

Patient Interest Groups

Submission of Evidence Template

Name of organisation submitting information	Royal National Institute of the Blind Scotland and Macular Disease Society
Date of SMC Meeting (if known)	

NB Not all sections on this form are required to be completed.

Disclaimer: *The comments contained in this document are not those of the company (licence holder), nor of SMC and are the responsibility of the submitting group.*

Section 1 – General Information

1.1

Submitting Organisation

Please provide an overview of the organisation making the submission, including the aims of the organisation and an outline of membership. Although SMC has access to epidemiological data, you may wish to provide additional information on numbers affected.

RNIB Scotland is Scotland's leading charity helping people with sight loss to lead independent and fulfilling lives. An increasing focus of our work is on sight loss prevention and access to treatment. As part of this work we aim to ensure that patients gain access to new, clinically proven treatments as quickly as possible.

The Macular Disease Society (MDS) has 782 subscribing members with macular degeneration in Scotland and provides services for many others who have not joined the Society. We aim to build confidence and independence for those with central vision impairment. MDS is the only Scottish charity dedicated exclusively to helping people with macular degeneration by providing practical support for visually impaired people, their families and carers. We also provide information for health professionals, campaign for better services, sponsor research and raise awareness of macular degeneration and its prevention.

Since the remit of both our organisations includes access to treatment appraisals of new treatments by the Scottish Medicines Consortium are of prime interest to us and we have decided to present a joint RNIB Scotland/MDS submission.

1.2**Declarations of Interest**

It is essential that you read the information on *declarations of interest* contained within the *Patient Interest Group Guidance* on submission of evidence before you complete this section.

A. *We have no declaration of interest to make*

B. *We have the following declaration(s) of interest in respect of corporate members and joint working/sponsorship:*

Both RNIB Scotland and the Macular Disease Society have working relationships with pharmaceutical companies (Lilly and Novartis) that include small one-off educational grants for our work. However, we take great care to avoid bias and fully support a clinician's role in deciding what medication is best for his or her patient. Unfortunately, we missed the deadline for making a submission to the SMC when Macugen (pegaptanib) was appraised for use in wet age-related macular degeneration. However, we have made a submission in favour of both treatments to the National Institute for Clinical Excellence and have been campaigning for access to the new anti-VEGF treatments on a generic basis wherever possible.

C. *We have the following declaration(s) of interest in respect of those playing a significant role in compiling this submission:*

1.3 In its advice to NHS Boards and their Area Drug and Therapeutics Committees, SMC normally makes reference to having considered a patient interest group submission. If you would prefer your organisation not to be named, please tick this box.

1.4 Currently available medicines

From a patient/carer perspective, please outline their experiences in respect of medicines currently available, including perceived advantages and disadvantages, preferences and needs both met and currently unmet. Provide us with any information that you feel will help SMC understand how this health problem affects patients/carers. Please identify how you obtained this information, e.g. helpline, existing database, published/unpublished research and user-perspective literature, focus groups, one-to-one conversations with a number of patients, etc.

Sight Loss in Scotland - Age-related macular degeneration (AMD)

An estimated 188,000 people in Scotland have serious sight loss¹ including 38,000 people who are registered as blind or partially sighted.²

Age-related macular degeneration causes a progressive, irreversible loss of central vision in older people and accounts for more than half of all cases of registration for blindness or partial sight. As its name suggests AMD affects the macula of the eye and refers to a spectrum of changes which appear with increasing age. In the early stages of the condition the macular retina exhibits characteristic changes. A proportion of eyes develop subretinal exudation and haemorrhage as a consequence of choroidal neovascularisation (CNV). CNV leads to fluid accumulation under the retinal pigment epithelial and/or the neurosensory retina with or without haemorrhage and the associated clinical picture is termed exudative or wet. Wet AMD is the most aggressive form of this disorder and has significant public health implications. People with severe vision loss often suffer chronic morbidity and diminished quality of life associated with high levels of emotional distress. They become unable to read, drive, recognise faces, tell the time and carry out many other everyday tasks. People with sight loss are at a substantially increased risk of falls, hip fractures and depression, and are high users of healthcare and community support services. People with AMD who are registered partially sighted or blind are eligible for benefit payments and are at increased risk of admission to residential care. The impact of AMD on patients is described in more detail below.

¹ RNIB Scotland Election manifesto – Actions for the Scottish Parliament 2007/2011. 2007

² Statistics Release. Executive National Statistics Publication: Registered blind and partially sighted persons, Scotland 2003.

www.scotland.gov.uk/Publications/2003/10/18386/28181

Our approach

As major patient organisations both RNIB Scotland and MDS are keen to present a patient perspective in the discussions that will lead to a decision by the SMC as to whether ranibizumab will be made available to patients through the National Health Service.

