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 diabetic macular oedema Technology appraisal guidance 799 Fast track 30-day implementation.		
Available at	Faricimab for treating diabetic macular oedema (nice.org.uk)		
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 are anti-VEGFs recommended by NICE for treating DMO and accepted as comparators to faricimab. Faricimab is an anti-VEGF and also target the Ang-2 pathway.*
Licensed indication	Faricimab is indicated for 'the treatment of adults with visual impairment due to diabetic macular oedema'.
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. The recommended dose is 6 mg (0.05 mL solution) administered by intravitreal injection every 4 weeks for the first 4 doses. Thereafter, treatment may be individualised using a treat-and-extend approach following an assessment of the individual patient's anatomic and visual outcomes. The dosing interval may be extended from every 4 to every 16 weeks, with extensions in

	increments of up to 4 weeks, based on the physician's judgement of the individual patient's anatomic and/or visual outcomes. If anatomic and/or visual outcomes change, the treatment interval should be adjusted accordingly, and interval reductions of up to 8 weeks may be implemented if deemed necessary. 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> Faricimab is intended for long-term treatment. If visual and/or anatomic outcomes indicate that the patient is not benefitting from continued treatment, faricimab should be discontinued.
Comparison with NICE TA use[2]	NICE TA sets out criteria for use i.e., as an option to use only if the eye has a central retinal thickness of 400 micrometres or more at the start of treatment. 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	https://www.moorfields.nhs.uk/sites/default/files/Diabetic%20macular%20oedema.pdf Diabetic eye disease is a leading cause of blindness registration among working age adults in England and Wales. It is caused by changes to the tiny blood vessels of the retina (the light sensitive layer at the back of the eye). In diabetic macular oedema, blood vessels leak fluid into the retina. Vision loss occurs when the fluid reaches the macula (the centre of the retina that provides sharp vision) and builds up, causing swelling. At first, you may not notice changes to your vision. Over time, diabetic macular oedema can cause your central vision to become blurred. A healthy macula is essential for good vision. All people with type 1 and type 2 diabetes are at risk of diabetic macular oedema.
Potential patient numbers per 100,000[4]	69/100,000 of the adult population.

SUMMARY

Guidance[2]

Recommendations
1.1 Faricimab is recommended as an option for treating visual impairment due to diabetic macular oedema in adults, only if:
• the eye has a central retinal thickness of 400 micrometres or more at the start of treatment
• 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 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.

Why the committee made these recommendations

Diabetic macular oedema is usually treated first with aflibercept or ranibizumab, which are already recommended by NICE for treating diabetic macular oedema if the eye has a central retinal thickness of 400 micrometres or more when treatment starts. 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 diabetic macular oedema 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:
Faricimab costs £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.

Annual or monthly cost per patient:

The drug costs:

Table 1: Costs over 5 years for faricimab (at hospital price for 1 vial of £857 – note this is NOT the PAS discount price) from NICE resource impact template with 6mg administered by IVT injection every 4 weeks for the first 4 doses then every 16 weeks as maintenance treatment.

Year	Dose (mg)	Average number of administrations needed in year (local input)	Proportion of people requiring treatment in both eyes (local input)	Average number of vials needed	Cost per 6 mg vial (local input)	Total cost of treatment exc. VAT	VAT rate	Total cost of treatment inc. VAT
Year 1	6	6.0	46.5%	8.8	£857.00	£7,533	20%	£9,040
Year 2	6	4.0	46.5%	5.9	£857.00	£5,022	20%	£6,026
Year 3+	6	2.0	46.5%	2.9	£857.00	£2,511	20%	£3,013
Average year 1 - 5	6	3.2	46.5%	4.7	£857.00	£4,018	20%	£4,821
						£15,066		**£18,079**

The administration costs:

Table 2: Administration costs based on 2022/23 National Tariff Payment System. Outpatient procedure, HRG code BZ87A Minor Vitreous Retinal Procedures, 19 years and over.

Year	Average number of appointments needed	Tariff	Total cost of administration
Year 1	6	£99	£594
Year 2	4	£99	£396
Year 3+	2	£99	£198
Average year 1 - 5	3.2	£99	£317
			£1,188

Has dose escalation been considered as part of the NICE costing template?
This is highly variable and individualised for each patient and the NICE resource impact template used the number of administrations per year from the company model and included discontinuation rates.

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.

1. NICE resource impact statement*

For SH HCP:

- Around 565 people with visual impairment due to diabetic macular oedema are eligible for treatment with faricimab after adjusting for population growth and prevalence growth in diabetes.

- Around 85 people will receive faricimab from year 5 onwards once uptake has reached 15% after adjusting for population growth and prevalence growth in diabetes as shown in appendix 1.

2. NICE resource impact template

	Change in costs £K year 1	Change in costs £K year 2	Change in costs £K year 3	Change in costs £K year 4	Change in costs £year 5
Drug costs	£36	£47	£33	£18	-£1
Administration costs	£4	£5	£2	£0	-£3
Total	**£40**	**£51**	**£35**	**£17**	**-£4**

Savings and benefits:
The company assumes that there will be fewer injections and monitoring visits needed for faricimab compared with the comparators. Expert clinical opinion is that faricimab may have a similar dosing regimen as aflibercept and ranibizumab. Therefore, the committee concluded that the total cost associated with faricimab was similar or lower than aflibercept or ranibizumab.

