

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Proposed Health Technology Appraisal

**Ranibizumab for the treatment of choroidal neovascularisation
associated with pathological myopia**

Draft scope

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of ranibizumab within its licensed indication for the treatment of choroidal neovascularisation associated with pathological myopia.

Background

Short-sightedness, or myopia, is a vision problem resulting from excessively long growth of the eye-ball, or a steeply curved cornea. Myopia causes light rays to focus in front of the retina and so close objects are seen clearly whilst distant objects appear blurred. Myopia can be classified as mild, moderate or high, depending on the length of the eye and curvature of the cornea. The focusing power of a lens is measured in dioptres. A negative dioptre indicates an eye with myopia, with the higher the negative value the more severe the myopia. Myopia up to minus three dioptres is termed mild, minus three to minus six dioptres is moderate, and high is minus six or more dioptres. High myopia (also known as pathological or degenerative myopia) is a chronic condition associated with degenerative changes at the back of the eye.

Choroidal neovascularisation (CNV) occurs when the choroid area of the eye produces new blood vessels (neovascularization) which grow up through the damaged layers and leak or bleed into the retina. CNV is a common cause of vision loss in people with pathological myopia.

There are approximately 200,000 people with pathological myopia in the UK. The prevalence or incidence of CNV associated with pathological myopia in the UK is not known. CNV is estimated to develop in approximately 10% of people with pathological myopia.

The aim of current management of CNV is to improve or halt the decline in visual acuity. Verteporfin photodynamic therapy is the only treatment with a marketing authorisation for indicated for use in subfoveal CNV associated with pathological myopia. In some clinical centres in England and Wales, the anti-vascular endothelial growth factors (anti-VEGF's) bevacizumab and ranibizumab are used outside their licensed indications for the treatment of CNV associated with pathological myopia.

The technology

Ranibizumab (Lucentis, Novartis UK) inhibits the action of VEGF-A, thereby preventing the development of abnormal blood vessels. By preventing the development of abnormal blood vessels, ranibizumab limits visual loss and improves vision. It is administered through intravitreal injection.

Ranibizumab does not currently have a UK marketing authorisation for the treatment of CNV. It has been studied in clinical trials of people with visual impairment due to CNV associated with pathological myopic, as a monotherapy compared with bevacizumab, and verteporfin photodynamic therapy.

Intervention(s)	Ranibizumab
Population	People with visual impairment due to choroidal neovascularisation associated with pathological myopia
Comparators	<ul style="list-style-type: none"> • Verteporfin photodynamic therapy • Bevacizumab
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • Best corrected visual acuity (the affected eye) • Best corrected visual acuity (both eyes) • Contrast sensitivity • Adverse effects of treatment • Health-related quality of life
Economic analysis	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>
Other considerations	Guidance will only be issued in accordance with the marketing authorisation.
Related NICE recommendations	None

Questions for consultation

How many people are likely to be diagnosed with CNV each year in the UK?

Have the most appropriate comparators for the treatment of CNV associated with pathological myopia been included in the scope? Are the comparators listed routinely used in clinical practice?

Have the most appropriate visual-related outcomes been included?

Are there any subgroups of people in whom the technology is expected to be more clinically effective and cost effective or other groups that should be examined separately?

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 the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- 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 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. Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at

http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp