NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Ranibizumab for the treatment of choroidal neovascularisation associated with pathological myopia

Final scope

Final 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. However, approximately 30% of people who develop CNV in one eye will develop it in the other eye within 8 years.

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 use in subfoveal CNV associated with pathological myopia. In some clinical centres in England and Wales ranibizumab is used outside its licensed indications for the treatment of CNV associated with pathological myopia. Bevacizumab is unlicensed for all eye conditions but it is used off-label 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 however it has a UK marketing authorisation for the treatment of: wet age-related macular degeneration, visual impairment due to diabetic macular oedema and visual impairment due to macular oedema secondary to retinal vein occlusion. Ranibizumab has been studied in clinical trials of people with visual impairment due to CNV associated with pathological myopia, 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	• Verteporfin photodynamic therapy • Bevacizumab
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.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation.

Related NICE recommendations	Related Technology Appraisals: Technology Appraisal TA271. January 2013. Fluocinolone acetonide intravitreal implant for the treatment of chronic diabetic macular oedema after an inadequate response to prior therapy. Review date: November 2015. Technology Appraisal TA237. November 2011. Ranibizumab for the treatment of diabetic macular oedema. Review date: March 2013. Technology Appraisal TA229. July 2011. Dexamethasone intravitreal implant for the treatment of macular oedema secondary to retinal vein occlusion. Review date: 2014 Technology Appraisal TA155. August 2008. Ranibizumab and pegaptanib for the treatment of age-related macular degeneration. Re-issued after a change to the patient access scheme: May 2012. Review date: February 2014. Technology Appraisal TA68. September 2003. The clinical effectiveness and cost effectiveness of photodynamic therapy for age-related macular degeneration. Review date: February 2014. Technology Appraisals in development: Ranibizumab for the treatment of macular oedema caused by retinal vein occlusion. Earliest date of publication May 2013. Aflibercept solution for injection for the treatment of wet age-related macular degeneration. Earliest date of publication August 2013.