Briefing Paper for Surrey Heartlands Integrated Care System (ICS) Area Prescribing Committee (APC)

Surrey Downs, Guildford & Waverley, North West Surrey, East Surrey Place & associated partner organisations

NICE Technology Appraisals: Local implementation

NICE TA Guidance name and number	Faricimab for treating wet age-related macular degeneration Technology appraisal guidance 800 Fast track 30-day implementation.		
Available at	Overview | Faricimab for treating wet age-related macular degeneration | Guidance | NICE		
Date of issue	29 June 2022	**Implementation deadline**	29 July 2022

Medicine details[1]	
Name, brand name and manufacturer	Faricimab (Vabysmo ®) 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. *Please note:* *Aflibercept and ranibizumab (brolucizumab also has a NICE TA but is not mentioned in the NICE TA for faricimab) are anti-VEGF recommended by NICE for treating DMO. Faricimab is an anti-VEGF and also targets the Ang-2 pathway. Trials have only shown equivalence and not superiority to aflibercept.*
Licensed indication	Faricimab is indicated for 'the treatment of adults with neovascular (wet) age-related macular degeneration'.
Formulation	Intravitreal injection.
Usual dosage	1 mL solution for injection contains 120 mg of faricimab. Each vial contains 28.8 mg faricimab in 0.24 mL solution. This provides a usable amount to deliver a single dose of 0.05 mL solution containing 6 mg of faricimab. The recommended dose for Vabysmo® is 6 mg (0.05 mL solution)

	administered by intravitreal injection every 4 weeks for the first 4 doses. Thereafter, an assessment of disease activity based on anatomic and/or visual outcomes is recommended 20 and/or 24 weeks after treatment initiation so treatment can be individualised. In patients without disease activity, administration of Vabysmo® every 16 weeks should be considered. In patients with disease activity, treatment every 8 weeks or 12 weeks should be considered. 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. <u>Duration of treatment</u> 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 with NICE TA use[2]	NICE TA only sets out criteria for use i.e., the eye has a best-corrected visual acuity between 6/12 and 6/96 etc. This is the same as for the other options, aflibercept and ranibizumab. No dosages or lengths of treatment are defined. *This is the current dose considered by NICE as part of this NICE evaluation. Subsequent changes in the license following NICE publication will need to be considered by the Area Prescribing Committee and **will not be routinely funded** by local commissioners.*
Disease and potential patient group	
Brief description of disease	Age-Related Macular Degeneration - Moorfields Eye Hospital How AMD affects vision The macula is a small, but extremely important area located at the centre of the retina, the light-sensing tissue that lines the back of the eye. It is responsible for seeing fine details clearly. If you have AMD, you lose the ability to see fine details, both close-up and at a distance. This affects only your central vision. Your side, or peripheral, vision usually remains normal. For example, when people with AMD look at a clock, they can see the clock's outline but cannot tell what time it is; similarly, they gradually lose the ability to recognise people's faces. Types of AMD There are two types of AMD. Most people (about 75%) have a form called "early" or "dry" AMD, which develops when there is a build-up of waste material under the macula and thinning of the retina at the macula. Most people with this condition have near normal vision or milder sight loss. A minority of patients with early (dry) AMD can progress to the vision-threatening forms of AMD called late AMD. The commonest form of late AMD is "exudative" or "wet" AMD. Wet

	AMD occurs when abnormal blood vessels grow underneath the retina. These unhealthy vessels leak blood and fluid, which can prevent the retina from working properly. Eventually the bleeding and scarring can lead to severe permanent loss of central vision, but the eye is not usually at risk of losing all vision (going 'blind') as the ability to see in the periphery remains. There is a rarer form of late AMD called geographic atrophy, where vision is lost through severe thinning or even loss of the macula tissue without any leaking blood vessels.
Potential patient numbers per 100,000[4]	1,264 / 100,000 of the people in England aged 50 years and over midpoint in 2020.

SUMMARY

Guidance[2]

Recommendations
1.1 Faricimab is recommended as an option for treating wet age-related macular degeneration in adults, only if:
• the eye has a best-corrected visual acuity between 6/12 and 6/96
• there is no permanent structural damage to the central fovea
• the lesion size is 12 disc areas or less in greatest linear dimension
• there are signs of recent disease progression (for example, blood vessel growth as shown by fluorescein angiography, or recent visual acuity changes)
• the company provides faricimab according to the commercial arrangement.

1.2 If patients and their clinicians consider faricimab to be 1 of a range of suitable treatments (including aflibercept and ranibizumab), choose the least expensive treatment. Take account of administration costs, dosage, price per dose and commercial arrangements.

1.3 Only continue faricimab if an adequate response to treatment is maintained. Criteria for stopping should include persistent deterioration in visual acuity and anatomical changes in the retina.

1.4 These recommendations are not intended to affect treatment with faricimab that was started in the NHS before this guidance was published. People having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

Evidence from clinical trials shows that faricimab is as effective as aflibercept. An indirect Faricimab for treating wet age-related macular degeneration comparison of faricimab with ranibizumab also suggests similar clinical effectiveness.
A cost comparison suggests faricimab has similar costs and overall health benefits to aflibercept or ranibizumab. So, faricimab is recommended for treating wet age-related macular degeneration if it is used in the same population as aflibercept and ranibizumab.

Why the committee made these recommendations

Wet age-related macular degeneration is usually treated with aflibercept or ranibizumab, which are already recommended by NICE for treating wet age-related macular degeneration. Faricimab is another treatment option that works in a similar way.

Evidence from clinical trials shows that faricimab is as effective as aflibercept. An indirect comparison of faricimab with ranibizumab also suggests similar clinical effectiveness.

