Appraisal Consultation Document: Pegaptanib and ranibizumab for the treatment of age-related macular degeneration Report:

**Report ID:** 435391 Responses: 61

> Dates: 11/06/07 10:46 to 12/07/07 15:27

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11/06/2007-	Jun-2007 10:46:36
commentid:	200706111046363323
uniqueid:	gillian.bibby@nice.org.uk_435391_200706111046363323
timestamp:	11/06/2007-Jun-2007 10:46:36
docid:	435391
title:	Appraisal Consultation Document: Pegaptanib and ranibizumab for the treatment of age-related macular degeneration
name:	Gill
mailfrom:	gillian.bibby@nice.org.uk
role:	Patient
altrole:	
location:	England
conflict:	no
discuss:	test
dataprotection :	-1
Section_1:	test
Section_2:	test
Section_3:	test
Section_4:	testy test test
Section_5:	testier and testier
Section_6:	testarama
Section_7:	testo
Section_8:	test

14/06/2007-	Jun-2007 9:0:5
commentid:	200706140900055308
uniqueid:	_435391_200706140900055308
timestamp:	14/06/2007-Jun-2007 9:0:5
docid:	435391
title:	Pegaptanib and ranibizumab for the treatment of age-related macular degeneration (appraisal consultation)
name:	
mailfrom:	
role:	Carer
altrole:	Husband carer
location:	England
conflict:	no
discuss:	We have experience of Wet AMD taking my wife
dataprotection:	-1
Section_1:	
Section_2:	
Section_3:	

Section_4:	
Section_5:	
Section_6:	
Section_7:	
Section_8:	
14/06/2007-J	un-2007 9:12:42
commentid:	200706140912424514
uniqueid:	_435391_200706140912424514
timestamp:	14/06/2007-Jun-2007 9:12:42
docid:	435391
title:	Pegaptanib and ranibizumab for the treatment of age-related macular degeneration (appraisal consultation)
name:	
mailfrom:	
role:	Carer
altrole:	
location:	England
conflict:	no
discuss:	
dataprotection:	-1
Section_1:	
Section_2:	My grandmother had AMD. No smokers in her family once she married, but probably subject to passive smooking as a child. She died aged 91, and by then had lost most of her sight, this preventing her from cooking and managing her own affairs (unable to read/write effectively). My mother (94) has AMD. Not a smoker but exposed to moderate smoke at home until age 40. Now unable to see at all well, cannot read or write, cannot see when clothes are dirty, can just manage ro reheat frozen meals in microwave. Without my support I think she would need carers several times a day or be in residential care. So treatment for her AMD could have saved a lot of money.
Section_3:	
Section_4:	I think that my previous notes on the cost effectiveness of reducing the loss of sight and therefore independence due to AMD cover this section too.
Section_5:	
Section_6:	
Section_7:	
Section_8:	
14/06/2007-J	lun-2007 10:41:41
commentid:	200706141041412245
uniqueid:	_435391_200706141041412245
timestamp:	14/06/2007-Jun-2007 10:41:41
docid:	435391
title:	Pegaptanib and ranibizumab for the treatment of age-related macular degeneration (appraisal consultation)
name:	
mailfrom:	
role:	Patient

Retired Professor of Paediatric Nephrology altrole:

England location: conflict:

3 intravitreal Lucentis injections for unilateral, predominantly classic CNV have yielded improvement in VA, which now equals the unaffected eye. Fluorescein angiography 1 year after the third injection shows no discuss:

further CNV or leakage, and the only defects are a tiny, off-centre scotoma and slight micropsia.

dataprotection: -1

I accept most of the recommendations, but question the appropriateness of confining Lucentis treatment to Section\_1: patients with bilateral CNV. Without treatment for my unilateral AMD I would by now be effectively

monocular. As I understand the prospect of involvement of a second eye is only about 5%, it seems inappropriate to deny treatment to those with unilateral, classic or predominantly classic disease, particularly when diagnosed early, as in my case. I am told blue eyes, and excessive sunlight exposure, are additional risk factors. If CNV is visible on the Section\_2: macular surface, PDT seems logical as a preliminary to Lucentis. I had the combination. Lucentis certainly seems more effective than Macugen. Complications appear to be minimal and uncommon Section\_3: (I had none) My Ophthalmologist recommended 3-monthly reassessments after 3 initial monthly injections, rather than Section\_4: continuing up to 1 or 2 years - provided that I remain vigilant and report any suggestion of deterioration, clinically and with use of the Amsler grid. Since every intravitreal injection carries a potential risk of complication, this flexible approach seems sensible. Section\_5: Agree. It might also be useful to compare the treatment I had - ie 3 monthly injections of Lucentis followed Section\_6: by "watch and wait" with 3-monthly reassessment - with 1 or 2 years" follow-up injections, as in Anchor and Marina Section\_7: No comment 3 years seems about right. Section\_8: 14/06/2007-Jun-2007 13:3:21 200706140103214313 commentid: \_435391\_200706140103214313 uniqueid: 14/06/2007-Jun-2007 13:3:21 timestamp: docid: 435391 Pegaptanib and ranibizumab for the treatment of age-related macular degeneration (appraisal consultation) title: name: mailfrom: role: other altrole: Close friend to sufferer of wet amd England location: conflict: discuss: dataprotection: -1 Section\_1: Section\_2: Section\_3: To only treat a "better seeing" eye is to allow people to go blind in one eye first. This is outrageous. Section\_4: Blindness in one eye affects people in many ways - it limits their vision significantly preventing ability to drive and read easily. It also means that "everything is hanging" on the treatment working in the second eye to prevent total blindness - given that treatment doesn"t always work, it should be tried on the first eye first. It would be equally outrageous to say "no" to treatment for someone with a broken arm on the basis that they have another arm they can use. It is not the case, in my experience of talking to people with Wet AMD, that people with Wet AMD present their symptoms too late for treatment in their first eye as a matter of course - a claim made in the NICE press release issued today. Wet AMD is aggressive and its affects on sight are quickly noticeable, for example as wavy lines before the eye. Section\_5: Section\_6: Section\_7: Section\_8: 14/06/2007-Jun-2007 14:7:10 commentid: 200706140207104926 435391 200706140207104926 uniqueid: 14/06/2007-Jun-2007 14:7:10 timestamp: docid: 435391 Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation title: name:

mailfrom: Patient role: altrole: location: England conflict: no discuss: dataprotection: -1 Section\_1: No comment on isolated stand alone comments As isolated results no comment Section\_2: As isolated results no comment Section\_3: No comment accept that improvement is noted Section\_4: Section 5: See comments in next section Families with a history for both parents and other close members of AMD associated with glaucoma should Section\_6: be considered a special case and prescribed the appropriate drug whilst the futher research is carried out, this process would at least ensure that any help is immediately available to this group of sufferers. Section\_7: See cooments in previuous section Considering the cost to the State od individuals that go blind or require additional help because of severe Section\_8: partial blindness this should be a policy of continual review and not put off for 3 years.

# 14/06/2007-Jun-2007 14:29:35

200706140229357334 commentid:

\_435391\_200706140229357334 uniqueid:

14/06/2007-Jun-2007 14:29:35 timestamp:

435391 docid:

Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation title:

name:

mailfrom:

role: other

altrole: Relative of patient

location: England conflict: no discuss:

dataprotection: -1

My father has ARMD and I can see at first hand the impact it has on his wellbeing and those around him. I Section\_1: believe these recommendations are driven by cost-limitation rather than a genuine cost-benefit analyis and

are ultimately untenable given the inequities between the English, Welsh and Scottish health systems. I am also concerned at what appears to be limited knowledge on the panel with regard to opthalmology.

Section\_2:

Section\_3:

Section\_4:

Section\_5:

Section\_6:

Section\_7:

Section\_8:

## 14/06/2007-Jun-2007 15:8:35

200706140308355273 commentid:

\_435391\_200706140308355273 uniqueid:

14/06/2007-Jun-2007 15:8:35 timestamp:

docid:

Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation title:

name:

mailfrom:	
role:	Public
altrole:	Son of a sufferer
location:	England
conflict:	no
discuss:	Over 20 years working in pharmaceutical R&D, mainly in bioanalytical and project management support to novel drug development (project member of over 40 NCE development teams, many of which are now established therapies (Wellcome Foundation/GSK).
dataprotection:	-1
Section_1:	Direct comparison studies would be helpful in supporting this conclusion, but understand why the companies would be reluctant to do this.
Section_2:	Understand that factors such as diet (increasing obesity?) and smoking increase likelihood of occurrence and progression to wet form. Should there be some comment on likely changes in number (i.e. percentage of population practically certain to increase)? I understand obesity has significantly increased over quite a short time and that this could reasonably be expected to impact on the number of new sufferers in the UK population.
Section_3:	Worthwhile adding comment on staff/equipment support needs for treatment? - and possibly some summary view on treatment event discomfort, i.e. if it was shown higher frequency treatment of certain benefit, how might this be balanced against the patients discomfort. <depends all="" at="" if="" is="" it="" traumatic=""></depends>
Section_4:	Accept conclusion, but wonder if there should be greater emphasis on the "hidden" costs (time, stress etc.) on both the patients and those taking care of someone who had previously reasonable eye sight? Suspect this value equation critical in accurately determining the longer view in the economic assessment. Given the importance to a significant number of UK patients I presume there would be value in encouraging longer trials/continuation studies and having a NICE re-assessment on the basis of new and improved data in 2-3 years time. BUT NOT ALLOWING THIS CONSIDERATION TO BE USED AS A REASON BY TRUSTS TO FOREGO INVESTMENT IN AMD TREATMENT CENTRES AND THERAPUETIC DELIVERY. Could a chronological chart be added, showing reporting dates for major current and planned studies with ranibizumab on AMD? i.e. finish with a little look ahead.
Section_5:	Is the NICE process to slow to kick in? Should the categorization of the different therapeutic remedies that NICE evaluates allow for a top rating where time is put aside to allow evaluation to start as soon as the first licence approval has been given by a major territory, or even as formal submission takes place? I understand that UK health Trusts routinely do little in taking on new treatments until the NICE process has been completed, and suspect this has a lot more to do with budget management and little to do with qualms about clinical need
Section_6:	Yes, but in investigating the long term effects an economic dimension on societial cost should be added.
Section_7:	No comment.
Section_8:	I guess much depends on the reporting horizon of current studies etc., the status of which I have no knowledge. But I suggest October, 2009 might be a better target date, given the increasing importance that will be given to this area as the 50"s baby boomers significantly increase the current patient population, possibly further potentiated by current diet.

	possion, further potentialed by earlier diet.
14/06/2007-	Jun-2007 17:48:19
commentid:	200706140548191442
uniqueid:	435391_200706140548191442
timestamp:	14/06/2007-Jun-2007 17:48:19
docid:	435391
title:	Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation
name:	
mailfrom:	
role:	Patient
altrole:	
location:	England
conflict:	no
discuss:	I was 64 when I was diagnosed with wet AMD last summer and was told that NHS treatment was not available. I was handed leaflets on how to contact help groups for the partially sighted! Instead I went privately to the same consultant who had made the diagnosis. I had two injections into my eye in November 2006 and January 2007 (because I was self funding the consultant suggested Avastin as a cost-effective alternative although he explained this can never be approved formally for this purpose). In April this year I was told that the condition had stabilised and certainly the sight problems I had have improved (all shadows and flashing have now gone). I have now been referred back to the NHS for regular checkups in case the condition re-occurs. In all the treatment cost me/my husband 2,500. If the NICE draft guidance is

implemented I would have had to allow myself to go blind in this eye before I could be considered for treatment if problems occurred with my remaining eye (while we were able to fund the 2.5k required on this occasion we certainly could not afford the 10k we have seen estimated for some treatments). That seems a considerable gamble with my health and well being. A lot of things would be more difficult, including driving, if I was blind in one eye. It's like saying we will let you lose one leg and try to save the other one. Eyesight is vital to most human activity and I believe treatment for this condition should be readily available on the NHS for both eyes. As my tax helps to fund Scotland why should people there have the treatment available while I am denied it on the NHS?. If I lost my sight I think it would cost the taxpayer a lot more in support payments than the scale of cost involved in the use of Macugen or Lucentis. If they are as effective as my cut-price Avastin injections they are well worth the investment.

dataprotection: -1

Section\_1: No comment

Section\_2: No comment

Section\_3: I realise that these costs seem high but eyesight is important and worth retaining. Support costs from the public purse would, in my view, be greater if more people were allowed to lose their sight. I would also

point out that my eyesight stabilised after only two injections so the ``cost" factor can be much less than the 9/10k a year.

Section\_4: A lot of this is guesswork with insufficient evidence. But why have other countries approved the use of these drugs. Why is Scotland going ahead with them? This all seems to be about keeping down cost rather

the welfare of patients. How do you put a price on a substantial loss in vision?

Section\_5: No comment

Section\_6: Fine. But don"t stop people getting the treatment they need meantime. If the further research

demonstrates conclusively that these drugs are not cost-effective their use might have to be re-considered. But don"t let people lose their sight while you are waiting for these investigations.

