Appendix G - professional organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Aflibercept for treating diabetic macular oedema

Thank you for agreeing to give us a statement on your organisation's view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement, we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them.

Please do not exceed the 8-page limit.

About you

Your name: Miss Sobha Sivaprasad

Name of your organisation: Moorfields Eye Hospital

Are you (tick all that apply):

- a specialist in the treatment of people with the condition for which NICE is considering this technology? YES
- a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)? YES
- an employee of a healthcare professional organisation that represents clinicians treating the condition for which NICE is considering the technology? If so, what is your position in the organisation where appropriate (e.g. policy officer, trustee, member etc)? No
- other? (please specify) No

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What is the expected place of the technology in current practice?

How is the condition currently treated in the NHS? Is there significant geographical variation in current practice? Are there differences of opinion between professionals as to what current practice should be? What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient? Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?

If the technology is already available, is there variation in how it is being used in the NHS? Is it always used within its licensed indications? If not, under what circumstances does this occur?

Please tell us about any relevant **clinical guidelines** and comment on the appropriateness of the methodology used in developing the guideline and the specific evidence that underpinned the various recommendations.

Diabetic macular oedema (DMO) is grossly divided into non-centre and centre-involving DMO. The current options for non-centre involving DMO is observation or macular laser treatment. Ranibizumab is the NICE recommended treatment option available for centre-involving macular oedema. However, ranibizumab is only recommended for patients with central macular thickness of 400um or more. There is significant variation in the management of patients with central macular thickness of less than 400um. Some centre treat this group with bevacizumab while most centres attempt laser or wait for the macular thickness to increase to 400um or more before ranibizumab is initiated. The current technology that is used for DMO of central macular thickness of 400um or more is ranibizumab. Patients have to be monitored monthly to ensure optimal benefit. This regimen is difficult to achieve in the NHS and hence, clinicians develop their own pathways to best suit the capacity of the service and the patients. We have seen from our experience in real life practice that such comprises has a negative impact on the visual outcomes despite the fact that most patients require 8-9 injections in the first year. Therefore, these patients are best treated with fixed dosing regimen that will ensure optimal treatment in the majority of patients.
Although there is some limited use of bevacizumab in the NHS for those whose central macular thickness is below 400um, this is quite restricted at most units by local pharmacy approvals. In light of the recently licensed pharmacotherapies, it is difficult to justify the need to use bevacizumab which is unlicensed for intraocular use. Any use of this unlicensed product must therefore be considered in light of GMC guidelines on 'Good Medical Practice' and the manufacturer's advice.
We use the RCOphth diabetic retinopathy guidelines.

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The advantages and disadvantages of the technology

NICE is particularly interested in your views on how the technology, when it becomes available, will compare with current alternatives used in the UK. Will the technology be easier or more difficult to use, and are there any practical implications (for example, concomitant treatments, other additional clinical requirements, patient acceptability/ease of use or the need for additional tests) surrounding its future use?

If appropriate, please give your view on the nature of any rules, informal or formal, for starting and stopping the use of the technology; this might include any requirements for additional testing to identify appropriate subgroups for treatment or to assess response and the potential for discontinuation.

If you are familiar with the evidence base for the technology, please comment on whether the use of the technology under clinical trial conditions reflects that observed in clinical practice. Do the circumstances in which the trials were conducted reflect current UK practice, and if not, how could the results be extrapolated to a UK setting? What, in your view, are the most important outcomes, and were they measured in the trials? If surrogate measures of outcome were used, do they adequately predict long-term outcomes?

What is the relative significance of any side effects or adverse reactions? In what ways do these affect the management of the condition and the patient's quality of life? Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently during routine clinical practice?

Aflibercept will allow a more rigid pathway with fixed injection appointments for our patients and therefore much easier to apply. Patients will be able to anticipate and plan their schedule and arrange caregivers appropriately.
The current clinical evidence on aflibercept also shows that it is effective in all patients with macular oedema defined as 300um or more of macular thickness on OCT due to clinical evidence of DMO. As such, we will not disadvantage patients with less than 400um. The earlier the DMO is treated the better the prognosis and therefore watchful waiting for the oedema to increase to 400um reduces the risk of visual loss.
The VIVID and VISTA trials reflect UK clinical practice. Visual outcomes is the most important outcomes. The adverse events of aflibercept is no different to the existing technology (ranibizumab).
Aflibercept should be used in the existing retinal clinics, under the supervision of an ophthalmologist experienced in medical retinal disorders.
There is a risk of endophthalmitis and haemorrhage from intravitreal injection. Endophthalmitis in clinical practice is very infrequent and most adverse effects can be managed in the retinal clinic.

Any additional sources of evidence

Can you provide information about any relevant evidence that might not be found by a technology-focused systematic review of the available trial evidence? This could be information on recent and informal unpublished evidence, or information from registries and other nationally coordinated clinical audits. Any such information must include sufficient detail to allow a judgement to be made as to the quality of the evidence and to allow potential sources of bias to be determined.

None known to date

Implementation issues

The NHS is required by the Department of Health and the Welsh Assembly Government to provide funding and resources for medicines and treatments that have been recommended by NICE technology appraisal guidance. This provision has to be made within 3 months from the date of publication of the guidance.

If the technology is unlikely to be available in sufficient quantity, or the staff and facilities to fulfil the general nature of the guidance cannot be put in place within 3 months, NICE may advise the Department of Health and the Welsh Assembly Government to vary this direction.

Please note that NICE cannot suggest such a variation on the basis of budgetary constraints alone.

How would possible NICE guidance on this technology affect the delivery of care for patients with this condition? Would NHS staff need extra education and training? Would any additional resources be required (for example, facilities or equipment)?

DMO patients would continue to be seen and treated in the retinal clinic. The numbers are manageable within the existing clinics. Our staff is fully trained to deliver a aflibercept service to DMO patients.

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Equality
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 that I am aware of.