National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Faricimab for treating diabetic macular oedema

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Comment 1: the draft remit

Section	Consultee/ Commentator	Comments [sic]	Action
Wording	Roche	The licence wording is anticipated to be "[redacted]" Therefore, we consider the wording of the draft remit to be appropriate.	Thank you for your comment. No action required.
	AbbVie	Yes [the wording of the remit reflects the issue(s) of clinical and cost effectiveness about this technology that NICE should consider].	Thank you for your comment. No action required.
	Bayer	No comment	Thank you. No action required.
	Novartis	The remit is appropriate.	Thank you for your comment. No action required.
	Macular Society	Yes [the wording of the remit reflects the issue(s) of clinical and cost effectiveness about this technology that NICE should consider].	Thank you for your comment. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
	Royal College of Ophthalmologists	Yes [the wording of the remit reflects the issue(s) of clinical and cost effectiveness about this technology that NICE should consider].	Thank you for your comment. No action required.
Timing Issues	Roche	DMO is a sight threatening condition caused by a multi-factorial disease process. While approved treatments including anti-VEGF monotherapy have been shown to improve outcomes, some patients do not fully respond and frequent injections are often required.[1,2] Regular trips to hospital for monitoring and treatment has a significant impact on patients' lives. Faricimab is a first-in-class, dual pathway inhibitor that targets both VEGF-A and Angiopoietin-2, two key drivers of retinal vascular disease. It has demonstrated non-inferior visual acuity outcomes to aflibercept with the ability to personalise treatment and achieve injection intervals of up 16 weeks in the majority of patients.[3] Faricimab provides an opportunity to reduce the burden of hospital visits which will have a positive impact for patients and clinicians who are delivering busy DMO services. Therefore, we believe that timely NICE guidance for Faricimab would be valuable to both patients and the NHS.	Thank you for your comment. NICE aims to publish guidance as soon as possible after the company receives the marketing authorisation and introduces the technology in the UK. NICE has scheduled this topic into its work programme.
	AbbVie	Although AbbVie encourages the availability of new therapeutic options for the management of DMO there is still a significant proportion of patients who do not respond to non-corticosteroid treatment (35%, Costing Template, TA349). The availability of faricimab does not expect to address this unmet need.	Thank you for your comment. The committee will consider the evidence submitted by the company and stakeholders during the appraisal process, including whether any unmet need will be addressed by the technology. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
	Bayer	No comment	Thank you. No action required.
	Novartis	No comments.	Thank you. No action required.
	Macular Society	N/A	Thank you. No action required.
	Royal College of Ophthalmologists	Routine [timing].	Thank you for your comment. No action required.
Additional comments on the draft remit	Roche	None	Thank you. No action required.
	AbbVie	N/A	Thank you. No action required.
	Bayer	N/A	Thank you. No action required.
	Novartis	N/A	Thank you. No action required.
	Macular Society	N/A	Thank you. No action required.
	Royal College of Ophthalmologists	No [additional comments].	Thank you. No action required.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Roche	We consider this section accurate and complete.	Thank you for your comment. No action required.
	AbbVie	Please highlight the unmet need with non-corticosteroid therapies by noting that “35% of patients do respond to non-corticosteroid treatment or for whom non-corticosteroid treatment is unsuitable” (Costing Template, TA349)	Thank you for your comment. The background section of the scope aims to provide a brief summary of the disease and how it is managed, it is not designed to be exhaustive in its detail. No changes were made to the scope.
	Bayer	No comment	Thank you. No action required.
	Novartis	This information is accurate and complete.	Thank you for your comment. No action required.
	Macular Society	N/A	Thank you. No action required.
	Royal College of Ophthalmologists	[The accuracy and completeness of this information is] adequate.	Thank you for your comment. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
The technology/ intervention	Roche	No comments.	Thank you. No action required.
	AbbVie	No comment	Thank you. No action required.
	Bayer	No comment	Thank you. No action required.
	Novartis	We would like to highlight that the comparison with ranibizumab in the BOULEVARD trial is based on a dose of ranibizumab that is not licensed in UK and EU (0.3mg).	Thank you for your comment. Where relevant and appropriate, the comparison between the technology and ranibizumab (and its dosages) will be considered by the committee during the appraisal process. No action required.
	Macular Society	N/A	Thank you. No action required.
	Royal College of Ophthalmologists	[The description of the technology is accurate and] adequate.	Thank you for your comment. No action required.

