

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Faricimab for treating wet age-related macular degeneration

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of faricimab 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 years 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) cases¹. 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 year².

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

Faricimab (brand name unknown, Roche) is a novel antibody targeting the growth factors vascular endothelial growth factor-A (VEGF-A) and angiopoietin-2 (Ang-2). Faricimab is administered as an injection into the eye.

Faricimab does not currently have a marketing authorisation in the UK for the treatment of wet AMD. It has been studied in clinical trials compared with aflibercept in adults with untreated choroidal neovascularisation secondary to AMD.

Intervention(s)	Faricimab
Population(s)	Adults with choroidal neovascularisation secondary to age-related macular degeneration
Comparators	<ul style="list-style-type: none"> • Aflibercept • Ranibizumab • Brolucizumab • Bevacizumab (does not currently have a marketing authorisation in the UK for this indication) • 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
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>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>Abicipar pegol for treating wet age-related macular degeneration. NICE technology appraisals guidance [ID1533]. Suspended July 2020.</p> <p>Ranibizumab port delivery system for treating wet age-related macular degeneration. NICE technology appraisals guidance [ID3983] Publication date to be confirmed.</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</p>

	<p>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). Guidelines for the management of neovascular age-related macular degeneration. 2014.</p>

References

1. Patient Info (2021). [Age-related Macular Degeneration](#). Accessed September 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