Section\_7: No comment

Section\_8: No comment

#### 15/06/2007-Jun-2007 6:56:44

commentid: 200706150656445376

uniqueid: \_\_435391\_200706150656445376

timestamp: 15/06/2007-Jun-2007 6:56:44

docid: 435391

title: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation

name:

mailfrom:

role: Public

altrole: previous experience in ophthalmology- former Nurse

location: England

conflict: no

discuss: Previously worked in Ophthalmology when nursing

dataprotection: -1

Section\_1: Why, oh Why do do NICE continually exclude patients from treatment when it can help the most!?? If used early in treating these patients then they are better able to preserve sight ands so less likely to render

people blind and so reliant on the care and expense of others

Section\_2: Looking at the comments this seems to be discrimination on the grounds of age once more as

predominently those affect are over 50- these rulings give hard pressed PCTs the power- yes power- to deny patients who can benefit from treatment that which they would receive elsewhere- the UK is falling further and further behind the rest of the world in the treatments that it can offer pateients

Section\_3: What this section demonstartes is that most adverse events are caused by problems with administration-

such as endophthalmitis- so these drugs should be more widely available- in terms of pts- so that those giving the treatemnt are highly skilled and able to decrease likelyhood of such complications occurring

So much waffle- you are condemning vulnerable people and their relatives to having to find the money to fund this themsleves at a point when their income is likely to have dropped considerably- you are also condemning younger pts (sub 60) to possibly have to give up nwork early with all the ramifications that has

on their pension payouts in future

Section\_5:

Section\_6:

Section\_7:

Section\_8: When you deny patients a drug and you know that research is onm going these drugs should be reviewed even if briefly every year to assess new evidence- they could then have a full review if this was warranted

# 15/06/2007-Jun-2007 11:12:23

commentid: 200706151112237015

uniqueid: \_\_435391\_200706151112237015

timestamp: 15/06/2007-Jun-2007 11:12:23

docid: 435391

title: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation

name: mailfrom:

role: Public

altrole: ex-patient, eye stabilised for past 15 months

location: England conflict: no

discuss: I suffered with CNV. Although my consultant does not refer to it as AMD due to my age, my condition is

exactly as AMD. My first occurrence happened in 1997 to my right eye, I had no treatment (the consultant

told me it

dataprotection: -1

Section\_1: I am not an expert in this matter so cannot comment on this, suffice to say that if a drug is proven to be

safe and effective then the judgement of which drug to use for which patient should be left up to the

experts in the field.

Section\_2: The problem as I understand it is the cause is unknown. With PDT which I had on five occassions you can deal with the symptons and hope to save as much eye sight as possible until the problem stops as suddenly

as it came - again why it stops is also unknown, but it appears that activity lasts between 12 and 24 months. As I understand it the new class of drugs go someway to stopping re-occurrence and therefore unlike PDT if they can control/stop activity during the active period then less long term damage is done to the sight.

Section\_3: I fully understand the issue regarding cost of r and d etc for the drugs companies, but more work should be

done with the drugs companies to get the cost of these drugs down and secondly as with all new technologies they are initially expensive but the costs will then drop with greater use, competitive

alternatives.

Section\_4:

Section\_5:

Section\_6: Health care is an emotive issue - when you start to talk about cost effectiveness you start to lose the

argument. The discussion should be about if the treatment is significantly better than treatments currently available. If you start putting cost effectiveness at the centre of the argument then people are going to get

upset.

Section\_7:

Section\_8:

### 15/06/2007-Jun-2007 15:18:52

**commentid**: 200706150318524146

**uniqueid:** \_\_435391\_200706150318524146

timestamp: 15/06/2007-Jun-2007 15:18:52

**docid**: 435391

title: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation

name:

mailfrom:

role: Patient

location: England

conflict: no

altrole:

discuss: I have wet AMD and am aged 77. Ihave been taking part in Lucentis trial, sponsored by Novartis, at the

Western Eye Hospital in Marylebone Rd, London. I have had 3 injections: Dec 06 and Jan/Feb 07. I now read 3 more lines with my bad eye and the stuff in my bad eye has cleared. This still the case after 4 review visits. It would be cruel to the group most likely to need t -many elderly people who can

dataprotection:	-1
Section_1:	All too technical
Section_2:	I"m not qualified to comment
Section_3:	
Section_4:	
Section_5:	
Section_6:	
Section_7:	
Section_8:	
16/06/2007-J	un-2007 0:9:9
commentid:	200706161209096445
uniqueid:	_435391_200706161209096445
timestamp:	16/06/2007-Jun-2007 0:9:9
docid:	435391
title:	Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation
name:	
mailfrom:	
role:	
altrole:	
location:	England
conflict:	no
discuss:	
dataprotection:	-1
Section_1:	1.1 : I suspect that lesion size here is 12 disc areas not 12 disc areas in greatest linear dimension
Section_2:	
Section_3:	
Section_4:	I dont fully understand the health economic analysis but I do acknowledge there is uncertainty over the total duration of treatment with ranibizumab, there is indeed likely to be a proportion of patients who may be on "maintainence" therapy for well beyond the 2 year period, this could be as high as 20% of patients from early indications. I note the absence of 3 and 4 year data on marina, anchor studies. On balance the assumption made by the committe in 4.3.10 is probably reasonable. Whilst the issue of treating the "better seeing eye" stirs huge media interest and emotion it is beyond question that losing visual acuity in the second eye is more damaging to a patients quality of life than losing visual acuity in the first eye. It also does not surprise me that teh QUALY"s are more favourable when the better seeing eye is treated with ranibizumab than when the worse seeing eye is treated with this technology. My issue here is if this is going to be the final decision by NICE I would strongly suggest clear guidance on the definitions. Acuity guidelines would be preferable than the somwhat vague termism of "better" and "worse" seeing eye. Please refine this position before issuing
Section_5:	
Section_6:	
Section_7:	
Section_8:	Due to several uncertaintys on the longer term picture with respect to dosing frequency and total duration of therapy with ranibizumab it may be worth considering a shorter than usual proposed date for review of guidance. Perhaps reveiw at 2years is more reasonable given the outpouring of research data expected.
16/06/2007-J	un-2007 19:20:44
commentid:	200706160720443707
uniqueid:	_435391_200706160720443707
timestamp:	16/06/2007-Jun-2007 19:20:44
docid.	435391

Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation

title: name: mailfrom:

role:

Public

altrole:	73 year old pensioner and Korean war veteran
location:	England
conflict:	no
discuss:	I have age related macular degeneration and have annual eye infirmary checks. Now Macugen and Lucentis are available in many countries please allow me to be treated in order to save this most precious gift.Blindness must cost society, and this would be a saving
dataprotection:	-1
Section_1:	These recommendations are surely based on costs. While the drugs are expensive they will surely compensate the cost that a blind person puts on society. Both drugs should be available if it will be a possible advantage to the patient. If all the technical detail is expressed in such a way to limit the use of these drugs, it needs revising.
Section_2:	The descriptions of CNV together with treatments and their limits is, to the uneducated, very explanitary but is photodynamic treatment, as good as, or as successful as Lucetus and Mcgugen
Section_3:	While much study, work and time has gone into providing all these facts for the relevant bodies and authority, I am afraid that cannot remark on section 3 apart from appreciating the costs. Has any research been done in costing the finance spent in treatment and aid for the blind as a comparison.
Section_4:	While these reports and costs are beyond me, the other countries, France, Germany and Canada for example have accepted this treatment together with the costs so is there a political influence being brought to bear or are there genuine doudts of the treatment.
Section_5:	The NICE report has much responsibility on it from a public, medical and cost implication
Section_6:	How long would this take, and time must not be an interloper in the introduction of these treatments which have been approved by other well founded medical bodies.
Section_7:	From my Imited viewpoint photodynamics is no substitute for Lucentus and Macugen
Section_8:	No comment apart from the sooner the better as I was led to believe that a decision would be finally made in September 2007.
18/06/2007-	Jun-2007 8:15:27

# 200706180815274252 commentid: \_435391\_200706180815274252 uniqueid: 18/06/2007-Jun-2007 8:15:27 timestamp: docid: 435391 Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation title: name: mailfrom: role: other altrole: location: England conflict: discuss: dataprotection: -1 Section\_1: Interested in the range and level of social support available...this tends to vary, in many areas it is practicaly non existant even during the immediate critical post diagnosis period. In some cases we have Section\_2: found services are only provided by small local charities not funded by statutory authorities. Section\_3: Section\_4: Section\_5: Section\_6: Section\_7: Section\_8:

# 18/06/2007-Jun-2007 14:22:38

commentid: 200706180222385516

uniqueid: \_\_\_\_\_435391\_200706180222385516

timestamp: 18/06/2007-Jun-2007 14:22:38

docid:	435391
title:	Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation
name:	
mailfrom:	
role:	other
altrole:	Niece of AMD Sufferer
location:	England
conflict:	no
discuss:	Only that my aunt, Mrs Enid Hallewell, is aware of the efforts which I and others are making to ensure that our locally PCT pays for her treatment and gets her the care she needs.
dataprotection:	-1
Section_1:	I cannot comment on the technical elements of this assessment, but I wish to register two points. Firstly,
	my aunt, assessments and is now being treated by in the Royal Eye Unit at Kingston Hospital. He is, I understand, a leading surgeon in his field. He has recommended that she should receive Macugen injections and she has so far paid for 4 treatments herself. He made a case to Sutton & Merton PCT in February 2007 for her to receive funding for further treatment with Lucentis (Ranibizumab) or Macugen (Pegaptanib) and he still hasn"t received a reply. Why, when surgeons recommend scuch courses of action, must this sort of decision get caught up in bureaucracy. Trust the surgeons" judgement and provide the funding - it will be more cost effective in the long run. Time is of the essence in providing this support and my aunt wants to minimise her call on the NHS, not take advantage. She wants the treatment she has been told she should have so she can get back to leading as normal a life as possible. It"s not her fault that she cannot afford to keep funding it.
Section_2:	
Section_3:	
Section_4:	
Section_5:	
Section_6:	
Section_7:	
Section_8:	Please review your guidance as quickly as possible, follow the lead from Scotland and give patients the treatment and hope which they need. Thank you.
18/06/2007-J	un-2007 21:15:16
commentid:	200706180915169305
uniqueid:	_435391_200706180915169305
timestamp:	18/06/2007-Jun-2007 21:15:16
docid:	435391
title:	Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation
name:	
mailfrom:	
role:	Patient
altrole:	
location:	England
conflict:	no
discuss:	
dataprotection:	-1
Section_1:	Ranibizumab has been recommeded by my Consultation at City hospital Birmingham
Section_2:	I have received 2 PDT treatment at present and an appointment in August for further treatments
Section_3:	I do accept the cost of Lucentis is expensive, but I am 60 years of age and still working at present. I would like to carry on working and may be after the age of 65. I have paid into the HNS since I start at the age of 15 - 45 years. I do feel I have paid in a good deal of money into the system. I have never claimed for benifits in 45 years
Section_4:	I feel ranibizumab (Lucentis) would improve my way of life. If I have to give up work it may cost the state in benifit ie: disability,mobility,carer allowances etc. I feel I have sevral more years in me regarding working and paying into the state. Surely this is simple logistics. 1, State benifits. 2, I carry on working and providing for my family.

My consultant has already applied for funding for Lucentis but at present this has been rejected, on the Section\_5: lines I have one good eye, but I have signs that AMD is in the other eye and I would not like to get to the position of not being about to see my family, especally by grand-children, 3 at present. ages 16, 3 and 1 month old after working so hard all my working life. This really does upset me at present !!!!! I do agree further research in AMD is VERY IMPORTANT. Your eyes are the window to the world. I feel I Section\_6: should have the right to enjoy my retirement, when it comes after working all these years, by the time I am thinking of retirement I would have worked for 50 years constantly, without claiming any benifits from the state. Which I feel is an achievement in is self. I am already receiving PDT teatment Section\_7: I have been informed that NICE may accept that Lucentis would be available for patients in October 2007 Section\_8: 2010 would could be to late for me !!!! As you can appreciate paying for this treatment privately is

19/06/2007-Jun-2007 16:47:45 200706190447453312 commentid: uniqueid: timestamp: 19/06/2007-Jun-2007 16:47:45 docid: 435391 Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation title: name: mailfrom: **NHS Professional** role: Consultant Ophthalmologist and Medical Retina Specialist altrole: England location: no conflict:

impossible

dataprotection: -1

discuss:

Section\_3:

Section\_4:

Section 5:

Section\_6:

1.1) 4 bullet points seem reasonable but preceding paragraph is unjustified: a) NICE preliminary appraisal of Section\_1: PDT requiring only second eye treatment was corrected to include first eye treatments. The same should be true of Ranibizumab treatments. b) If we are expected to treat one eye only I feel that is incorrect to treat the better seeing eye if for example the better seeing eye has evidence of subretinal fibrosis. A long standing lesion is less likely to respond than the more acutely affected eye (more chance of permanent structural damage to the central fovea). 1.2 a)Ranibizumab is also effective for the treatment of occult CNVM. Since there are no other modalities of treatment that are effective in this subtype of AMD, Ranibizumab should be made available in these forms of wet macular degeneration: Classic with no occult, Predominantly classic, Minimally classic, and occult. This is the conclusion of the european licencing body,

and the Scottish Medicines Consortia. It is notable that although cost per QALY is less for the classic lesions, cost per QALY in occult CNVM is also considerably less than the cost of retinal dialysis for example. 1.3 Reasonable 1.4 Reasonable

2.4 PDT is an option for classic no occult (NICE approved) and predominantly classic (cohort study group) Section\_2: Comment may need to be made that PDT may complement or be complemented by other modalities of treatment such as anti-VEGF therapies

> Reasonable summary but it might also be noted that long term safety of these agents remain to be evaluated since VEGF has a role in maintenance of normal blood vessels.