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Population	Roche	To align with other NICE appraisals in DMO, consider updating to “People with visual impairment because of diabetic macular oedema.”	Thank you for your comment. The scope has been updated with the suggested wording.
	AbbVie	No comment	Thank you. No action required.
	Bayer	No comment	Thank you. No action required.
	Novartis	[The population is defined] appropriate[ly].	Thank you for your comment. No action required.
	Macular Society	Yes, the population is defined appropriately.	Thank you for your comment. No action required.
	Royal College of Ophthalmologists	Adequate, [the population is defined appropriately]. No, [there are no subgroups that should be considered separately], the population can be considered as a whole.	Thank you for your comments. No action required.
Comparators	Roche	Laser photocoagulation alone, and aflibercept, and ranibizumab (both with or without laser) are appropriate comparators for faricimab for the treatment of DMO. These therapies are standard of care for the treatment of DMO in the NHS. Bevacizumab (Avastin©) is not licensed for the treatment of DMO in the UK and is not considered standard of care. Bevacizumab was developed and is manufactured for intravenous use in the treatment of a number of cancers.	Thank you for your comment. At the scoping stage of the appraisal, identification of comparators should be inclusive. The potential comparators

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		[redacted] When bevacizumab is used in clinical practice it is primarily used to treat DMO in people with central retinal thickness (CRT) <400µm.[5] [redacted] So, bevacizumab is not a relevant comparator for this appraisal because: 1. it is not licensed for DMO in the UK, [redacted] We do not believe fluocinolone acetonide intravitreal implant (with or without laser) or dexamethasone intravitreal implant (with or without laser) are appropriate comparators for faricimab in DMO. Fluocinolone (TA301)[7] and dexamethasone (TA349)[8] are only recommended in those patients with chronic diabetic macular oedema that is insufficiently responsive to available therapies, or when available therapies are unsuitable. They are also only recommended for use in an eye with an intraocular (pseudophakic) lens. We expect faricimab to be used before fluocinolone acetonide or dexamethasone, so it will not displace these treatments in the pathway of care. Therefore, we suggest that fluocinolone acetonide or dexamethasone are removed as comparators in this scope. [redacted]	listed in the scope represent treatments used to treat diabetic macular oedema in NHS clinical practice. Additionally, the comparators are consistent with previous scopes for diabetic macular oedema. Any exclusion from the decision problem in the company submission should be fully justified and will be considered during the course of the appraisal.

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	AbbVie	Bevacizumab has not been appraised by NICE for treating DMO therefore it should not be considered as a comparator, similar to TA672 in AMD.	Thank you for your comment. At the scoping stage of the appraisal, identification of comparators should be inclusive. The potential comparators listed in the scope represent treatments used to treat diabetic macular oedema in NHS clinical practice. Additionally, the comparators are consistent with previous scopes for diabetic macular oedema. Any exclusion from the decision problem in the company submission should be fully justified and will be considered during the course of the appraisal.
	Bayer	Bevacizumab is not an appropriate comparator to faricimab. Bevacizumab cannot be considered 'routine practice' or 'best alternative care' as it is not licensed for use in the eye and its use in the NHS is very low.	Thank you for your comment. At the scoping stage of the appraisal, identification of comparators should be inclusive. The

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			potential comparators listed in the scope represent treatments used to treat diabetic macular oedema in NHS clinical practice. Additionally, the comparators are consistent with previous scopes for diabetic macular oedema. Any exclusion from the decision problem in the company submission should be fully justified and will be considered during the course of the appraisal.
	Novartis	Unlicensed bevacizumab is not an appropriate comparator for this topic as it is neither standard of care nor has a marketing authorisation in the UK for DMO. The other comparators listed are used in patients with DMO, but as outlined in the background section these are recommended in different populations so the appropriate comparators for this appraisal will defined by the population the company is submitting for appraisal.	Thank you for your comment. At the scoping stage of the appraisal, identification of comparators should be inclusive. The potential comparators listed in the scope represent treatments used to treat diabetic macular oedema in NHS clinical practice.