This submission aims to make the case for a patient-centred discussion of the benefits of this treatment. We will start with a discussion of the impact of AMD on a patient's life. We will then go on to discuss patient experiences in respect of existing treatments.

As a point of principle we should emphasise that we believe strongly that it would be wrong and unfair to consider imposing any form of rationing on the use of anti-VEGF treatments, including ranibizumab. Treatment should be made available for any eye judged by a qualified clinician to be likely to benefit from the treatment and clinicians should be the ones to decide whether patients would benefit most from ranibizumab or pegaptanib, the second licensed anti-VEGF treatment that has already been appraised by the SMC.

Methodology

For this submission we have used the following methodology:

- Literature review and primary research commissioned by the AMD Alliance International into AMD and its impact on quality of life
- Telephone interviews about the impact of AMD on their quality of life with 4 patients
- Case studies of 4 Scottish patients treated with ranizibumab

Impact of AMD on quality of life

Scientific evidence

Studies into the impact of AMD on a patient's quality of life have used a variety of measuring tools ranging from health status measures to functional status measures, vision-specific functional status measures, psychological well-being measures and vision-specific quality of life measures. In addition time trade-off and standard gamble techniques have been used to calculate Quality Adjusted Life Years (QALYs) as a way of assessing the benefits of treatments. QALY's were used by NICE in its appraisal of photo-dynamic therapy.

A literature review commissioned by the AMD Alliance International argues that many of the measures used do not actually measure quality of life but individual elements that each contribute to a person's quality of life. The authors argue that the majority of studies measure visual function (7 out of 23), four measure functional status, three health status, two well-being, four well-being including positive wellbeing, one life satisfaction and only two measure quality of life (the Psychological and General Well-being Index – PGWB – and the Measure of the impact of MD on QoL – MacDQoL).

The authors strongly question the use of QALY values to measure quality of life in AMD patients. They contend that: "The QALY values obtained using time trade-off and standard gamble methods are not measuring quality of life and such measures give no impression of the ways in which MD impacts on a person's life. There are many reasons why a person may not want to relinquish any years of life in spite of serious visual impairment but this does not imply that they are content with the present situation or that their quality of life would not be much better without their vision problems." They go on to assert that the studies reviewed by them show that AMD has a damaging effect on many aspects of people's lives ranging from reading, driving, recognising faces, watching TV and other near activities to psychological well-being. However, the extent to which macular degeneration impacts quality of life depends largely on individual lifestyles and personal characteristics as well as factors such as social support, co-morbidity and access to comprehensive low vision services that include the provision of low vision devices and daily living aids as well as mobility training, financial and benefits advice and, most importantly, emotional support.

Recognising the problems of measuring Quality of Life with just one measuring tool, Pfizer sponsored research into the impact of AMD on quality of life that combined a number of measuring tools to cover all aspects affected by the condition.^{3 4 5} 401 people with choroidal

³ Mitchell J, Bradley C: QoL in AMD: A review of the literature

⁴ Soubrane G, Cruess A, Lotery A, Pauleikoff D, Monès J, Xu X, Zlateva G, Buggage R, Conlon J, and Goss T: Burden of illness, visual impairment, and health resource utilization of neovascular age-related macular degeneration patients: results from a five-country cross-sectional study.

neovascularisation in both eyes and 471 people who did not have AMD were interviewed by telephone in five countries (Canada, France, Germany, Spain and the UK). Participants were asked to complete the National Eye Institute Visual Function Questionnaire (NEI-VFQ-25), the EuroQol Questionnaire (EQ-5D), and the Hospital and Anxiety and Depression Scale Questionnaire (HADS). In addition, the interviewer took a history of falls, fractures and health resource utilisation.

The results of the study confirm the significant impact that wet AMD has on a patient's life. A diagnosis of age-related macular degeneration often brings with it both practical and psychological problems. AMD leads to loss of central vision needed for activities requiring fine vision such as reading, driving and recognising faces. Peripheral vision is usually retained but the majority of daily living activities and emotional well-being can nonetheless be severe.

People with AMD score 45 per cent lower on the NEI-VFQ-25 scale than people in the control group. In terms of health status, as measured by the EuroQol questionnaire, the relative difference between people with AMD and the control group is 13 per cent.

Significantly, the study highlights the importance of dealing with the emotional needs of people with AMD. The results show significantly higher levels of anxiety and depression in this group. Whereas members of the control group had anxiety levels of 4.7 out of 21 the anxiety levels of those with AMD were 30 per cent higher with 6.7 out of 21. The difference for depression is even higher at 42 per cent with the control group scoring 4.1 out of 21 on the depression scale against 7.1 for the group of AMD patients.