4.2.3.2 and 4.3.8 It is not established whether the assumption made in this section would hold \_ i.e. one cannot assume from the evidence that the treatment benefits are lost on cessation of treatment, or at a rate that parallels the natural history of the untreated disease 4.3.6 and 4.3.17 Did the committee look at the combination of anti-VEGF agents with other modalities of treatments such as PDT? 4.3.14 the decision to use the higher estimate of ICER as a daycase procedure is perhaps unreasonable if it excludes patients with minimally classic or occult lesions from receiving the only effective therapy. 4.3.16 see my comments above. It may not be reasonable to treat the better seeing eye if this was of longer standing. It makes just as much sense, if treatment is to be given only to one eye, to give it to the more recently affected eye, whether or not it was the better seeing eye. In practice it is likely that the second eye would present sooner, with smaller lesion size and better acuity, but to recommend treatment to a longstanding lesion is less likely to be cost effective. There is No mention of the Scottish Medicines Consortia analysis, and recommendations for treatment

Comment on section 4 continued: There are no comments about whether we need to choose between PDT and antiVEGF therapies, and comparitors assuming the cost to patients of having to travel much farther to a major centre for treatment with PDT rather than a local centre for antiVEGF therapy for example.

Safety & efficacy of Ranibizumab vs Bevacizumab and pegaptanib in other conditions such as diabetic maculopathy, proliferative diabetic retinopathy and so on. Pegaptanib may be less likely to result in capillary closure for example than the former.

There are no comments about whether we need to choose between PDT and antiVEGF therapies, and Section\_7:

comparitors assuming the cost to patients of having to travel much farther to a major centre for treatment with PDT rather than a local centre for antiVEGF therapy for example. I assume guidelines for PDT need to

be updated in the light of guidelines re anti-VEGF therapy.

Section\_8: Reasonable Question - why are there no ophthalmologists on the appraisal committee??

### 20/06/2007-Jun-2007 8:54:58

commentid: 200706200854584065

\_435391\_200706200854584065 uniqueid:

timestamp: 20/06/2007-Jun-2007 8:54:58

435391 docid:

Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation title:

name:

mailfrom:

role: Public

altrole:

location: England conflict: no

discuss:

dataprotection: -1

Section\_1:

Section\_2: Section\_3:

Section\_4:

believe your terms for prescribing the drugs are unacceptable, and that the assessment criteria you have used to make this decision are seriously flawed. The rest of Europe, including even part of the UK, holds a different position. This practically proves that your position is untenable. If an older person"s sight deteriorates to the point that they cant drive, suddenly they have lost not only the majority of one of their most essential senses, but their interaction with society reduces considerably and they can quickly lose the will to live. With an increasing ageing population this is a travesty and a velvet lined death sentence which you can prevent. You are wrong to assume treatment has to be carried out as day patients rather than out patients - and it is obvious that this errant assumption on your part has added a financial aspect to the decision.

Section\_5:

Section\_6: Section\_7:

Section\_8:

## 20/06/2007-Jun-2007 18:59:49

200706200659491374 commentid:

\_435391\_200706200659491374 uniqueid:

20/06/2007-Jun-2007 18:59:49 timestamp:

docid: 435391

Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation title:

name:

mailfrom:

role: other

altrole: son of a patient.

location: England

conflict: no

discuss.

dataprotection: -1

Section\_1: Section\_2:

My mother is currently recieving treatment for AMD funded by my father. Current spend is approx. 8000 from Section\_3:

May 06.She has now been told she requires treatment to both eyes which is beyond our means.At 83 & 84 years old respectively, they are self sufficient and need no outside help around the home, this may change. Presently, her sight is quite good as her condition was diagnosed at a routine diabetes check up. As I understand it, if both eyes are affected, then you are entitled to NHS treatment, is that correct? If so, and the deteriation stabalised, then she could continue to live without any NHS funded outside assistance necessary due to impaired vision. To me its a case of prevention while possible rather than reaction to a problem which could and should be avoided. This situation is taking a mental toll on my parents due to the stress this is all causing. Is it morally just to let someone go blind before they are accepted for treatment? I stronly believe this to be a cruel and wicked policy to inflict on a couple who have paid taxes and worked all their lives and never have had, before or even now, any state benefit of any kind. They have contributed for 60 years plus, they now need help.

#### Section\_4:

Are you advocating above that going blind is all dependant on financial ofsetting of the cost of the drugs opposed to the cost of care and visual aids? If so, you should be ashamed and pray to god you are never in this position. Why is the situation different in Scotland? We are currently corresponding by mail, and personally with our MP David Davis, who is awaiting a response from the relevant minister. If the drugs are cleared clinically in some areas, then I can only conlude its a finacial issue, how appalling if thats the case. Even drug addicts get support and medication for a self inflicted condition. I am incandessant with rage that in a so called civilised and first world country, this is allowed to happen.

#### Section\_5:

If your statement about "standards for better health" are sincere, then I on behalf of many others I"m sure, urge you to approve the use of these drugs where appropriate on the NHS to alleviate this distressing condition. Please display a responsible attitude and consider a duty of care to people who deserve it by right. Is it too radical to think there is a risk with these drugs? not from what I can conclude from your text. Do the right thing, and prove your commitment to the people of England, who can be helped and for who it is not too late.

Section\_6:

Section\_7:

Section\_8: Why wait so long?surely a rolling development and evolving programme could be considered.

### 20/06/2007-Jun-2007 21:43:21

commentid: 200706200943214383

**uniqueid:** \_\_435391\_200706200943214383

timestamp: 20/06/2007-Jun-2007 21:43:21

docid: 435391

title: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation

name:

mailfrom:

role: Patient

altrole:

location: England

conflict: no

dataprotection: -1

Section\_1:

I strongly disagree that patients are to be denied National Health treatment unless both eyes are badly affected. This treatment should be avaiable to all patients diagnosed with wet AMD on the NHS. It is far cheaper than paying out Attendance allowances, etc. It is completely unfair that bthis treatment(Lucentis)

is available in Scotland and not here.

Section\_2:

Section\_3:

Section 4:

Section\_5:

Section\_6:

Section\_7:

Section\_8:

# 21/06/2007-Jun-2007 0:32:58

commentid: 200706211232584955

uniqueid: \_\_435391\_200706211232584955

timestamp: 21/06/2007-Jun-2007 0:32:58

docid:	435391
title:	Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation
	macural degeneration (age-related) - pegaptanib and ranibizumab. Appraisal consultation
name:	
mailfrom:	NHS Professional
role:	NH3 PLOTESSIONAL
altrole:	Fordand
location:	England
conflict:	yes
discuss:	
dataprotection:	
Section_1:	I challenge these preliminary recommendations. Having used both ranibizumab and pegaptanib in an NHS setting only, I would agree that ranibizumab is a better a treatment for ARMD than pegaptanib. I have used ranibizumab in all lesion types and found it to improve the anatomy of the macula in almost all cases. This results in stabilization or improvement of vision, both as a patient perception and as a formal visual acuity measurement. To recommend treatment for vision between 6/12 and 6/96, is not workable, this is an example of where a study design has been inapproriately applied to a clinical setting. Assume a patient presents with visual symptoms in the second eye, having suffered severe visual loss in the first eye, investigations show the patient to have an active predominantly classic lesion and there visual acuity is 6/6 or 6/9, do I as a clinican advise them to return when the vision gets a bit worse then I will treat them? If you follow this advice and the patient returns with 6/60 vision, they are treated and their vision remains stable, now registered patially sighted! When they could drive before and live independantly. This is litigation waiting to happen.
Section_2:	I agree with these comments. What I would like to add is that the type of wet ARMD, can be different in the two eyes. Given your preliminary recommendations of only treating the second eye with lucentis, if it"s a predominantly classic lesion, this will result in a number of patients being denied any treatment and resulting in possible blindness. Also, the response to treatment between the two eyes is often different, even with the same lesion type, as result of the presence of haemorrhage, fibrosis and macula oedema. PDT is a much more destructive treatment compared to lucentis, and does effect vision quality despite maintained visual acuities. Contrast sensitivity is better preserved with lucentis.
Section_3:	In this section, the regimen used and the associated drug costs is the main area of contention. Only considering ranibizumab, the studies MARINA and ANCHOR, showed good levels of vision stabilization, along with visual improvement in 33-40% of patients respectively in the two studies, in the 0.5mgm dose. This was an intention to treat study and it is recognised a number of patients would have been over treated, exposing them to possible side effects. The PIER study used a loading dose of 3 injections, followed by a 3 monthly review, with the opportunity to re-inject, the initial visual benefit was lost at 12 month review. The PrONTO study used a loading 3 injections, with monthly review, gave similar results to the MARINA and ANCHOR results, mean injections 5.5, range 3-13 in a year, 2 year cost of 8400. The PrONTO data fits more with clinical practice, patients don"t want to have an injection if things are stable/unneccesary, but if required they will. If after a loading dose of 3 injections the vision is better, is it right to continue injecting? What if the patient is happy after 1 injection and decline any further injections has as happened!
Section_4:	The committee, have tried to explain their economic rational for coming up with there recommendations, having considered the two drug companies submission and an independant assessment group and found the assessment group to have a more ""plausible"" explaination given all the uncertainities involved. Economic assessment using Markov models is full of assumptions, with time-dependant transition probabilites for loss or gain in vision, and the movement between the different pre-determined states, this allows for a lot of latitude in calculation. They then used work published by Brown et al to estimate utility values for the different visual acuity states and then obtain the QALYs. Browns study had 5 VA states, a total of 80 patients and as few as 5 in some groups, he did not consider contrast sensitivity. Economically, what would happen in clinical practice is not an intention to treat as based on a study, if a patient undergo"s treatment and there vision deteriorates, treatment will be stopped. If a patient responds to treatment, it will continue as per protocol (PrONTO). When PDT was introduced there were concerns over 8 treatments in 3 years, we average 3 treatments per patient.
Section_5:	This section states a standard of care, which does not happen in a number of areas. In our area we are well supported by our commissioners, trust and collageues and have been able to introduce new treatments and accessibilty in a timely manner. I was aware of some areas not having a PDT service up to 1 year after the last NICE directive on ARMD.
Section_6:	These research proposals are all very good and it would be good to obtain the answers, but who is going to fund the trials? The cost effectiveness of ranibizumab compared to bevacizumab seems straight forward, one drug is very cheap and they seem to have the same clinical outcome. Bevacizumab has had no phase II trial, assuming it is safe because it has been used so widely around the world, how will it get it's licence with no drug company applying for a licence? Can you recommend to a clinican to use an off-licence product when there is a licensed ""equally good"" alternative. What if there are complications that come to light in the future, who carries the legal responsibility for bevacizumab? We have a unique health service, which has estabilised safety procedures over many years to protect our patients, will we set a precedent we may later regret. The rest of the world essentially has private medicine, the patient and doctor come to an agreement and give what the see fit. I believe we should treat both our patients eyes with ranibizumab.

Our minister for health should negotiate a price for the drug direct with the company; in New Zealand, ranibizumab is a third of the UK cost.

Section\_7:

It was interesting to note, that when this guidance was first issued there was no large print version, audio or braille formats available. I would therefore assume this was overlooked, and as such, I would have some concerns that all areas of interest are not represented on this appraisal committee.

Section\_8: To review ARMD again in April 2010 appears appropriate.

### 21/06/2007-Jun-2007 19:36:28

commentid: 200706210736286637

**uniqueid**: \_\_435391\_200706210736286637

timestamp: 21/06/2007-Jun-2007 19:36:28

docid: 435391

title: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation

name:

\_\_\_\_\_

mailfrom:

role: other

altrole: son / carer of sufferer of wet AMD

location: England conflict: no

discuss: How wonderful lucentis is and how upset I am by your draft guidance.

dataprotection: -1

Section\_1: This is really unfair and discriminatory. Lucentis works perfectly well for most sufferers of minimally classic

and occult forms which still lead to blindness. It should be available to them on the NHS without delay.

Section\_2: My father has the occult form of wet AMD. He was told that photodynamic therapy was not appropriate for

him so it is wrong to suggest it is always an option.

Section\_3: Lucentis is amazing and has saved the sight in my father"s remaining eye. I dread to think what his life would be without it - probably forced to move into a home, involve continual carers and lose virtually all his

remaining independence. This would cost the NHS etc. more than treatment with lucentis.

Section\_4: Lucentis is very effective for ALL forms of wet AMD (over 90% success in stopping sight loss) and not just the

classic type. My father has the occult form but nevertheless was very rapidly losing his sight over two months before treatment. If you are going blind, lucentis is a cure and the type of wet AMD you have is

irrelevant as they all lead to blindness with all the extra social costs resulting from it.

