National Institute for Health and Care Excellence

Health Technology Evaluation

Bevacizumab gamma for treating wet age-related macular degeneration [ID6320]
Response to stakeholder organisation comments on the draft remit and draft scope

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Comment 1: the draft remit and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	Outlook Therapeutics (company)	Outlook Therapeutics support the evaluation of bevacizumab gamma (Lytenava®) by NICE.	Thank you for your comment.
	Macular Society	Evaluating this topic and the proposed route are appropriate.	Thank you for your comment.
	The Royal College of Ophthalmologists	It is appropriate to evaluate bevacizumab gamma for treating wet age-related macular degeneration as a Single Technology Appraisal.	Thank you for your comment.
	Royal National Institute of the Blind	Any cost comparison approach such as this should account for all aspects of a patient's experiences, including elements such as the frequency with which they need to visit the hospital for treatment and the quality of life which the treatment can enable.	Thank you for your comment.

Section	Stakeholder	Comments [sic]	Action
Wording	Outlook Therapeutics (company)	Outlook Therapeutics considers the wording of the remit to be appropriate.	Thank you for your comment.
	Macular Society	The wording does reflect the issues.	Thank you for your comment.
	The Royal College of Ophthalmologists	The wording of the remit does reflect the clinical and cost effectiveness of bevacizumab gamma for treating wet age-related macular degeneration.	Thank you for your comment.
Timing Issues	Royal National Institute of the Blind	We estimate that as of 2023 there were 463,000 people in the UK living with late stage Wet AMD. Therefore treatments such as this, if successful, could yield significant reductions in health and social care costs. There is also a well-documented link between sight loss and poor mental health outcomes. This treatment, if successful, could reduce the burden on mental health services.	Thank you for your comment.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Outlook Therapeutics (company)	Outlook Therapeutics considers the background information to be appropriate.	Thank you for your comment.

Section	Consultee/ Commentator	Comments [sic]	Action
	Macular Society	The background information covers the main topics accurately.	Thank you for your comment.
	The Royal College of Ophthalmologists	The background information in accurate and complete.	Thank you for your comment.
	Royal National Institute of the Blind	For completeness, we would suggest it be made clear in the background section whether or not bevacizumab gamma is also administered via an intravitreal injection rather than a different novel approach, as that would be a factor worthy of further consideration.	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 intended to be exhaustive in its detail. No change to scope required.
Population	Outlook Therapeutics (company)	Outlook Therapeutics considers the defined population to be appropriate.	Thank you for your comment.
	Macular Society	Yes [the population is defined appropriately].	Thank you for your comment.
	The Royal College of Ophthalmologists	The population is defined appropriately.	Thank you for your comment.

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	Royal National Institute of the Blind	Yes	Thank you for your comment.
Subgroups	Outlook Therapeutics (company)	Outlook Therapeutics believes that bevacizumab gamma has a beneficial effect in the full licensed population, and is not expecting to highlight any specific patient subgroups for further analysis.	Thank you for your comment.
	Macular Society	No [there are no groups within the population that should be considered separately].	Thank you for your comment.
	The Royal College of Ophthalmologists	No [there are no groups within the population that should be considered separately].	Thank you for your comment.
Comparators	Outlook Therapeutics (company)	Outlook Therapeutics agrees that the anti-VEGF treatment options licensed for wet-AMD, namely ranibizumab, aflibercept, brolucizumab and faricimab are all relevant comparators, following NICE appraisal via TA155, TA294, TA672 and TA800 respectively. Outlook Therapeutics does not consider bevacizumab to be an appropriate comparator for the following reasons: Licensing: Bevacizumab does not hold a license for ophthalmic use. Furthermore, the Summary of Product Characteristics (SmPC) for bevacizumab states that “Avastin is not formulated for intravitreal use”. Commissioning:	Thank you for your comments. Bevacizumab has been removed from the final scope.

