

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Ranibizumab port delivery system for treating wet age-related macular degeneration

Draft scope

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of ranibizumab port delivery system within its marketing authorisation for treating wet age-related macular degeneration.

Background

The macula is the central part of the retina responsible for colour vision and perception of fine detail. Age-related macular degeneration (AMD) refers to the deterioration in the cells of the retinal pigment layer at the macula area, which can lead to severe visual impairment in the affected eye.

AMD is a common cause of vision loss in people aged over 50 and is associated with the loss of central vision and visual distortion. There are 2 main types of AMD, wet (neovascular) and dry (non-neovascular). Wet AMD usually develops much more quickly than dry AMD and is characterised by choroidal neovascularisation, which describes the formation of immature blood vessels that grow between the retinal pigment epithelial cells and the photoreceptor cells in the centre of the retina. These new blood vessels are fragile and more likely to haemorrhage, which causes scarring of the macula leading to vision impairment. Wet AMD accounts for around 10% of all cases of AMD and about 60% of advanced (late-stage) cases.¹ In the UK, prevalence of wet AMD is estimated to be 1.2% (2.5% in those aged 65 or above and 6.3% in those aged 80 or above) with an estimated 40,000 new cases of wet AMD in the UK each year.²

The NICE guideline on AMD ([NG82](#)) recommends offering intravitreal anti-vascular endothelial growth factor (VEGF) treatment. Anti-VEGF medications that are licensed options for the treatment of wet AMD are ranibizumab, aflibercept solution for injection and brolucizumab. NICE [TA155](#), [TA294](#) and [TA672](#) recommend treatment with these options when the best-corrected visual acuity is between 6/12 and 6/96, there is no permanent structural damage to the central fovea, the lesion size is less than or equal to 12 disc areas in greatest linear dimension and there is evidence of recent presumed disease progression. NG82 also recommends considering anti-VEGF treatment for wet AMD with best-corrected visual acuity of 6/96 or worse if it will benefit the person's overall visual function (for example, if the affected eye is the person's better-seeing eye).

The technology

Ranibizumab port delivery system (brand name unknown, Roche) is a long-acting drug delivery system loaded with ranibizumab that is inserted into the eye as an implant. Ranibizumab inhibits the action of VEGF-A and prevents the development of abnormal blood vessels. By preventing the development of abnormal blood vessels, ranibizumab limits visual loss and improves vision. Ranibizumab is also administered as an injection into the eye.

Ranibizumab port delivery system does not currently have a marketing authorisation in the UK for the treatment of wet AMD. Ranibizumab as an intravitreal injection does have a marketing authorisation in the UK for the treatment of wet AMD. Ranibizumab port delivery system has been studied in clinical trials compared with ranibizumab as an intravitreal injection in adults with previously treated neovascular age-related macular degeneration.

Intervention	Ranibizumab port delivery system
Population	Adults with wet age-related macular degeneration
Comparators	<ul style="list-style-type: none"> • Aflibercept • Ranibizumab (intravitreal injection) • Brolucizumab • Bevacizumab (does not currently have a marketing authorisation in the UK for this indication) • Faricimab (subject to an ongoing NICE appraisal) • Best supportive care
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • visual acuity (the affected eye) • overall visual function • central subfield foveal thickness (CSFT) • adverse effects of treatment • health-related quality of life.

<p>Economic analysis</p>	<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>If the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost-comparison may be carried out.</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> <p>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability of any managed access arrangement for the intervention will be taken into account.</p> <p>Cost effectiveness analysis should include consideration of the benefit in the best and worst seeing eye.</p>
<p>Other considerations</p>	<p>If the evidence allows the following subgroups will be considered:</p> <ul style="list-style-type: none"> • lesion is classic or occult neovascularisation in nature. <p>The availability and cost of biosimilar and generic products should be taken into account.</p> <p>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.</p>
<p>Related NICE recommendations and NICE Pathways</p>	<p>Related Technology Appraisals:</p> <p>Brolucizumab for treating wet age-related macular degeneration (2021). NICE Technology Appraisal 672. Review date: 2024.</p> <p>Aflibercept solution for injection for treating wet age-related macular degeneration (2013). NICE Technology Appraisal 294. Guidance moved to static list.</p> <p>Ranibizumab and pegaptanib for the treatment of age-related macular degeneration (2012). NICE Technology Appraisal 155. Guidance moved to static list.</p> <p>Appraisals in development (including suspended appraisals):</p>

