the patients are in employment including a midwife, a healthcare assistant and a social care worker. As intelligent people I dont feel I have to spell out the cost savings that must been made just by my

	patients alone. All DMTs are in injection form compared to a small capsule a day which is definitely in the best interest of the patient. I have not noticed any side effects from the medication. All the patients are extremely happy on the medication and I feel as a nurse with the best interest of the patients under my care that I have a duty to add to this consultation.
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/19/2011 4:41:00 PM

Role	NHS Professional
Other role	
Location	England
Conflict	yes
Notes	I work on the manufacturers medical Advisory Board for this technology, but my comments reflect in general those of a clinical neurologist with a special interest in multiple sclerosis.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	This preliminary recommendation will disappoint the large number of people with multiple sclerosis who continue to experience disabling relapses of their condition despite treatment with currently available therapies, and for whom fingolimod would offer a more potent, second line alternative. Disabling relapses have been associated with significant increments of disability, and quite apart from the detrimental effects on quality of life, they add to the economic burden on the NHS and wider community.
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	Concerning the submission of evidence with Avonex as a comparitor, I think this is a reasonable choice of agent, which can be justified on the basis that neurologists generally accept that all three of the beta-interferon preparations are comparable in efficacy. The suggestion that best supportive care may be used as a comparator in patients who relapse during treatment with first line disease modifying agents does not agree with current clinical realities, where such patients would either be considered for treatment with natalizumab, or else continued on their current therapy on the basis that any therapeutic effect, even if blunted, was likely to be better than supportive care alone. The current guidelines on the use of natalizumab allow its use in patients experiencing two or more severe relapses in the previous 12 months. Fingolimod, which has an MA for use after a single relapse in the same period, would offer a much-

	needed second line therapy for this patient group.
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	The delay until Jan 2015 of the review of this guidance will come as a tremendous disappointment to clinicians and their patients, who are keen to have any responses to the guidance considered as quickly as possible. Fingolimod is available to people with MS in the rest of the world, and it would support the MS population if the review could be expedited, as either a favourable or an unfavourable review would establish clarity concerning their treatment options.
Date	8/18/2011 1:00:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	As a recently dignosed patient, the prospect of an oral medication which could slow the progression of this disease was something I have watched with interest.My first treatment for this disease resulted in 5 days in hospital followed by 5 physio sessions (and ongoing!), a number of pieces of equipment from OT and now counselling - so the costs are mounting. I think of myself as a previously fit and active mother of two young children with a regular exercise regime and was shocked by the effects of this disease. I am yet to await what type of MS I am facing.

	I am disappointed to see that Fingolimod has not been approved on what seem to be mainly financial grouds. Having read the above, it does seem that the evidence submitted by the manufacturer may be somewhat flawed, however I would suggest that 2015 is a long wait for the manufacturer to conduct further trials and would urge NICE to set an earlier date for a further review.
Date	8/18/2011 12:32:00 PM

Role	Patient
Other role	Healthcare professional
Location	England
Conflict	no
Notes	Having taken fingolimod for the past 3 years and been relapse free during this time I am extremely disappointed in your preliminary ruling not to endorse this drug for the NHS. Since my diagnosis of relapsing/remitting MS in 2004 until commencing fingolimod in 2008 I experienced regular relapses resulting in increasing amounts of sick time the least being 5 weeks and longest being 7 months. At increasing cost to my NHS employer, let alone my physical symptoms. Over the past 3 years this has dropped to 4 days being directly attributed to my MS. My previous treatment was Avonex injections, which are painful and have distressing side-effects which impacted on every aspect of my day to day life. I urge you to re-think this decision the long term quality of life for many people in the prime of their lives depend upon it. Thank-you Amanda Cook Fingolimod patient
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/18/2011 9:58:00 AM