Section\_5: Why is lucentis available in Scotland and the rest of Europe for all sufferers and not in England. It is

clinically proven for the vast majority of sufferers. In addition I don"t see why someone should be forced to lose the sight in one eye (which could be saved) before the NHS might consider offering help. How would you like it if you were that sufferer? Also there may be human rights issues. My father"s PCT is refusing to pay for treatment so despite paying Nat. Ins. for 40 years and being an 85 year old widower he is being forced to use up his life savings to keep vision in his remaining eye. Why should he have to pay when other PCT"s / Scotland offer it free? Is is not a NATIONAL Health Service? What about when the money runs out / people with no savings? Your draft guidance is completely unacceptable and needs to be revised to include

all types of wet AMD and all sufferers.

Section\_6: It is very obvious how important lucentis is in maintaining quality of life. Comparing it to PDT is not

necessarily relevant as PDT is not effective for all sufferers who rely on lucentis.

Section\_7: No comment

Section\_8: Hurry up! I think a review should be much sooner.

## 22/06/2007-Jun-2007 12:46:16

commentid: 200706221246165025

**uniqueid:** \_\_435391\_200706221246165025

timestamp: 22/06/2007-Jun-2007 12:46:16

docid: 435391

title: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation

mailfrom:

cole: Carer

altrole:

location: England

conflict:	no
discuss:	I have applied for
dataprotection	
Section_1:	My 80-year-old mother-in-law,, a) having already lost sight in her right eye to AMD already b) has left eye with minimally classic AMD C) having had private treatment with Avastin, 7 injections, monthly, (Mr R Antcliff) has experienced i) prevention of further deterioration, ii) steadily reduced haemorrhage and swelling (which increased after a brief pause in regime after 6 injections) iii) some measurable improvement in visual acuity (can read 2nd line on chart where, before treatment could not see top line) iv) can now see her own face again and that of others v) is able to continue to care, unaided, for disabled, stroke-patient companion The Guidance, to "fence" the treatment according to the proportion of CNV, is inappropriate. Any reduction in loss of sight is worth treating. Criteria defined at this level have the semblance of scientific basis but Connie"s experience (above-mentioned) and other reported evidence suggests it is not statistically significant. The far-reaching consequences of sight loss are completely ignored by this recommendation and consigns 80% of MD sufferers to receive no treatment whatever based on an arbitrary distinction
Section_2:	Overall, a good summary. However at the end of 2.1, insert: ""For this reason, once diagnosed, the condition must be treated without delay."" 2.3 could comment on lack of supportive evidence for dietary influence on MD. 2.4 Replace ""Patient management consists of "" with ""Palliative care includes" Patient Management is exec-speak and smacks of impersonality.
Section_3:	There really must be discussion of Avastin. You are aware it use widely-used, ""off-label"", in the private sector and Norfolk PCT board has already sanctioned Avastin treatment for wet AMD under the NHS. It"s well-known as being pretty much equally effective as Lucentis and at probably 1/3 the cost. This will make cost-effectiveness dramatically different.
Section_4:	It is utterly absurd to conclude by implication that it is acceptable to become blind in one eye. Furthermore there is no evidence to suggest that the CNV characteristic of one will be the same as that of the other, experienced later on. You cannot turn the clock back, as if to determine that the first eye to go blind was actually the better of the two and so should have been treated. As mentioned previously, the consequences of loss of vision must be addressed. It sactually a binary decision: do you want to save or even restore some sight or not. It is cost-effective treatment if it does. Sight is not a luxury, it sa fundamental necessity. With the gradually increasing proportion of older people in the population, the incidence of AMD is set to increase. Hiding behind QALYs is inadequate. We may hope that stem-cell science offers an alternative to intra-vitreal injections in the medium to long term. Right now, let not a generation - many of whom have paid more into the NHS than anyone else - go blind needlessly.
Section_5:	After ""normally within 3 months" in 5.1 and 5.2, insert: ""However, in recognition of the importance of early treatment after diagnosis and the resulting likelihood of lower cost of treatment, funding should be made available as soon as practicable and in any event within 3 weeks.
Section_6:	As above, Avastin must be covered. This is a serious omission.
Section_7:	
Section_8:	April 2010 is arbitrary? Or what event predicates this date? The science is advancing rapidly and, especially when you may consider Avastin a much more cost-effective treatment, interim bulletins at yearly (without exception, no slippage) intervals would seem appropriate.
22/06/2007	-Jun-2007 13:34:34
commentid:	200706220134345269
uniqueid:	_435391_200706220134345269
timestamp:	22/06/2007-Jun-2007 13:34:34
docid:	435391
title:	Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation
name:	
mailfrom:	
role:	NHS Professional
altrole:	
location:	England
conflict:	no
discuss:	NII

Section\_1:

dataprotection: -1

There is no justification based on the evidence for restricting the treatment to Predominantly classic. It should be available for occult as well. There is no justification for restricting the treatment to better eye. Funding only of second eyes was suggested for PDT by NICE previously but this decision was reversed. Based on the same principles, Anti VEGF should be available for BE. Having had experience of treatmentabout 40-50 patients with Lucentis, I agree with the range of Va to be treated. I also agree with all the other circumstances named above.

Section_2:	In the Anchor study, Lucentis was clearly superior to PDT therefore should be available for patients even if they are suitable for PDT.
Section_3:	Pegaptanib may be useful in certain circumstances eg recent stroke/MI.
Section_4:	Patients with occult and minimally classice membrane also improved with Lucentis. Lucentis should be available for this cohort.
Section_5:	
Section_6:	
Section_7:	
Section_8:	

## 24/06/2007-Jun-2007 14:24:1

commentid: 200706240224014308

**uniqueid:** \_\_435391\_200706240224014308

timestamp: 24/06/2007-Jun-2007 14:24:1

docid: 435391

title: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation

name: mailfrom:

role: Patient Carer

location: England conflict: no

dataprotection: -1

discuss:

Section\_1: Every sufferer should be offered the best chance of maintaining their vision, on humanitarian grounds not based on cost.

Section\_2: No Comment mainly because I do not understand. I have only been informed that I have the wet type AMD so do not know whether I will be treated or not.

Section\_3: Cost should not enter the equation. Whilst I understand that it is an important factor to the NHS, treatment should be given when needed

Section\_4: I understand that it is more cost effective to treat the "good" eye. However I cannot understand by only 20% of AMD sufferers will be eligible when treatment has been proved to be, if not completely, but partially

effective. Sight is our most precious sense & enbles people to live a life rather than be a burden to either family or the state.

Section\_5: Why is this treatment available in Scotland & most other European countries and rejected in England & presumably Wales & Nortern Ireland?

Section\_6: How many people will lose their sight during this further research & become dependant on the state for care?

Section\_7: No Comment

Section\_8: Ridiculous! Another 3 years for how many more sufferers to lose their sight

## 24/06/2007-Jun-2007 15:38:20

commentid: 200706240338207474

uniqueid: \_\_\_\_435391\_200706240338207474

timestamp: 24/06/2007-Jun-2007 15:38:20

docid: 435391

title: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation

name:

mailfrom:

role: other

altrole: Son of patient location: England

conflict: no discuss:

dataprotection:	-1
Section_1:	
Section_2:	
Section_3:	
Section_4:	
Section_5:	What about as in my mothers case were she has been diagnosed with wet AMD in one eye and dry AMD in the other. She has been told that there is no treatment for dry AMD and by your decision you are excluding her from treatment for the eye with wet AMD as at the moment this is the eye with the least vision. You are therefore condeming her to blindness and the resulting cost of care plus the personal mental harm caused by the threat and actuality of blindness will far outweigh the cost of treatment. This is no way to treat the nations elderly even more so when you consider this treatment is available in Scotland. Why should I pay my NI and tax for people in Scotland to receive medical care not available to people of England?
Section_6:	
Section_7:	
Section_8:	
24/06/2007-J	lun-2007 16:12:43
commentid:	200706240412439115
uniqueid:	_435391_200706240412439115
timestamp:	24/06/2007-Jun-2007 16:12:43
docid:	435391
title:	Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation
name:	
mailfrom:	
role:	Patient
altrole:	
location:	England
conflict:	no
discuss:	
dataprotection:	-1
Section_1:	The visual acuity of 6/12 listed in 1.1 appear to be that where major impairment occurs.ie stop driving. If the products would be of benefit at an earlier stage (as advised by the case specialist) in the better seeing eye then they should be allowed.
Section_2:	No comment
Section_3:	No comment
Section_4:	Under Para 4.3.6 no consideration appears to have been given to the potential consequences if the worsening condition were to cause loss of employment through visual impairment. Surely, the ability to earn a living, pay taxes, maintain dependants and generally contribute to society, is an important factor. There are increasing numbers of pensioners still working.
Section_5:	Implementation should be atandardised across the UK. Whilst this is a political issue, it is one that causes immense resentment with the general public and NICE should do all in its power to influence government on this issue.
Section_6:	The use of these treatments, if recommended by the case specialist, should be commenced at the earliest opportunity to benefit the condition, even if this has to be to "the best sighted eye" rather than both.
Section_7:	No comment
Section_8:	No comment
25/06/2007-J	un-2007 0:15:36
commentid:	200706251215365241
uniqueid:	_435391_200706251215365241
timestamp:	25/06/2007-Jun-2007 0:15:36
docid:	435391
title:	Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation
name:	
mailfrom:	

role:	Patient
altrole:	
location:	England
conflict:	no
discuss:	
dataprotection:	-1
Section_1:	While I can see the logic of not recommending Pegaptanib, as trials have indicated that it is not as successful a treatment, I am outraged that you assume that patients only seek help when vision has seriously deteriorated. Both my parents had AMD and at the first signs of a deterioration in my vision, I was quickly referred to my local hospital. I was considered for PDT but considered unsuitable due to my suffering from PMLE (skin sensitivity to light). My only hope is in the anti-angiogenic drugs. Put yourselves in my shoes! Please reconsider and allow approval for the drugs for use in the first or both eyes.
Section_2:	
Section_3:	
Section_4:	Your cost effectiveness criteria are making this seem like a third world country! We are inundated with appeals for people of poorer nations to correct sight impairment - admittedly of a less difficult to treat nature - but treatment for a condition that affects thousands of people each year in the UK seems to be dismissed on purely cost grounds. How many of the NICE panel"s relatives suffer from this condition? Have they tried wearing simulation spectacles to "feel" how AMD affects the vision? Do they know how debilitating the loss of central vision can be? Will it take an AIDS type campaign to raise awareness of the need for funding?
Section_5:	
Section_6:	
Section_7:	
Section_8:	
25/06/2007-	lun-2007 10:42:1

	-
25/06/2007-	Jun-2007 10:42:1
commentid:	200706251042010045
uniqueid:	_435391_200706251042010045
timestamp:	25/06/2007-Jun-2007 10:42:1
docid:	435391
title:	Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation
name:	
mailfrom:	
role:	Carer
altrole:	
location:	England
conflict:	no
discuss:	
dataprotection:	-1
Section_1:	
Section_2:	
Section_3:	
Section_4:	What you do not seem to take into account is the "cost" to the aptient and their carers. Neither do you seem to take account of the extra costs involved in giving patients who have severe sight loss the help they need to keep their independence or if they lose their independence the cost of looking after them in the community.
Section_5:	It is totally wrong that there are different standards of care depending on where a patient lives in the UK. If you live in Scotland treatment is available but in Emgland and Wales not. Total discrimination. Is this because most of our current governemt is Scottish, too cynical to think so but one has to wonder!

I am not medically trained and can only speak as a lay carer but I can only stress the difficulty loss of central vision can cause. My mother"s has now very little central sight in either eye and suffers from Wet AMD. I understand that her AMD is beyond treatment, however, I urge NICE to think again about the use of the proposed treatments because any help they can give to these patients would be a valuable help. Whilst costs must come into the equation the main critewria should be whether the treatment gives benefit to the aptient to enable them to retian their independence and thereby reduce their cost to the NHS and economy

Section\_6: Section\_7:

	as a whole.
Section_8:	
26/06/2007-	Jun-2007 9:45:59
commentid:	200706260945598577
uniqueid:	_435391_200706260945598577
timestamp:	26/06/2007-Jun-2007 9:45:59
docid:	435391
title:	Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation
name:	
mailfrom:	
role:	NHS Professional
altrole:	relative of Wet AMD patients
location:	England
conflict:	no
discuss:	
dataprotection:	-1
Section_1:	1. Restriction of treatment to the second eye this is ridiculous and counter-intuitive. Lucentis (ranibizumab) appears to have a good safety profile and should be offered when the diagnosis of Wet AMD is made in the first eye. My mother (an active 84 year-old) last year had treatment with Avastin (bevacizumab) on an unlicensed basis with appropriate discussion and informed consent. This was first eye treatment and has led to considerable and sustained improvement in distorted vision. I can only begin to imagine the distress of knowing safe effective treatment is available but not being able to have it until the (highly likely) second eye becomes affected or of course getting treatment in the private sector if you can afford it. 2. Restriction of treatment to certain types of Wet AMD only. Like many members of NICE committees I am a medical doctor. What would we want for ourselves, our relatives and friends?
Section_2:	
Section_3:	restrictions of treatment to second afected eye are proposed on grounds of health economics. Unlike many arguments in favour of expensive treatments, there are costs to withholding treatment if older people become needlessly blind falls, loss of independence, costs to social services, et, etc.
Section_4:	I am pleased that NICE is assessing new highly effective treatment.
Section_5:	
Section_6:	I think the recommendations for future research are sound.
Section_7:	
Section_8:	
26/06/2007-	Jun-2007 12:0:47
commentid:	200706261200473996
	435204 20070424200472004

26/06/2007-	Jun-2007 12:0:47
commentid:	200706261200473996
uniqueid:	_435391_200706261200473996
timestamp:	26/06/2007-Jun-2007 12:0:47
docid:	435391
title:	Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation
name:	
mailfrom:	
role:	Patient
altrole:	
location:	England
conflict:	no
discuss:	
dataprotection:	-1
Section_1:	
Section_2:	
Section_3:	
Section_4:	I have been diagnosed with wet macular degeneration in one eye and anm at present being treated with

Lucentis. This has stopped my eyesight progressing further and actually improved my sight. I am able to drive which is necessary as otherwise I would not be able to visit my elderly mother in a home. This treatment must be available to all on the NHS as soon as this disease is diagnosed, as early treatment is This treatment must be made available to all patients without discrimination, as in Scotland. Section\_5: Section\_6: This treatment is far more cost effective than paying attendance allowances and providing social care. Section\_7:

27/06/2007-Jun-2007 14:56:36

200706270256350767 commentid:

\_435391\_200706270256350767 uniqueid:

27/06/2007-Jun-2007 14:56:36 timestamp:

435391 docid:

Section\_8:

title: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation

name. mailfrom:

**NHS Professional** role:

optometrist/professional adviser/ophthalmic clinical assistant altrole:

location: England conflict: no

discuss:

dataprotection: -1

Section\_1:

Section\_2: PDT is a more expensive treatment with more clinical support required. Results are not as significant as

trials would suggest with anti vegF drugs.

