Surrey Heartlands Integrated Care System
Area Prescribing Committee (APC)

Integrated Care Partnership - Surrey Downs, Guildford & Waverley, North-West Surrey, and East Surrey Places & associated partner organisations.

NICE Technology Appraisals (TA) briefing paper for local implementation

NICE TA Guidance name and number	Faricimab for treating visual impairment caused by macular oedema after retinal vein occlusion (TA1004)		
Available at	**https://www.nice.org.uk/guidance/ta1004**		
Date of issue	11 September 2024	**Implementation deadline**	30 days (11 October 2024) To note that this briefing will breach NICE implementation timelines by 19 days and will be presented to the APC on 6th November 2024

Medicine details	
Name and brand name	Faricimab (Vabysmo)
Manufacturer	Roche
Mode of action	Faricimab is a humanised bispecific immunoglobulin G1 (IgG1) antibody that acts through inhibition of two distinct pathways by neutralisation of both angiopoietin-2 (Ang-2) and vascular endothelial growth factor A (VEGF-A). Ang-2 causes vascular instability by promoting endothelial destabilisation, pericyte loss, and pathological angiogenesis, thus potentiating vascular leakage and inflammation. It also sensitises blood vessels to the activity of VEGF-A resulting in further vascular destabilisation. Ang-2 and VEGF-A synergistically increase vascular permeability and stimulate neovascularisation. By dual inhibition of Ang-2 and VEGF-A, faricimab reduces vascular permeability and inflammation, inhibits pathological angiogenesis and restores vascular stability.
Licenced indication	Visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO).
Formulation	Intravitreal injection
Dosage	The recommended dose is 6 mg (0.05 mL solution) administered by intravitreal injection every 4 weeks (monthly); 3 or more consecutive, monthly injections might be needed. Thereafter, treatment may be individualised using a treat -and-extend approach. Based on the physician's judgement of the patient's anatomic and/or visual outcomes, the dosing interval may be

	extended in increments of up to 4 weeks. If anatomic and/or visual outcomes change, the treatment interval should be adjusted accordingly, and interval reduction should be implemented if anatomic and/or visual outcomes deteriorate (see section 5.1). Treatment intervals shorter than 21 days and longer than 16 weeks have not been studied. Monitoring between the dosing visits should be scheduled based on the patient's status and at the physician's discretion but there is no requirement for monthly monitoring between injections. **Duration of treatment** Vabysmo is intended for long-term treatment. If visual and/or anatomic outcomes indicate that the patient is not benefitting from continued treatment, Vabysmo should be discontinued
Comparison of NICE TA with Summary of Product Characteristics (SmPC)	There is no initiation or continuation criteria in the NICE guidance other than the patient has visual impairment. This is the current dose considered by NICE as part of this NICE evaluation. Subsequent changes in the licence following NICE publication will need to be considered by the Area Prescribing Committee and will not be routinely funded by local commissioners, as the incremental cost per QALY would not have been considered.

NICE TA recommendations
Recommendations
1. Recommendations 1.1. Faricimab is recommended, within its marketing authorisation, as an option for treating visual impairment caused by macular oedema after central or branch retinal vein occlusion in adults. It is only recommended if the company provides it according to the commercial arrangement. 1.2. If people with the condition and their healthcare professional consider faricimab to be 1 of a range of suitable treatments, after discussing the advantages and disadvantages of all the options, the least expensive should be used. Administration costs, dosages, price per dose and commercial arrangements should all be taken into account. **Why these recommendations were made** Visual impairment caused by macular oedema after retinal vein occlusion is usually treated with an anti-vascular endothelial growth factor (anti-VEGF) treatment (aflibercept or ranibizumab). Faricimab is another treatment option that works in a similar way and would be offered to the same population. Using NICE's cost comparison methods, if a treatment has similar benefits and costs to a comparator recommended in technology appraisal guidance it can be recommended as a treatment option. Evidence from clinical trials shows that faricimab is likely to work as well as aflibercept for people who have not had an anti-VEGF treatment. There is limited evidence for how well faricimab works for people who have had an anti-VEGF treatment. But clinical experts agreed that faricimab is likely to work as well as aflibercept for people who have had an anti-VEGF treatment.