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		A 2020 Judicial Review of the use of repackaged, off-label bevacizumab for the treatment of nAMD, concluded that it must only be used in accordance with the conditions set out by the Court of Appeal in Bayer plc v NHS Darlington CCG & Ors; Novartis Pharmaceuticals UK Limited v NHS Darlington CCG & Ors (2020). Furthermore, the lawfulness of supply of bevacizumab compounded by commercial entities was highlighted as uncertain. The above restrictions, alongside NHS England's commissioning guidance for wet AMD, both contribute to a highly restricted ability for NHS commissioners to support local use of repackaged, off-label bevacizumab, likely contributing to the very low volume of UK use. Real-world use: Oncologic bevacizumab is repackaged and used for off-label ophthalmic use in a small minority of patients in the UK, but is typically reserved for patients not meeting the access criteria for other NICE approved therapeutic options, following the 2020 Judicial Review. The National Ophthalmology Database Audit, describes the proportion of injections administered for each anti-VEGF medicine (based on clinical practice in 2020), describing a repackaged, off-label bevacizumab (Avastin) share of only 2.7%. It is therefore unlikely that bevacizumab in its current form is a relevant comparator for the vast majority of newly diagnosed wet-AMD patients. Safety: Repackaged, off-label bevacizumab requires aliquoting, and repackaging for ophthalmic injection. Aliquoting is associated with safety concerns including issues with personnel gowning, and a lack of procedures to prevent contamination and infectious endophthalmitis.	

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		Associated safety and sterility adverse events may include patients experiencing lost eyesight due to infections. Multiple recalls of unapproved repackaged IV bevacizumab have taken place in the US, due to unsterile compounding practices, and unvalidated syringe hold times. The aliquoting procedure requires use of non-standardized syringes that are not specifically intended for ophthalmic use, introducing further safety concerns, notably, the difficulty in expressing drug, resulting in ocular damage during administration. Syringe related adverse events included variability in repackaging, reduced quality of syringe products, and the potential for silicone oil droplet release from the syringe into the eye. Inconsistent distribution, supply, and storage policies, as well as a lack of controlled shipping and storage practices for aliquoted bevacizumab may further create inconsistencies in quality and supply, potentially impacting product effectiveness and tolerability. Efficacy: Use of repackaged, off-label bevacizumab in an ophthalmic setting, is associated with inconsistent or degraded potency, with demonstrated variability in protein concentration of bevacizumab samples aliquoted for wet-AMD, both across different pharmacies AND within the same pharmacy. In the study by Yannuzzi et al., 81% of samples had lower protein concentrations than required, with statistically significant variations in protein concentration among samples. Similarly, the differences in IgG concentration measured from repackaged bevacizumab syringes has shown a trend for an increase in micron-sized protein aggregates, with a decrease in IgG concentration.	

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		In summary: repackaged, off-label bevacizumab should not be implied as a safe or appropriate option for patients with wet-AMD by inclusion in this appraisal, and is not routinely available to clinicians for the treatment of newly diagnosed wet AMD patients due to specific commissioning restrictions.	
	Macular Society	Yes, the comparators listed are considered to be the standard treatments. Eylea 8mg (aflibercept 8mg) recently received marketing authorisation for the treatment of neovascular AMD - will this be included as a comparator under aflibercept, alongside its original 2mg dose?	Thank you for your comment. Treatments that are established practice in the NHS at the time of NICE evaluation are considered to be appropriate comparators. No change to scope required.
	The Royal College of Ophthalmologists	Bevacizumab which does not have a marketing authorisation in the UK for this indication should not be used as a comparator. It is used in NHS for treatment of non-age-related macular degeneration indications and sparingly, for patients with wet age-related macular degeneration not fitting within NICE guidelines. Aflibercept, Ranibizumab and Faricimab are widely used to treat wet age-related macular degeneration in UK and are appropriate comparators. Brolucizumab is used sparingly and should not be treated as a comparator. Another anti-VEGF drug, higher dose aflibercept (8mg) has obtained marketing authorisation in UK recently. This should also be used as a comparator.	Thank you for your comments. Bevacizumab has been removed from the final scope.