Role	NHS Professional
Other role	Multiple Sclerosis Specialist Nurse
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	In practice people with rapidly evolving, aggressive Multiple Sclerosis would be offered second line treatment, they would also, of course, be offered supportive care and symptom management but this would in no way reduce further relapse rates or delay disease progression with the associated impact on quality of life, employment and demands on multidisciplinary care. Current second line treatment options such as Natalizumab is currently administered via intravenous infusion in secondary care settings on a monthly basis. For those patients who live outwith urban areas accessing the treatment can be costly and time consuming for the patient and the NHS. Oral disease modifying treatments would not need regular secondary care input over and above usual consultations. Patient reviews would be well managed in primary or community settings. Patients who require second line treatment and, because of personal choice or increased risk of PML, do not receive Natalizumab will be disadvantaged if Fingolimod is not recommended for the treatment of relapsing?remitting multiple sclerosis. I feel that Fingolimod and other emerging oral disease modifying drugs should be recommended as a second line treatment option in multiple sclerosis.
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	In practice people with rapidly evolving, aggressive Multiple Sclerosis would be offered second line treatment, they would also, of course, be offered supportive care and symptom management but this would in no way reduce further relapse rates or delay disease progression with the associated impact on quality of life, employment and demands on multidisciplinary care. Current second line treatment options such as Natalizumab is currently administered via intravenous infusion in secondary care settings on a monthly basis. For those patients who live outwith urban areas accessing the treatment can be costly and time consuming for the patient and the NHS. Oral disease modifying treatments would not need regular secondary care input over and above usual consultations. Patient reviews would be well managed in primary or community settings. Patients who require second line treatment and, because of personal choice or increased risk of PML, do not receive Natalizumab will be disadvantaged if Fingolimod is not recommended for the treatment of relapsing?remitting multiple

	sclerosis. I feel that Fingolimod and other emerging oral disease modifying drugs should be recommended as a second line treatment option in multiple sclerosis.
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/17/2011 5:13:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	As a person with MS I appreciate the need for careful use of NHS funds and after reading your report I understand the grounds on which NICE have made their decision. However, I believe it is incorrect. I am aware of the lack of MS treatment options and the wide variation in patient response to the drugs available. My understanding of interferon and other MS drugs is that the efficacy for individual patients varies widely, leading to an overall, broadly positive, average. I would like to see NICE guidelines recommending Fingolimod for groups that did not respond to cheaper alternatives, provided that with regular monitoring a minimum patient improvement was observed over the course of a year. The aim being to provide Fingolimod to those fortunate enough to respond best to it.
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	It would be useful to know the variation in response across patient groups as opposed to a simple average improvement. Does the drug improve everyone by 50% or half by 90% and half by 10%? If the best and worst responders can be rapidly identified, that would rather change the economics.
Section 4 (Consideration of the evidence)	I agree with the premise that Fingolimod should be compared to best-care rather than another drug. If the idea is to prescribe it only for patients who never, or no longer, respond to other drugs then the best comparator is no drug at all.
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	

Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/17/2011 4:14:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	I am a patient who has has RRMS for 20 years. I still work full time but have regular disabling relapses which greatly affect my quality of life and also limit my effectiveness in my job. I recently was prescribed Tysabri as Copaxone did not work, and I was taken off Avonex (the weakest inteferon) as it reduced my WCC to 2.8 which made using the other inteferons inadvisable. At the third Tysabri infusion I developed Hives and so was taken off that. We are trying Avonex again under close monitoring in the hope that it wont reduce my WCC. If Avonex fails, I am now left with nothing. At 20 years with MS it is not the time to be messing around with my treatment. Im only 40 and with treatment may stay working and paying my way for many years to come. What are you going to to do to help those of us who are left with nothing after your ruling? Thankyou [redacted]
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/17/2011 11:19:00 AM