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			Additionally, the comparators are consistent with previous scopes for diabetic macular oedema. Any exclusion from the decision problem in the company submission should be fully justified and will be considered during the course of the appraisal.
	Macular Society	Yes [these are the standard treatments currently used in the NHS with which the technology should be compared].	Thank you for your comment. No action required.
	Royal College of Ophthalmologists	Yes, comprehensive standard treatment. None can be described as best alternative care which is determined according to individual needs.	Thank you for your comment. No action required.
Outcomes	Roche	Contrast sensitivity was not measured in the pivotal trials YOSEMITE and RHINE. Also, we question its inclusion as an outcome given the following comment from NICE taken from the aflibercept for DMO (TA346) scoping comments table, “The scoping workshop attendees agreed that contrast sensitivity did not need to be considered as an outcome because it was not included in the pivotal trials, and was generally considered an outcome more appropriate for research rather than being meaningful clinically for patients.”	Thank you for your comment. We acknowledge the comments from a scoping workshop attendee that contrast sensitivity did not need to be considered as an outcome because it was not included in the

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			pivotal trials, and was generally considered an outcome more appropriate for research rather than being clinically meaningful for patients. However, to maintain consistency with previous appraisals in this disease area, contrast sensitivity has been retained as an outcome.
	AbbVie	Please add “complete resolution of macular oedema.	Thank you for your comment. The outcome has been added to the scope.
	Bayer	No comment	Thank you. No action required.
	Novartis	Appropriate [these outcome measures capture the most important health related benefits (and harms) of the technology].	Thank you for your comment. No action required.
	Macular Society	Yes [these outcome measures capture the most important health related benefits (and harms) of the technology].	Thank you for your comment. No action required.

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	Royal College of Ophthalmologists	Yes, [these outcome measures capture the most important health related benefits (and harms) of the technology]. Health-related quality of life may be related to frequency of hospital visits/dosing schedule but this may be a separate outcome in itself.	Thank you for your comment. Where appropriate, frequency of hospital visits and dosing schedule would be considered as part of economic modelling. No changes made to the scope.
Economic analysis	Roche	Both phase III clinical trials, YOSEMITE and RHINE, met their primary endpoint with BCVA gains from baseline with faricimab dosed up to Q16W being non-inferior to aflibercept Q8W.[3] [redacted]	Thank you for your comment. No action required.
	AbbVie	No comment	Thank you. No action required.
	Bayer	No comment	Thank you. No action required.
	Novartis	No comments	Thank you. No action required.
	Macular Society	No comments	Thank you. No action required.

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	Royal College of Ophthalmologists	Time horizon was not specified; “sufficiently long” should account for the younger age of persons with diabetes and the potential episodic nature the intervention	Thank you for your comment.
Equality and Diversity	Roche	If a person is registered as blind or partially sighted they are considered disabled, as stated in the Equality Act 2010.[9] Therefore, the patient population addressed in this submission is a protected group under this act.	Thank you for your comment. Where relevant and appropriate, protected characteristics as stated in equality legislation will be considered by the committee during the appraisal. No action required.
	AbbVie	No comment	Thank you. No action required.
	Bayer	No comment	Thank you. No action required.
	Novartis	No comments	Thank you. No action required.
	Macular Society	No comments	Thank you. No action required.
	Royal College of Ophthalmologists	I see no issues with unlawful discrimination	Thank you for your comment. No action required.

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Other considerations	Roche	Roche is investigating whether or not the subgroup analyses suggested in the draft scope can be provided. We do not have any suggestions for additional subgroups at this time. The availability and cost of future biosimilar products is uncertain for the following reasons: • There are currently no licensed biosimilar products available for DMO and no confirmed timelines for when these will be made available in the UK. • Predicting the cost of future biosimilars is challenging. Whilst we are aware of differing pricing strategies across disease areas with different treatment pathways and market dynamics, an extrapolation based on this information may not necessarily lead to an accurate representation of future acquisition costs and market share in the DMO setting.	Thank you for your comment. The committee will consider the availability and cost of biosimilar and generic products available at the time of the appraisal, rather than in the future. No action required.
	AbbVie	N/A	Thank you. No action required.
	Bayer	No comment	Thank you. No action required.
	Novartis	No comments	Thank you. No action required.
	Macular Society	N/A	Thank you. No action required.
	Royal College of Ophthalmologists	[Suggestions for additional issues to be covered by the appraisal] Diabetes and non-diabetes related co-morbidities such as renal failure	Thank you for your comment. The list of issues included in the scope is not designed

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		Disabilities that preclude frequent hospital attendances	to be exhaustive. However, where relevant and appropriate, evidence relating to the population and technology of interest are welcome and will be considered by the committee during appraisal. Additionally, where appropriate, protected characteristics included in equality legislation such as disability will be considered by the committee during the appraisal. No action required.
Innovation	Roche	<u>Molecule</u> Faricimab is the first bispecific antibody designed for intravitreal injection (IVT) that neutralises two distinct pathways of retinal disease: Ang-2 and VEGF-A. Faricimab has been developed using CrossMab (monoclonal antibody) technology. It independently binds and neutralises both Ang-2 and VEGF-A with high specificity and potency without steric hindrance. The Fc portion of the antibody has been specifically engineered for intraocular use to reduce systemic exposure and inflammatory potential.[10] Ang-2 has been shown to play a role in maintenance of the blood-retinal barrier via its effect on pericyte survival and endothelial cell integrity. Pre-	Thank you for your comment. The appraisal committee will consider the extent to which faricimab is innovative in its decision making. No action required.

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		clinical evidence suggests that dual inhibition of VEGF-A and Ang-2 can have synergistic benefits including reducing leakage and microvascular inflammation.[11,12,13] Faricimab may therefore lead to improved vascular stabilisation and retinal function in patients with DMO. Outcomes YOSEMITE (NCT03622580) and RHINE (NCT03622593) are two identical, randomised, multicentre, double-masked, global phase III studies, evaluating the efficacy and safety of faricimab compared to aflibercept in 1,891 people with diabetic macular edema (940 in YOSEMITE and 951 in RHINE). Year 1 results from the Phase III YOSEMITE and RHINE clinical trials demonstrated robust visual acuity gains for faricimab which were non-inferior to aflibercept. Analysis of anatomical endpoints demonstrated that the mean change in central subfield thickness over time favoured faricimab and more patients treated with faricimab had absence of DMO (defined as a CST <325µm) and absence of intraretinal fluid.[3] Treatment burden Robust visual acuity gains and favourable anatomical results were achieved with faricimab given according to a personalised treatment interval with >70% of patients achieving ≥12 week treatment intervals and >50% achieving 16 week intervals. The median number of injections up to week 56 of YOSEMITE/RHINE was 10 injections for aflibercept compared to 8 injections for faricimab when delivered via a personalised treatment interval.[8] DMO contributes to central vision loss, negatively impacting patient independence and productivity, and limiting the ability to perform tasks essential for daily life and maintaining self-sufficiency in this patient population comprised primarily of working-age adults. The condition is associated with increased social isolation and decreased mental health in adults.[14,15,16] Current treatment options for patients with DMO are onerous for patients, caregivers and health systems, impacting adherence to treatment and limiting patients' ability to maintain their vision over time. Ocular injections are often a	

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		source of fear, stress and anxiety for patients with retinal diseases[17] and the frequent clinic visits and patient monitoring required to achieve optimal long-term outcomes for patients with DMO results in a high burden of treatment for patients and their caregivers.[18,19,20] Real-world data in patients with DMO suggests that this burden creates a barrier to optimal anti-VEGF treatment, with patients undergoing fewer injections and exhibiting worse vision outcomes at 1 year compared with patients in clinical trials.[18] Innovations that reduce injection frequency are highly valued by patients with retinal diseases; 42% of patients surveyed in the US rated having fewer injections to achieve the same visual results as the single most desirable improvement in their treatment regimen, and 22% rated the requirement for fewer appointments as the most desirable improvement.[17] There is therefore an unmet need for treatment strategies that maintain the clinical benefits of intravitreal anti-VEGF therapy and DMO while reducing overall treatment and visit burden. So, patients, caregivers and the NHS could benefit from increased treatment intervals and reduced injections that faricimab offers compared to anti-VEGF monotherapies. It is unlikely that the QALY calculations will fully capture the reduction in burden associated with fewer faricimab injections. Overall faricimab should be considered a highly innovative therapy which provides benefit to patients and the NHS in the management of DMO.	
	AbbVie	Although AbbVie encourages the availability of new therapeutic options for the management of DMO there is still a significant proportion of patients who do not respond to non-corticosteroid treatment (35%, Costing Template, TA349). The availability of faricimab does not expect to address this unmet need.	Thank you for your comment. The appraisal committee will consider the extent to which faricimab is innovative in its decision making. No action required.

