NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Aflibercept for treating myopic choroidal neovascularisation

Draft scope (pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of aflibercept within its marketing authorisation for treating myopic choroidal neovascularisation.

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 3 dioptres is termed mild, minus 3 to minus 6 dioptres is moderate, and high is minus 6 or more dioptres[1]. 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 (neovascularisation) 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 myopia.

The prevalence of myopia is approximately 1–3% in adults, and 5–11% of people with myopia will develop CNV[2]. In England, it has been estimated that over 300,000 people have myopia and that the incident population of myopic CNV is 3200[3]. Approximately 35% of people who develop CNV in one eye will develop it in the other eye within 8 years[4].

The aim of treating CNV is to improve or halt the decline in visual acuity. NICE technology appraisal guidance 298 has recommended ranibizumab as an option for treating visual impairment due to CNV secondary to pathological myopia. Verteporfin photodynamic therapy is also used in clinical practice for treating subfoveal CNV associated with pathological myopia. Bevacizumab does not have a marketing authorisation in the UK for treating eye conditions but it is used off-label in clinical practice.

The technology

Aflibercept (Eylea, Bayer Pharma) is a soluble vascular endothelial growth factor (VEGF) receptor fusion protein that binds VEGF-A and the placental growth factor. It is administered by intravitreal injection.

Aflibercept has a marketing authorisation in the UK for "adults for the treatment of visual impairment due to myopic choroidal neovascularisation". It has been studied in a clinical trial of 122 adults of Asian family origin with vision loss due to CNV secondary to pathologic myopia compared with sham injection (placebo).

Intervention(s)	Aflibercept
Population(s)	Adults with visual impairment due to myopic choroidal neovascularisation
Comparators	• bevacizumab (does not currently have a marketing authorisation in the UK for this indication) • ranibizumab • verteporfin photodynamic therapy
Outcomes	The outcome measures to be considered include: • 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	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. 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. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any patient access schemes for the intervention or comparator technologies will be taken into account. Cost effectiveness analysis should include consideration of the benefit in the best and worst seeing eye.

Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations and NICE Pathways	Related Technology Appraisals: 'Ranibizumab for treating choroidal neovascularisation associated with pathological myopia' (2013). NICE Technology Appraisal 298. Review date March 2016. Related NICE Pathways: Eye conditions (2015) NICE pathway http://pathways.nice.org.uk/eye-conditions
Related National Policy	NHS England Manual for prescribed specialised services 2013/2014. Adult specialist ophthalmology services [section 12, page 43]: http://www.england.nhs.uk/wp-content/uploads/2014/01/pss-manual.pdf Department of Health, NHS Outcomes Framework 2015-2016, Dec 2014. Domains 1–5. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/385749/NHS_Outcomes_Framework.pdf

Questions for consultation

Is afilbercept likely to be used in clinical practice for treating all adults with myopic choroidal neovascularisation, or only for adults with choroidal neovascularisation secondary to pathological myopia?

Have all relevant comparators for aflibercept been included in the scope? Which treatments are considered to be established clinical practice in the NHS for myopic choroidal neovascularisation?

Are the outcomes listed appropriate?

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

Where do you consider aflibercept will fit into the existing NICE pathway, 'Eye conditions'?

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 aflibercept is 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 aflibercept 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 aflibercept 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/article/pmg19/chapter/1-Introduction)

References

1. Royal National Institute of Blind People (2015). Myopia and high degree myopia. Accessed December 2015.

2. Wong TY, Ferreira A, Hughes R, et al. (2014). Epidemiology and disease burden of pathologic myopia and myopic choroidal neovascularization: an evidence-based systematic review. *Am J Ophthalmol*, 157:9–25 e12.

3. Ranibizumab for treating choroidal neovascularisation associated with pathological myopia (2013). NICE costing statement for technology appraisal guidance 298.

4. Ohno-Matsui K, Yoshida T, Futagami S, et al. (2003). Patchy atrophy and lacquer cracks predispose to the development of choroidal neovascularisation in pathological myopia. *Br J Ophthalmol*, 87:570–3.