Role	Patient
Other role	
Location	England

Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	Costs incurred by those of us who are NOT responding to other treatment (i.e. copaxone, rebif and an unsafe reaction to Tysabri) the costs of increasing rehabilitation therapy long term (I am only 39yrs old with potentially 40yrs of treatment, both i.v. steroids and physio therapy plus costs of inpatient care when the relapse is severe.Costs if I am unable to drive myself due to increasing disability, my husband is partially sighted so I would need hospital transport with those costs included.Costs of potential long term orthopaedic inpatient stays as I already have Osteopinea due to extensive iv steroid treatment. My tissue viability also becoming vastly compromised and the implications of future needed pressure sore care inclu district nurse or inpatient stay or preventative pressure area care. Costs from complications arising from my progressively poorer mobility medical - chest infections rate increasing with untreated ms confining me permanently to a wheelchair. If treatment limited to those who dont respond to other treatments, the cost to NHS would be considerably less.Without treatment the costs increase to NHS and other departments ie benefits.I am mum of 4 children imlp
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/16/2011 2:56:00 PM

Role	other
Other role	Family member - Sister
Location	England
Conflict	no
Notes	Although I understand that this treatment has a high cost, the fact that the patients who have tried this have had no relapses and therefore not had to see a consultant or be admitted to hospital has saved money for the NHS. The patients quality of life has been greatly improved and we have seen our sister so much happier, feeling well and enjoying life again. Carina Clarke is only young and she has many years

	of life ahead of her and why should she not have the treatment that will enable her to have a good quality of life? Whilst I understand that costs must be an issue when using this treatment, spending now to save on future budgets is a good way forward for the NHS and is practised in many organisations with fantastic results. Another thing I would like you to consider is the cost to the benefit system. If these patients are allowed to continue this treatment under the NHS they will be able to continue working and will not then be a burden on the benefit system. These costs could be very high and the government has identified this as a high priority area where costs must be cut. I therefore ask please that you allow this fantastic treatment to continue under the NHS for the future as what is the point in all the work to get this drug to the market with great health benefits if the NHS will not fund it and the patients who need it cannot afford to fund it themselves. Thank you Andrea Mitchard
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/16/2011 12:00:00 PM

Role	Public
Other role	
Location	England
Conflict	no
Notes	A close friend has MS and she was given hope by this new drug, her whole life was going to change and now she has been knocked back and feels that is it worth going on with the same old medication injecting every day, her husband kids and whole family were so excited that she would have back quality of life, but once again our so called Government are only interested in saving MONEY but always have plenty to give to all the immigrants we keep letting into our country and allowing them

	to join the NHS without question
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/15/2011 5:37:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	I have aggressive Relapsing-Remitting MS and when I heard about Gilenya earlier in the year I was delighted that a more effective drug than the one I was taking (Copazone) was to be made available. Crucially, this medication was to be in tablet form so I would no longer have to inject myself. I also was glad not to have to consider Tysabri infusions as a trip into hospital each month and the worry of developing a brain infection were things I did not want to have to go through. Gilenya would give me a much better prognisis for the future - less relapses and so I would retain the ability to work and very importantly, retain my independence meaning I would not have to have a greater degree of medical assistance or start to take benefits from the council. A tablet in a pill form means so much more freedom. Each time I go on holiday or even to stay somewhere overnight I have to worry about my fragile injections and keeping them cool. A pill will be so much less disruptive to my day to day life. The benefits of the drug are outstanding - both my specialist nurse and my consultant were horrified that it had not been accepted by NICE and I was devastated. This medication has the capacity to transform my future. Please reconsider your decision and make Gilenya available.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I have aggressive Relapsing-Remitting MS and when I heard about Gilenya earlier in the year I was delighted that a more effective drug than the one I was taking (Copazone) was to be made available. Crucially, this medication was to be in tablet