**NICE funding requirements are based on Quality Adjusted Life Years (QALY) threshold. If there is evidence that the incremental cost rises above this threshold in the future, the APC may reconsider the commissioning status.*

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):
Yes

Alternative treatments and cost per patient per year

Other NICE recommended products:
See appendix 1, table 3.

The company base case assumed there would be fewer injections and monitoring visits needed for faricimab compared with the comparators. But the committee was aware that in NHS clinical practice faricimab may have a similar dosing regimen as aflibercept and ranibizumab. This is to reduce inconsistencies in clinical practice and chance of error in busy clinical settings. Because of this, along with the lack of long-term data, the committee considered scenarios in which the number of injections and monitoring visits was the same for faricimab, aflibercept and ranibizumab after the initial loading doses.

The committee acknowledged that if the time needed between injections is lengthened, then the cost of faricimab would reduce. When taking account of the commercial arrangements for all treatments, the committee was satisfied that the total cost associated with faricimab was similar or lower than aflibercept or ranibizumab (the exact results are confidential and cannot be reported here).

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

Impact to patients

- An additional treatment option would be valued by patients.

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. 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.

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 diabetic macular oedema. Available at: https://www.nice.org.uk/guidance/ta799 Accessed <4.7.22>

3 NICE Resource impact report: Faricimab for treating diabetic macular oedema. Available at: https://www.nice.org.uk/guidance/ta799/resources Accessed <4.7.22>

4 NICE Resource Impact template: Faricimab for treating diabetic macular oedema. Available at: https://www.nice.org.uk/guidance/ta799/resources Accessed <4.7.22>

Declaration of interest:

	Name	Role	Date	Declaration of interests (please give details below)
Prepared by	Tejinder Bahra	Lead Commissioning Pharmacist		None
Reviewed by	Carina Joanes	Lead Commissioning Pharmacist		

Explanation of declaration of interest:
None.

Version control sheet:

Version	Date	Author	Status	Comment
1	6.7.22	Tejinder Bahra	Draft	Out for consultation
2			Final	Out for clinical comment
3	26.7.22	Carina Joanes		Post Consultation

Appendix 1:

Table 1: Number of people eligible for treatment in England and Surrey Heartlands Health and Care Partnership (SH HCP)

	Local assumption current practice (year 5) (local input)	Local assumption current practice (year 5) (local input) England	Local assumption current practice (year 5) (local input) SH HCP
	% of people	Number of people	Number of people
Adult population at midpoint 2020		44,456,850	817,850
Adult population forecast at 2026/27		46,263,200	851,080
Prevalence of diabetes	7.42%	3,432,729	63,150
Prevalence of visual impairment due to diabetic macular oedema	2.77%	95,087	1,749
Proportion with central retinal thickness of 400 micrometres	26.00%	24,723	455
Proportion of prevalent population with a central retinal thickness < 400 micrometres who change to ≥ 400 micrometres each year	8.50%	5,981	110
Total number of people eligible for treatment with faricimab		**30,700**	**565**
Total number of people estimated to receive faricimab by year 2026/27 after adjusting for population growth	15%	4,600	85

Table 2: Estimated market share for faricimab, aflibercept and ranibizumab (local assumptions of current and future (5 years) practice.

	Local assumption current practice (year 5) (local input)	Local assumption current practice (year 5) (local input) England	Local assumption current Practice (year 5) (local input) SH HCP	Local assumption future practice (year 5) (local input)	Local assumption future practice (year 5) (local input) England	Local assumption future practice (year 5) (local input) SH HCP
	% of people	Number of people	Number of people	% of people	Number of people	Number of people
Estimated market share for faricimab	0.00%	0	0	15%	4,606	85
Estimated market share for aflibercept	84.00%	25,791	474	75%	23,028	424
Estimated market share for ranibizumab	16.00%	4,913	90	10%	3,070	56

Table 3: Cost of comparators (NICE resource template, full hospital costs – NOT PAS discount prices).

	Cost per vial	Total cost of treatment exc. VAT	Total cost of treatment inc. VAT	Total cost of administration	Cost per vial	Total cost of treatment exc. VAT	Total cost of treatment inc. VAT	Total cost of administration	Cost per vial	Total cost of treatment exc. VAT	Total cost of treatment inc. VAT	Total cost of administration
Year	**Faricimab 6mg**				**Aflibercept 2mg**				**Ranibizumab 0.5mg**			
Year 1	£857	£7,533	£9,040	£594	£816.00	£9,564	£11,476	£792	£551	£6,458	£7,749	£792
Year 2	£857	£5,022	£6,026	£396	£816.00	£4,782	£5,738	£396	£551	£3,229	£3,875	£396
Year 3+	£857	£2,511	£3,013	£198	£816.00	£2,391	£2,869	£198	£551	£1,614	£1,937	£198
Average year 1 - 5	£857	£4,018	£4,821	£317	£816.00	£4,304	£5,164	£356	£551	£2,906	£3,487	£356
		£15,066	**£18,079**	**£1,188**		**£16,736**	**£20,083**	**£1,386**		**£11,301**	**£13,561**	**£1,386**