NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Faricimab for treating macular oedema caused by retinal vein occlusion

Final scope

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	• 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
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 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

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)