	form so I would no longer have to inject myself. I also was glad not to have to consider Tysabri infusions as a trip into hospital each month and the worry of developing a brain infection were things I did not want to have to go through. Gilenya would give me a much better prognisis for the future - less relapses and so I would retain the ability to work and very importantly, retain my independence meaning I would not have to have a greater degree of medical assistance or start to take benefits from the council. A tablet in a pill form means so much more freedom. Each time I go on holiday or even to stay somewhere overnight I have to worry about my fragile injections and keeping them cool. A pill will be so much less disruptive to my day to day life. The benefits of the drug are outstanding - both my specialist nurse and my consultant were horrified that it had not been accepted by NICE and I was devastated.
Section 2 (The technology)	With Gilenya I have the chance to transform my future to one away from dependence on benefits and continual hospital treatment. I will be able to continue to work and be independent thus removing the strain on council budgets etc.
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	Gilenya was shown to be effective on the whole population on the trial. It is not right to keep it from other patients who would clearly benefit hugely from taking the medication.
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	I have already signed up on the new UK MS Register.
Section 7 (Related NICE guidance)	None of these are in tablet form.
Section 8 (Proposed date of review of guidance)	2015. My MS wont wait that long - it will be progressing and taking up time and money from health care professionals and the council.
Date	8/15/2011 2:48:00 PM

Role	NHS Professional
Other role	Clinical Lead MS risk-sharing scheme
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	As a practicing MS neurologist it is not clinically rational to consider best supportive care as a reasonable comparator in this setting. Though clinical practice will vary substantially the

	availability of Natalizumab and unlicenced second-line therapies (Mitoxantrone, Alemtuzumab) means that for a patient experiencing some degree of on-going (relapse defined) disease activity on a first-line agent (for which Avonex is a reasonable, though perhaps not ideal proxy), current practice - in all UK centres - would be to either continue the current therapy (accepting that some degree of disease activity is inevitable with partially effective treatments) or to switch class of first line therapy or escalate (in terms of dosage or to second-line). Withdrawal of treatment would simply not be a viable option.
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/15/2011 2:27:00 PM

Role	NHS Professional
Other role	General Public
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	On examining the evidence for this below and personal experience of a relatives improvement on this drug I believe that this decision should not be not recommended but not currently recommended with the evidence available at the present time. This is because the refusal seems to be related to problems with the submission rather than the clinical effectiveness.
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	Although side effects of alternative treatments have been mentioned ,the severity of adverse reactions on fingolimod and other treatments has not been compared and must contribute to the cost analysis. A close relative has been treated with beta interferon on which she had severe adverse reactions that restricted her life and ability to work dramatically. She has had fingolimod on a trial with no side effects improving her life and subsequent NHS costs dramatically.
Section 5 (Implementation)	It seems unfair that a patient who has improved on trial medication should not have access to that drug after NICE consideration.
Section 6 (Proposed recommendations for	

further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	It apperas from this report that the main criteria for refusal stem from problems with the submission from the drug company rather than clinical evidence. An earlier review date would therefore seem more appropriate.
Date	8/12/2011 12:13:00 PM

Role	other
Other role	Parent of MS sufferer
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	My daughter is currently on a trial of this drug and it has made a large difference to her standard of life and her hope for the future. I am still working at age 76+ and paying my dues to society. I therefore expect that any drug assisting my young daughter with the terrible scourge of MS should be provided without the cost being a consideration. Why else are we testing drugs if not to use them to treat the suffering and sick amongst us ?
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/12/2011 11:58:00 AM

Role	Patient
Other role	
Location	Scotland
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I am 2nd progresive and not on any "treatment" yet,i am being considerd for Beta Interferon but would rather not inject myself!. Its not about money but QUALITY of life.
Section 2	

(The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/11/2011 5:13:00 PM

Role	Patient
Other role	
Location	N Ireland
Conflict	no
Notes	Severe relapsing remitting ms. ie more than two disabling relapses per year. Was a microbiologist, had to give up due to ill health. Would love to work again. Two sons age 10 and 9. 33 years old. Have been on Avonex for 5 years, its not effective enough. Too young for the scrapheap.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/11/2011 3:43:00 PM