Not surprisingly, most of the results were affected by the level of acuity in the better-seeing eye. The higher the level of sight loss, the lower the NEI-VFQ-25 scores, particularly in relation to near activities (reading, watching television), distance activities (recognising faces across a room) and driving. Also, the higher the level of sight loss, the higher the anxiety and depression levels.

⁵ Chakravarty, U: A crisis in vision loss: Social, financial and health impact of AMD. Why Wait: Responding to a growing crisis of vision loss. Proceedings Paper from AMD Action Summit. AMD Alliance International. October 2006

People with reduced visual functioning rely more on assistance from others. If they are not treated to help them overcome their anxiety and depression, rehabilitation outcomes may be compromised even further, increasing the need for assistance.

The study clearly shows the assistance needs of people with AMD that affect health and care systems as well as informal carers. Study participants with AMD were three and a half times more likely to need help with daily activities and home care than people from the control group. They were also almost three times more likely to need help with self care. In addition to problems looking after themselves in their own home, people with AMD face considerable challenges when dealing with the outside world: they are four times more likely to need assistance with leisure activities, five times more likely to need help with transportation to access health care, almost eight times more likely to need help with transportation in general and 17 times more likely to require help with administrative tasks.

Their risk of falls is double that of someone with normal sight, they are twice as likely to require treatment for falls and three times as likely to suffer fall-related fractures.

These results make it very clear that any treatment that halts the progress of age-related macular degeneration or even reverses existing sight loss will not only help people with AMD avoid the distressing emotional consequences of AMD and the increased risk of dependency on others, it will also significantly reduce the cost of AMD to society by reducing the costs associated with blindness. These will be discussed in more detail below.

At this stage, we would like to give a voice to two patients who have lost their sight due to AMD.

Name	Patient A
Age	66
Marital status	Married

Patient A retired from his post as lecturer in economics due to vision loss and depression.

Patient A has wet AMD in both eyes. He was diagnosed with extrafoveal AMD in his first eye in 1995 and within a year the second eye developed subfoveal AMD. Since photocoagulation in his first eye was unsuccessful and there were no treatment options for subfoveal AMD he was registered as blind in 1996. His initial reaction was one of confusion and shock at suddenly losing an ability that he had taken for granted. As a lecturer he took for granted the intensive reading requirement of his job and continuous marking of student scripts. Now with a key part of his sight gone and with no obvious sources of help to support him and his own assumption that he would not be able to get back to a normal level of competence as a lecturer, he accepted early retirement.

Losing his job was devastating. He lost his confidence and became extremely dependent on his wife struggling to recapture any degree of self-motivation and independence. He developed a fear of going outside even into familiar environments. Daily routine tasks such as shaving or dressing became a challenge. His personal world shrank.

"Before I lost my sight I enjoyed being active socially, going to the cinema, theatre, art galleries and concerts. Having lost my sight these recreational activities are largely unavailable to me in accessible forms for proper enjoyment. Consequently I feel I now have very restricted opportunities for pursuing the range of recreational, cultural and intellectual interest that were open to me previously. With this impoverished quality of life came a more restricted range of social contacts thus reinforcing my sense of social isolation. Another aspect of the eye condition that I continually experience is a real sense of being disconnected from normal social contact by not being able to see people, faces, expressions, body language, all of which are so important in

normal personal / social communication."

The fact that his disability is not immediately obvious makes this even more difficult as he keeps having to tell people that he is blind which in turn is a constant reminder of his disability and the limitations it puts on him.

An additional point made by Patient A was that confidence and low self esteem led him to become de-motivated with regard to his returning to paid employment. This had an adverse effect on his earnings over the subsequent years and affected his pensionable earnings as well. Furthermore, due to the burden of care placed on his wife, she was not able to continue in employment for some time with a knock-on effect on her earning capacity.

Breakthrough

The breakthrough for Patient A came around two to three years after he had lost his sight when he "stumbled across" the Macular Disease Society and realised that there were many more people in the same situation. He was also referred to counselling by a sympathetic GP which helped him move through the grieving process that is associated with severe sight loss.

10 years on he has learned to cope much better. "I have discovered many new things and low vision devices and computers make life easier." However, Patient A does make the important point that to equip oneself with these and to undertake the necessary training can be expensive and very time consuming. Many sufferers are put off as a result.

"I would still say that my quality of life is much reduced. However, the difference is that I, along with many other people with wet AMD, have learnt to accept that. The investment of time, money to try to access visual and printed media which is readily available to sighted people is often disproportionate relative to any perceived benefit. Nonetheless, it is sometimes hard to avoid self pity and even now I experience ups and downs that are a direct result of my sight loss."

