NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Faricimab for treating macular oedema caused by retinal vein occlusion ID6197

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of faricimab within its marketing authorisation for treating macular oedema secondary to retinal vein occlusion.

Background

The macula is the central part of the retina responsible for colour vision and perception of fine detail. Macular oedema refers to the accumulation of fluid within the retina at the macular area, causing persistent swelling, which can lead to severe visual impairment in the affected eye. Retinal vein occlusion (RVO) is a common cause of reduced vision due to retinal vascular disease. It is classified into central retinal vein occlusion (CRVO) and branch retinal vein occlusion (BRVO). In general, visual loss is more severe if the central retinal vein is occluded. Such blockages in the retinal veins increases retinal capillary pressure leading to discharge of blood and plasma into the macula. These changes trigger an increased amount of vascular endothelial growth factor (VEGF), which can increase the growth of new abnormal blood vessels in the retina.[1]

RVO is most common in people aged 60-80 and is rarely seen in those aged under 40 years. It is associated with risk factors such as arterial hypertension, diabetes, hyperlipidaemia, glaucoma, smoking, and a history of certain conditions such as stroke or coagulation disorders.[2] The impact of vision loss associated with RVO can have a profound effect on vision-related quality of life. Patients may struggle with daily tasks, lose confidence, and become increasingly dependent on family and carers. RVO is also associated with an increase in the risk of vascular causes of death.

No prevalence or incidence data has been identified for England and Wales. In England between 2021 and 2022 there were 12,496 finished consultant episodes for RVOs, with 12,258 hospital admissions.[3]

The aims of current treatments are to preserve vision and prevent complications. Treatment is usually through anti-VEGF injections or steroid implants injected into the eye. The injections have to be repeated over a period of time to work effectively. NICE technology appraisal 229 recommends a dexamethasone intravitreal implant as an option for the treatment of macular oedema secondary to CRVO, and secondary to BRVO only if treatment with laser photocoagulation has not been beneficial or is not considered suitable. NICE technology appraisal 283 recommends ranibizumab as an option for treating visual impairment caused by macular oedema secondary to CRVO, and secondary to BRVO only if treatment with laser photocoagulation has not been beneficial or is not considered suitable. NICE technology appraisal TA305 and NICE technology appraisal 409 recommend aflibercept as an option for treating visual impairment caused by macular oedema secondary to CRVO and BRVO, respectively. Intravitreal injections of bevacizumab, which does not have a marketing authorisation in the UK for treating any ocular condition, may also be used.

The technology

Faricimab (Vabysmo, Roche) does not currently have a marketing authorisation in the UK for the treatment of adults with macular oedema secondary to RVO. It has been studied in clinical trials compared with aflibercept in adults with CRVO and BRVO.

Faricimab currently has marketing authorisations in the UK for the treatment of adult patients with neovascular (wet) age-related macular degeneration, and for visual impairment due to diabetic macular oedema.

Intervention(s)	Faricimab
Population(s)	People with macular oedema secondary to retinal vein occlusion
Subgroups	• People with macular oedema secondary to central retinal vein occlusion (CRVO) • People with macular oedema secondary to branch retinal vein occlusion (BRVO)
Comparators	• laser photocoagulation • dexamethasone intravitreal implant (for BRVO only after laser photocoagulation has been tried, or is not suitable) • ranibizumab (for BRVO only after laser photocoagulation has been tried, or is not suitable) • aflibercept • bevacizumab (not licensed in the UK for this indication)
Outcomes	The outcome measures to be considered include: • visual acuity (the affected eye) • visual acuity (the whole person) • 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 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:** Dexamethasone intravitreal implant for the treatment of macular oedema secondary to retinal vein occlusion (2011) NICE technology appraisal guidance 229. Ranibizumab for treating visual impairment caused by macular oedema secondary to retinal vein occlusion (2013) NICE technology appraisal guidance 283. Aflibercept for treating visual impairment caused by macular oedema secondary to central retinal vein occlusion (2014) NICE technology appraisal guidance 305. Aflibercept for treating visual impairment caused by macular oedema after branch retinal vein occlusion (2016) NICE technology appraisal guidance 409. **Related interventional procedures:** Arteriovenous crossing sheathotomy for branch retinal vein occlusion (2010) NICE interventional procedures guidance 334. **Related quality standards:** Serious eye disorders (2019). NICE quality standard 180.

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

Questions for consultation

Where do you consider faricimab will fit into the existing care pathway for macular oedema caused by retinal vein occlusion?

Would faricimab be a candidate for managed access?

Do you consider that the use of faricimab 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 faricimab 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-tehnology-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 comparators? 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 comparators?
- 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. Moorfields Eye Hospital (NHS Foundation Trust). Patient information: Retinal vein occlusion. 2022. https://www.moorfields.nhs.uk/sites/default/files/Retinal%20vein%20occlusion%20%28RVO%29.pdf [Accessed August 2023).

2. The College of Optometrists. Clinical management guidelines: retinal vein occlusion. 2021. https://www.college-optometrists.org/clinical-guidance/clinical-management-guidelines/retinal-vein-occlusion (Accessed August 2023)

3. National Health Service (NHS) Digital Office for National Statistics. Hospital Admitted Patient Care Activity, 2020-21: Diagnosis. 2021. https://digital.nhs.uk/data-and-information/publications/statistical/hospital-admitted-patient-care-activity/2020-21#chapter-index (Accessed August 2023)