Role	Patient

Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	This decision does not take into account the economic implications of reducing the number of relapses suffered by patients such as ensuring that they stay in work for longer and off benefits. I also do not understand how it cannot be cost effective to reduce the number of hospital in and out paitent visits by precribing a treatment that has been proven effective in significantly reducing relapse rates and disability progression. Once again the NHS is throwing those with incurable diseases on to the scrap heap. They dont seem interested in offering treatment if it isnt able to cure a patient and thus it is always deemed not to be "cost effective". The only other current potential treatments for MS (disease modifying drugs) are only available because of a cost sharing scheme as they were also deemed not to be cost effective. What do we as MS sufferers have to do to get treatment for an extremely debilitating disease on the NHS? Please reconsider your decision and think about the implications for MS patients in the UK - you are playing God and it has a huge impact on real peoples lives here.
Section 2 (The technology)	I have been on a clinical trial for fingolimod since last December and since that date I have not had any relapses and have felt significantly improved in health and wellbeing. For example my levela of fatigue have dropped massively. Please do not also discount the mental health improvements in taking this drug such as a sense of empowerment because of taking treatment.
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/11/2011 2:16:00 PM

Role	NHS Professional
Other role	MS Specialist Nurse
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's	

preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	I have nursed MS patients for 8 years and we have over 800 patients on disease modifying therapies. We have never discontinued a failed treatment (injectables) without considering second line treatment as opposed to best available care (symptom management). I suggest that NICE reconsider the approval of Gilenya which is the first and only oral therapy that patients are awaiting based on neurological prerscribing practice in the UK. This will be a more accurate consideration.
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/11/2011 9:59:00 AM

Role	NHS Professional
Other role	MS Specilist Nurse
Location	England
Conflict	no
Notes	I am very disappointed to here that Finglomoid has not been approved by NICE. There is clearly an unmet need for those patients who are failing on the injectable DMT?s who do not want to advance onto Natalizumab or do not fit the clinical criteria to do so.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review	

of guidance)	
Date	8/9/2011 8:31:00 AM

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I feel this should be approved. My friends daughter has been waiting for this oral treatment to be approved by NICE as she has alergic reaction to the needles in the other treatments.
Section 2 (The technology)	There are AEs/SAEs with all medication. They are still given approval so why not this drug.
Section 3 (The manufacturer's submission)	This has been approved in other EU countries with the same manufacturers submission.
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	It is all down to cost this is not a self inflicted illness and yet isnt approved but you can have a gastic bypass because you have been greedy and weigh in excess of 20 stone and that is done on the NHS. You can drink yourself stupid and damage your liver and have an operation for that on the NHS but if you get MS tough the NHS wont fund it.
Section 6 (Proposed recommendations for further research)	If NICE are not going to licence the drugs why are patients going to bother going into a trial.
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	That is nearly 4 years away what about the poor MS sufferers that want a treatment now.
Date	8/8/2011 1:57:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	I have been using this drug since August last year
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I cannot agree that Fingolimod is not cost effective. I have been taking this drug for a year and am so much improved I am considering going back to work. My walking has stabilised, I have had no relapses (prior to taking this I had 3 in a year) and both my nurse and neurologist are pleased with the progress I have made. I could not tolerate the injections so if I am made to come off this drug then my health is likely to deteriorate meaning more GP and hospital visits. It is important to take into consideration the social care impact as well - without this drug then those costs escalate as well. I know many people who are on no treatment at all because

	they cannot bear the injections, whereas they would happily take an oral treatment. To deny this drug to thousands of people is unjust and counter productive
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/8/2011 1:53:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	I have relapsing-remitting MS. I was diagnosed in 2005 and have been taking Beta-Interferon (Avonex) since January 2007
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I understand from reading NICEs recommendation that the main reasoning behind your decision is the Cost Effectiveness of the medication, surely this medication cannot be in excess of the BetaInterferon medications which i understand cost Â£13,000 per year. if so the markup of the drugs companies would appear excessive. If only the Cost effectiveness of the medication does NICE no longer consider patient care (as in The Duty of Care which the NHS prides itself on)?I personally have not had a single day following taking my medication when i have not experienced sever side effects, which gilenya is not suggested to have, and ther is also the reduction in disease progression. surely patient care is the ultimate priority of the NHS. or have I been paying National Insurance for something? I would welcome a response. [redacted]
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for	

