NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Pegcetacoplan for treating geographic atrophy

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of pegcetacoplan within its marketing authorisation for treating adults with geographic atrophy.

Background

Age-related macular degeneration (AMD) is a disease that affects the macula, which is the central region of the retina. The condition has distinctive clinical stages. Early and intermediate AMD is associated with drusen (yellow deposits under the retina) and macular pigmentary changes, usually with normal or near-normal vision. Late AMD is characterised by a decrease or loss of central vision. Late AMD is further classified in two forms: geographic atrophy ("dry" AMD) and neovascular AMD ("wet" AMD). Geographic atrophy is a chronic progressive degeneration of the macula that causes irreversible loss of the retinal pigment epithelium, photoreceptors, and underlying choriocapillaris.[1,2]

In the early stages of geographic atrophy, people may experience a reduction of visual capacity under low-light conditions. As the disease progresses visual blind spots develop, leading to loss of central vision and blindness.[2,] In most cases the loss of visual function occurs in both eyes.[1] People with geographic atrophy may have difficulty in reading, judging distance and seeing in dark conditions and so may encounter a loss of mobility and independence, and a reduction in quality of life.[3]

Some of the known risk factors for developing geographic atrophy are increased age, obesity, having high blood pressure, race (more prevalent in Caucasians), smoking and having family history of AMD.[4-6]

The prevalence of geographic atrophy in the UK is between 1.3% for those aged over 50 and 6.7% in those aged over 80 years.[7]

There are currently no pharmacological therapies approved for the treatment of geographic atrophy.

The technology

Pegcetacoplan (Aspaveli, Apellis Pharmaceuticals) does not currently have a marketing authorisation in the UK for treating geographic atrophy. It has been studied in clinical trials compared with placebo in adults with geographic atrophy.

Intervention(s)	Pegcetacoplan
Population(s)	Adults with geographic atrophy secondary to age-related macular degeneration.
Comparators	Established clinical management without pegcetacoplan

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Outcomes	The outcome measures to be considered include: • change in geographic atrophy lesion size • visual acuity (the affected eye) • 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 commercial arrangements for the intervention, comparator and subsequent treatment technologies will 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:** Faricimab for treating wet age-related macular degeneration (2022) NICE technology appraisal guidance 800. Brolucizumab for treating wet age-related macular degeneration (2021) NICE technology appraisal guidance 672. Ranibizumab for treating choroidal neovascularisation associated with pathological myopia (2013) NICE technology appraisal guidance 298. Aflibercept solution for injection for treating wet age-related macular degeneration (2013) NICE technology appraisal guidance 294. Ranibizumab and pegaptanib for the treatment of age-related macular degeneration (2008) NICE technology appraisal guidance 155. **Related NICE guidelines:** Age-related macular degeneration (2018) NICE guideline NG82.

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Related National Policy	The NHS Long Term Plan (2019) NHS Long Term Plan NHS England (2018) NHS manual for prescribed specialist services (2018/2019) Chapter 12. NHS England (2013/2014) NHS Standard contract for Specialised Ophthalmology (Adult)

Questions for consultation

Where do you consider pegcetacoplan will fit into the existing care pathway for geographic atrophy?

Would eligibility to receive pegcetacoplan would be dependent on age?

What is established clinical management for geographic atrophy?

Which outcomes are most relevant to measure intervention effectiveness in geographic atrophy?

Would pegcetacoplan be a candidate for managed access?

Do you consider that the use of pegcetacoplan 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 pegcetacoplan 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 intends to evaluate this technology through its Single Technology Appraisal 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-tehnology-appraisal-guidance/changes-to-health-technology-evaluation).

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References

1.British Medical Journal. Age related macular degeneration. 2023. Accessed May 2023.

2. Boyer DS, Schmidt-Erfurth U, van Lookeren Campagne M, Henry EC, Brittain C. The pathophysiology of geographic atrophy secondary to age-related macular degeneration and the complement pathway as a therapeutic target. Retina (Philadelphia, Pa). 2017;37(5):819- 35.

3. Patel PJ, Ziemssen F, Ng E, Muthutantri A, Silverman D, Tschosik EA, et al. Burden of Illness in Geographic Atrophy: A Study of Vision-Related Quality of Life and Health Care Resource Use. Clinical ophthalmology (Auckland, NZ). 2020;14:15-28.

4. Sacconi R, Corbelli E, Querques L, Bandello F, Querques G. A Review of Current and Future Management of Geographic Atrophy. Ophthalmology and Therapy. 2017; 6:69-77

5. Risk factors for geographic atrophy (2023) Macular degeneration. Accessed May 2023.

6. Age-related macular degeneration (2023) NHS. Accessed May 2023.

7. Owen CG, Jarrar Z, Wormald R, Cook DG, Fletcher AE, Rudnicka AR. The estimated prevalence and incidence of late stage age related macular degeneration in the UK. Br J Ophthalmol. 2012 May;96(5):752-6.

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