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	Bayer	No comment	Thank you. No action required.
	Novartis	No comments	Thank you. No action required.
	Macular Society	There is a significant unmet need for more effective and more durable therapies for DMO. Faricimab innovative as it is the first bispecific antibody designed for the eye and targets two distinct pathways – via angiopoietin-2 (Ang-2) and vascular endothelial growth factor-A (VEGF-A). It is also longer lasting than the current anti-VEGF drugs, offering the potential for 16 weeks between injections, compared to 8 weeks with aflibercept. This would be less burdensome for patients, their family/friends who support them and hospital eye clinics.	Thank you for your comment. The appraisal committee will consider the extent to which faricimab is innovative in its decision making. No action required.
	Royal College of Ophthalmologists	This is an incremental change. The main impact will be that potentially 50% of persons can receive 4 monthly dosing and 70% 3 monthly at one year, instead of the 2-3 monthly which is current standard practice, with similar vision gains. This would relieve the capacity issues of injection clinics at many hospitals. Driving vision standards, numbers of hospital visits for any other health condition, should be, if not already considered in the QALY calculation The YOSEMITE and RHINE phase III clinical trial data should be considered Clinical Trials.gov. A study to evaluate the efficacy and safety of faricimab (RO6867461) in participants with diabetic macular edema (YOSEMITE) [Internet; cited 2021 February]. Available	Thank you for your comment. The appraisal committee will consider the extent to which faricimab is innovative in its decision making. No action required.

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		from: https://clinicaltrials.gov/ct2/show/NCT03622580 Clinical Trials.gov. A study to evaluate the efficacy and safety of faricimab (RO6867461) in participants with diabetic macular edema (RHINE) [Internet; cited 2021 February]. Available from: https://clinicaltrials.gov/ct2/show/NCT03622593	
Questions for consultation	Roche	Is the population defined appropriately? Is the population expected to include people with visual impairment due to diabetic macular oedema? Yes, the population is expected to include people with visual impairment because of diabetic macular oedema. See comments in “population” Have all relevant comparators for faricimab been included in the scope? Which treatments are considered to be established clinical practice in the NHS for diabetic macular oedema? Laser photocoagulation alone, and aflibercept, and ranibizumab (both with or without laser) are appropriate comparators for faricimab for the treatment of DMO. Bevacizumab, fluocinolone acetonide intravitreal implant or dexamethasone intravitreal implant (all with or without laser) are not appropriate comparators for faricimab in DMO. Please see the “Comparators” section of our response. Are the outcomes listed appropriate? Please see the “outcomes” section of our response.	Thank you for your comment. No action required. Thank you for your comment. No action required. Thank you for your comment. No action required.

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		Are the subgroups suggested in 'Other considerations' appropriate? Please see the 'Other considerations' section of our response. Are there any other subgroups of people in whom faricimab is expected to be more clinically effective and cost effective or other groups that should be examined separately? None. Where do you consider faricimab will fit into the existing NICE pathways? We expect that faricimab will be offered as an alternative to aflibercept or ranibizumab. Therefore, it will sit within the "eye disease" section of the following pathways: ● Identifying and managing complications in adults with type 1 diabetes: eye disease[21] ● Identifying and managing complications in adults with type 2 diabetes: eye disease[22] Do you consider faricimab to be innovative? Please see the "Innovation" section of our response. Do you consider that the use of faricimab can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?	Thank you for your comment. No action required. Thank you for your comment. No action required. Thank you for your comment. No action required. Thank you for your comment. No action required. Thank you for your comment. No action required.

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		It is unlikely that the reduction in treatment burden associated with fewer faricimab injections will be fully captured in the QALY calculations. Please see the “Innovation” section of our response for further detail. Will there be any barriers to adoption of this technology into practice? No barriers are expected. NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. Please see the “Economic analysis” section of our response.	Thank you for your comment. No action required. Thank you for your comment. No action required.
	AbbVie	No comment	Thank you. No action required.
	Bayer	N/A	Thank you. No action required.
	Novartis	No additional comments.	Thank you. No action required.
	Macular Society	N/A	Thank you. No action required.
	Royal College of Ophthalmologists	Is the population defined appropriately? Is the population expected to include people with visual impairment due to diabetic macular oedema?	Thank you for your comment. No action required.

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		- Yes, it is expected to include people with diabetic macular oedema who do not have visual impairment, but impending visual impairment. Have all relevant comparators for faricimab been included in the scope? Which treatments are considered to be established clinical practice in the NHS for diabetic macular oedema? - Yes Are the outcomes listed appropriate? - Yes Are the subgroups suggested in 'Other considerations' appropriate? - Yes Are there any other subgroups of people in whom faricimab is expected to be more clinically effective and cost effective or other groups that should be examined separately? - Persons likely to require treatment for >1 year - Limited data currently on clinical phenotypes that may benefit more than others but data will emerge from real-world and Phase 4 studies	Thank you for your comment. No action required. Thank you for your comment. No action required. Thank you for your comment. No action required. Thank you for your comment. Where relevant and appropriate, relevant subgroups will be considered by the committee during appraisal. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
		Where do you consider faricimab will fit into the existing NICE pathways, Identifying and managing complications in adults with type 1 diabetes: eye disease and Identifying and managing complications in adults with type 2 diabetes: eye disease? - It should be an option for treatment naïve patients as well as a switch from existing treatment if it is suboptimal, ineffective, or if a longer treatment interval is desired - Type 1, 2 and mixed type persons with diabetes and macular oedema	Thank you for your comment. No action required.
		could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which faricimab will be licensed; No	Thank you for your comment. No action required.
		could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology; No	Thank you for your comment. No action required.
		could have any adverse impact on people with a particular disability or disabilities. No	Thank you for your comment. No action required.
		could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which faricimab will be licensed; No	Thank you for your comment. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
		could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology; No could have any adverse impact on people with a particular disability or disabilities. No	Thank you for your comment. No action required. Thank you for your comment. No action required.
		Do you consider faricimab to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)? Yes Do you consider that the use of faricimab can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation? Yes – see answer above Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits. The 2 Phase 3 multicentre randomized controlled clinical trials - see answer above To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly. - Commissioning across the UK by different ICS'es - Clinical pathways and protocols can be shared via the RCOphth	Thank you for your comment. No action required. Thank you for your comment. No action required. Thank you for your comment. No action required. Thank you for your comment. No action required.

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		Would it be appropriate to use the cost comparison methodology for this topic? Yes but I'm not a health economy expert	Thank you for your comment. No action required.
		Is the new technology likely to be similar in its clinical efficacy and resource use to any of the comparators? According to the phase 3 outcomes it is likely to be superior in terms of dosing frequency	Thank you for your comment. No action required.
		Is the primary outcome that was measured in the trial or used to drive the model for the comparator(s) still clinically relevant? Yes, and the secondary outcome would be more relevant in addressing clinic capacity issues within the NHS	Thank you for your comment. No action required.
		Is there any substantial new evidence for the comparator technology/ies that has not been considered? No	Thank you for your comment. No action required.
		Are there any important ongoing trials reporting in the next year? I'm sure there will be extension studies to the YOSEMITE and RHINE studies published early 2021, however I am not privy to that information.	Thank you for your comment. No action required.
Additional comments on the draft scope	Roche	None	Thank you. No action required.
	AbbVie	A significant proportion of patients who do not respond to non-corticosteroid treatment (35%, Costing Template, TA349) and are phakic do not have access	Thank you for your comment. No action required.

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		to non-corticosteroid treatment. This appraisal will not address the unmet need in this population since faricimab is another VEGF inhibitor.	
	Bayer	N/A	Thank you. No action required.
	Novartis	N/A	Thank you. No action required.
	Macular Society	N/A	Thank you. No action required.
	Royal College of Ophthalmologists	N/A	Thank you. No action required.