further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/8/2011 1:40:00 PM

Role	Public
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	Attention should be paid to the cost of hospital admission for serious relapses and comparisons made to the cost of drugs used currently. Also the effect of disability on the individual and the NHS.
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	This recommendation is short sighted and only considers the short term expense of the drug not the long term savings for the NHS.
Section 6 (Proposed recommendations for further research)	What is the point of research if NICE can block the use of effective drugs and thereby deny a decent quality of life to many?
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/8/2011 12:59:00 PM

Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	Consultant neurologist with interest in MS
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	

Section 4 (Consideration of the evidence)	No patient with active disease should be on best supportive care so the comparison of fingolimod to this is meaningless. Patients failing standard injected therapies are often switched to natalizumab (or other agents including mitoxantrone, and alemtuzemab) because there is no intermediate alternative and so the notion that fingolimod must be compared to natiluzamb is wrong-it should be compared to some other, as yet non-existant, treatment for patients failing interferon but who are not rapidly evoloving. I note that the consensus specialist opinion is that fingolimod would be second line, and this is a reasonable and standard cautious approach with all new drugs. However, I can see no logic for why it could not be first line treatment and in the future this surely is likely to become the case. The advantage of an oral preparation cannot be underestimated, in your comparison to natalizumab was the huge burden on time and resource for giving monthly infusions in hospital on a potentially un-ending basis considered?
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/8/2011 9:48:00 AM

Role	Private Sector Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	I think your consideration of cost-effectiveness doesnt account for improved EDSS (rating of disability) scores. I understand from friends and clients with MS that that recovery of physical and cognitive ability after a relapse is possible as long as the gap between relapses is long enough, so reducing the rate of relapses has a larger impact on patients ability to work and reliance on benefits and care provision than theyre taking into

	account. I also think that you have not taken into account sufficiently the effect of all this on the patients mental health. I work as a Psychotherapist and see clients with MS, and the improvement I have seen with clients taking Fingolimod has been noticeable enough for me to confidently say that it makes a significant impact.
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	I think further research should include factors around quality of life and mental health as well as the physical impact of the drug.
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/6/2011 5:32:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	I do not believe that the committee have given due consideration to the socio-economic benefits of a reduced rate of relapses. In not considering reductions in EDSS, the appraisal fails to account for recovery from disability induced by relapses, and the rate at which this recovery occurs. With sufficient periods of remission, recovery can be extreme (thanks to Tysabri and a strict diet/exercise regime, I personally have gone from needing a stick to walk with and being unable to hold a pen to write with, to working full time, running 10K races, writing my PhD thesis and touch-typing). A reduced rate of relapses can have a strong impact on the ability of the patient to work and on their reliance on financial benefits and provision of care.
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	A trial comparing the effectiveness of fingolimod with that of natalizumab might enable the introduction of a wider range of treatment options for patients with severe rapidly evolving relapsing-remitting multiple sclerosis.
Section 7 (Related NICE guidance)	