A cost comparison suggests faricimab has similar costs and overall health benefits to

aflibercept or ranibizumab. So, faricimab is recommended for treating wet age-related macular degeneration if it is used in the same population as aflibercept and ranibizumab.

Other factors e.g. equality issues

There are no equality issues relevant to the recommendations.

Cost implications* [2,3,4]

Cost:
List price for faricimab is £857 for 1 vial of 120 mg per 1 ml solution for injection (excluding VAT; company submission, accessed April 2022).

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. It is the company's responsibility to let relevant NHS organisations know details of the discount.

NICE TA has stated that 'patients and their clinicians consider faricimab to be 1 of a range of suitable treatments (including aflibercept and ranibizumab), choose the least expensive treatment. Take account of administration costs, dosage, price per dose and commercial arrangements'

From the clinical trials and the product licences, faricimab requires a larger number of loading doses than aflibercept (4 vs 3) resulting in what is possibly a higher number of injections in the first year, with the suggestion that fewer injections are required in the second year. This was, however, compared with 2-monthly aflibercept whereas in practice, as recognised in the NICE TA, aflibercept is often used in a treat-and-extend protocol which also allows for the increase of dose intervals between injections. True relative costs will only be known when this product has been on the market for a number of years.

The place in therapy, and how this product fits in with the NICE recommendation to take account of the administration costs, dosage, and price per dose and commercial arrangements will be discussed at the next Ophthalmology Network meeting, and in line with the national procurement of anti-VEGF currently underway and the imminent introduction of biosimilar ranibizumab.

As there isn't compelling evidence of superiority, it is unlikely that this product will be taken up very rapidly as clinicians are most confident with well established treatments. It is therefore not expected to have a significant cost impact.

Costing information per CCG:
Please note: Prices are likely to change from 1st August due to the national procurement of anti-VEGF and the imminent introduction of biosimilar ranibizumab.

Availability of PAS and details (if appropriate):
Yes - the PAS price will be given to trusts which would reduce the cost price stated above.

The PAS price only applies to trusts and primary care services would not be able to prescribe and supply at this reduced price, in line with the NICE TA.

Availability of homecare service (if appropriate):
N/A

Alternative treatments and cost per patient per year

Other NICE recommended products:
Ranibizumab, aflibercept, brolucizumab.
Currently prices are all similar, but place in therapy will need to be considered in light of the costs of biosimilar ranibizumab (not available at the time of this NICE TA), in line with the

National Procurement of anti-VEGF currently under way, and with detailed review of the evidence for reduced number of injections, together with the capacity of individual departments to deliver treat and extend protocols.

Options not reviewed by NICE but used in standard practice:
None.

Impact to patients

- An additional treatment option would be valued by patients. No significant ocular or systemic safety signals were seen in the faricimab groups.

Impact to primary care prescribers

- This is a National Tariff excluded high-cost drug and is commissioned by integrated care systems (ICS) / clinical commissioning groups (CCG) 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.

Impact to secondary care

- Providers are NHS hospital trusts.
- The initiation, administration and on-going treatment is managed by secondary care.
- An additional treatment option would be valued by clinicians.

Impact to commissioners

- The technology is commissioned by ICS/CCGs and they are required to comply with the recommendations in a NICE TA within 30 days its date of publication.
- Faricimab has similar costs and overall health benefits to aflibercept or ranibizumab. Brolucizumab has not been referred to, in this NICE technology appraisal.
- However, if the time needed between injections for faricimab is lengthened, then the cost of faricimab would reduce.

Implementation

- NICE TA fast track implementation must be within 30 days of publication.
- Blueteq forms to be developed.
- Trusts to follow internal governance procedures to add to their formulary.
- Pathway to be discussed at Ophthalmology Network and to consider the place in the pathway.
- Prices are likely to change from 1st August due to the national procurement of anti-VEGF and the imminent introduction of biosimilar ranibizumab. This will impact pathways and preferred products.
- Whether this product is to be included in the Switch options for anti-VEGF treatments is to be discussed at the next Ophthalmology Network Meeting.

Recommendation to APC

National Tariff excluded high-cost drug: Yes

Recommended traffic light status: RED

Additional comments:

References:

1 Specification of Product Characteristics. emc. Available at: https://www.medicines.org.uk/emc/product/13741 Accessed <4.7.22>

2 NICE Technology Appraisal Guidance: Faricimab for treating wet age-related macular degeneration. Available at: https://www.nice.org.uk/guidance/ta800 Accessed <6.7.22>

3 NICE Resource impact report: Faricimab for treating wet age-related macular degeneration. Available at: https://www.nice.org.uk/guidance/ta800/resources Accessed <6.7.22>

4 NICE Resource Impact template: Faricimab for treating wet age-related macular degeneration. Available at: https://www.nice.org.uk/guidance/ta800/resources Accessed <6.7.22>

5 What faricimab for DME means for safe, durable treatment over the long term, Ophthalmology Times, February 12, 2022, https://www.ophthalmologytimes.com/view/what-faricimab-for-dme-means-for-safe-durable-treatment-over-the-long-term

Declaration of interest:

	Name	Role	Date	Declaration of interests (please give details below)
Prepared by	Tejinder Bahra	Lead Commissioning Pharmacist	7.7.22	None
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Explanation of declaration of interest:
None.

Version control sheet:

Version	Date	Author	Status	Comment
1	7.7.22	Tejinder Bahra	Draft	Out for peer review
2	11/7/22	Carina Joanes	Draft	
3				Out for clinical comment
4	26/7/22	Carina Joanes	Incorporation of comments	Out for APC consultation