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	Royal National Institute of the Blind	Yes – On the assumption that bevacizumab gamma is also administered via an intravitreal injection.	Thank you for your comment.
Outcomes	Outlook Therapeutics (company)	Outlook Therapeutics does not recognise 'overall visual function' as a consistently reported endpoint in comparator clinical trials. We will be conscious of the impact of the more specific visual acuity and quality-of-life endpoints in the bevacizumab gamma and comparator trial programs, and how they contribute to a subjective assessment of overall visual function, but are interested to hear from NICE if they have previously agreed a quantitative measure of this endpoint?	Thank you for your comment. The list of outcomes in the scope is not intended to be exhaustive. The appraisal committee can consider other outcomes if appropriate. Information on outcomes not specified in the scope can be provided by the company in its submission. No change to scope required.
	Macular Society	Yes [the listed outcomes are appropriate].	Thank you for your comment.
	The Royal College of Ophthalmologists	The outcome measures are appropriate.	Thank you for your comment.

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	Royal National Institute of the Blind	We believe the outcomes should also include an assessment of whether the treatment provides similar or better results but with a reduced frequency of injections. Not only would this have less of an economic impact on the patient as they would not have to visit the hospital as frequently but it would also reduce the risk of mis-application, improve patient mental wellbeing and improve service capacity.	Thank you for your comment. The list of outcomes in the scope is not intended to be exhaustive. The appraisal committee can consider other outcomes if appropriate. No change to scope required.
Equality	Outlook Therapeutics (company)	Outlook Therapeutics does not foresee any specific equity issues to be considered as part of this appraisal, but would reiterate that visual impairment resulting from wet AMD is recognised as a disability in the UK (as highlighted in prior NICE appraisals in wet AMD).	Thank you for your comment.
	The Royal College of Ophthalmologists	No clinically relevant groups can be identified who are expected to have a differential outcome. This appraisal would not exclude people with protected characteristics or should have adverse impact of their health.	Thank you for your comment.
Other considerations	Bayer (comparator)	The SmPC for aflibercept allows patients to follow a treat-and-extend regimen whereby the time between injections can be extended beyond 8-weeks. The comparison of bevacizumab with aflibercept should consider a treat-and-extend regimen for aflibercept which is established practice in the NHS. Clinical evidence for the treat-and-extend regimen for aflibercept comes from two trials in which the majority of patients received aflibercept at an interval between injections that was greater than 8 weeks.	Thank you for your comment. The NICE scope is intended to be a broad overview of the PICO considerations that will guide the evaluation. The committee will carefully consider all the evidence from the

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			relevant clinical trials. No change to scope required.
	Macular Society	NG82 indicated that anti-VEGF treatment for eyes with wet AMD and visual acuity better than 6/12 is clinically effective and may be cost effective depending on the regimen used. Bevacizumab is therefore used off label in some hospitals in situations where the level of vision in the eye to be treated is better than 6/12 and therefore outside the recommended parameters for use of the other comparator drugs, as set out in the HTAs. If the parameters for the use of bevacizumab gamma are the same as for the other anti-VEGF drugs, clarification on its use where vision is better than 6/12 and good vision could be maintained, is an important issue to be covered.	Thank you for your comment. The NICE scope is intended to be a broad overview of the PICO considerations that will guide the evaluation. The committee will make any recommendation within the product's marketing authorisation. No change to scope required.
Questions for consultation	Outlook Therapeutics (company)	**Where do you consider bevacizumab gamma will fit into the existing care pathway for wet AMD?** Outlook Therapeutics expects bevacizumab gamma to be offered as a first-line treatment for all newly diagnosed patients with wet AMD. [redacted]	Thank you for your comments.

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		Is bevacizumab currently used off label to treat wet age-related macular degeneration? Repackaged, off-label bevacizumab is rarely used for ophthalmic treatment. Expert feedback from UK clinicians proposes that it is typically reserved for patients not meeting the access criteria for other NICE approved therapeutic options, or in private practice where co-payment costs are sought to be minimised for the patient. This positioning is largely driven by the 2020 Judicial Review into wet-AMD treatment options. The National Ophthalmology Database Audit, describes the proportion of injections administered using repackaged, off-label bevacizumab (Avastin) to be 2.7%. Based on the limitations of the compounding process, ophthalmic use of repackaged, off-label bevacizumab is not appropriate based on the increased safety risks and likely reduced potency of the drug (as described in the above 'Comparators' comment) **Are there any subgroups of people in whom bevacizumab gamma is expected to be more clinically effective and cost effective or other groups that should be examined separately?** Outlook Therapeutics believes that bevacizumab gamma has a beneficial effect in the full licensed population, and is not expecting to highlight any specific subgroups of patients for specific analysis. **Would bevacizumab gamma be a candidate for managed access?**	