Section 8 (Proposed date of review of guidance)	
Date	8/6/2011 4:56:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	I am currently on the clinical trial for this drug and although that may be a conflict of interest i thought you should know the benefits that this drug can give, i have remitting relapsing ms and have been on the trial since january 2011, i have never felt better than i do at the moment i have replapsed just once in this time (which was at the beginning of the trial after getting a chest infection, throat infection and urine infection) which the normal for me was to relapse whenever contracting an infection, but since then i have contracted chest infections etc and I end up being no more ill than any other normal person, my day to day quality of life has been greatly improved and i am able to spend so much more time enjoying my children. I would also add that I have had beta interferon injections to which made me very very ill and i was unable to do very much at all and didnt reduce relapses. This really does feel to me such an important drug for ms patients that are unable to tolerate the use of the injection drugs, having ms is a daunting and unpredictable disease and this drug is an amazing breakthrough to help fellow suffers fight this disabilling disease, please think very carefully as the amount of cost an ms patient will cost the nhs i feel will greatly be reduced but not just about cost the benefits this drug can give to a patient is invaluable i could never put a price on what this drug is doing for me and that is without taking into account the future this drug could give me and my family
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I have been on a trial for this drug and thought you should know the benefits that this drug can give, i have remitting relapsing ms and have been on the trial since january, i have not felt better than i do at the moment i have replapsed just once due to having a chest, throat and urine infection) i would normally relapse during all infections, but since then i have contracted infections and end up being no more ill than any other normal person, my day to day quality of life has been greatly improved and am able to spend so much more time with my children. I have had beta interferon injections to which made me extremely ill and i was unable to do very much at all and didnt reduce relapses. This really does feel to me such an important drug for ms patients that are unable to tolerate the use of the injection drugs, having ms is a daunting and unpredictable disease and this drug is an amazing breakthrough to help fellow suffers fight this disabling disease, this is not about the cost but the benefits this drug can give to a patient it is invaluable i could never put a price on what this drug does without taking into account the future this drug could give me and my family
Section 2	the side effects for this drug in my experience are extremely

(The technology)	slight in comparison to avonex and rebif which i was not able to tolerate and actually made me more ill than the ms! on fingolimod the only thing i have is headaches/migraines which are completely managed by pizotifen
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/6/2011 3:52:00 PM

Role	Patient
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	This is extremely disappointing. I am 29 years old and have highly relapsing remitting MS and have had no success with the disease modifying drugs such that i am having regular relapses. Oral medication would improve my standard of life considerably as the weekly injection ruins my week, and i suffer from flu symptoms after every injection. Oral medication would not only be a huge improvement but the evidence suggests that it would hopefully slow down the rate of relapses i am having and grant me a healthier and more predictable prognosis.
Section 2 (The technology)	I was really hopeful that NICE would recommend the medication. As a newly wed with a child on the way, i will do anything to try and slow the disease down. I think NICE have made the wrong decision here as if they met people like myself, someone who leads a high powered job, has full mobility currently, but who has had little success with dmds, this rejection by NICE comes as a major blow, as the reduced relapse rate and the option of no longer having to do painful injections was something extremely positive for me and the first bit of hope....i wonder if NICE have met sufferers like me when making this decision....?
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	This really should not be what looks like an economic decision. Once again the UK falls back in the race to be the market leader and forward facing country. As an MS sufferer on Avonex, this decision seems fundamentally flawed and

	ultimately wrong.
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	That proposed date is a disgrace and shows a blatant disregard for MS sufferers and a complete misunderstanding of the disease and how it impacts patients. I have had MS for 7 years now, each year it gets worse. Amanda Adler, my body rejects Avonex, why should i wait until 2015 when i may no longer be highly remitting relapsing but wheelchair bound before NICE make the right decision? This is like a life sentence....
Date	8/6/2011 9:35:00 AM

Role	Carer
Other role	
Location	Other
Conflict	no
Notes	It is enough to restore faith in government to see NICEs Gilenya decision which was in sharp contrast to the actions of the US FDA. NICE appears to be quite serious about protecting the public and taxpayers unlike the US FDA which appears to think its role is protecting pharmaceutical manufacturers from the public. Loud applause for your courage in doing the right thing! The MS Societies worldwide seem more interest in maintaining pharmaceutical income than protecting the interests of their members for whom they do NOT speak!
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	As someone who wife has MS, I hope it is clear to NICE that the MS Societies worldwide are far more interested in protecting their relationship with pharmaceutical manufacturers than people with MS. They do nothing to solicit views of their patient members, but are quick to issue statements in their name if they support their pharmaceutical sponsors.
Section 2 (The technology)	Fair overview.
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8	

