Appendix G - professional organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Ranibizumab for the treatment of 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: [redacted]

Name of your organisation: UCL Institute of Ophthalmology – (Responding on behalf of The Royal College of Pathologists)

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)?
- 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)?
- other? [redacted] ***with a particular interest in the diagnosis and pathogenesis of disorders at the back of the eye involving retina and / or choroid***

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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.

Choroidal neovascularisation in the context of pathological myopia is a difficult condition to treat effectively. I would defer to clinical colleagues but it is my view that the main therapy, prior to anti-VEGF agents, was conventional laser photocoagulation. This can not be used for foveal lesions as it is destructive. There is evidence for efficacy in juxtafoveal and extrafoveal lesions but I am not aware of any randomised clinical trials and laser appears to be less successful than in the context of age-related macular degeneration and also its long-termed benefit is uncertain. Increasingly, the use of anti-VEGF therapies is taking precedence.

There are clear racial differences in risk but it seems approach to therapy should be the same on the basis of current knowledge.

Intravitreal injections are now common – place in specialist ophthalmology settings for the treatment of age-related macular degeneration and diabetic retinopathy and myopic CNV should be treated in the same situation with access to appropriate imaging technology and injecting expertise etc.

This technology is used widely for licensed indications.

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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?

Anti-VEGF therapy represents the best approach for the treatment of pathological myopic CNV. I am aware of only limited comparisons between Lucentis and Avastin but on the basis of current evidence I see no compelling pros or cons one way or the other.

From basic principles it is appropriate to start as soon as CNV apparent. Stopping is harder and clear guidelines for this are likely to be more tractable as experience with anti-VEGF agents and 'burning – out' of neovascular lesions becomes a more precisely recognisable end – point. From a pragmatic point of view it seems sensible to continue with prn therapy indefinitely.

I am not an expert on the side-effects of anti-VEGF agents but clearly they reach the systemic circulation. Patients with myopic CNV are generally younger than those with AMD and should be less susceptible but conversely they may be on treatment longer. As long as potential risks are explained to patients I see the benefit greatly in excess of risk.

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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 that I am aware of

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)?

Although the prevalence of pathological myopia is significant CNV from this cause can presumably be accommodated within the existing provision for delivery of this therapy for other conditions.

Equality

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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.

The main issues here are around how visually impaired gain access to healthcare in general. I can not think of anything that is particularly pertinent to this technology but others may.

A selection of references

1: Wang E, Chen Y. INTRAVITREAL ANTI-VASCULAR ENDOTHELIAL GROWTH FACTOR FOR CHOROIDAL NEOVASCULARIZATION SECONDARY TO PATHOLOGIC MYOPIA: Systematic Review and Meta-Analysis. Retina. 2013 Mar 19. [Epub ahead of print] PubMed PMID: 23514793.

2: Tufail A, Patel PJ, Sivaprasad S, Amoaku W, Browning A, Cole M, Gale R, George S, Lotery A, Majid M, McKibbin M, Menon G, Yang Y, Andrews C, Brittain C, Osborne A. Ranibizumab for the treatment of choroidal neovascularisation secondary to pathological myopia: interim analysis of the REPAIR study. Eye (Lond). 2013 Mar 1. doi: 10.1038/eye.2013.8. [Epub ahead of print] PubMed PMID: 23449508.

3: Iacono P, Parodi MB, Papayannis A, Kontadakis S, Sheth S, Cascavilla ML, Bandello F. Intravitreal ranibizumab versus bevacizumab for treatment of myopic choroidal neovascularization. Retina. 2012 Sep;32(8):1539-46. doi: 10.1097/IAE.0b013e31826956b7. PubMed PMID: 22922846.

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4: Long Q, Ye J, Li Y, Wang S, Jiang Y. C-reactive protein and complement components in patients with pathological myopia. Optom Vis Sci. 2013 May;90(5):501-6. doi: 10.1097/OPX.0b013e31828daa6e. PubMed PMID: 23538433.