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		Outlook Therapeutics does not believe that a managed access program is appropriate for bevacizumab gamma. **Do you consider that the use of bevacizumab gamma can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?** Outlook therapeutics believe that the quality-of-life benefits associated with delaying vision loss are well documented, and given the similar posology to other licensed treatments, QALY calculations are likely to be representative of a complete benefit. **Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.** The efficacy and safety of bevacizumab gamma was assessed in two randomised, multicentre, double-masked, active controlled Phase III studies (NORSE ONE and NORSE TWO) in patients with nAMD. Given the mixed application process presented to the EMA, the submission will also detail data from prior bevacizumab studies including IVAN and CATT. In NORSE ONE (*a clinical experience trial used to inform the design of NORSE TWO*), both previously treated and treatment naive study eyes were enrolled, and a total of 61 patients were randomized 1:1 (31 subjects in the bevacizumab group and 30 subjects in the ranibizumab group). Patient ages ranged from 61 to 97 years, with a mean age of 79 years; 97% of patients were over 65 years.	

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		In NORSE TWO, treatment naive study eyes were enrolled and a total of 228 patients were randomised 1:1 (113 subjects in the bevacizumab gamma group and 115 subjects in the ranibizumab group). Patient ages ranged from 54 to 98 years, with a mean age of 79 years; 95% of patients were over 65 years. In both studies, patients randomised to receive bevacizumab gamma were administered at a dose of 1.25 mg by intravitreal injection in the study eye every month for 12 months. Patients randomised to ranibizumab were administered at a dose of 0.5 mg by intravitreal injection in the study eye every month for 3 months (i.e. on Days 0, 30, and 60) followed by every 90 days (i.e. on Days 150 and 240), which was a sublabel dosing regimen. The primary endpoint was assessed at the Month 11 visit, which was approximately 30 days after the last bevacizumab gamma dose and 90 days after the last ranibizumab dose. The primary endpoint in both studies was the proportion of subjects who gained ≥15 letters in best corrected visual acuity (BCVA) from baseline to month 11, as measured by the early treatment diabetic retinopathy study (ETDRS) letter score, with the primary objective being to demonstrate the efficacy of bevacizumab gamma in a nAMD population. Secondary endpoints evaluated the change from baseline at month 11 in mean BCVA and the proportion of subjects who lost fewer than 15 letters in BCVA. Supplementing the above clinical trial program, Outlook Therapeutics will also submit data from NORSE THREE, an open label safety study, an indirect comparison of bevacizumab gamma versus other, licensed, anti-VEGF treatments available in the UK, and a cost-comparison model presented in Microsoft Excel.	

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		Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts. **Outlook Therapeutics believe that comprehensive data exists in the literature to describe the treatment pathway, burden, and currently available anti-VEGF treatments. As such, no specific additional data is expected to be required.** **NICE is considering evaluating this technology through its cost comparison evaluation process.** **Please provide comments on the appropriateness of appraising this topic through this process.** Outlook Therapeutics supports the appraisal of bevacizumab gamma via a cost-comparison process. Wet age-related macular degeneration in the UK is predominantly treated with aflibercept, ranibizumab or faricimab, which are already recommended by NICE in the same indication. Bevacizumab gamma (ONS-5010/Lytenava) is another treatment option that works in a similar way and evidence from clinical trials demonstrates that bevacizumab is as effective as other anti-VEGFs. There is precedent from NICE in using cost comparison as the appraisal route of choice for the most recent treatments evaluated for wet age-related macular degeneration. During UK market research, bevacizumab gamma was regarded by clinical experts as a low-risk treatment, compared to similar therapies that have already been appraised by NICE for the treatment of wet age-related macular degeneration. Safety and efficacy of the parent molecule bevacizumab has been extensively evaluated, in this indication, over many years during IVAN and CATT studies (*despite the potential inconsistencies*	

