NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Macular oedema (central retinal vein occlusion) - aflibercept solution for injection (1st line)

Thank you for agreeing to give us your views on the technology and the way it should be used in the NHS.

Patients and patient advocates can provide a unique perspective on the technology, which is not typically available from the published literature.

To help you give your views, we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. Please do not exceed the 8-page limit.

About you

Your name: Cathy Yelf

Name of your organisation: Macular Society

Are you (tick all that apply):

- a patient with the condition for which NICE is considering this technology?
- a carer of a patient with the condition for which NICE is considering this technology?
- an employee of a patient organisation that represents patients with the condition for which NICE is considering the technology? If so, give your position in the organisation where appropriate (e.g. policy officer, trustee, member, etc) X
- other? (please specify)

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition?

1. **Advantages**
(a) Please list the specific aspect(s) of the condition that you expect the technology to help with. For each aspect you list please describe, if possible, what difference you expect the technology to make.

Macular oedema secondary to retinal vein occlusion is a significant cause of sight loss. Loss of central vision is extremely distressing and often leads to depression, loss of income and a poor quality of life.

Laser treatment causes collateral damage to the retina and so cannot be used when the central macula is involved. Steroids are useful for some patients but can lead to cataract and increased intraocular pressure. For these reasons anti-VEGF therapy has become the preferred treatment for CRVO by many retina specialists.

Ranibizumab has been approved as a treatment for patients with macular oedema cause by CRVO. However, not all patients respond well to ranibizumab.

Aflibercept's different mode of action may make it effective in patients for whom ranibizumab does not work. It is therefore important for clinicians to have it available.

In comparing the results of trials of aflibercept and ranibizumab it may be relevant that the trials of aflibercept accepted patients regardless of their perfusion status and so were likely to include patients with more serious disease than those which excluded ischemic patients and may allow treatment for a wider range of patients.

(b) Please list any short-term and/or long-term benefits that patients expect to gain from using the technology. These might include the effect of the technology on:

- the course and/or outcome of the condition
- physical symptoms
- pain
- level of disability
- mental health
- quality of life (lifestyle, work, social functioning etc.)
- other quality of life issues not listed above
- other people (for example family, friends, employers)
- other issues not listed above.

The majority of patients treated with aflibercept can expect to maintain and in some cases improve their vision after a CRVO. This outcome would enable them to continue their lives, work, hobbies and family responsibilities, reduce the level of

disability they would otherwise have, reduce the risk of depression, maintain their quality of life and that of their family.

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition? (continued)

2. **Disadvantages**
Please list any problems with or concerns you have about the technology. Disadvantages might include:

- aspects of the condition that the technology cannot help with or might make worse.
- difficulties in taking or using the technology
- side effects (please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate)
- impact on others (for example family, friends, employers)
- financial impact on the patient and/or their family (for example cost of travel needed to access the technology, or the cost of paying a carer).

The main disadvantage of treatment with aflibercept is the frequency of hospital visits and injections. However, in our experience, patients are very willing to accept this if it means their sight is saved. In the main (from our experience of AMD patients) they are enormously grateful to have a treatment available and go to great lengths to ensure they receive their treatment.

3. Are there differences in opinion between patients about the usefulness or otherwise of this technology? If so, please describe them.

None of which we are aware.

4. Are there any groups of patients who might benefit **more** from the technology than others? Are there any groups of patients who might benefit **less** from the technology than others?

Patients who do not respond to ranibizumab may respond to this treatment. Clinical experience will be needed to identify which patients will respond better. Clinical experience will also demonstrate which re-treatment intervals work best over time (beyond the clinical trial time).

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Comparing the technology with alternative available treatments or technologies

NICE is interested in your views on how the technology compares with with existing treatments for this condition in the UK.

(i) Please list any current standard practice (alternatives if any) used in the UK.

Laser, steroid treatment and other anti-VEGF agents are all used to treat this condition.

Laser cannot be used in patients who have haemorrhage in the central macula area because of the damage caused by the laser itself.

Steroid treatment is useful but does not produce visual acuity results as good as the anti-VEGFs. In addition there is the likelihood of cataract formation and increased intraocular pressure. Some clinicians are interested in combination therapy.

Anti-VEGFs ranibizumab and bevacizumab are used to treat some CRVO patients. Aflibercept, if approved, would extend the choice of anti-VEGF treatments available and may make it possible to treat a wider range of, that is to say, more patients, than would otherwise be possible.

(ii) If you think that the new technology has any **advantages** for patients over other current standard practice, please describe them. Advantages might include:

- improvement in the condition overall
- improvement in certain aspects of the condition
- ease of use (for example tablets rather than injection)
- where the technology has to be used (for example at home rather than in hospital)
- side effects (please describe nature and number of problems, frequency, duration, severity etc.)

The advantages would most obviously be for those patients who do not respond well to the other anti-VEGFs and those excluded from earlier therapies because of the severity of their condition.

(iii) If you think that the new technology has any **disadvantages** for patients compared with current standard practice, please describe them. Disadvantages might include:

- worsening of the condition overall
- worsening of specific aspects of the condition
- difficulty in use (for example injection rather than tablets)

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

- where the technology has to be used (for example in hospital rather than at home)
- side effects (for example nature or number of problems, how often, for how long, how severe).

None of which we are aware.

Equality and Diversity

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that this appraisal:

- Could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/will be licensed;
- Could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- Could lead to recommendations that have any adverse impact on people with a particular disability or disabilities

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts

None

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Research evidence on patient or carer views of the technology

If you are familiar with the evidence base for the technology, please comment on whether patients' experience of using the technology as part of their routine NHS care reflects that observed under clinical trial conditions.

Are there any adverse effects that were not apparent in the clinical trials but have come to light since, during routine NHS care?

Are you aware of any research carried out on patient or carer views of the condition or existing treatments that is relevant to an appraisal of this technology? If yes, please provide references to the relevant studies.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Availability of this technology to patients in the NHS

What key differences, if any, would it make to patients and/or carers if this technology was made available on the NHS?

This technology adds to the range of therapies available and so may provide an effective treatment for some patients who would otherwise lose their sight.

What implications would it have for patients and/or carers if the technology was **not** made available to patients on the NHS?

The implications are that clinicians would be restricted in the options available to them potentially reducing the number of people who would benefit from an effective and safe anti-VEGF therapy.

Are there groups of patients that have difficulties using the technology?

There are no additional difficulties compared with other anti-VEGFs.

Other Issues

Please include here any other issues you would like the Appraisal Committee to consider when appraising this technology.