National Institute for Health and Care Excellence

Health Technology Evaluation

Port Delivery Platform with ranibizumab for treating wet age-related macular degeneration [ID3983]
Response to stakeholder organisation comments on the draft remit and draft scope

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: the draft remit and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	Roche Products Ltd	This appraisal should be evaluated via the single technology appraisal (STA) in line with standard STA timelines.	Thank you for your comment. The topic will proceed via the single technology appraisal route as proposed.
	Macular Society	The topic and the evaluation route are appropriate.	Thank you for your comment. The topic will proceed via the single technology appraisal route as proposed.
	Bayer Plc	None	Thank you for your comment. The topic will proceed via the single

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			technology appraisal route as proposed.
Wording	Roche Products Ltd	The current wording does reflect the proposed marketing authorisation: [redacted] Please note that the overall technology should be known as Port Delivery Platform (Contivue®) with a customised formulation of ranibizumab (Susvimo®). Additionally, “Port delivery Platform” is referred to as “Port Delivery System” in the regulatory dossier, as aligned with the pivotal ARCHWAY trial, but will be known as “Port Delivery Platform (Contivue®)” commercially (as aligned with NICE scope).	Thank you for your comment. The scope has been updated to include the company’s preferred wording for the technology.
	Macular Society	*Does the wording of the remit reflect the issue(s) of clinical and cost effectiveness about this technology or technologies that NICE should consider?* Yes	Thank you for your comment. No change to the scope required.
	Bayer Plc	None	Thank you for your comment. No change to the scope required.
Timing issues	Roche Products Ltd	There is a high unmet need for patients who respond clinically to anti-VEGF therapy but require frequent injections to maintain disease control. Current	Thank you for your comment. This topic

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		standards of care for maintaining vision require frequent visits and regular injections, creating a substantial burden for patients, caregivers, and healthcare providers. Evidence shows that this burden often leads to "under-treatment" in real-world practice, where patients receive fewer injections than recommended, resulting in suboptimal visual outcomes. The data collection period for the phase III ARCHWAY trial has concluded. This appraisal should therefore be conducted in line with standard STA timelines to avoid any delays in access to patients. In addition, the proposed STA timelines are currently in line with the expected marketing authorisation and will avoid any delay in access to patients.	has been scheduled into the work programme.
	Macular Society	Not urgent as there are a number of treatments already available for the condition.	Thank you for your comment. This topic has been scheduled into the work programme.
	Bayer Plc	None	Thank you for your comment. This topic has been scheduled into the work programme.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Roche Products Ltd	The company has no comments on the background information.	Thank you for your comment. No change to the scope required.
	Macular Society	Good	Thank you for your comment. No change to the scope required.
	Bayer Plc	None	Thank you for your comment. No change to the scope required.
Intervention	Roche Products Ltd	The company suggests changing the intervention from 'Port Delivery Platform with ranibizumab' to **'Port Delivery Platform with a customised formulation of ranibizumab'.** The Port Delivery Platform uses a customised formulation of ranibizumab, specifically developed for use with the implanted device. This formulation is distinct from standard intravitreal ranibizumab, as it is designed to enable continuous intraocular delivery and extended durability within the device. The innovation and development of the drug-device combination should be clearly highlighted in the scope and throughout the appraisal to avoid confusion with ranibizumab as an intravitreal injection formulation among stakeholders. Please see the Wording section for more information.	Thank you for your comment. The scope has been updated to include the company's preferred wording for the technology.

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Population	Roche Products Ltd	The population is defined appropriately within the scope and in line with the proposed marketing authorisation: [redacted]	Thank you for your comment. No change to the scope required.
	Macular Society	*Is the population defined appropriately?* Yes	Thank you for your comment. No change to the scope required.
	Bayer Plc	None	Thank you for your comment. No change to the scope required.
Subgroups	Roche Products Ltd	**'People with glaucoma'** should be removed as glaucoma represents a comorbidity rather than a clinically meaningful subgroup. In addition, people with glaucoma were excluded from the pivotal ARCHWAY trial, meaning that robust clinical evidence is not available to support subgroup analyses in this population. **"People with highly active wet AMD lesions"** should also be removed as the term "highly active" is not consistently defined in routine clinical practice. Additionally, the ARCHWAY trial was not powered to assess outcomes in this subgroup. For context, patients were enrolled based on clearly defined and clinically relevant eligibility criteria for the study eye, including an initial diagnosis of exudative nAMD for 9 months, prior treatment with at least 3 anti-VEGF IVT injections within 6 months, and a demonstrated response to prior anti-VEGF therapy at screening.	Thank you for your comment. Both subgroups have been removed from the scope.

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		To summarise, the target population of this appraisal is “wet AMD patients who respond clinically to anti-VEGF therapy”. No additional subgroups should be considered for this appraisal.	
	Macular Society	It’s noted that two sub-groups have been added to the draft scope. People with highly active wet AMD lesions has been included, which seems appropriate as they would benefit most from continuous dosing provided by the platform. They would also be those receiving frequent injections and the platform offers the chance for fewer hospital appointments. What would be the definition of ‘highly active’? The other sub-group is people with glaucoma. This encompasses a broad range of people with the condition so more detail and the reason behind including this sub-group would be helpful to understand the rationale. There may also be another sub-group of people who particularly benefit from the platform, those who find frequent appointments difficult to attend. This might be for reasons such as distance from clinic due to rural location, difficulty with travel and finding someone to take them or accompany them and the prohibitive cost of travel/parking.	Thank you for your comment. Both subgroups have been removed from the scope as per the company’s request.
	Bayer Plc	No comment	Thank you for your comment. No change to the scope required.
Comparators	Roche Products Ltd	Based on UK clinical practice and based on market share data, the three key comparators that should be included in this appraisal are: • Faricimab (TA800) (1) • Ranibizumab (intravitreal injection formulation) (TA155) (2)	Thank you for your comment. The committee will decide which are the relevant comparators. The

