NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

ONS-5010 for treating wet age-related macular degeneration ID6320

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of ONS-5010 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) is when ageing causes damage to the macula, 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 the growth of abnormal blood vessels beneath 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, brolucizumab and faricimab. NICE TA155, TA294, TA672 and TA800 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

ONS-5010 (Lytenava, Outlook Therapeutics Limited), an ophthalmic formulation of bevacizumab, 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 ranibizumab in adults with wet AMD.

Intervention	ONS-5010
Population	Adults with wet age-related macular degeneration
Comparators	• Aflibercept • Ranibizumab (intravitreal injection) • Brolucizumab • Faricimab • Bevacizumab (does not currently have a marketing authorisation in the UK for this indication)
Outcomes	The outcome measures to be considered include: • visual acuity (the affected eye) • overall visual function • central subfield foveal thickness (CSFT) • 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. 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. 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 commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability and cost of biosimilar and generic products should be taken into account. The 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	**Related Technology Appraisals:** Brolucizumab for treating wet age-related macular degeneration (2021). NICE Technology Appraisal 672. Review date: 2024. Aflibercept solution for injection for treating wet age‑related macular degeneration (2013). NICE Technology Appraisal 294. Guidance moved to static list. Ranibizumab and pegaptanib for the treatment of age-related macular degeneration (2012). NICE Technology Appraisal 155. Guidance moved to static list. Faricimab for treating wet age-related macular degeneration (2022). NICE Technology Appraisals 800. Review date: 2025. **Appraisals in development (including suspended appraisals):** Port Delivery System with ranibizumab for treating wet age-related macular degeneration [ID3983] Abicipar pegol for treating wet age-related macular degeneration [ID1533]. Suspended July 2020. **Related Guidelines:** Age-related macular degeneration (2018). NICE guideline 82 Review date: None stated. **Related Interventional Procedures:** Miniature lens system implantation for advanced age-related macular degeneration (2016). NICE interventional procedures guidance 565. Epiretinal brachytherapy for wet age-related macular degeneration (2011). NICE interventional procedures guidance 415. Macular translocation with 360° retinotomy for wet age-related macular degeneration (2010). NICE interventional procedures guidance 340. Limited macular translocation for wet age-related macular degeneration (2010). NICE interventional procedures guidance 339.

	Transpupillary thermotherapy for age-related macular degeneration (2004). NICE interventional procedures guidance 58. Radiotherapy for age-related macular degeneration (2004). NICE interventional procedures guidance 49. **Related Quality Standards:** Serious eye disorders (2019). NICE quality standard 180.
Related National Policy	NHS England (2019) The NHS long term plan. 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 NHS England (2023) Prescribed specialised services manual (version 6) Chapter 12 - Adult specialist ophthalmology services The Royal College of Ophthalmologists. Age-Related Macular Degeneration: Guidelines for Management. September 2013. The Royal College of Optometrists and the Royal College of Ophthalmologists. Age-related macular degeneration. Commissioning better eye care - Clinical commissioning guidance. November 2013. European Society of Retina Specialists (EURETINA). Guidelines for the management of neovascular age-related macular degeneration. 2014.

Questions for consultation

Where do you consider ONS-5010 will fit into the existing care pathway for wet AMD?

Is bevacizumab currently used off label to treat wet age-related macular degeneration?

Are there any subgroups of people in whom ONS-5010 is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Would ONS-5010 be a candidate for managed access?

Do you consider that the use of ONS-5010 can result in any potential 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 committee to take account of these benefits.

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 ONS-5010 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.

NICE is considering evaluating this technology through its cost comparison evaluation process.
Please provide comments on the appropriateness of appraising this topic through this process.
(Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

Technologies can be evaluated through the cost-comparison process if they are expected to provide similar or greater health benefits, at a similar or lower cost, compared with technologies that have been previously recommended (as an option) in published NICE guidance for the same indication. Companies can propose cost-comparison topics to NICE at any stage during topic selection and scoping. NICE will route technologies for evaluation through the cost-comparison process if it is agreed during scoping that the process is an appropriate route to establish the clinical and cost effectiveness of the technology.

NICE's health technology evaluations: the manual states the methods to be used where a cost comparison case is made.

- Is the technology likely to be similar in its clinical effectiveness and resource use to any of the comparators? Or in what way is it different to the comparators?
- Will the intervention be used in the same place in the treatment pathway as the comparator(s)? Have there been any major changes to the treatment pathway recently? If so, please describe.
- Will the intervention be used to treat the same population as the comparator(s)?

- Overall is the technology likely to offer similar or improved health benefits compared with the comparators?
- Would it be appropriate to use the cost-comparison methodology for this topic?

References

1. Patient Info (2021). Age-related Macular Degeneration. Accessed January 2024.

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