Name	Patient B
Age	66
Marital status	Married

Patient B was forced to resign due to his wet AMD.

Patient B has wet AMD in both eyes. He was diagnosed at the age of 61 and registered blind within a year.

The blow was especially bitter because Patient B lost his vision just before photodynamic therapy (PDT) was licensed. He was living in the USA at the time of his diagnosis, and his physician asked the FDA for special permission to treat Patient B urgently. This request was turned down.

At the time of diagnosis Patient B was a senior executive at the height of his career in a global business. He had held this job for 12 years and was responsible for 3,000 staff and a multi-million dollar budget. When he lost his vision, Patient B could no longer keep his job. He moved back to the UK.

It was sudden and shocking change. "One day I had a 14-hour calendar with a lot of decision-making, and business and social meetings. Then I was walking along a beach in Scotland with no support."

Patient B quickly descended into deep depression. He thought about suicide and even planned exactly how he would end his life. His family rallied around, and with help from his GP Patient B got treatment, including anti-depressant medication and psychotherapy. His recovery took several years.

Patient B eventually came to terms with his disability but there are still many things that he misses. The biggest loss by far, he says, is being able to read non-verbal cues when talking to others. He knows from his executive experience that the majority of communication depends on facial expression and body language, on gestures that go far beyond the meaning of the spoken word.

He'd like "just to be able to look across a room and see if my wife's smiling at me ... or grimacing." The uncertainty has changed him

and made him more reticent, he says. He is less likely to tell a joke – or speak up and say something that another person might not like – because he can't read reactions.

Patient B and his wife have given up their dream of retiring in California, where they had bought a home. Public transport is poor and it's impossible to live there without driving.

Getting involved with the MDS helped Patient B find a purpose in life again. His own life has been difficult but he worries more about the thousands of people who don't have the resources that carried him through. Too many, he says, creep back home after hearing their diagnosis to live silently with their despair. "That's what keeps me awake at night."

Name	Patient C
Age	68
Marital status	Married

Patient C worked as a nurse but had to retire early due to her sight loss.

Patient C has wet AMD in both eyes. Her condition was diagnosed ten years ago, but she still remembers it as clearly as if it were yesterday.

She had gone to her optometrist because of some changes her vision. The optometrist suggested visiting the GP but based on her experience as a nurse, she decided to save precious time by going straight to the top. She camped out in the consultant's clinic until she was seen.

Hearing the news was dreadful, though. "I couldn't believe what the doctor had said. He said he would register me as blind. It was a sunny day. We drove home in absolute silence."

Crying in the night

In the course of a long nursing career, Patient C had never heard of AMD. She searched long and hard for information. Next came

feelings of denial. "You end up not wanting to accept what you've heard," she says. This phase lasted for a few months. "I'm not the sort of person to be miserable but it really does get you depressed, and insecure, and very angry. I couldn't believe there was no treatment."

She felt uncomfortable telling her family the news, partly because her new disability wasn't physically apparent – to anyone else, she still looked the same as ever. At night, while her family slept, Patient C would sit alone and cry. The dog kept her company, with his head in her lap. "Some people never get past that point," she adds.

Spontaneity gone

Patient C is not a timid person, either, but since she lost her vision she's afraid to answer the door at night when she's on her own. Life is not spontaneous any more, because every outing has to be carefully planned. "You avoid things that will make you feel uncomfortable. It's a very isolating problem."

And she misses the freedom of being able to drive and go shopping by herself. "I don't go out window shopping any more, or shopping on my own. Crowded places are dreadful because you can't see people coming towards you." Patient C has had a few falls, too, which were frightening, and she worries about having a serious injury one day.

Can't see grandchildren

It is the emotional gaps that hurt the most, though. She adores her grandchildren but is not able to see their faces. One defining moment came when she went to watch a grandson's first football match, and could not make out the figures on the field. It was then that the full extent of her disability hit home.

Over the years she has done her best to get on with things. "I tell people macular disease is an uninvited guest in my life, but it's not the centre of my life."

Currently available treatments

The currently available treatments for wet AMD are:

- Photocoagulation

- Photodynamic therapy
- Pegaptanib (Macugen)

Photocoagulation

Photocoagulation is a treatment option that is only available to patients with extrafoveal choroidal neovascularisation, ie with new blood vessels that have formed outside the centre of the macula, the fovea. Extrafoveal CNV only affects a small minority of patients (less than 10%). Since the new anti-VEGF treatments have not been tested in this category of patients photocoagulation is likely to remain the preferred option for treatment of these patients.