A cost comparison suggests faricimab has similar costs and overall health benefits to aflibercept. In addition, a majority of people currently have aflibercept for this condition, particularly people starting treatment. So faricimab is recommended as an additional treatment option.

There are no equality issues relevant to the recommendations.

For all evidence see the committee papers. For more information on NICE's evaluation of aflibercept, see the consideration of the evidence section in NICE's technology appraisal guidance on aflibercept for treating visual impairment caused by macular oedema secondary to central retinal vein occlusion, and the committee discussion section in aflibercept for treating visual impairment caused by macular oedema after branch retinal vein occlusion.

Decision making framework (DMF)

National guidance and priorities

The ICS has a legal obligation to commission this medicine in line with the NICE TA.

- This NICE TA has been assigned an implementation deadline of fast tracked to 30 days.
- The implementation deadline is 11 October 2024. That this briefing will breach NICE implementation timelines by 26 days and will be presented to the APC on 6th November 2024

Clinical effectiveness

- Evidence from clinical trials shows that faricimab is likely to work as well as aflibercept for people who have not had an anti-VEGF treatment. There is limited evidence for how well faricimab works for people who have had an anti-VEGF treatment. But clinical experts agreed that faricimab is likely to work as well as aflibercept for people who have had an anti-VEGF treatment.

Patient safety

- The product should be used within its product licence.
- ▼ This is a Black Triangle drug – this medicinal product is subject to reporting of all suspected adverse drug reactions to the MHRA. This will allow timely identification of new safety information.

www.medicines.org.uk

- Vabysmo must be administered by a qualified healthcare professional trained in intravitreal injections. Each vial should only be used for the treatment of a single eye.
- The safety and efficacy of Vabysmo in children and adolescents have not been established. No data are available.
- The intravitreal injection procedure should be carried out under aseptic conditions.
- Immediately after the intravitreal injection, patients should be monitored for elevation in intraocular pressure.
- Patients should be instructed to report any symptoms suggestive of endophthalmitis (e.g. vision loss, eye pain, redness of the eye, photophobia, blurring of vision) without delay.

Patient factors

- Patients would need to attend the Ophthalmology clinics every 4 weeks initially (for 3 months), then a patient's treatment can be individualised using a treat and extend protocol.

Please note:

- **Patients who require 4 weekly dosing after induction are expected to be treated with biosimilar ranibizumab which is the least costly anti-VEGF preparation.**
- **Some local hospitals are not in a position to deliver treat and extend protocols and this is being worked through at local and regional level.**
- An additional treatment option would be valued by patients. Aflibercept and ranibizumab biosimilar are other (anti-VEGFs) that are recommended by NICE for the treatment of Retinal Vein Occlusion.
- Biosimilar ranibizumab should be used 1st line as the least costly preparation.

- Patients would need to be reviewed on a regular basis by the prescribing clinician to ensure concordance, monitor for adverse effects and efficacy.

Environmental impact

- Additional packaging will be generated and will be an environmental impact with regards to waste management.
- Patients will be required to travel to appointments which will have an impact on the carbon footprint

Equality & diversity

- There are no equality issues identified with this recommendation

Note 1: Drugs approved by NICE for adult conditions will be commissioned in children at specialised paediatric centres if the patient meets the NICE criteria and there is evidence to suggest that the drug is safe and clinically appropriate to use in children as per the NHS England Medicines for Children Policy (see https://www.england.nhs.uk/publication/commissioning-medicines-for-children-specialised-services/ and a Blueteq form is available.

Place in therapy relative to available treatments

- Proposed pathway is attached with this briefing paper.
- The proposed place in therapy for faricimab is 2nd (after aflibercept) or 3rd line (after aflibercept & ranibizumab biosimilar) for treatment of Retinal Vein Occlusion. Evidence shows that faricimab is likely to work as well as aflibercept.
- Anti-VEGF switching for this condition has not been agreed to date by the APC. However, switching in wet AMD and Diabetic Macular Oedema is now well established in Surrey Heartlands ICB.

Stakeholder views

- The paper was sent out for consultation and comments are listed on the front sheet.