Section 3:

Section\_4: Trials have suggested that treatment is most effective at an earlier rather than advanced stage. There

seems to have been little consideration to the social and psychological effects of the loss of vision on patients and their carers and the financial burden on PCTs for low vision services. Patients should not be left until the point at which this is a last ditch effort to save residual vision.

Section\_5:

Section\_6:

Further research into the cost benefits of avastin should be encouraged as this seems to be a significantly

cheaper therapy.

Section\_7:

This is too long - as there are ongoing trials on these therapies, if implemented, the guidance should be Section\_8:

reviewed earlier than 2010.

28/06/2007-Jun-2007 11:4:20

commentid: 200706281104201573

\_435391\_200706281104201573 uniqueid:

28/06/2007-Jun-2007 11:4:20 timestamp:

docid: 435391

Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation title:

name: mailfrom:

**NHS Professional** role:

altrole:

England location:

conflict: no

1. Ranibizumab is suitable for ALL lesion types of Wet AMD. The results of the MARINA and ACNCHOR trials discuss: clearly defines this. To descriminate between lesion types is therefor UNETHICAL as the final visual

outcome for all types of Wet AMD is very poor indeed. 2. Ranibizumab is more effective for early lesions than well established lesions with fibrosis. Perhaps this could be used to ration the treatment. 3. To

discrimiate between one and two eyes is also UNETHICAL. It is like saying to a patient,

dataprotection: -1 1. ANCHOR and MARINA trials isdicate that Ranibizumab is suitable for all lesion types. 2. The earlier Section\_1: Ranibizumab is given the better the final vision. Hence the 6/12 arbitration is unethical. 3. Lesion size is not a limit to treatment. All respond to the treatment no matter what the size is. Section\_2: section 3.4 - The PIER trial clearly states that patients only need 3 injections at 3 monthly intervals Section\_3: initially. Further injections are only needed if there is demonstrable fluid on angiograms or OCT. The average number of injections is 5.5 and therefore the cost is far less than anticipated. Section\_4: Section\_5: Section\_6: Section\_7: Section\_8: 29/06/2007-Jun-2007 11:45:7 200706291145070545 commentid: \_435391\_200706291145070545 uniqueid: 29/06/2007-Jun-2007 11:45:7 timestamp: 435391 docid: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation title: name: mailfrom: role: Carer altrole: England location: conflict: discuss: dataprotection: -1 If there is evidence to show that Lucentis is effective for treating wet AMD it seems unethical that those Section\_1: who can pay for it can get it, but those who can"t afford it are condemmed to progressive sight loss. Surely it is more cost effective to prevent sight loss than support those who are visually impaired. Section 2: Section\_3: Section\_4: Section\_5: Section\_6: Section\_7: Section\_8: 29/06/2007-Jun-2007 13:52:52 200706290152526645 commentid: uniqueid: \_435391\_200706290152526645 29/06/2007-Jun-2007 13:52:52 timestamp: 435391 docid: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation title:

mailfrom: role: altrole:

location: conflict: discuss: England

dataprotection: -1

#### Section\_1:

Response to NICE guidance on Ranibizumab (Lucentis) 29/6/07

I am glad that some ranibizumab is being supported as this is the first treatment for Macular degeneration that has shown visual improvement in a significant number of patients. However I am disappointed that the treatment is being restricted to only predominantly classic lesions. I presume the reasons for this relates to the amount of benefit found between treating and not treating minimally classic and occult lesions compared to treating and not treating predominantly classic lesions. There are a number of unsatisfactory issues related to this decision. 1. The difference between the treated and placebo groups in the occult and minimally classic groups in terms of preventing visual loss is just as much as that for PDT in treating or not treating predominantly classic lesions which NICE did decide to support. 2. The difference increases in the second year (MARINA study) which is reassuring evidence that the treatment is working. 3. The consequence of this guidance is that Ranibizumab should replace PDT for second eyes as the provision of ranibizumab for predominantly classic lesions is the same as saying treat the previous NICE 1.1 and 1.2 (PDT guidance). 4. 1.2 (PDT guidance) is already being treated as part of the Cohort study by all PDT centres so there is no increase in the number of patients who will receive treatment rather a change in treatment. 5. This acknowledges that ranibizumab is the better treatment compared to PDT so it is appropriate that ranibizumab is used rather than PDT, but if that is so why should we still do PDT for first eyes? 6. The evidence demonstrates that we should be using Ranibizumab for all wet AMD and as PDT was allowed for first eye, first eyes also.

Section_2:	
Section_3:	
Section_4:	
Section_5:	
Section_6:	
Section_7:	
Section 8:	

# 29/06/2007-Jun-2007 15:38:10

commentid:

uniqueid:

timestamp:

435391

docid:

title: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation

name:

mailfrom:

**NHS Professional** role:

Consultant Ophthalmic Surgeon subspecialty Retina altrole:

29/06/2007-Jun-2007 15:38:10

England location:

conflict: no

discuss:

I would like to share the experience of using anti-VeGF in wet ARMD, a study of 40 patients presented in the Royal College of Ophthalmologists annual meeting in Birmingham in May this year as well in ARVO Florida and EURETINA congress Monte Carlo this year.

# dataprotection: -1

# Section\_1:

As a clinician treating such patients I agree with some but strongly reject most of the above recommendations. The reasons are as follows: 1. Firstly the cost effective analysis model used by NICE for treating all wet ARMD cases is not based on individual patient data. 2. I welcome the authorisation of Lucentis but critical about the restricted guidelines. 3. There is enough evidence from the american studies published so far that the anti-VEGF are best helpful for all sorts of wet lesions be it occult, min.classic or pred.classic. Based on this Yorkshire SHA commsioners have approved the use of Ranibizumab in all types of lesions whereas the Merseyside has followed NICE guidelines. How can this discrepancy be explained to our patients who do not live in such areas and therefore are being deprived of treatment. 3. I also object regarding the issue of treating the second eye. This was scrapped in our local SHA commissioning meeting as patients can present with fibrovasular untreatable lesions in their second eye which can be legally challengable. Hence I would like the NICE pannell to revise their views. 4. AS shown in studies early presenters respond best to treatment wit

#### Section\_2:

Personally feel the long term scotomas given by PDT with huge scarring of retina makes PDT unacceptable in the days of Anti-VEGF. My own study using Macugen showed 60% stability in VA at one year and Occult CNVs responded exceedingly well (p==0.05)leading to improvement in vA. This study was performed by treating all types of lesions restricting to only 3 treatments per year.

## Section\_3:

To the above costs costs of administering are added. NICE worked out the costs based on day case model but we treat as an outpatient model and therefore it depreciates the costs significantly (as on RCOpth website. I recommend NICE to review this on a out patient basis.

Section_4:	Evidence suggests that the cost of treatment of Wet ARMD is less than Blindness. According to Neads et al (BJO 2003) cost of blindness is 6500 per patient per year and others quited it to be 9500 per patient per year. Based on this model a population of 350000 would have 42 patients with treatable lesions cost of Pegaptanib 544,000 whereas cost of blindness would be 798,000.
Section_5:	I strongly recommend NICE should review its guidelines and be fair to patientws and clinicians. We have been trying to work with our local SHA since a year and produced guidelines and evidences towards it, but unfortunately with the restricted guidelines everything has reverted back and the time and money of NHS has been wasted. Moreover as clinicians we are equially frustrated about the increasing amount of time we spend trying to explain patients. I suggest that if NICE is not going to change its stance then the panell should give an accountable contact from NICE to answer all queries raised by patients.
Section_6:	
Section_7:	
Section_8:	

03/07/2007-J	lul-2007 17:15:19
commentid:	200707030515193009
uniqueid:	_435391_200707030515193009
timestamp:	03/07/2007-Jul-2007 17:15:19
docid:	435391
title:	Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation
name:	
mailfrom:	
role:	NHS Professional
altrole:	
location:	Wales
conflict:	no
discuss:	
dataprotection:	-1
Section_1:	
Section_2:	The Anchor study comparing PDT and Lucentis clearly shows that Lucentis is much better and almost 30-40% patients showed visual gain of 15 or more letters. Hence the role of PDT will be less important in future apart from in combination therapy.
Section_3:	Lucentis is much superior to Macugen as there were no patients showing visual gain in ""VISION"" STUDY
Section_4:	1. The major factor determining cost is the number of treatments required. The cost effectiveness model assumes 24 treatments over two years. Current evidence suggests that similar visual outcomes are obtained with 14 treatments in the same period. This is acknowledged in paragraph 4.2.3.12. However in the concluding paragraph 4.3.14 the cost of monthly injections is quoted. 2. If 24 treatments were administered (paragraph 4.3.10) but over a longer period than two-years, it is likely that the visual gain would be maintained. However the cost effectiveness model assumes that vision declines at a similar rate to the natural history of the disease beyond two-years (paragraph 4.3.8). We concede that the frequency of assessment and treatment required beyond the second year is unknown and that this ongoing cost is not included in the model. 3. The cost effectiveness model fails to take account of early cessation of treatment. In clinical practice treatment would not be continued if the visual acuity drops consistently below 6/60. 4. The assumption that treatment is provided on a day case basis artificially inflates the cost (paragraph 4.2.3.13). In practice most centres are planning to administer the treatment in a clean room in outpatients. 5. The model underestimates the costs related to blindness (paragraph 4.3.13). 6. We too recognise the need to make effective use of NHS resources (paragraph 4.3.1). We are very concerned by the potential shortfall in capacity (physical space and manpower) in many units. However this should not be used as an excuse for limiting access to an effective treatment. The service must evolve to meet the demands of the population it serves.
Section_5:	
Section_6:	
Section_7:	
Section_8:	
00/05/0005	

# 03/07/2007-Jul-2007 17:23:12

**commentid**: 200707030523122588

uniqueid: \_\_\_\_\_435391\_200707030523122588

timestamp: 03/07/2007-Jul-2007 17:23:12

docid:	435391
title:	Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation
name:	
mailfrom:	
role:	Patient
altrole:	
location:	England
conflict:	no
discuss:	
dataprotection:	-1
Section_1:	I have wet AMD in the right eye & dry AMD in the left. The wet AMD will not be treated as it is the 1st eye so I shall lose the sight. The dry AMD will progress slowly and, as it is untreatable, I shall lose the sight in the remaining eye.
Section_2:	
Section_3:	I am recommended to pay for a course of 3 injections of ranibizumab costing around 5000. The injections cost 2600 - the day surgery 2400. The literature suggests 14 injections over 2 years and probably ongoing thereafter. This is not a realistic financial option for a pensioner.
Section_4:	Cataract operations as an outpatient are provided by the NHS. The cost of day surgery (around 800 per day seems to be an unacceptable deciding factor in your recommendations. It costs less to support me as I lose my sight than to treat me, but is not treating me an ethical decision? How about the "What if it were MY mother test?
Section_5:	
Section_6:	In view of the difference in cost (which would cut my bill for private treatment by 50%) the effectiveness and possible use of bevacizumab should be fully explored as soon as possible.
Section_7:	
Section_8:	
03/07/2007	Jul-2007 23:36:48
	200707031136480204
commentid:	_435391_200707031136480204
uniqueid:	
timestamp:	03/07/2007-Jul-2007 23:36:48 435391
docid:	
title:	Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation
name:	
mailfrom:	Drivate Sector Professional
role:	Private Sector Professional
altrole:	Freetrand
location:	England
conflict:	no
discuss:	
dataprotection:	
Section_1:	There is no scientific basis to discriminate only in favour of classic/predominantly classic CNV. Ranibizuma was shown to be significantly better than PDT for these lesions, and the trial of two doses of ranibizumab.