Photodynamic therapy (PDT)

Photodynamic therapy (PDT) uses a cold laser to activate a substance that has reached the macula through an intravenous injection. This substance allows the leaking blood vessels to be sealed. It slows down or halts the progression of vision loss in approximately 20% of patients with subfoveal CNV. PDT is likely to remain a valuable treatment option for eligible patients where

- They are less suitable for treatment with Anti-VEGFs, for instance because they have had a stroke.
- They refuse treatment that involved an injection into the eye.
- The treating clinician feels that a combination therapy using both PDT and anti-VEGF treatment is the preferred option.

Pegaptanib (Macugen)

Pegaptanib is the first anti-VEGF treatment to be licensed in the UK for the treatment of subfoveal choroidal neovascularisation (CNV) in wet AMD. It was approved for use on the NHS in Scotland in August 2006 with certain restrictions regarding treatment thresholds. Pegaptanib has been proven to be effective in halting deterioration of sight in most patients and to improve sight in a small minority of patients (primarily those presenting early for treatment). Before Lucentis was licensed Macugen was the only licensed treatment option for patients with subfoveal CNV who were not eligible for PDT. However, even though the SMC has approved Macugen for use on the NHS it is not widely available. To date only a minority of patients are being treated so any judgement about both anti-VEGF treatments, pegaptanib and ranizibumab have to be based on the outcome of clinical trials rather than experiences in clinical practise.

Section 2 – Product Specific Details

2.1 Potential Impact

If this new medicine were to be made available how would it match up to user needs and preferences; what would be its advantages and disadvantages over currently available medicines: and how might it impact upon the lives of patients and carers? Please identify how you obtained this information, e.g. helpline, existing database, published/unpublished research and user-perspective literature, focus groups, one-to-one conversations with a number of patients, etc.

Making ranibizumab available on the NHS alongside pegaptanib will determine whether we can turn wet AMD into an avoidable cause of sight loss.

This is putting it in a nutshell. In terms of user needs and preferences it is very clear that the majority of patients with wet AMD will be keen to be treated with Lucentis because it has been shown to be more effective than pegaptanib at halting sight loss and it offers the very real chance of improving sight in patients who have not received early treatment. There are disadvantages in treating patients with ranibizumab rather than pegaptanib in that the treatment frequency is higher. Even if patients do not need injections every four weeks as initially thought they will still have to go for regular check-ups every month. This can be a disadvantage to patients especially where they rely on relatives or friends for transport. However, the initial concerns about the treatment frequency have so far been shown to be unjustified as compliance with treatment appears to be extremely high⁶.

There are also concerns about giving ranibizumab to patients with a history of stroke. Pegaptanib or PDT may be the preferred option for these patients. This is not necessarily because the risk is very high (1.2% of 1000 patients treated with 0.5mg ranibizumab) but because of the perceived risk based on press reports which may sway patients to consider alternative options.

⁶ Statement by Sandy Taylor, Royal College of Nursing at meeting of the Cheshire & Merseyside AMD Task and Finish Group in Chester on 6 February 2007.

In general, the thought of an injection into the eye may not be acceptable to all patients and those who are eligible for PDT may therefore decide to refuse treatment with anti-VEGFs.

In reality very few patients will pass the opportunity to be treated with a drug that has such a good record of maintaining sight and even offers the promise of retrieving sight already lost. It is understood that no patients to date have refused an injection (EyeCare Scotland). The following four case studies illustrate how ranibizumab affects the lives of patients.

Name	Patient D
Age	78
Marital status	Married

Patient D started experiencing difficulties reading in artificial light around June 2006 and thought he may need stronger glasses. He was also experiencing some blackish grey spots in his vision but was still driving at this point.

After a visit to his optician Patient D was told he needed an immediate appointment at the local hospital for further assessment. However Patient D had to get a referral from his GP to the hospital before he could get an appointment, which took another month. Tests were then carried out and Patient D was given the unfortunate news that he had wet AMD in his left eye and that he would have to give up driving (his right eye was still ok).

“It is difficult to read the labels on packets of food,” he says, “but this does depend on the colour of the label and the colour of the print they use. Also with newspapers – it depends on what font the paper uses, some are easier to read than others. Good quality papers I can read like the Scotsman but the Radio Times Video Plus figures are very difficult although I can still watch the television.”

“Reading has been my main problem,” continues Patient D “but I do still play golf, although when I am putting on the green, the ball doesn’t line up as well as it used to.”

Patient D accepted the bad news about his left eye but decided that he wanted a second opinion and so two weeks later in August 2006 he had an appointment booked to see a second consultant in Glasgow. After lots more tests the consultant advised that injections with Lucentis would help and Patient D decided to go ahead with three treatments, in October, November and December 2006, paying privately for both the injections and private hospital facilities

After the first injection Patient D did see a degree of improvement in his vision and said: "I feel reading is better and further deterioration in my sight has been arrested. I can also now read again with a side light on."