Cost-effectiveness

A cost comparison suggests faricimab has similar costs and overall health benefits to aflibercept. In addition, a majority of people currently have aflibercept for this condition, particularly people starting treatment. So faricimab is recommended as an additional treatment option.

Section 1: cost of the technology

- The list price of faricimab is £857 for 1 vial of 120 mg per 1 ml solution for injection (excluding VAT; BNF online accessed May 2024)

- The company has a commercial arrangement. This makes faricimab available to the NHS with a discount. The size of the discount is commercial in confidence.

Annual cost per patient (or complete course if shorter)

The license for faricimab states:

- The recommended dose is 6 mg (0.05 mL solution) administered by intravitreal injection every 4 weeks (monthly); 3 or more consecutive, monthly injections might be needed.

In the clinical trials (Committee papers), faricimab has been compared to aflibercept 8 weekly dosing.
Therefore, there is an assumption made that after the first 3 induction doses of faricimab, treatment would be extended to 8 weekly dosing.

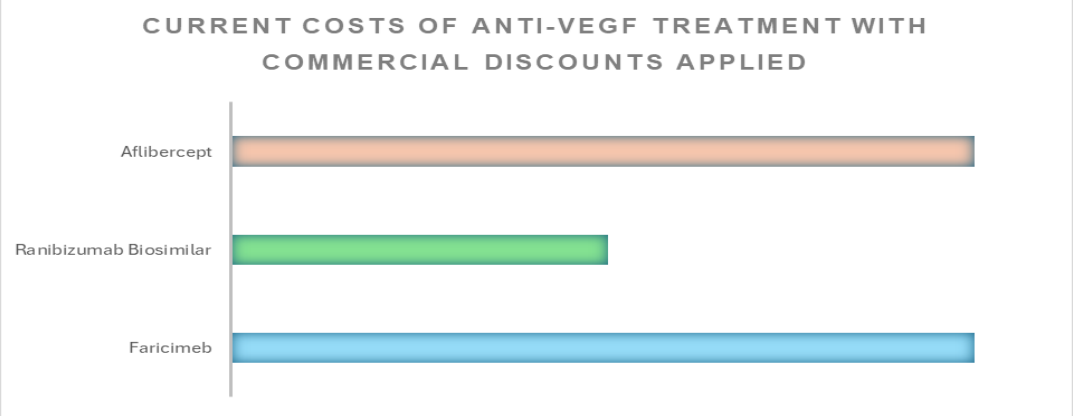
Year one cost for faricimab (8 doses) - £6,856 (list price)
Second and subsequent year costs for faricimab (6 doses) - £5,142

Patients who require 4 weekly doing after induction should be switched to ranibizumab biosimilar (if not already trialled)

Availability of CAP/PAS price:

A commercial discount is available

Price relative to comparable medicines:



NICE Resource Template

The resource template requires the user to predict the number of patients that will be treated with ranibizumab biosimilar, aflibercept, dexamethasone intravitreal implant and faricimab over time, no NICE assumptions are made and so cost per 100,000 population has not been predicted.

There is no evidence that faricimab is more effective than aflibercept. By allowing the use of faricimab instead of aflibercept, unless there is a substantial increase in interval between injections (e.g. double the interval) this will reduce the opportunity for maximising cost savings of biosimilar aflibercept when it becomes available, (estimated March 2025).

This would then exceed the £100,000k per place per year approval threshold of APC. Subject to numbers of faricimab used and cost of biosimilars when these are known.

Resource statement

NICE has recommended faricimab within its anticipated marketing authorisation, as an option for treating visual impairment caused by macular oedema after central or branch retinal vein occlusion in adults. It is only recommended if the company provides it according to the commercial arrangement.

It is estimated that the incidence of retinal vein occlusion with visual impairment caused by macular oedema in England is around 22,000 people per year. It is assumed that all of these people are aged 40 and over and are therefore eligible for treatment with faricimab **and relevant comparators.**

Visual impairment caused by macular oedema after retinal vein occlusion is usually treated with anti-vascular endothelial growth factor (VEGF) treatments aflibercept and ranibizumab. Faricimab is another treatment option that works in a similar way to aflibercept and ranibizumab and would be offered to the same population.

