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] ([redacted]) , Clare Bailey (CB)

Name of your organisation: Representing The Royal College of Ophthalmologists

Are you (tick all that apply):

- a specialist in the treatment of people with the condition for which NICE is considering this technology? Yes ([redacted] and CB)

- a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)? Yes – REPAIR and RADIANCE, Studies, PI, writing committee lead, co author ([redacted]). Investigator REPAIR study (CB)

- 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)? Royal College of Ophthalmologists members: [redacted] and CB

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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?

Choroidal neovascularisation secondary to pathological myopia (PMCNV) can be treated with thermal laser, photodynamic therapy or intravitreal anti-VEGF agents. Thermal laser photocoagulation is almost never used now in the UK even for extra-foveal lesions due to the problem of laser scar extension and progressive visual loss on longer term follow up (after 3-5years). Photodynamic treatment has been used for a number of years, secondary to the publication of the VIP study (Verteporfin in Photodynamic Therapy Study Group Ophthalmology 2001;108:841-52). PDT was shown to reduce the risk of moderate visual loss compared to no treatment and PDT is still used for this indication in some units in the UK, and more so in the Far East where PMCNV is more prevalent. Many units in the UK no longer provide PDT services. Since the advent of anti-VEGF treatment, many units in the UK have had limited access (such as exceptional funding) for anti-VEGF treatment for PMCNV. If there is no access to ranibizumab most retinal specialists in the UK would be likely to recommend bevacizumab on an off label basis in preference to PDT.
Submacular surgery is no longer considered an appropriate treatment option for PMCNV.

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?

There is probably not a wide spectrum of heterogeneity amongst patients with PMCNV. Even patients with subfoveal blood can do as well as those without blood. Other co-existing features of PM such as macular hole, myopic foveoschisis, dome shape maculopathy with fluid and epiretinal membrane formation can limit the visual prognosis to treatment of PMCNV as anti VEGF therapy does not influence the prognosis of these other macular problems which also occur rarely in PM. Patients with very high myopia and severe peripheral retinal degeneration can be at a higher risk of developing retinal detachment as a result of intravitreal injections.

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)?
The technology should be used in secondary care, using the same facilities as those use to treat neovascular AMD, retinal vein occlusion and diabetic macular oedema with ranibizumab. Due to small numbers of patients and infrequent injections needed per patient, it should not require any significant additional capacity on top of those being provided for wet AMD TA155 and DMO TA 274 and RVO- TA283.

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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?

The technology of intravitreal ranibizumab therapy is already available in the NHS. It is being used for the licensed indications of AMD and DMO.

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.

There are no national level guidelines for management of PMCNV at present. There are RCOphth guidelines on the technique for the delivery of intravitreal treatment.

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?

Compared to PDT, intravitreal ranibizumab therapy leads to better visual outcomes. Retreatment episodes are also less frequent. PDT is not widely available in all units. Delivery of intravitreal ranibizumab has advantages over PDT in terms of visual outcome, ease of use, treatment burden and also availability of facilities.

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.

These are informal rules:- Active leakage from PMCNV is confirmed on Fundus fluorescein Angiography (FFA) and OCT imaging. Differential diagnosis include CSR, Dome Shape macula, foveoschisis ERM and VMT. Once confirmed, therapy can be initiated. Treatment response is judged by visual acuity, clinical examination and OCT. Treatment is not required if there are no signs of active leakage. Very occasionally FFA is needed to look for leakage to help decision making on retreatment. Repeated monitoring for recurrent leakage should be advised for up to one year following the most recent episode of treatment with intravitreal ranibizumab. Patient education on early symptoms of recurrent leakage is also important.

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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?

Two large trials on ranibizumab for PMCNV have been done. REPAIR was a phase II trial involving multiple sites in the UK designed to test a pragmatic retreatment algorithm. This evidence is highly translatable to UK clinical practice. RADIANCE was phase III RCT comparing PDT to intravitreal ranibizumab. The ranibizumab arm could be extrapolated to UK practice. The most important outcomes of the REPAIR study are the low levels of moderate visual loss for treated eyes (95.4% lost less than 15 letters on the logMAR chart at 1 year) , and the significant percentage of eyes (36.9%) who gained at least 15 letters of vision on the logMAR chart at 1 year. Treated eyes gained a mean of 13.8 letters at 1 year. These visual outcomes are superior to those reported with PDT in the VIP study. The RADIANCE study results have presented similar outcomes date for ranibizumab treated eyes.

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?

Both trials found a very low rate of ocular and systemic adverse events. The side-effects of intravitreal ranibizumab treatment have been well documented in the clinical trials, and subsequent real-world use of ranibizumab for other indications such as AMD. There is a less than 1/1000 risk of endophthalmitis per intravitreal injection. This can be treated, although can result in a permanent reduction in vision. Highly myopic eyes are at greater risk of retinal detachment even without any treatment, and it is therefore possible that the risk of retinal detachement or retinal tear will be higher in this highly myopic group of patients given intravitreal treatments.

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.

No other information available

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)?

It is unlikely to require additional resources in terms of facilites or equipment as the expertise and infrastructure already exist for this treatment in units already treating wet macular degeneration with ranibizumab. The numbers of patients to be treated with PMCNV will be relatively small, with low retreatment rates, so any impact on staffing will be very small.

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.

It is unlikely to have inequality issues.