Following the second injection Patient D began to notice that there was a definite improvement in his vision and he was advised that there was no further leakage of fluid from the back of his left eye. After the third injection Patient D was advised that the macula was completely dry.

"Had I heard of macular degeneration and its effects sooner I probably would have pushed to get seen earlier," says Patient D. "I would encourage people to have a go with Lucentis."

Name	Patient E and wife
Age	76 years
Marital status	Married

In September 2005 Patient E was concerned that there was something wrong with the vision in his left eye, as vertical lines started to appear all wavy. He thought it was something to do with his glasses and went back to his optician thinking he had been given the wrong prescription.

The optician checked Patient E's eyes and decided to refer him to the local hospital for further investigations, where he was diagnosed with wet AMD in his left eye. The right eye at this time was normal. Patient E saw his consultant on a couple of occasions over the next few months and noticed a slight further deterioration

in his vision during this time. Although no treatment was recommended Patient E continued to see his consultant on a three-monthly basis to have his sight monitored.

Due to the deterioration in his sight, Patient E was forced to give up reading newspaper print and now has to use an infra red camera which puts the print onto the television screen so he can read it.

While reading the news in this way in June 2006 Patient E read about a new treatment for wet AMD which was not mentioned by name. He asked his consultant about the treatment and was referred for a private consultation for further discussion. Patient E was advised by the doctor that there were two treatments for wet AMD that may be suitable for him – Macugen and a newer treatment called Lucentis. Patient E was advised that although more expensive Lucentis was the better option and so he decided he wanted to try it.

Patient E has subsequently had five Lucentis injections in his right eye to maintain vision and four injections in his left eye. The right eye is the better eye as the central vision in the left eye has now more or less gone.

After the first injection Patient E noticed a continual gradual improvement in the vision in his left eye. “I can read subtitles; I can read better than before, although I still can’t see to read my organ music,” he says. “I have stopped driving but I can see the bigger road signs and my vision is a good deal better than it was two to three months ago.

“I can still see enough to hit the ball when I play golf,” says Patient E “but I can’t see where the ball goes. I can see twenty yards away from the ball so there has been some improvement in my sight and I am still trying to do all the things I did before including pouring a cup of tea although I can’t see when the tea gets to the top of the cup!”

“If you can afford it, have this treatment,” he continues. “My sight could have got worse if I had not had this done. The vision in my right eye is holding on, if not even improved slightly. The treatment appears to be helping, has been very valuable and I would

recommend it.”

Patient E’s wife also comments: “I can see small improvements in his sight. One day quite suddenly he will be able to see something that he couldn’t see before. The treatment is definitely helping – I think he is frightened to believe that his sight is improving. For example, he can now see the clock on the video which he couldn’t see before.”

Name	Patient F
Age	82 years
Marital status	Married

Unlike most people with AMD, Patient F knew about the condition long before he was diagnosed, because a friend had it.

So when he first heard his own diagnosis in the Spring of 2006, Patient F was devastated. He knew this was a condition that causes blindness, and which progresses very quickly. AMD is sudden, occurs without warning and the decline is very rapid, he explains.

The doctor said that Patient F had wet AMD in his right eye and he was told that laser treatment would not help. He did go on to have a treatment called Macugen, through a series of three injections into his eye. But the results were disappointing.

Then, when he was having a routine eye check with his optometrist, the second blow came. He now had AMD in his other eye. “I was absolutely shattered,” Patient F says. He had always lived an active life, serving as an RAF pilot in the second world war and travelling around Scotland in his job as a salesman in the oil industry. Now he faced the prospect of going blind, and he was already having trouble reading, pruning the garden or recognising faces in the street.

But this time, his doctor was able to offer him a new option, a treatment called Lucentis. This is also given as an injection in the eye – a prospect that Patient F did not relish. In the event, he

found the procedure “uncomfortable rather than painful.”

He feels the treatment has been worth it. There has been some improvement in his right eye and the vision in his left eye has for the time being stabilised. He’s driving again, at least in the daytime. “Faced with the prospect of going blind, you’ve just got to go ahead with it.”

Saving his sight has come at a high cost, though. Lucentis is not available on the NHS so Patient F has had to pay for private treatment. He wants to congratulate his local health board for making Macugen available on the NHS, and hopes it will soon decide to fund Lucentis as well.

Name	Patient G
Age	73 years
Marital status	Widowed

In November 2005 Patient G woke up one morning to find the sight in her right eye had nearly gone. All she could see was blackness so she made an appointment straight away to see her optician who immediately put her in touch with the local hospital. Patient G was given an appointment the next day where she was told there was bleeding at the back of her right eye. The left eye was normal. Her optician advised her to keep a watch on the left eye and if she experienced any changes in her vision to get in touch straight away.

At the end of March 2006 Patient G’s sight started to change in her left eye. Looking at an eye chart her vision had become ‘wobbly’ so she was referred back to the hospital for further investigations. Patient G was referred to a hospital in Glasgow but whilst waiting for her appointment the left eye had started to deteriorate. She then had to travel up to Glasgow every six weeks for check-ups for her left eye to be monitored.

“I was devastated when I was told I had macular degeneration,” says Patient G, which has had a big impact on her life. Patient G used to enjoy sewing, patchwork and reading and now she finds

these impossible. “I can’t see, knit and I can’t read,” she says. “It is difficult to read labels and to cook. I can’t cope without equipment to help me. I can’t phone people I know as finding their telephone number is difficult and it has been devastating trying to cross the road as cars suddenly appear.”

During one of these check-ups Patient G asked her consultant about Lucentis. Although she would have to pay for it herself Patient G was keen to try the treatment. “You have got to try,” she said. “I have savings which I can use if this means I can continue living on my own.”

Patient G received her first Lucentis injection in August 2006 – the treatment stabilised her vision. After the second injection, a month later, Patient G did notice a slight improvement in her vision. Two further injections have maintained Patient G’s vision. She reports, “the first four injections have maintained my vision and it has not got any worse. I have had a fifth injection but it is too soon to say what has happened as a result of this one.”

“My general roundabout vision has improved though,” continues Patient G. “I couldn’t read the overhead gantries over the motorway before treatment but after two injections I could and I can also still see the gantries at night from a distance.”

“Things have worked out quite well with this treatment. It lets you continue to live. I couldn’t see the table opposite or people before but now I can see the detail of the sun shining on a building. If I am close to people I can also see their faces,” says Patient G “and I will do anything to help get this treatment on the NHS.”

These cases illustrate the benefits of treatment. They also show how important it is for people to be diagnosed early to maximise their chances of retaining their sight and minimising the effect of wet AMD on their lives.

Finally, they show the importance of making the ranibizumab available on the NHS. We believe that there is no justification for putting somebody in a position where they can only save their sight if they can afford private treatment. Given the way wet AMD affects patients’ lives there is a strong moral imperative to provide treatment to all those who need it, not only to those who can afford it. There are also good financial reasons why

treatment should be provided on the NHS. These are discussed in the following section.

2.2 Additional information

Please include any additional information you believe would be helpful to SMC.

The costs of not treating patients with wet AMD

A prevalence based estimate for 2001/2

In the appraisal of new treatments for eye disease it is important to look at the costs of sight loss both to the individual and the wider society. Whilst this "burden of illness" approach will not replace cost effectiveness analysis, it provides a valuable context and an insight into the effects of either providing or not providing treatments.

In 2004 RNIB published prevalence based estimates of the economic and social costs of vision loss for the UK. These were based on detailed expenditure data for 2001/2, assembled from central government, local government, voluntary sector and private sector sources. As can be seen from Table 1 below, the study indicates that the total annual cost of sight loss was in the region of £4.9 billion.

Of this total some £1.3 billion is accounted for by direct health and social care costs. This covers, for example, general ophthalmic services, ophthalmic treatments, GP consultations and drug costs. It does not however include the cost of mental health services for those experiencing depression following the onset of sight loss. Also it does not include the cost of falls due to sight loss which has been estimated as in the region of £200m a year.

It should be noted that the £1.5 billion cost of informal care provided by family and friends is just as much a real cost as the £150m spent by local government on social care. Whilst this care is unpaid and not subject to market valuation, it is nevertheless important. It contributes to well-being just as much as paid care provided by the local authority or private agency.

Table 1 Economic cost of sight loss in the UK: 2001/2

Service	Total Cost (£ millions)
General ophthalmic service	366
Ophthalmology treatments	668
GP consultations	98
Prescriptions/drugs	92
Low vision services	8
Local authority community care	150
DLA/AA	254
Blind persons tax allowance	10
Transport	150
Education and training	165
Employment services	16
Voluntary sector	163
Informal care by family and friends	1,500
Non-NHS eye tests	122
Private Sector:	
Articles for the Blind	35
Audio description	2
Productivity loss	1,083
Total cost	4,892

Source: The cost of sight loss in the UK, RNIB, 2004

Another important cost is attributable to productivity loss. Blind and partially sighted people are far less likely to be in a job than the general population. Overall they face a 75% unemployment rate and, as we have seen from a number of the case studies, the onset of sight loss frequently leads to the loss of paid employment. This we would argue is not a short-term transitional problem, rather than a real cost both to the individual and to the economy.