	<p>Faricimab for treating wet age-related macular degeneration. NICE technology appraisals guidance [ID3898]. Publication expected August 2022.</p> <p>Abicipar pegol for treating wet age-related macular degeneration. NICE technology appraisals guidance [ID1533]. Suspended July 2020.</p> <p>Related Guidelines:</p> <p>Age-related macular degeneration (2018). NICE guideline 82 Review date: None stated.</p> <p>Related Interventional Procedures:</p> <p>Miniature lens system implantation for advanced age-related macular degeneration (2016). NICE interventional procedures guidance 565.</p> <p>Epiretinal brachytherapy for wet age-related macular degeneration (2011). NICE interventional procedures guidance 415.</p> <p>Macular translocation with 360° retinotomy for wet age-related macular degeneration (2010). NICE interventional procedures guidance 340.</p> <p>Limited macular translocation for wet age-related macular degeneration (2010). NICE interventional procedures guidance 339.</p> <p>Transpupillary thermotherapy for age-related macular degeneration (2004). NICE interventional procedures guidance 58.</p> <p>Radiotherapy for age-related macular degeneration (2004). NICE interventional procedures guidance 49.</p> <p>Related Quality Standards:</p> <p>Serious eye disorders (2019). NICE quality standard 180.</p> <p>Related NICE Pathways:</p> <p>Age-related macular degeneration (2018) NICE pathway</p>
<p>Related National Policy</p>	<p>NHS England (2019) The NHS long term plan.</p> <p>Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domain 2. https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017</p> <p>The Royal College of Ophthalmologists. Age-Related Macular Degeneration: Guidelines for Management. September 2013.</p> <p>The Royal College of Optometrists and the Royal College of Ophthalmologists. Age-related macular degeneration. Commissioning better eye care - Clinical commissioning guidance. November 2013.</p> <p>European Society of Retina Specialists (EURETINA).</p>

	Guidelines for the management of neovascular age-related macular degeneration . 2014.
--	---

Questions for consultation

Have all relevant comparators for ranibizumab port delivery system been included in the scope?

Which treatments are considered to be established clinical practice in the NHS for wet age-related macular degeneration?

Are the outcomes listed appropriate?

Are the subgroups suggested in 'other considerations' appropriate? Are there any other subgroups of people in whom ranibizumab port delivery system is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Where do you consider ranibizumab port delivery system will fit into the existing NICE pathway, [Age-related macular degeneration](#)?

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 ranibizumab port delivery system 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 ranibizumab port delivery system 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 ranibizumab port delivery system 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.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

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/pmq19/chapter/1-Introduction>).

NICE has published an addendum to its guide to the methods of technology appraisal (available at <https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/methods-guide-addendum-cost-comparison.pdf>), which states the methods to be used where a cost comparison case is made.

- Would it be appropriate to use the cost comparison methodology for this topic?
- Is the new technology likely to be similar in its clinical efficacy and resource use to any of the comparators?
- Is the primary outcome that was measured in the trial or used to drive the model for the comparator(s) still clinically relevant?
- Is there any substantial new evidence for the comparator technologies that has not been considered? Are there any important ongoing trials reporting in the next year?

References

1. Patient Info (2021). [Age-related Macular Degeneration](#). Accessed November 2021.
2. Owen, C.G., Jarrar, Z., Wormald, R., Cook, D.G., Fletcher, A.E. and Rudnicka, A.R. [The estimated prevalence and incidence of late stage age related macular degeneration in the UK](#). British Journal of Ophthalmology, 2012, 96: 752-756