It is anticipated that aflibercept will be accessible as a biosimilar option during the timeframe encompassed by the resource impact assessment. Ranibizumab is already available as a biosimilar. The availability of biosimilars could lead to significant financial implications. To accurately gauge these effects, users can input local estimates of the market shares for biosimilar and all other treatments directly into the resource impact template that accompanies this summary report.

The company has a commercial arrangement. This makes faricimab available to the NHS with a discount. The size of the discount is commercial in confidence.

Treatments for people with macular oedema are commissioned by integrated care boards.

Providers are NHS hospital trusts.

The payment mechanism for the technology is determined by the responsible commissioner and depends on the technology being classified as high cost.

This page was last updated: 11 September 2024

The Surrey Heartlands Director of Pharmacy and Medicines Optimisation has delegated authority to enable the Committee to be a decision-making committee providing the impact of any single decision does not exceed £100,000 within an individual Place per annum. Decisions with a cost impact of over £100,000 within an individual Place per annum require authorisation from Surrey Heartlands Health & Care Professionals Committee at their next meeting. Exception to this will be for any decision made in relation to a NICE Technology Appraisal (which are subject to requiring mandatory funding by commissioners) and other urgent items. The exceptions will be taken to the next Executive Meeting (which meets weekly) for authorisation.

Traffic light recommendation to APC

NHS Payment Scheme (NHSPS) excluded high-cost drug: see NHS England » 2023-25 NHS Payment Scheme
Yes

Recommended traffic light status and rationale:
RED – Specialist ONLY drugs - treatment initiated and continued by specialist clinicians.

Implementation

NICE TA implementation must be within 30 days of publication.

Primary care

- This is a National Tariff excluded high-cost drug and is commissioned by ICSs for use in secondary care. There should be no prescribing in primary care.
- Primary care prescribers should be aware that their patient is receiving this medicine and ensure that this is recorded in the patient's notes in order to be alert to potential side-effects and interactions with other medicines prescribed in primary care. This will also ensure that GP records, which are accessed by other healthcare providers, are a true and accurate reflection of the patient's medication.

Secondary care

- Providers are NHS hospital trusts.
- Trusts to follow internal governance procedures to add to their formulary and initiate homecare.
- The initiation, administration and on-going treatment is managed by secondary care.
- Specialists will be required to notify the high-cost drugs teams of initiation and response to treatment using the Blueteq® system.

ICS

- This technology is commissioned by integrated care systems and they are required to comply with the recommendation in the NICE TA within the time set in the publication.
- Pathway to be discussed by the Ophthalmology Medicines Network members prior to wider consultation

PAD and Joint Formulary

- A treatment pathway has been developed and will be discussed at the APC with this briefing paper.
- Currently the PAD has a profile for each treatment option for Branch or Central Retinal Vein Occlusion (BRVO OR CRVO) Proposal would be to have the following pages on PAD:
    - Retinal Vein Occlusion Guidelines page
    - Ranibizumab biosimilar – Retinal Vein Occlusion
    - Aflibercept – Retinal Vein Occlusion (currently split to BRVO & CRVO profile pages)
    - Faricimab – Retinal Vein Occlusion

○ Intravitreal Dexamethasone Implant – Retinal Vein Occlusion • Remove document ○ Achieving and demonstrating compliance with NICE TA and HST guidance - NICE January 2016 and the corresponding PAD/JF narrative.
Proposed tick box forms
Blueteq® form has been developed.

References:

1 Summary of Product Characteristics. emc. Available at: www.medicines.org.uk Accessed 07/10/2024

2 NICE Technology Appraisal Guidance: . Available at: www.nice.org.uk Accessed 07/10/2024

3 NICE Resource Impact Report: . Available at: www.nice.org.uk Accessed 07/10/2024

4 NICE Resource Impact Template: . Available at: www.nice.org.uk Accessed 07/10/2024

Declaration of interest:

	Name	Role	Date	Declaration of interests (please give details below)
Prepared by				None
Supported by				
Reviewed by				

Explanation of declaration of interest:
None.

Version control sheet:

Version	Date	Author	Status	Comment
1			Draft	Out for consultation
			Final	Out for clinical comment

Blueteq® form: