NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Ranibizumab for treating choroidal neovascularisation associated with pathological myopia

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: 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)

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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.

The condition is rare. However, choroidal neovascularization (CNV) is known to affect 4–11% of patients with pathological myopia and if untreated, causes severe central visual loss in 90% of cases. In addition, 30% may have bilateral involvement. It usually occurs in people below the age of 50 years so their working life may be compromised if timely treatment is not initiated.

The treatment for this condition in the NHS is very variable. Photodynamic therapy is effective based on the VIP data but not every NHS trust has access to the laser machine to provide this treatment. The treatment is offered in specialist centres only. Secondly, the treatment has side effects that include retinal pigment epithelial atrophy and choroidal non-perfusion. So, antiVEGF treatment is an effective alternate option as it only modulates the disease process and the safety profile is good.

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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?

Clinical trials that compared ranibizumab to PDT in myopic CNV confirmed a nearly 3 line gain of vision in the ranibizumab compared to the PDT arm at month 12 proving the superior efficacy of ranibizumb to PDT.

The studies also show that a low frequency of re-treatment required for this disease. The REPAIR study showed that approximately 90% required only 5 or less injections in 12 months and 35% required up to a maximum of 2 injections.

The safety profile of ranibizumab is well-tested for several diseases over the last 8 years. It is widely used in the NHS as first line for age related macular degeneration and centre involving diabetic macular oedema with very good results.

Regarding quality of life post treatment with ranibizumab, the recruitment of patients to he REPAIR study done in the UK very closely reflects patients seen in clinical practice. This study showed that in 14% of the cohort, the treated eyes converted from being the worse-seeing eye to being the better-seeing eye.

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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

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

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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.

There are several case series done in the Far East where this condition is prevalent that shows very similar results.

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)?

This Guidance is unlikely to affect the delivery of care for these patients negatively because:
1. the number of patients with this condition is limited.
2. All NHS trusts are running ranibizumab services for other more prevalent conditions such as AMD and centre involving DMO and so adding less than 5 more patients a year to the existing service should not affect delivery at all.
On the contrary, making ranibizumab available for these patients will definitely save these individuals from a devastating blinding condition to being able to work again and look after their family and reduce societal burden. The gain for these individuals should definitely outweigh any delivery constraints.

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