National Institute for Health and Care Excellence

Health Technology Evaluation

Faricimab for treating macular oedema caused by retinal vein occlusion [ID6197]

Response to stakeholder organisation comments on the draft remit and draft scope

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: the draft remit and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	Roche (company)	NICE has recommended the technology be evaluated through the cost-comparison process. This is considered an appropriate route as faricimab is expected to provide similar or greater health benefits, at a similar or lower cost, compared with previously recommended technologies in published NICE guidance for the same indication. The new intervention is intended to be used in the same place in the treatment pathway as comparators in the same population.	Thank you for your comment. No change to scope required.
Wording	Roche (company)	The licence wording is anticipated to be: [redacted] Therefore we consider the wording of the remit to be appropriate.	Thank you for your comment. No change to scope required.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Roche (company)	Roche considers this section to be accurate and complete.	Thank you for your comment. No change to scope required.
Population	Roche (company)	[redacted]	Thank you for your comment. No change to scope required.
Subgroups	Roche (company)	Roche considers the subgroups suggested within the scope appropriate.	Thank you for your comment. No change to scope required.
Comparators	Roche (company)	Aflibercept, ranibizumab and dexamethasone intravitreal (IVT) implant are licensed treatments for patients with retinal vein occlusion with associated NICE guidance. All three of these technologies are part of the treatment pathway for this patient population and are appropriate to include as comparators to faricimab in this appraisal. Dexamethasone IVT implant is currently considered routine practice in the NHS (including existing NICE guidance) for the first-line treatment of macular oedema secondary to CRVO. Dexamethasone is recommended by both the Royal College of Ophthalmologists (RCO) for the management of CRVO, and by NICE for the treatment of macular oedema secondary to CRVO and BRVO. Unlicensed bevacizumab (Avastin©) is not a relevant comparator for this appraisal. Bevacizumab does not have a marketing authorisation for retinal	Thank you for your comments. The NICE technical team agrees that laser photocoagulation and bevacizumab are not relevant comparators, and these have now been removed from the scope. Where a technology is expected to be evaluated through the cost comparison process, only comparison against the

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		vein occlusion and has been developed and manufactured for intravenous use in the treatment of a number of cancers. [redacted]. Since the availability of IVT-based treatments, laser photocoagulation is no longer the standard of care for retinal vein occlusion, with the exception of CRVO with ischaemic features. Therefore, this is not considered a relevant comparator. Further supportive evidence for this are as follows: While laser treatment can improve vision in macular oedema due to BRVO, anti-VEGF therapy is recommended as the primary option, with focal laser photocoagulation recommended as a second-line treatment. Studies indicate longer disease duration with early IVT treatment compared to initial laser-only treatments. RCO guidelines suggest that IVT therapy results are generally superior to laser for BRVO with oedema. Treatment choice, whether anti-VEGF or IVT dexamethasone injections, should take into consideration the frequency of treatment, risk of intraocular pressure (IOP) rise, and cataract formation. Additionally, a study showed that IVT ranibizumab was more effective than laser for macular edema after BRVO, with better vision improvements at 12 months.	most relevant comparator is necessary.
Outcomes	Roche (company)	Roche broadly agrees with the outcome measures stated, except for visual acuity (the whole person). The assumption by Roche is that whole person refers to both eyes. RVO typically affects one eye (generally not a bilateral	Thank you for your comment. The NICE technical team agrees that this outcome is not

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		disease) as such Roche does not agree with the inclusion of the visual acuity whole person measure.	appropriate because RVO is typically not a bilateral disease. This outcome has been removed from the scope.
Equality	Roche (company)	Visual impairment resulting from RVO is recognised as a disability and so the patient population under consideration in this appraisal is a protected group under the Equality Act of 2010.	Thank you for your comment. No change to scope required.
Questions for consultation	Roche (company)	Where do you consider faricimab will fit into the existing care pathway for macular oedema caused by retinal vein occlusion? *Faricimab would be positioned as an alternative treatment option for* [redacted] Would faricimab be a candidate for managed access? *No, faricimab would not be a candidate for a managed access but rather routine commissioning.* 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. *Faricimab is uniquely engineered to target and inhibit two signalling pathways, which are linked to a number of vision-threatening retinal conditions, by*	Thank you for your comment. No change to scope required.

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		neutralising angiopoietin-2 (Ang-2) and vascular endothelial growth factor-A (VEGF-A) to restore vascular stability (9, 10). The level of Ang-2 is elevated in RVO and it is thought that increased Ang-2 expression drives disease progression. *Patients, caregivers and the NHS could benefit from increased treatment intervals and reduced injections that faricimab is able to offer compared to currently available treatment. It is unlikely that the QALY calculations will fully capture the reduction in burden associated with fewer faricimab injections.* [redacted] 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	

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		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 see the response to the "Equality" section above.*	

The following stakeholders indicated that they had no comments on the draft remit and/or the draft scope

AbbVie