The provision of effective treatments that prevent sight loss due to wet AMD will mean fewer people in their 50's and 60's losing their jobs. This is to be welcomed and will help to reduce the numbers of blind and partially sighted people moving onto Incapacity Benefit and Income Support. It must be of particular importance given the Government's intention to raise the retirement age to 68 and its aim to achieve an 80% employment rate overall.

The need for a wider focus

RNIB and the MDS would urge the SMC to take into account a much broader range of costs when making decisions about new treatments for eye disease. By only looking at NHS and Personal Social Services costs the full impact of sight loss on society and the Exchequer is missed. As we have seen, the true cost of letting someone go blind and providing "best supportive care" is very high. By failing to focus on the whole picture there is a real danger of sub-optimal investment in new treatments

Implementation

Even though SMC guidance is not mandatory and the SMC is not involved in its implementation we feel that it is essential to discuss the predicted problems with the provision of treatment if ranibizumab is approved by the SMC.

The introduction of PDT in 2004 was delayed by nine months after the final appraisal because no work had been done to prepare services for the provision of this new treatment. We know that SMC guidance on Macugen is only now slowly being adopted by most Health Boards in Scotland⁷. Macugen is not widely available other than on a private basis and requests to fund Lucentis on a case by case basis prior to SMC guidance are regularly turned down. The same is likely to happen with Lucentis unless urgent steps are taken to prepare services for the predicted increase in patient numbers. Work is currently being carried out by the Royal College of Ophthalmologists to recommend fast track referral pathways and the most efficient service configuration to provide the new anti-VEGF treatments.

Health Boards have been aware of the need to increase service capacity since Macugen was approved for use on the NHS. There are a variety of reasons why they did not implement SMC guidance including:

- Lack of planning
- Lack of adequately trained staff
- Accommodation shortage (need for clean rooms or theatres to provide treatment)
- Funding.

⁷Evidence from conversations with clinicians in Scotland and with affected patients who have contacted RNIB and the Macular Disease Society for help.

This is not surprising since a report by the National Audit Office published in 2005 found that only 26 per cent of NHS bodies participating in their study regularly undertook horizon scanning to assess the financial impact of forthcoming guidance on their organisation. We have to accept the sad fact that many patients with wet AMD will have lost their sight needlessly unless they were able to fund treatment privately. This situation is unacceptable to patients and to their families.

Conclusion

Nine out of ten people say that their sight is the sense they most fear losing. It is therefore not surprising that many people react with despair to a diagnosis of eye disease, especially, if it is accompanied with the statement that there is nothing that can be done for them. Until five or six years ago the diagnosis of wet age-related macular degeneration was almost always the beginning of a journey towards registrable blindness, leading to severe limitations in the ability to carry out daily activities from driving to reading to cooking as well as any number of leisure activities that require good central vision. The impact of these limitations on the quality of life of people with AMD is discussed in this submission. Severe sight loss can be life-shattering, affecting not only the individual but also their family and friends.

Yes, rehabilitation and support for independent living can help people with AMD adjust to their sight loss but the journey towards recovery can be costly, not only for the individual who has to overcome many obstacles to continue living an independent, fulfilling life. The costs to society are also considerable. They go beyond the provision of rehabilitation services and the treatment of sight loss induced falls and include Disability Living Allowance and other social security benefits, subsidised transport and the informal care provided by family and friends.

PDT offers hope to a small number of patients whose sight may be stopped from deteriorating further through treatment. Still too many people with wet AMD have to be told that they are not eligible for treatment. Ranibizumab offers hope to all patients with wet AMD. The earlier people receive treatment, the higher the chances that good vision will be maintained. AMD will not affect their quality of life. Ranibizumab represents a significant step towards turning the most severe form of AMD into a treatable condition thereby preventing thousands of people each year from losing their sight. Ranibizumab should be approved alongside pegaptanib leaving the responsibility with the clinician to decide on the best avoidable treatment.

Approving ranibizumab for use on the NHS will make a major contribution to turning wet AMD into an avoidable cause of sight loss. A positive decision by the SMC would make a significant contribution towards meeting the UK's Vision 2020 objective of eliminating avoidable sight loss.

As patient organisations we not only help people with sight loss, we are also strongly committed to the Vision 2020 project. Rapid and universal access to effective treatments is an essential element of any strategy to eliminate avoidable sight loss. We therefore call on the SMC to add ranibizumab to the therapies for wet AMD approved for use on the NHS in Scotland.