NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Vamikibart for treating uveitic macular oedema ID6671

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of vamikibart within its marketing authorisation for treating uveitic macular oedema.

Background

Uveitic macular oedema (UMO) is a complication of uveitis. Uveitis is an eye condition in which the middle layer of the eye (uvea) becomes inflamed. It is diagnosed as UMO when the inflammation affects the macula, the central part of the retina responsible for detailed central vision. Breakdown of the outer or inner blood–retina barrier leads to pigments needed for vision leaking and fluid accumulating, with eventual loss of vision. The cause of uveitis is often unknown but can be linked to the immune system. It can also be caused by infection, injury or surgery, although this is less common.

Uveitis is a rare condition, with only around 2 to 5 in 10,000 people in the UK affected by it each year.[1] Despite this, uveitis is the fifth leading cause of visual impairment in developed countries and responsible for about 20% of legal blindness.[2] UMO is a complication in about 8% of uveitis patients and causes serious visual impairment in about 40% of cases.[3]

NICE has recommended adalimumab and dexamethasone and fluocinolone acetonide intravitreal implant to treat non-infectious uveitis. Currently UMO is mainly treated with corticosteroids, and immunomodulatory and biologic treatments can also be used.

The technology

Vamikibart (Vamikibart, Roche) does not currently have a marketing authorisation in the UK for treating uveitic macular oedema. It has been studied in clinical trials compared with sham treatment in adults with macular oedema associated with non-infectious uveitis.

Intervention(s)	Vamikibart
Population(s)	Adults with macular oedema associated with non-infectious uveitis

Comparators	• Corticosteroids, including dexamethasone intravitreal implant and fluocinolone acetonide implant • Antimetabolites (for example, methotrexate, azathioprine, mycophenolate) • Calcineurin inhibitors (for example, ciclosporin, tacrolimus) • Alkylating agents (for example, cyclophosphamide, chlorambucil) • Biologics (for example, adalimumab, infliximab, rituximab)
Outcomes	The outcome measures to be considered include: • visual acuity • overall visual function • central subfield thickness • resolution of UMO, defined by central subfield retinal thickness • rescue treatment – timing, number needed and type • 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 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:** Fluocinolone acetonide intravitreal implant for treating recurrent non-infectious uveitis (2019) NICE technology appraisal guidance 590 Adalimumab and dexamethasone for treating non-infectious uveitis (2017) NICE technology appraisal guidance 460

Questions for consultation

Where do you consider vamikibart will fit into the existing care pathway for uveitic macular oedema?

What treatments would:

- you expect vamikibart to replace?
- continue to be taken alongside vamikibart?
- be tried first before vamikibart?

Please select from the following, will vamikibart be:
A. Prescribed in primary care with routine follow-up in primary care
B. Prescribed in secondary care with routine follow-up in primary care
C. Prescribed in secondary care with routine follow-up in secondary care
D. Other (please give details):
For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would vamikibart be a candidate for managed access?

Do you consider that the use of vamikibart 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.

Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.

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 vamikibart 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-technology-appraisal-guidance/changes-to-health-technology-evaluation).

References

1. Moorfields Eye Hospital NHS Foundation Trust. Uveitis. Accessed April 2026.

2. Fardeau C, Champion E, Massamba N et al. (2016) Uveitic macular edema. Eye (Lond) 30(10): 1277–92.

3. Teper SJ (2021) Update on the management of uveitic macular edema. J Clin Med 10(18):4133.