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		and variability of potency introduced during the compounding and repackaging of off-label Avastin). Outlook are confident that a cost comparison case can be made to suggest bevacizumab gamma is likely to provide similar health benefits, [redacted]	
	Bayer (comparator)	**Would it be appropriate to use the cost comparison methodology for this topic?** The SmPC for aflibercept allows patients to follow a treat-and-extend regimen (which is established clinical practice) whereby injection intervals can be extended beyond 8-weeks. Economic analyses should consider the reduced number of injections (and hence cost) of aflibercept when this regimen is used. If bevacizumab gamma has comparable annual costs (and efficacy) compared to aflibercept following a treat-and-extend regimen then it may be appropriate to use the cost comparison methodology	Thank you for your comments.
	Macular Society	**Where do you consider bevacizumab gamma will fit into the existing care pathway for wet AMD?** It will fit into the existing care pathway for wet AMD alongside the comparators/current anti-VEGF treatments. **Is bevacizumab currently used off label to treat wet age-related macular degeneration?**	Thank you for your comments.

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		Yes, we understand mostly for those with vision better than 6/12 and outside the parameters for use on the NHS of the other anti-VEGF drugs set out in the HTAs. **Are there any subgroups of people in whom bevacizumab gamma is expected to be more clinically effective and cost effective or other groups that should be examined separately?** No **Would bevacizumab gamma be a candidate for managed access?** No **Do you consider that the use of bevacizumab gamma can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?** No **NICE is considering evaluating this technology through its cost comparison evaluation process.** **Please provide comments on the appropriateness of appraising this topic through this process.** It is appropriate to appraise this topic through this process. • **Is the technology likely to be similar in its clinical effectiveness and resource use to any of the comparators? Or in what way is it different to the comparators?** Yes	

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		• **Will the intervention be used in the same place in the treatment pathway as the comparator(s)?** Yes • **Will the intervention be used to treat the same population as the comparator(s)?** Yes • **Overall is the technology likely to offer similar or improved health benefits compared with the comparators?** It will likely offer similar health benefits. • **Would it be appropriate to use the cost-comparison methodology for this topic?** Yes	
	The Royal College of Ophthalmologists	**Where do you consider bevacizumab gamma will fit into the existing care pathway for wet AMD?** Bevacizumab gamma should be evaluated against the comparators for clinical and cost effectiveness. If considered to be clinically and cost effective for use within NHS and has marketing authorisation, this can be used as a treatment option for wet age-related macular degeneration alongside current medications like Aflibercept, Ranibizumab, Faricimab, Brolucizumab and Aflibercept 8mg. **Is bevacizumab currently used off label to treat wet age-related macular degeneration?**	Thank you for your comments.

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		Bevacizumab is used in NHS for treatment of non-age-related macular degeneration indications and sparingly, for patients with wet age-related macular degeneration not fitting within NICE guidelines. It is not used for treating patients wet age-related macular degeneration who are within NICE guidelines. **Are there any subgroups of people in whom bevacizumab gamma is expected to be more clinically effective and cost effective or other groups that should be examined separately?** As above, the patients who do not fall within NICE guidelines for wet age-related macular degeneration or those who do not have wet age-related macular degeneration but have conditions where anti-VEGF treatment may be effective should be examined separately. In these patients, bevacizumab gamma may be clinically and/or cost effective. **Would bevacizumab gamma be a candidate for managed access?** As there is minimal high-level evidence of effectiveness of bevacizumab for indications other than wet age-related macular degeneration, diabetic macular oedema, or retinal vein occlusion, it could be a candidate for managed access of all other conditions when it is used. **Do you consider that the use of bevacizumab gamma can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?** It is unlikely that bevacizumab gamma will provide any substantial health related benefits over and above QALY calculation.	