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		• Aflibercept (TA294) (3) The company would, therefore, suggest excluding bevacizumab gamma and brolucizumab as comparators due to their limited use within clinical practice. Additionally, the company suggests that any time ranibizumab as a comparator is mentioned, it should be specified that it is an "intravitreal injection formulation", whilst when the intervention is mentioned, it should be named "customised formulation of ranibizumab".	scope has been updated to include the company's preferred wording for the technology and comparator.
	Macular Society	*Are the comparators listed considered to be the standard treatments currently used in the NHS with which the technology should be compared? Have all relevant comparators been included?* Yes	Thank you for your comment. No change to the scope required.
	Bayer Plc	Aflibercept is available as 2 mg per injection and 8 mg per injection. If comparing against aflibercept it would be appropriate to consider both doses	Thank you for your comment. No change to the scope required.
Outcomes	Roche Products Ltd	**'Overall visual function'** should be removed as an outcome because it is not routinely assessed in clinical practice and was not assessed in the pivotal ARCHWAY trial. As such, inclusion of this outcome would not align with available clinical evidence or reflect real-world decision-making in clinical practice.	Thank you for your comment. The committee will decide on the relevant outcomes in its deliberations.
	Macular Society	*Are the outcomes listed appropriate? Will these outcome measures capture the most important health related benefits (and harms) of the technology?* Yes	Thank you for your comment. No change to the scope required.

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	Bayer Plc	None	Thank you for your comment. No change to the scope required.
Equality	Roche Products Ltd	No immediate equality issues were identified as part of this appraisal.	Thank you for your comment. No change to the scope required.
	Macular Society	No comment	Thank you for your comment. No change to the scope required.
	Bayer Plc	None	Thank you for your comment. No change to the scope required.
Other considerations	Roche Products Ltd	The company suggests removing the section "**Related Interventional Procedures**" in the draft scope as none of the interventions listed are related to drug delivery, hence they are not related procedures and relevant for this appraisal.	Thank you for your comment. This section presents an overview of NICE guidance for this disease area. No change to the scope required.
	Macular Society	No comment	Thank you for your comment. No change to the scope required.

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	Bayer Plc	None	Thank you for your comment. No change to the scope required.
Questions for consultation	Roche Products Ltd	**Where do you consider Port Delivery Platform with ranibizumab will fit into the existing care pathway for wet age-related macular degeneration?** [redacted] **Please select from the following, will port delivery platform with ranibizumab be:** **A. Prescribed in primary care with routine follow-up in primary care** **B. Prescribed in secondary care with routine follow-up in primary care** **C. Prescribed in secondary care with routine follow-up in secondary care** **D. Other (please give details):** **For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.**	Thank you for your comment. No change to the scope required. Thank you for your comment. No change to the scope required.

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		The Port Delivery Platform with a customised formulation of ranibizumab is expected to be prescribed in secondary care with routine follow-up in secondary care. **Would Port Delivery Platform with ranibizumab be a candidate for managed access?** At the time of writing, the company is still assessing the Port Delivery Platform with a customised formulation of ranibizumab as a candidate for managed access. **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.** The ARCHWAY trial is a Phase III, multicentre, open-label, randomised, visual acuity assessor-masked comparator study of the Port Delivery System (or Platform, as explained in the Wording section) with ranibizumab in patients with wet nAMD. The study met its primary objective and showed that the customised formulation of ranibizumab delivered via the Port Delivery Platform was non-inferior and had equivalent efficacy to monthly ranibizumab injections, as measured by change from baseline in best corrected visual acuity (BCVA) at the average of Week 36 and 40. Therefore, the most appropriate appraisal type for this submission is the cost comparison model.	Thank you for your comment. No change to the scope required. Thank you for your comment. Due to the difference in population between this appraisal and the appraisals of the comparators, this appraisal will continue as an STA.
	Macular Society	Ranibizumab is not innovative but the method of delivery via the port delivery platform is innovative and has the potential to have a direct benefit for patients.	Thank you for your comment. No change to the scope required.

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		It will reduce the number of injections and increase time between hospital appointments. Fewer hospital appointments would be less burdensome for patients, their family/friends who support them and hospital eye clinics. The platform will reduce the risks associated with intravitreal injections (e.g. endophthalmitis) but there would be potential adverse consequences from the surgery required to insert the platform. The general concern with longer acting treatments is the impact on monitoring of the fellow eye. Currently any wet AMD is picked up quickly in the fellow eye, as a result of regular check-ups and treatment visits, so that eye is treated earlier in the course of the disease and therefore has a better visual outcome than the first eye. With longer between treatment/ monitoring appointments this position may change. It is not clear yet how the platform will be administered in practice and if this could be mitigated in higher risk patients via alternative follow up/ check up/ monitoring procedures (home monitoring) to gain all the advantages of longer treatment/ injections but still maintain the important second eye monitoring.	
	Bayer Plc	None	Thank you for your comment. No change to the scope required.
Additional comments on the draft scope	Roche Products Ltd	None	Thank you.
	Macular Society	None	Thank you.
	Bayer Plc	None	Thank you.

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

- MDBiologics