There is no scientific basis to discriminate only in favour of classic/predominantly classic CNV. Ranibizumab was shown to be significantly better than PDT for these lesions, and the trial of two doses of ranibizumab versus sham for minimally classic/occult CNV showed a similar IMPROVEMENT of vision (1.5 lines)versus a decline of 3 lines/15 letters over two years. These two trials are exemplary design and provide a high standard of evidence of effectiveness for the range of CNV in wet AMD other than the intermediate group. It is unreasonable to not treat bilateral active disease given that the outcome of treatment is not predictable and the worse eye may potentially have a better outcome. The rationale of treating only the better eye has not been rigorously tested by a randomised clinical trial, and until there is evidence that better seeing eyes always have a better outcome, then treatable disease in both eyes should be treated. The term ""permanent structural damage to the central fovea" requires clarification - is a full thickness macular hole permanent damage which excludes anti-VEGF treatment?

permanent damage which excludes anti-VEGF treatment?

The results of the ranibizumab vs PDT show the relative ineffectiveness of PDT, the visual loss over 2 years being similar to untreated occult CNV. Clinicians with experience of PDT and anti-VEGF therapy are acutely aware of the significantly better outcome with anti-VEGF with anti-VEGF patients improving by more than one line on average, and PDT treated patients deteriorating by two lines, a difference of 3 lines.

Section\_3:

Section\_2:

The models above are based on treating patients for up to two years. This is only true for patients who have responded to treatment, as those who have shown no clinical response to the first three (or even two) injections are unlikely to continue to receive further treatment. Failure to respond to early treatment.

injections are unlikely to continue to receive further treatment. Failure to respond to early treatment should therefore lead to a cessation of treatment.

Section\_5:

Section\_6: A comparison of bevacizumab versus ranibizumab is urgently required. As clinical effectiveness is

discernible after 3 injections, a short term randomised 1:1 trial comparing the two agents for a three month period could result in the the relative effectiveness being seen without the need for an extended two year

study.

Section\_7:
Section\_8:

04/07/2007-Jul-2007 10:17:4

commentid: 200707041017045630

**uniqueid:** \_\_435391\_200707041017045630

timestamp: 04/07/2007-Jul-2007 10:17:4

docid: 435391

title: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation

name:

mailfrom:

role: Private Sector Professional

altrole: Inventor
location: England
conflict: No

discuss: No

dataprotection: -1
Section\_1:

Section\_2:

Section\_3:

Section\_4:

Section\_5:

Section\_6: Why was Bevacizumab not considered for comparison in this particular HTA when there is enough evidence of its cost-effectiveness in literature and it has been approved by The National Health Service in Italy for

use in Wet Age-related macular degeneration?

Section\_7:

Section\_8:

04/07/2007-Jul-2007 17:0:11

**commentid:** 200707040500118870

uniqueid: \_\_435391\_200707040500118870

timestamp: 04/07/2007-Jul-2007 17:0:11

docid: 435391

title: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation

name:

mailfrom:

role: NHS Professional

altrole:

location: England

conflict: no

dataprotection: -1

discuss:

Section\_1: 1.1 It is unclear how patients with unilateral wet AMD fit within this guidance (eg patients with first eye

disease or only one eye). The paragraph seems a little ambiguous as you start off by saying that

Ranibizumab is only indicated for wet AMD, but treatment should only be given to the better seeing eye. I

could envisage someone who has dry AMD in their better seeing eye who has wet AMD that is suitable for treatment in the other eye getting their dry AMD treated with the drug! Presumably the BCVA (and other bullet points) apply to the better seeing eye? please make this more explicit. Maybe you could change "", and only for the better seeing eye..."" to ""in their better (or only) seeing eye when the following conditions are met:"" Even with this change there will still be cirumstances when patients with progressive but untreatable conditions in one eye and treatable wet AMD in the other will be declined treatment. 1.4 Is there any guidance on stopping treatment? Examples include no response to treatment, occurence of complications. Section\_2: Section\_3: Section\_4: Section\_5: There is likely to be a bulge in referrals for this treatment which may overwhelm ophthalmology services; is there any work being done on capacity planning for acute Trusts to use? Does the threshold for treatment match available treatment infrastructure and is there any gudiance on what would define a qualified and competent practitioner to perform this treatment? Section\_6: Section\_7: How does this date marry with the completion of the NCCHTAs comparison of Bevacizumab and Section\_8: Ranibizumab? 04/07/2007-Jul-2007 19:40:15 200707040740159308 commentid: \_435391\_200707040740159308 uniqueid: 04/07/2007-Jul-2007 19:40:15 timestamp: docid: 435391 title: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation name: mailfrom: Private Sector Professional role: altrole: location: England conflict: I am concerned that in treating the discuss: dataprotection: -1 I am concerned that in specifying treatment to only the better seeing eye, you exclude treatment to the Section\_1: first eye affected. It is true that first eyes are often missed as the patient does not present in time but, when the patient does it should be treated. The other eye may present with dry degeneration unsuitable for treatment or the other eye may be amblyopic and therefore untreatable. In costing the treatment you assume regular injections over a two year period and this may not necessarily Section\_2: be the case. Also there is no mention of the cost to carers who will have to amend their lives should the patient lose sight and become dependent. Section\_3: Section\_4: Section\_5: Section\_6: Section\_7: Section\_8: 05/07/2007-Jul-2007 9:39:28 commentid: 200707050939282123 \_435391\_200707050939282123 uniqueid: 05/07/2007-Jul-2007 9:39:28 timestamp: 435391 docid: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation title: name: mailfrom:

role:	NHS Professional
altrole:	
location:	England
conflict:	no
discuss:	consultant eye surgeon with specialist interest in medical retinal diseases
dataprotection:	-1
Section_1:	I disagree with the proposal to limit Ranibizumab to second eyes. It is not possible to predict that the visual loss in the second eye will be due to wet-type AMD, nor that it will be predominantly classic. All cases of wet-type AMD should be offered treatment, first or second eyes, and regardless of lesion type.
Section_2:	PDT is not a cheap treatment and has not lived up to expectations in terms of visual gain. Ranibizumab is first treatment where a visual gain is found. Patients should not be made to suffer visual loss when a better treatment is available.
Section_3:	Costs can be reduced by giving the drug in clean treatment room in out-patient setting as per guidance from Royal College of Ophthalmology
Section_4:	The psychological impact on patients is hard to put in terms of monetry value but the cost of loss of vision alone especially as Ranibizumab can be administered in an out-patinet setting thus reducing the cost to the NHS
Section_5:	
Section_6:	
Section_7:	
Section_8:	
05/07/2007-	Jul-2007 10:38:59
	200707051020507

commentid: 200707051038595987

uniqueid: \_\_435391\_200707051038595987

timestamp: 05/07/2007-Jul-2007 10:38:59

docid: 435391

title: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation

name:

mailfrom:

role: NHS Professional

altrole: Daughter of AMD sufferer (Mum)

location: England conflict: no

discuss:

dataprotection: -1

Section\_1: It seems totally unethical to only offer treatment for one eye if both are affected by wet AMD and would benefit from treatment. You don"t only offer one hip or knee replacement.

Section\_2: There seems to be very little recognition of the actual social consequences of swift loss of vision to an elderly person. Less than a year ago my Mum was driving regularly (50 mile trips to friends, not just local)

Now she can"t recognise the number on a bus until it goes past, is in danger crossing the road as she can"t see cars more than 2 car lengths away and needs a magnifying glass to read, which is very tiring and difficult for someone who, for as long as I can remember, read the Daily Telegraph in depth every day. It also means she doesn"t do crosswords in the paper and as we know if you don"t use it you lose it.....so there"s a risk to a person"s brain power and confidence. As well as the ultimate terrifying thought of

in the elderley when they are in hopsital +/- risk and costs associated with any hospital acquired infections)

possibly going blind and losing independence.

The higher costs associated with Lucentis (<1500 over 2 years) are certainly justified when you consider the costs of hospitalisation eg following fracture femur crossing the road and being hit by the car you didn"t see, where initial costs could be between 8 - 10,000 according to 2005/06 reference costs (inc A&E, surgery and 4 physio follow up appointments, but excluding cost of ambulance, any domestic support that may be subsequently needed and the cost of treating other problems diagnosed while in hospital which is common

It would appear that the research has been quite selective as I understand from other experts in the field (local clinicians and the Macular Disease Society)that there is evidence that treatment is effective on all types of wet AMD if treated early enough, not just the 20% with ""predominantly classic"" wet AMD. The recommendation to wait until both eyes are affected and then only treat one is immoral beyond belief.... have we really reached the stage where NHS commissioners are to be encouraged to stand back and see 80% of their population of AMD sufferers go blind when there is effective treatment available?

In local cash strapped PCTs, many commissioners are hiding behind ""must wait for NICE guidance before Section\_5: funding"", while many of their elderly population spend life savings [those that are lucky enough to be able to find enough] on having their AMD treated privately rather than go blind waiting for a decision. as this is such a rapidly progressing disease, its vital that appropriate guidance is given urgently. According to the macular Disease Society figures, over 4,000 people will have been denied NHS treatment that could have saved their sight just during this consultation period. The idea for further research is, as always, to be recommended, but it must not be allowed to delay fair Section\_6: and ethical prescribing of Lucentis for all who could benefit in as many eyes as could benefit according to clinician expertise, not financial constraints Section\_7: Section\_8: 05/07/2007-Jul-2007 10:53:59 200707051053596430 commentid: \_435391\_200707051053596430 uniqueid: 05/07/2007-Jul-2007 10:53:59 timestamp: docid: 435391 title: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation name: mailfrom: role: Public altrole: England location: conflict: no discuss: dataprotection: -1 I write to urge reconsideration of the unreasonable restrictions on this treatment, which cut out anyone Section\_1: with occult or minimally classic lesions, - that is 80% of all patients with AMD. That patients must first go blind in one eye, before treatment of the second eye is considered is a shocking decision, when arresting the disease and saving eyesight is now a possibility. A close friend, an artist, has AMD. She is currently facing the very likely loss of sight in one eye, when it would be scientifically and medically possible to save it. She can"t afford to pay for the treatment privately. It is tragic for any person to lose the sight of one eye or potentially both, but for an artist this seems even crueler especially when treatment could be made available. It is a scandalous decision. These restrictions must be urgently reconsidered. Section\_2: Section\_3: Section\_4: Section\_5: Section\_6: Section\_7: Section\_8: 05/07/2007-Jul-2007 16:43:17 200707050443178434 commentid: uniqueid: 435391 200707050443178434 05/07/2007-Jul-2007 16:43:17 timestamp: 435391 docid: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation title: name: mailfrom: Healthcare Other role: altrole: location: England

conflict:

discuss:

no

dataprotection:	-1
Section_1:	
Section_2:	
Section_3:	There is significant wastage of ranibizumab within each vial. Could consideration be given to vial sharing through drawing up doses into syringes under aseptic conditions for batch treatment of patients? We appreciate that this may be outside of licensing and would require consideration of governance and risk issues.
Section_4:	
Section_5:	
Section_6:	Consideration of a place in therapy for bevacizumab as well as cost effectiveness would be helpful
Section_7:	Consideration of which treatment option of PDT or Lucentis should be used would be helpful.
Section_8:	
05/07/2007-	Jul-2007 21:43:34
commentid:	200707050943341032
uniqueid:	_435391_200707050943341032
timestamp:	05/07/2007-Jul-2007 21:43:34
docid:	435391
title:	Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation
name:	
mailfrom:	
role:	NHS Professional
altrole:	Chair of Welsh Retina Group
location:	Wales
conflict:	no
discuss:	
dataprotection:	-1
Section_1:	The Welsh Retina Group are disappointed by the very restrictive interim guidance on treatment of wet macular degeneration published by NICE. If applied in its current form it is clear to us that many patients who could benefit will be denied treatment. We find it difficult to explain to our patients how the Scottish Medicines Consortium, after reviewing the same data arrived at such a different conclusion.
Section_2:	
Section_3:	
Section_4:	The major factor determining cost is the number of treatments required. The cost effectiveness model assumes 24 treatments over two years. Current evidence suggests that similar visual outcomes are obtaine with 14 treatments in the same period. This is acknowledged in paragraph 4.2.3.12. However in the concluding paragraph 4.3.14 the cost of monthly injections is quoted. If 24 treatments were administered (paragraph 4.3.10) but over a longer period than two-years, it is likely that the visual gain would be maintained. However the cost effectiveness model assumes that vision declines at a similar rate to the natural history of the disease beyond two-years (paragraph 4.3.8). The cost effectiveness model fails to take account of early cessation of treatment. In clinical practice treatment would not be continued if the

Section\_5:

The Welsh Retina Group recognises the need to make effective use of NHS resources (paragraph 4.3.1). We are very concerned by the potential shortfall in capacity (physical space and manpower) in many units. However this should not be used as an excuse for centrally limiting access to an effective treatment. Local services must evolve to meet the demands of the population they serve.

visual acuity drops consistently below 6/60. The assumption that treatment is provided on a day case basis artificially inflates the cost (paragraph 4.2.3.13). Most centres are planning to administer the treatment in a clean room in outpatients. The model underestimates the costs related to blindness (paragraph 4.3.13).