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		Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits. Randomised controlled trials with head-to-head comparison between bevacizumab and ranibizumab, aflibercept (2mg or 8mg) or faricimab, in wet age-related macular degeneration would be the most appropriate evidence to consider for cost and/or clinical effectiveness of bevacizumab gamma. However, other than CATT and IVAN trials comparing bevacizumab with ranibizumab, high quality randomised controlled trial evidence is not available on head-to-head studies. Papers with real world evidence on use of bevacizumab in wet age-related macular degeneration in terms of its clinical and cost effectiveness should be considered. Also, lower-level evidence can be gathered on efficacy of aflibercept (2mg or 8mg) or faricimab against each other or ranibizumab and compared indirectly with bevacizumab. **NICE is considering evaluating this technology through its cost comparison evaluation process. Please provide comments on the appropriateness of appraising this topic through this process.** It is appropriate to evaluate bevacizumab gamma through cost comparison evaluation process. Particular attention should be paid on the number of appointments required to gain similar clinical effect as comparators and the resources required to deliver such treatment. The resources evaluated should include but not be limited to staff, estate, and drug cost. **NICE's health technology evaluations: the manual states the methods to be used where a cost comparison case is made.**	

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		Is the technology likely to be similar in its clinical effectiveness and resource use to any of the comparators? Or in what way is it different to the comparators? This technology is similar in its clinical effectiveness as ranibizumab in treatment of wet age-related macular degeneration. There is lack of comparative evidence with aflibercept (2mg or 8mg) or faricimab. There is lack of substantial data on resource use when using bevacizumab in comparison to aflibercept (2mg or 8mg) or faricimab although there is some data versus ranibizumab. **Will the intervention be used in the same place in the treatment pathway as the comparator(s)? Have there been any major changes to the treatment pathway recently? If so, please describe.** Bevacizumab may be used as the first line treatment for wet age-related macular degeneration like its comparators. However, some medications like faricimab are used as first and/or second line treatment. Use of bevacizumab as a second line has not been evaluated widely. Newer drugs like faricimab and aflibercept 8mg have changed the treatment pathway of wet age-related macular degeneration recently. These drugs are deemed to require fewer treatments to achieve same visual benefit which may make these drugs more cost effective. Comparison with bevacizumab should consider treatment frequency and resulting resource use. **Will the intervention be used to treat the same population as the comparator(s)?** Yes, same population would be treated.	

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		Overall is the technology likely to offer similar or improved health benefits compared with the comparators? There is lack of high-quality evidence that bevacizumab offers improved health benefits in comparison to its comparators. Most of the evidence is against ranibizumab where it shows similar visual benefits. **Would it be appropriate to use the cost-comparison methodology for this topic?** Yes, cost comparison methodology use would be appropriate.	
	NHS England	**NICE is considering evaluating this technology through its cost comparison evaluation process. Please provide comments on the appropriateness of appraising this topic through this process.** Given the equivalent clinical effectiveness and safety of different anti-VEGF agents (aflibercept, bevacizumab and ranibizumab) NHS England agrees that a cost-comparison for ID6320 may be suitable. This opinion is based on NICE Guideline NG82 for Age-related macular degeneration that states that 'no clinically significant differences in effectiveness and safety between the different anti-VEGF treatments have been seen in the trials previously considered by the guideline committee'. Given the guideline committee's view that there is equivalent clinical effectiveness and safety of different anti-VEGF agents (aflibercept, bevacizumab and ranibizumab), comparable regimens will be more cost	Thank you for your comments.

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		effective if the agent has lower net acquisition, administration and monitoring costs. Since the publication of NG82, bevacizumab biosimilars having been available and have been used off-label in the treatment of Wet Age-related macular degeneration. Similarly biosimilar versions of ranibizumab have launched in the UK, significantly lowering the acquisition cost to the NHS. Furthermore, an aflibercept biosimilar has received GB Marketing Authorisation in advance of an expected launch next year. NHSE would expect that bevacizumab gamma, which is not a novel drug, would therefore require to be competitively priced not against the originator products, but, against the lower cost anti-vegf biosimilar products in order to obtain NICE approval under the cost comparison process.	

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

- Fight for Sight
- Retina UK