(Proposed date of review of guidance)	
Date	8/6/2011 7:22:00 AM

Role	NHS Professional
Other role	Associate Professor of Neurology, University of Nottingham
Location	England
Conflict	no
Notes	I have applied for a Â£5,000 unconditional grant from Novartis to support laboratory research. I prescribe disease modifying treatments for MS.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	My main comment at this stage is that I disagree with the fact that the Committee Members do not include Neurology Consultants, and in particular MS experts. I do commend that Professor C Young was given the opportunity to give her expert personal view, however I believe the Committee should include MS experts.
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/5/2011 12:25:00 PM

Role	Private Sector Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Disappointing
Section 2 (The technology)	.
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	

Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/5/2011 12:19:00 PM

Role	**MS patient presently receiving Fingolimod as part of a trial**
Other role	
Location	**Northamptonshire**
Conflict	
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	**Prior to starting the Fingolimod trial, I had been taking Copaxone for 9 years. As my consultant has said "Copaxone suits fat men". Injecting Copaxone causes lipoattrophy and I had long since run out of viable injection sites. Since embarking on the Fingolimod trial last October, I have been relapse-free, enjoyed a sense of relief at no longer having to inject everyday have experienced far less fatigue than when I was on Copaxone and now also have considerably higher energy levels.**
Section 2 (The technology)	**I have experienced no adverse side effects whereas, with Copaxone, I had ongoing issues with injection-site reactions and lipoattrophy.**
Section 3 (The manufacturer's submission)	**NICE were asked by the DH to produce guidance on Fingolimod for use, and this specific review is entitled "Multiple sclerosis (relapsing-remitting) - fingolimod". However, the Manufacturer's submission and thus this review only appears to cover three specific populations within the broader range of people diagnosed with the relapsing-remitting form of MS (RRMS). I do not understand why Gilenya has been licensed in the US as a treatment for RRMS and yet in Europe, it is licensed only as a second-line treatment for RRMS.**
Section 4 (Consideration of the evidence)	**As a lay person, I feel unqualified to comment on the committee's review of the presented evidence. However, in my 13 years since diagnosis, I have yet to experience what I would regard as "best supportive care" and certainly nothing that would reflect the costs allocated to it in this assessment.**
Section 5 (Implementation)	

Section 6 (Proposed recommendations for further research)	**I agree that further research should be undertaken. Specifically this should cover the entire RRMS population.**
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	**25 August 2011**

Name	**samantha jones**
Role	**health care professional**
Other role	
Location	**england**
Conflict	**none**
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	**I have read the recommendations of the provisional draft guidance published 5 August by NICE, and I am so disappointed with this decision.** **I have been diagnosed with relapsing/remitting MS for over a year now. And as a result have had to change my job three times as a Staff Nurse as well as cut my hours and only work nights to help reduce the periods of time I spend on my feet. And at 24 I am struggling to deal with the diagnosis. I am trying so hard to stay in work for as long as I can. As a Nurse I acknowledge that money is an issue for the NHS but MS is an illness that cannot be tret, nor is it an illness that I have caused, therefore this drug is was the only thing that was really keeping me going. It is stated by Professor Carole Longson that the 'committee wasn't given sufficient evidence to show that fingolimod could reduce relapses considerably better than the other treatments currently being used'. Personally this is not the issue for me and patients I care for, it's the fact that it comes in oral form and not injection!! Please help me to understand this decision as I am very distressed, angry and upset about the decision.**
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	
Section 5 (Implementation)	
Section 6 (Proposed recommendations for	

further research)	
Section 7 (Related NICE guidance)	**In regards to the decision to the recommendation of fingolimod (Gilenya) not to be a licensed drug for the treatment of Multiple Sclerosis patients with relapsing/remitting**
Section 8 (Proposed date of review of guidance)	
Date	**26/06/2011**