Section\_6:
Section\_7:
Section\_8:

# 09/07/2007-Jul-2007 16:10:59

**commentid:** 200707090410599917

uniqueid: \_\_\_435391\_200707090410599917

timestamp: 09/07/2007-Jul-2007 16:10:59

docid: 435391

Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation title: name: mailfrom: role: NHS Professional altrole: location: England conflict: no discuss: I am a consultant ophthalmologist with a specialist interest in medical retina, particularly macular degeneration dataprotection: The preliminary recommendations are extremely restrictive. Limiting the use of antiVEGF agents to these Section\_1: recommendations will leave a high proportion of the population with treatable wet AMD to go blind. The studies clearly show effectiveness across all disease subtypes. Macugen is clearly effective in the prevention of visual loss and would be a reasonable choice of agent in certain disease characteristics and in certain patient populations. There is a clear need for treatments that are effective in shutting down the neovascular process in AMD. Section\_2: The number of patients affected is large and the age group that are affected is increasing in size. The socioeconomic cost of caring for elderly people with poor vision is significant. Current best care is limited to PDT in classic lesions and in predominatly classic lesions if the patient is enrolled in the cohort study. The technologies are described accurately and well Section 3: Section\_4: The inclusion and exclusion criteria for the different trials are not given in detail. There were clear differences in the criteria for MARINA and VISION trials that mean that different populations were studied and the trials are not directly comparable. The comparison of lucentis in the ANCHOR trial with the control group data from the TAP study may well be flawed, unless the criteria for inclusion and exclusion from these studies were exactly the same. Conclusions drawn then on the cost-effectiveness of lucentis treatment may be wrong. Wtih regard to treating only the better-seeing eye, surely it is better to save the first affected eye if possible and offer treatment to the second affected eye if treatment fails in the first eye? What happens to patients whose dominant eye is affected first? Most recent data from the PRONTO study using 3 loading doses of lucentis and prn treatment after that, showed that the average number of treatments per eye was 5.6, a significant reduction on the initial 12. This data should be taken into account as it will significantly alter the cost-effectiveness calculations, for all types. Section\_5: Research into the efficacy and safety and cost effectiveness of bevacizumab in comparison with Section\_6: ranibizumab should be encouraged. The long term effects of anti VEGF agents should be studied. In theory the long term use of a selective anti VEGF agent is safer than that of the non-selective agents, both within the eye and systemically. There may well be a role for sequential treatment with different agents, e.g. use of Lucentis initially to shut down neovasularisation rapidly, followed by maintenance treatment with Macugen on an as required basis. This would have many advantages for the patient and for the NHS in terms of cost.

Section\_7:

Section\_8: This is a fast-moving area and I would suggest that the review date be brought forward to 2009.

# 09/07/2007-Jul-2007 17:14:35

commentid: 200707090514359562

uniqueid: \_\_435391\_200707090514359562

timestamp: 09/07/2007-Jul-2007 17:14:35

**docid**: 435391

title: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation

name:

mailfrom:

role: NHS Professional

altrole:

conflict:

location: England

discuss: Attended academic meetings sponsored by Pfizer/Novartis

dataprotection: -1

Section\_1: Second eye only treatment is not acceptable. There is no guarantee that the second eye will present with a treatable lesion (eg sudden haemorrhage, sudden drop in acuity, or minimally classic /occult (if excluded)).

Contrary to Andrew Dillon's comment patients usually do present with 1st eye involvement. The major advantage of these agents is treatment of minimally classic or occult CNV for which no treatment exists at present. Pegaptanib should be available as alternative in certain circumstances (eg following recent

Section\_2:

The mean number of Lucentis injections given in the PRONTO study was 5.5 in year 1 and expected to be Section\_3: fewer in year 2. Equivalent to a drug cost of approximately 7231.

PRONTO suggests in practice we will use fewer doses-perhaps 9.5 on average over 2 years. This will be Section\_4: performed as an outpatient procedure. Hence model grossly over estimates costs. With time lesions fibrose. It is therefore reasonable to assume that vision will be fairly stable at conclusion of treatment and not to decline at rate of usual care. This underestimates efficacy. Therefore based on clinical practice I believe cost effectiveness is much better than that calculated on the basis of a number of unsupported assumptions.

Section\_5:

Section\_6: Agree

Section\_7:

This is a rapidly changing field. Early review is recommended Section 8:

### 10/07/2007-Jul-2007 10:16:18

commentid: 200707101016182541

k\_435391\_200707101016182541 uniqueid:

10/07/2007-Jul-2007 10:16:18 timestamp:

435391 docid:

Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation title:

name:

mailfrom:

**NHS Professional** role:

altrole:

location: England

conflict: no

discuss:

I have been undertaking Anti-VEGF treatments since August 2006 both in the NHS and privately. We have undertaken some 70 patients and over 200 treatments. Our audited data just presented to the North West London Ophthalmology group at Western Eye hospital are very positive. Mean age 73, 90% of patients Static or improved vision, Overall improvement of 0.24 LogMar or 12 letter improvement. 70% of total improvement occurs after just the first injection. We used both Avastin and Lucentis and only one Macugen. Excluding failures ie where massive haemorrhages occured due to the disease etc... which we did not exclude above. Avastin produced on average +0.34 improvement and Lucentis +0.4. This is astonishing results, you really do not need statistics to see the benefit. We are a PDT treating centre and are well use to the results we get with PDT. Anti-VEGF of either agent Avastin or Lucentis is far superior. There is no question that these drugs work and work in all lesion types. Our audited figures confirm the Reseasrch data, this is real world results. Also it is evident that Avastin is just as good as Lucentis but hugely cheaper. The protection people are giving Novartis to insist that only Lucentis is used and not Avastin has to be challenged. One must keep in mind these drugs work and they save sight, the politics of the two drugs should be put aside and recommend to use the most cost effective. Also as an aside the Novartis Lucentis comes in a multi dose bottle, with enough for upto 6 probalby reaslistically 3-4 injections. Thus on a list of patients it is quite possible and safe to share the vial amongst 3-4 patients just as we do with Xylocaine and Lignocaine for instance. Pharmacies can prepare this in a sterile environment or it can simply be drawn up at the time. The fact that Novartis decided to go to market with a multi dose bottle rather than a more convenient single does syringe like Macugen and Avastin, leaves one to draw only one conculsion that they intended to supply more druge 0.3mls than is required 0.05mls so that one vial can be used for more than one pateint. This obviously reduces the cost also. Our expereione at The Hillingdon Hospital is very positive. Failure to allow all sube types and first and second eyes for AMD to be treated under the NHS will put Clinicians in a difficult position as the duties of a doctor as laid out by the GMC are quite clear that we have to put all options to the patient. You need to comment on what to say to patients who NICE do not recommend to treat. There is a duty of the doctor to point out there is effective treatment for your condition but you have to have this privately. Also you need to be aware this treatment is very effective in Vein occlusions, we have had pattents go from Hand movements to 6/9 with severe CRVO, and also in Diabetic macular odema. This is obviously not in the scope of the apprasial and like the PDT you may wish to comment on this.

# dataprotection:

### Section\_1:

Our audited figures show a 90% response rate across all lesion types. People do presesnt early for their first eyes in our area where we have a very supportative Optometrist network. Allowing a lesion to grow to a massive disciform causing distortion and vision down to hand movements, which is hte natural history of many classic lesions will affect the vision in the good eye. You cannot switch off an eye, thus any distortion or false images that these terrible lesions creat will be very annoying. There is clear benefit from these treatments and in an ideal world of course you would treat both eyes and allow the clincians based on our experience to apply the art of medicine which is based on the science which is always limited. Thus I do not agree with the finidings. This will force many to have their first eyes treated privately.

#### Section\_2:

Are we to continue with PDT for the first eye? What sort of consent will be needed as this treatment in the USA is now rarely done and rarely now done in the private sector. As PDT is not as effective we will ahve to consent them to this. Also is PDT more or less expensive than Anti-VEGF"s?? Thus how do we link the PDT assessment with the Anti-VEGF appraisal. My view is that PDT should be second line or as an adjunct where clinically needed and anti-VEGF should be first line in place of PDT at least in the sub-types PDT was recommended for though ideally for all lesion types.

#### Section\_3:

As mentioned Lucentis comes in a multidose vial - therofre cost savings can safely be made when you are doing a list of patients. One vial can do 3-4 pateints easily. The technique is either to get Pharmacy to prepare the syringes or during the list to draw the Lucentis up through the filter needle into a one mls syringe, then take an insulin syringe and draw up alloqots of 0.05mls. In this way 3-4 syringes are prepared from one vial and providing you then do the pateints one after the other, there is no increase risk of infection as you have to draw up the lucentis from the vial any way. Obviously does not apply to Macugen. Also it is a serious ommision not to include Avastin which Moorfields provide. It is chearper and in our audited figures very effective. In the real world people are using it safely and without problems, In the USA the usage is split between Avastin and Lucentis (AAO meeting survey). Thus if it is good enough for the Americans surly good enough for the NHS? Some pride has to be put aside here and be more practical if you are trying to save money and save sight. Put the patients first and politics and vested interests second.

#### Section\_4:

The studies were on different patient groups and it is not entierely clear if Lucentis is better than Macugen - head to head studies have not been done. However head to head study with Avastin would be very interesting and the IVAN, NEI and MEH trials will provide useful information.

#### Section\_5:

Additional funding will be required to implement smoothly. Currently PCT"s are often saying that as these durgs are not exculded in PBR then the hospitals have to fund them. Howver the hospitals cannot afford to do this due to the costs. So some guidance on fudning issues is required if this is to be smoothly and quickly impleneted. Acknowledgment of how much additioanl work this is to eye departments is important esp if the treatment criteria are widened. Delivery of this will be just as big a problem as with PDT and will take time to set up.

#### Section\_6:

COnsideration to at least some basic monitoring and audit data collected nationally is essential I think. I would not wisht the complex VPDT study, just basic information would be helfpul. You might though consider a brave move which is to allow the category you have mentieond to be done. But for the other category start a VPDT cohort study using Avastin which is far cheaper.

Section\_7:

PDT - you need to comment on whether this is still guidance for the first eye and what to do regard PDT or Anti-VEGF for the second eyes?

Section\_8:

Fine.

10/07/2007-	lul-2007 12:11:2
commentid:	200707101211021001
uniqueid:	_435391_200707101211021001
timestamp:	10/07/2007-Jul-2007 12:11:2
docid:	435391
title:	Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation
name:	
mailfrom:	
role:	NHS Professional
altrole:	
location:	England
conflict:	no
discuss:	
dataprotection:	-1
Section_1:	It is important to treat patient early as vision can deterioriate rapidly and irreversibly. So to restrict treatment until vision has deteriorated to 6/12 is inappropriate. Treatment should be offered however good the central vision. Ranibizumab has been shown to benefit patients with occult or minimally classic lesions so they should be treated.
Section_2:	There is good evidence that PDT results in loss of vision for most patients. After treatment very few can see to read or have useful central vision
Section_3:	
Section_4:	I am in favour of Lucentis being available for all subtypes of AMD in any eye as there is clear evidence of benefit. It is inappropriate to restrict treatment to the better eye as this reflects only a short term

rationing tool. Patients may develop untreatable AMD or any other condition in their better eye having been

refused treatment in the other eye. In Clinical practise many patients have a marked improvement in vision after 2 injections and preserve good vision for many months without further treatment. Treatment should be tailored to the individual patient and not given monthly if not required. Patients often present with poor vision. These patients may develop a marked visual improvement in which case treatment should continue (30%). However if there is no significant improvement then treatment will not need to continued in the long term as the vision will not deteriorate further.

Section\_5:
Section\_6:
Section\_7:
Section\_8:

## 11/07/2007-Jul-2007 13:16:52

commentid: 200707110116529514

**uniqueid:** \_\_435391\_200707110116529514

timestamp: 11/07/2007-Jul-2007 13:16:52

docid: 435391

title: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation

name: mailfrom:

role: other

altrole: relative of sufferer

location: England

conflict: no

discuss:

dataprotection: -1

Section\_1:

Section\_2: Section\_3:

Section\_4:

Whatever can be done to help AMD sufferers should be done, and quickly. The life difficulties arising from having only some peripheral vision are considerable, and mean that eventually the individual will become costly to the state because care will be needed. My relative has suffered progressively-worsening AMD for about 10 years. She was not told which type she has, just that her eyesight would deteriotate and she would have to live with it. There has been no follow-up, and no advice was given about prevention or amelioration of symptoms. I do urge that NICE propose the use of the best treatment available to as many sufferers as possible and as early as possible, and that people like my unfortunate relative, now lost to the system, should be re-appraised and treated accordingly.

Section\_5:

Section\_6:

It"s absolutely vital to carry out further research. As the population ages, more & more of us will suffer from AMD, we must know how treat it effectively and the DO IT. There is more state help for the hard of hearing than for those with poor vision, and this should be addressed.

