

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Ranibizumab for the treatment of macular oedema caused by retinal vein occlusion (RVO)

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: [REDACTED]

Name of your organisation: Royal College of Nursing (RCN Ophthalmic Forum)

Are you (tick all that apply):

- a specialist in the treatment of people with the condition for which NICE is considering this technology?
- a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)? Y
- 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.)? [REDACTED]
- other? (please specify)
- [REDACTED]
- [REDACTED]

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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.*

RVO is a condition that currently is treated using various methodologies and no definitive pathway.

The majority of patients are over 50 years but even the younger age group can be affected. RVO can be a devastating eye condition and it is this group of patients who will appear at the local casualty unit complaining of “sudden loss of vision, or visual symptoms” patients are often extremely distressed and an intervention that offers improvement of the outcomes should be supported.

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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?

The advantage of a technology of this nature is that it is a licensed indication for this condition and offers potential of visual improvement for this patient population.

There is currently no licensed treatment so clinicians currently have to base their decisions on past experience rather than evidence based medicine. The commonest used drugs to date are steroids which the Cochrane review in 2009 could not draw any conclusions on their efficacy in RVO and yet clinicians continue to use it. Also the patients have the added burden of managing steroid side effects, in particular raised intra ocular pressure. In contrast, Ranibizumab has not shown any significant adverse events in this cohort of patients.

We must emphasize that visual outcome can be very poor especially if the non-ischaemic CRVO, which presents with mild to moderate visual loss progresses to the ischaemic type. Therefore these patients should have the opportunity to receive a proven effective treatment as early as possible after diagnosis. We would therefore, urge NICE not to delay in approving this therapy.

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Without it unfortunately the burden to society will continue to escalate. Epidemiological data shows an increase in the ageing population, diabetes and cardiovascular related disease, all risk factors for RVO, so without a proven treatment patients will continue to lose vision, and require sight impaired registration.

The disadvantages are the impact upon services and the intensity of the delivery that is required to provide the treatment such as investigations and the requirement of intra-vitreous injections.

Any additional sources of evidence

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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.

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)?

Any unit currently providing the intra-vitreous injections for other ophthalmic conditions such as AMD would have the education and equipment to provide the treatment, but they may require additional resources in terms of more staff and equipment in order to deliver this therapy.

Equality

Are there any issues that require special attention in light of the NICE's duties to have due regard to the need to eliminate unlawful discrimination and promote equality and foster good relations between people with a characteristic protected by the equalities legislation and others?

We are not aware of any specific issue at this stage. We would however, ask that the appraisal should demonstrate that an analysis of equality impact have been considered and the outcome demonstrates an understanding of issues concerning patients' age, faith, race, gender, disability, cultural and sexuality where appropriate.