Section\_7:

Section\_8:

## 11/07/2007-Jul-2007 20:23:5

commentid:

uniqueid:

timestamp: 11/07/2007-Jul-2007 20:23:5

docid: 435391

title: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation

name:

mailfrom:

role: NHS Professional

altrole:

location: England conflict: no

A member of my family suffers from this condition and has previously had to spend her savings on private discuss: treatment as recommended by her NHS doctor. dataprotection: -1 Section\_1: Section\_2: Section\_3: It is a shame that with ever tightening purse strings a hugely expensive treatment is being considered when an alternative, which many eye specialists are willing to use, is available- bevacizumab. It is even more of a shame that currently patients who need this treatment are footing the whole bill by having the treatment done privately, to save their sight who can blame them? If doctors are willing to and indeed recommending that patients use bevacizumab can it not be considered by NICE. Yes, there is the technicality that it is not a specifically intravitreal formulation, but considering the fact that it does not require 12 injections per year it already appears to be superior over the new treatment being considered. I am disappointed that Roche has not funded any trials into the use of their own product in what is a relatively common condition. Perhaps it would have been in the NHS's best interests to fund a RCT itself rather than now putting itself in the situation of having to pay a massive 18,300 per patient. All this means is that fewer people are going to have access to the treatment, can you justify this? Section\_4: Section\_5: Section\_6: Section\_7: Section\_8: 11/07/2007-Jul-2007 23:52:25 200707111152257983 commentid: uniqueid: \_435391\_200707111152257983 timestamp: 11/07/2007-Jul-2007 23:52:25 docid: 435391 Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation title: name: mailfrom: Patient role: altrole: England location: conflict: no discuss: dataprotection: -1 It should be for retinal specialists to make decisions on effective treatments. These treatments are Section\_1: accepted as being able to treat some patients and used in other countires. Therefore the guidance should be wider to ensure that they will be given where the Doctor sees a real benefit. I am very concerned about the proposal to treat the better eye. As you may know, the disease progresses differently in each eye and that each eye may respond differently to the treatments. So you could wait for the first eye to go blind even though it could have responded well to the treatment and then finding that the second eye responds less well. Too late!!! It would be interesting to know if this principle relating to dual organs is to be extended to other parts of the body (eg ears, lungs, limbs etc) or is it just a one off? The cost effectiveness comparisons (eg for no treatment) seem low and exclude key costs of carers, support, welfare benefits and lost economic activity and tax. Macular disease affects a lot of people. It can have a major impact on peoples lives and those of their Section 2: families. The Wet type can progress very quickly and hence early action is needed. These new drugs are the first ones that are able to tackle the disease and must be available where appropriate. In addition to the support given through the NHS, local authorities and others, a significant level of support is often needed from families. These are hidden needs, impacts and costs which do not seem to be taken into account in any of the review for this guidance. Whilst my condition is stable (a form of wet macular degeneration) and therefore not in need of the treatment today, I would be very concerned if it was not available on the NHS if my condition deteriorated and these treatments were clinically appropriate. These treatments are used in many countries and there is clear evidence that they can be effective. As Section\_3: these are new treatments it is understandable that the long term prognosis through their usage is less clear but they may be effective in the long term or superceded by other technologies but at least could have been able to preserve a useful level of sight As a patient, this section is difficult to fully understand, however there are some key points that I see here: Section\_4: - The human impact seems to have got lost in the figures and analysis. We are talking about real people being significasntly impacted by sight loss and this does not come across. - In relation to the "better eye"

proposal your analysis says to me that losing one eye is only marginal, hence there is not cost effectiveness to treat but it really does forget the way the disease affects two eyes differently and of course increase the liklihood of full blindness in the future. - The financial model does not seem to take into account the impact on family members. These are people who may have to give up work to help someone who is blind. These are significant impacts with high costs. In my situation I am fortunate to still be able to work. I earn a good salary and pay about 25k in tax each year (about 500k in todays money until I retire). If my condition worsens and I am not able to access relevant treatment then I could end up having to give up my job and requiring benefits to support me and my family. This could add to 1m or more, far more than the treatment.

Section\_5:

Thre must be consistency across the UK. It is simply not acceptable that there is a dependency on where you live. Should I have to rent a flat in Scotland to get treatment? Implementation must be based on clinical need.

Section\_6:

I support further research. Technolgy is rapidly improving and the guidance needs to reflect this, but this should not stop the availability of existing treatments.

Section\_7:

Section\_8:

If the issued guidance is as proposed then it should be reviewd in 12 months time. This will reduce the impact if the guidance, as I believe it is, is proved to be wrong. Waiting to 2010 is far too long.

### 12/07/2007-Jul-2007 0:42:47 commentid: 200707121242474517 \_435391\_200707121242474517 uniqueid: 12/07/2007-Jul-2007 0:42:47 timestamp: 435391 docid: Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation title: name. mailfrom: NHS Professional role: altrole: England location: conflict: yes discuss: dataprotection: -1 Ranibizumab is equally effective in all types of CNV, there is no reason to fund only predominantly classic Section\_1: CNV. Allowing the first eye to go blind before treating the other eye is immoral. Patients may suffer from other conditions and there are variable responses to the treatment. Section\_2: Section\_3: The committee ignore the clinical experience of using Lucentis around the world. Like most diseases, AMD is Section\_4: different in different patients. The fixed regimen in PIER is not appropriate. That is why the label on Lucentis in Europe is based on visual changes after the loading dose. Clinical experience has shown that this regimen can reduce injection frequency and to be equally effective as monthly injection. Since EMEA has accepted the evidence and decided on this label, why would NICE not accept it. The use of day case or outpatient tariff is also inappropriate. The clinical specialists are not specialists in given intravitreal injections. Most of us who has done large number of injections use a clean room rather than an operating theatre. The cost should be somewhere between day case and outpatient tariff. In the US, it is an office procedure ie the cost is similar to an outpatient tariff. That would reduce the cost and makes Lucentis cost effective for all lesion type. Section 5: Section\_6: Bevacizumab is not licensed for this condition. It has not gone through the usual safe guard. Patient safety is more important. If patient safety is not safeguard, why would EMEA and MHRA ask for so many steps before allowing a drug licensed. It is reasonable to consider an unlicensed drug when there is unmet medical need, but there is no evidence that Avastin is clinically more active than Lucentis. Once Lucentis is available in the NHS, it is not ethical to carry out the study. It is inappropriate to force patients to join such a study by restricting Lucentis use in the NHS. Section\_7:

If current draft document is carried, the review date should be much sooner as there are several on-going

### 12/07/2007-Jul-2007 11:27:40

trials looking at reducing in injection frequency.

commentid: 200707121127402104

Section\_8:

uniqueid:	_435391_200707121127402104
timestamp:	12/07/2007-Jul-2007 11:27:40
docid:	435391
title:	Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation
name:	
mailfrom:	
role:	other
altrole:	Public Affairs Adviser to the AOP
location:	England
conflict:	no
discuss:	
dataprotection:	-1
Section_1:	We support the views expressed by the Royal College of Ophthalmologists as outlined in their submission. We believe the NICE guidance is unacceptable and misguided for three reasons; Firstly, that treatment for patients with wet AMD will be restricted to those who have the Predominantly Classic form of the disease thus restricting treatment to around 20 percent of potentially treatable patients. Secondly, that delaying treatment until sight loss occurs in a patients second eye, having already lost the sight in the other eye, will lead to unnecessary visual loss and therefore greater rehabilitation and support costs Thirdly, restricting treatment to only one of the two possible treatments is illogical, has no real cost benefit and further restricts treatment options. Sight loss a devastating experience for the patient and a significant drain on national resources. Restricting and/or delaying treatment in the way NICE suggests is ultimately, we believe, a false economy as well as doing little to help those suffering permanent and disabling sight loss
Section_2:	
Section_3:	
Section_4:	
Section_5:	
Section_6:	
Section_7:	
Section_7.	
Section_8:	
Section_8:	Jul-2007 11:30:48
Section_8:	Jul-2007 11:30:48 200707121130487247
Section_8:	
Section_8:  12/07/2007-J commentid:	200707121130487247
Section_8:  12/07/2007-J commentid: uniqueid:	200707121130487247 _435391_200707121130487247
Section_8:  12/07/2007-J commentid: uniqueid: timestamp:	200707121130487247 
Section_8:  12/07/2007-J commentid: uniqueid: timestamp: docid:	200707121130487247
Section_8:  12/07/2007-J commentid: uniqueid: timestamp: docid: title:	200707121130487247
Section_8:  12/07/2007- commentid: uniqueid: timestamp: docid: title: name:	200707121130487247
Section_8:  12/07/2007-J commentid: uniqueid: timestamp: docid: title: name: mailfrom:	200707121130487247
Section_8:  12/07/2007-J commentid: uniqueid: timestamp: docid: title: name: mailfrom: role:	200707121130487247
Section_8:  12/07/2007-J commentid: uniqueid: timestamp: docid: title: name: mailfrom: role: altrole:	200707121130487247
Section_8:  12/07/2007-J commentid: uniqueid: timestamp: docid: title: name: mailfrom: role: altrole: location:	200707121130487247
Section_8:  12/07/2007-J commentid: uniqueid: timestamp: docid: title: name: mailfrom: role: altrole: location: conflict: discuss: dataprotection:	200707121130487247
Section_8:  12/07/2007-J commentid: uniqueid: timestamp: docid: title: name: mailfrom: role: altrole: location: conflict: discuss:	200707121130487247

Section_3:	
Section_4:	
Section_5:	
Section_6:	
Section_7:	
Section_8:	
12/07/2007-	Jul-2007 11:32:30
commentid:	200707121132302637
uniqueid:	_435391_200707121132302637
timestamp:	12/07/2007-Jul-2007 11:32:30
docid:	435391
title:	Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation
name:	
mailfrom:	
role:	other
altrole:	Public Affairs Adviser to ABDO
location:	England
conflict:	no
discuss:	
dataprotection:	-1
Section_1:	ABDO supports the views expressed by the Royal College of Ophthalmologists as outlined in their submission. We believe the NICE guidance is unacceptable and misguided for three reasons; Firstly, that treatment for patients with wet AMD will be restricted to those who have the Predominantly Classic form of the disease thus restricting treatment to around 20 percent of potentially treatable patients. Secondly, that delaying treatment until sight loss occurs in a patients second eye, having already lost the sight in the other eye, will lead to unnecessary visual loss and therefore greater rehabilitation and support costs Thirdly, restricting treatment to only one of the two possible treatments is illogical, has no real cost benefit and further restricts treatment options. Sight loss a devastating experience for the patient and a significant drain on national resources. Restricting and/or delaying treatment in the way NICE suggests is ultimately, we believe, a false economy as well as doing little to help those suffering permanent and disabling sight loss.
Section_2:	
Section_3:	
Section_4:	
Section_5:	
Section_6:	
Section_7:	
Section_8:	
12/07/2007	Jul-2007 11:33:38
commentid:	200707121133386932
uniqueid:	_435391_200707121133386932
timestamp:	12/07/2007-Jul-2007 11:33:38
docid:	435391
title:	Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation
name:	
mailfrom:	
role:	other
altrole:	Public Affairs Adviser to the College of Optometrists
location:	England
conflict:	no
discuss:	

dataprotection:	-1
Section_1:	The College of Optometrists support the views expressed by the Royal College of Ophthalmologists as outlined in their submission. We believe the NICE guidance is unacceptable and misguided for three reasons; Firstly, that treatment for patients with wet AMD will be restricted to those who have the Predominantly Classic form of the disease thus restricting treatment to around 20 percent of potentially treatable patients. Secondly, that delaying treatment until sight loss occurs in a patients second eye, having already lost the sight in the other eye, will lead to unnecessary visual loss and therefore greater rehabilitation and support costs Thirdly, restricting treatment to only one of the two possible treatments is illogical, has no real cost benefit and further restricts treatment options. Sight loss a devastating experience for the patient and a significant drain on national resources. Restricting and/or delaying treatment in the way NICE suggests is ultimately, we believe, a false economy as well as doing little to help those suffering permanent and disabling sight loss.
Section_2:	
Section_3:	
Section_4:	
Section_5:	
Section_6:	
Section_7:	
Section_8:	
12/07/2007-	ul-2007 15:26:49
commentid:	200707120326498346
uniqueid:	k_435391_200707120326498346
timestamp:	12/07/2007-Jul-2007 15:26:49
docid:	435391
title:	Macular degeneration (age-related) - pegaptanib and ranibizumab: Appraisal consultation
name:	
mailfrom:	
role:	Private Sector Professional
altrole:	Health Professional (within NHS)
location:	England
conflict:	no
discuss:	
dataprotection:	-1
Section_1:	As an optometrist in the community I regularly see patients with Macula Degeneration. Even before these new treatments it was always accepted that early intervention of wet changes was preferable to maintain good VA, not just to keep any level of vision. A binocular acuity of 6/12, presumably also poorer contrast sensitivity function is not comfortable or safe for driving, and would in most cases not meet the legal requirement to keep a licence. Our ""ageing population" are often fit and well with active lives, some still working. These injections can both prevent VA loss and sometimes improve it, I find it hard to believe this treatment is being reserved as a ""last resort" still!
Section_2:	
Section_3:	Is it really likely that this many treatments will be needed, and alternative PDT requires a more invasive angiogram each time.
Section_4:	Why wait until one eye already lost, if the first affected is treated successfully, then maybe the second eye won"t need to be!
Section_5:	
Section_6:	
Section_7:	
Section_8:	