National Institute for Health and Care Excellence

Health Technology Evaluation

Pegcetacoplan for treating geographic atrophy [ID4041]

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	Apellis (company)	Yes, it is appropriate to refer this topic to NICE for a single technology appraisal. Geographic atrophy (GA) is an advanced form of age-related macular degeneration that leads to progressive and irreversible vision loss (Fleckenstein et al. 2018). There is currently no standard of care for patients with GA. In addition, there are currently no approved pharmacological therapies for the treatment of GA; no interventions exist to prevent, reduce or halt its progression (Caswell et al. 2021, Patel et al. 2020, Sacconi et al. 2017). References: Caswell D, et al. Ophthalmol Ther 2021; 10:367–382. Fleckenstein M, et al. Ophthalmology 2018;125(3):369-90. Patel PJ, et al. Clinical Ophthalmology 2020; 14:15–28. Sacconi R, et al. Ophthalmol Ther 2017; 6(1):69-77.	Comment noted. Thank you for providing these references.

Section	Stakeholder	Comments [sic]	Action
	Macular Society	Single technology appraisal is appropriate.	Comment noted. Thank you.
	Fight for Sight	No additional comment.	Noted. Thank you
Wording	Apellis (company)	Appropriate for the brevity but please note that the population will be described as 'geographic atrophy (GA) secondary to age-related macular degeneration' in the anticipated label.	Comment noted. The population is described as 'Adults with geographic atrophy secondary to age-related macular degeneration.' No change required.
	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.	Comment noted.
	Fight for Sight	No additional comment.	Noted. Thank you.
Timing	Apellis (company)	Apellis considers this appraisal to be urgent because there are currently no approved pharmacological treatments available for treating geographic atrophy (GA), which is a progressive irreversible condition (Khan et al. 2023). Pegcetacoplan is a targeted C3 therapy, and the first disease-modifying therapy in GA, which reduces lesion growth rate (Liao et al, 2019). Pegcetacoplan offers patients and the NHS the first potential treatment for GA. Its launch will contribute to addressing the unmet need for approved GA treatments that are effective in reducing lesion growth rate and slowing the rate of irreversible disease progression (Loewenstein & Trivizki, 2023).	Thank you for your comment.

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		Therefore, we believe pegcetacoplan should be assessed at the earliest opportunity. References: Khan H, et al. Clin Ophthalmol 2023;17:221–327 Liao DS et al. Ophthalmol, 2020;127(2):186–195. Loewenstein A & Trivizki O. Graefes Arch Clin Exp Ophthalmol, 2023;261(6):1525–1531.	
	Macular society	With an aging population the number of people with geographic atrophy (GA) is estimated to double by 2050 to 720,000, with an estimated 97,000 new cases a year. (Dr Alicja R Rudnicka, Professor Christopher G Owen, Personal Communication. Macular Society 2016) There is currently no treatment available for GA, therefore there is significant unmet need and an urgent requirement to prevent the sight loss that is consequent to GA. Every day the Macular Society sees the impact on people's quality of life from sight loss due to GA. It not only has a direct impact on the person but the impact on families can be significant, as they increasingly need to provide everyday support and care. Treatments for wet AMD, which can occur alongside GA, have been transformative in preserving vision. Those with GA however are only able to be offered ways to help them live with sight loss, such as low vision aids. Such tools are provided at a cost to local health budgets or the individual and would be useful to consider as part of the economic analysis.	Thank you for your comment.
	Fight for Sight	Fight for Sight welcomes the authorisation of any technology that will benefit the quality of life for those suffering from vision loss due to age-related macular degeneration.	Thank you for your comment.

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		A report that Fight for Sight published a few years ago, called the Time to Focus report, highlighted some important points, bulleted below, regarding AMD and its impact on both the individual and the health service in the UK. It is even more important today as the population is an ageing one. • As mentioned, there's currently no treatment for 'dry' macular degeneration, which accounts for around 90 percent of cases. • There are over half a million people (605,880) between 50-69 in the UK living with sight loss. • Reducing age-related macular degeneration prevalence by one percent each year could save the UK economy nearly £1.2 billion by 2050. • Each year, age-related macular degeneration costs the UK economy £2.6 billion – over half of which (53 percent) falls outside health and social care. • The lifetime cost of a new case of age-related macular degeneration in an adult aged 50 or over, causing at least moderate visual impairment, is £73,350. In addition to the above, the impact on the quality of life for an individual is high. There are greater levels of loneliness and isolation and central vision loss risks injury due to falls.	
Additional comments on the draft remit	Apellis (company)	No additional comments.	Thank you.
	Macular Society	None.	Thank you.
	Fight for Sight	No additional comment..	Thank you.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Apellis (company)	For accuracy, the pegcetacoplan brand name should be Syfovre and not Aspaveli as stated in the draft scope. Further detail on burden and quality of life could be included from a caregiver perspective (Sarda et al. 2021). Caring for a patient with GA can require social and mental health support (Amoaku et al, 2023). The burden experienced by both patients and caregivers translates to a societal impact (Amoaku et al, 2023). The rest of the information is accurate and appropriate. <u>References:</u> Amoaku W, et al. Presented at Royal College of Ophthalmologists Annual Congress, Birmingham, UK; May 22–25, 2023. Sarda SP, et al. Clin Ophthalmol, 2021;15:4629–4644	Comment noted. The brand name in the scope has been updated. The background section of the scope aims to provide a brief overview of the background for the appraisal; additional details may be considered by the committee, if appropriate, at the time of the appraisal. No further changes are needed.
	Macular Society	As wet AMD and GA can co-exist in the same eye in a significant proportion of people, this should be factored in as an important consideration.	Comment noted. The background section of the scope aims to provide a brief overview of the background for the appraisal; additional details may be considered by the committee, if appropriate, at the time of the appraisal. Attendees at the scoping workshop

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			discussed the relevance of co-existing wet AMD. It was noted that wet AMD was an exclusion criteria in the trial populations which will inform this evaluation. No changes are required.
	Fight for Sight	The background provided is good.	Comment noted.
Population	Apellis (company)	The population should be defined as “Adults with geographic atrophy (GA) secondary to age-related macular degeneration (AMD)” to align with the anticipated label.	Comment noted. The population is described as ‘Adults with geographic atrophy secondary to age-related macular degeneration.’ No change required.
	Macular Society	Is the population defined appropriately?- Yes but with the provision above, that GA is one presentation of late stage AMD and wet AMD, and treatment for it, must be taken into consideration as well.	Comment noted. Attendees at the scoping workshop discussed the relevance of co-existing wet AMD. It was noted that wet AMD was an exclusion

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			criteria in the trial populations which will inform this evaluation. No changes are required.
	Fight for Sight	No additional comment.	Noted.
Subgroups	Apellis (company)	Geographic atrophy (GA) lesions can grow in the foveal region (subfoveal lesions) or outside the fovea (non-subfoveal lesions). Non-subfoveal lesions tend to grow at a faster rate compared to subfoveal lesions (Fleckenstein et al, 2018). Pegcetacoplan reduces GA lesion growth rate in patients with subfoveal and non-subfoveal lesions at baseline versus sham. There is a trend towards a higher treatment effect for pegcetacoplan in patients with non-subfoveal lesions at baseline, compared to subfoveal lesions (Wykoff, 2022). References: Fleckenstein M, et al. Ophthalmol, 2018;125(3):369–390. Wykoff C. American Academy of Ophthalmology Annual Meeting, Chicago, IL, USA, 2022.	Comment noted. The subgroups have been updated to include consideration of lesions within or outside of the foveal region.
	Macular Society	Those with existing wet AMD in the eye with GA, or at risk of developing wet AMD in the eye with GA because they already have wet AMD in the fellow eye.	Comment noted. Attendees at the scoping workshop discussed the relevance of co-existing wet AMD. It was noted that wet AMD was an exclusion criteria in the trial

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			populations which will inform this evaluation. No changes are required.
	Fight for Sight	No additional comment.	Noted. Thank you.
Comparators	Apellis (company)	We agree and note that there are also no proven pharmacological treatments available. All relevant comparators have therefore been included.	Comment noted. Thank you.
	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, as there is currently no pharmacological treatment, standard of care is supportive only	Comment noted. Thank you.
	Fight for Sight	No additional comment.	Noted. Thank you.
Outcomes	Apellis (company)	There are other measures currently available for geographic atrophy (GA) assessment, such as microperimetry, which should be considered in addition to the listed outcomes (Csaky et al. 2019). Apellis agrees with the usage of change in GA lesion size as an outcome and this can be measured by fundus autofluorescence (FAF), which is the current standard imaging technology used for the morphological assessment of GA (Sadda et al. 2016). It is an objective and reproducible anatomical technique with a high spatial resolution (Sadda et al. 2016). FAF imaging represents the loss of retinal pigment epithelium (RPE), which correlates with photoreceptor loss (Mai et al, 2023). FAF imaging has been deemed a clinically meaningful endpoint by regulators (Sadda et al. 2016; Csaky, 2018).	Comment noted. Thank you for providing these references. Attendees at the scoping workshop discussed the relevance of the outcomes. It was noted that microperimetry is currently being assessed in research. So, it has not been fully validated. It was considered that this would not be an appropriate outcome.

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		It should be noted that the instruments used to assess functional outcomes (e.g. visual acuity and health-related quality of life) are associated with high variability (Heier et al. 2020). <u>References:</u> Csaky KG, et al. Invest Ophthalmol Vis Sci, 2018;58(9):3456–3463. Csaky KG, et al. Surv Ophthalmol. 2019;64(3): 353–364. Heier JS, et al. Ophthalmol Ret, 2020;4(7):673–688 Mai J, et al. Nat Sci Rep, 2023;13:7028.	Attendees agreed that change in geographic atrophy lesion size, visual acuity and health-related quality of life are appropriate to be included in the scope. No changes are required.
	Macular Society	Visual acuity is only one measure of the ability to see and be able to carry out normal activities of daily life. The DERBY (NCT03525600) and OAKS (NCT03525613) trials included functional vision assessments on reading ability. What matters to patients is the benefit of the treatment to their overall vision long term, which should be captured under health-related quality of life.	Comment noted
	Fight for Sight	These outcomes look appropriate. No additional comment.	Noted. Thank you.
Equality	Apellis (company)	No equality issues identified. Age should not be discriminatory in the patient population.	Thank you for your comment.
	Macular Society	Patients considered suitable for pegcetacoplan treatment will need to attend hospital on a monthly or bimonthly basis, possibly for years. This treatment burden is significant and there is experience of this level of treatment burden and its consequences from wet AMD.	Thank you for your comment. Access to treatments is not an issue that can be

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		Those less able to be supported to enable them to travel to appointments will be disadvantaged. Patients cannot drive after an intravitreal injection or dilating eye drops, and may have difficulty using public transport and not be able to afford taxis. They may therefore not take up an offer of treatment or not be able to sustain the regime for the months/years required. Access to hospitals for those in rural and more remote areas, where travel distances can be long and access to public transport is poor, means such patients are particularly disadvantaged. As those with GA are likely to have some vision loss already. This may impact on their ability to manage interactions with healthcare services, such as read appointment letters, text alerts etc. Accessible communication will be needed throughout the patient journey.	addressed in a NICE technology appraisal.
	Fight for Sight	No additional comment.	Noted. Thank you.
Other considerations	Apellis (company)	No further considerations are requested.	Comment noted. Thank you.
	Macular Society	None.	Noted. Thank you.
	Fight for Sight	No additional comment.	Noted. Thank you.
Questions for consultation	Apellis (company)	**Where do you consider pegcetacoplan will fit into the existing care pathway for geographic atrophy?** There are currently NICE guidelines for the treatment of wet and dry age-related macular degeneration (AMD). Geographic atrophy (GA) would currently follow the dry AMD pathway (NICE, 2018). However, there is no pharmacological treatment or intervention to slow the progression of GA within the pathway and pegcetacoplan will be the first	Comments noted. The attendees at the scoping workshop discussed the relevant care pathway. No changes to the scope are needed.

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		treatment option available; current guidance would need to be updated accordingly (Khan et al, 2023; NICE, 2018). Based on the recommendations of clinical experts and optometrists, Apellis foresees the most reasonable approach to using pegcetacoplan would be after the patient undergoes an assessment at an optometry clinic and are referred to an ophthalmologist, who will make the clinical decision whether to start the treatment. The ophthalmologist will likely consider several factors before initiating treatment (e.g. the physical and mental health of the patient). Based on clinical feedback, following the treatment, the patient would be monitored in the orthodox follow-up clinics. Patients will undergo a low vision assessment as appropriate and also be referred to the Eye Care Liaison Officer (ECLO) nurse and vision aid services if required (NICE, 2018). **Would eligibility to receive pegcetacoplan be dependent on age?** No. It should solely be dependent on geographic atrophy (GA) diagnosis because there are no other treatments approved (Khan et al. 2023). Patients with GA should ideally start treatment as soon as possible because there is evidence that the treatment effect may increase over the course of the treatment duration (Chiang et al, 2023). Apellis would not like NICE to discount any patients within the scope based on age, as there is a broad spectrum of younger and older patients that could gain significant benefit in slowing the progression of sight loss (Wilde et al. 2020). As stated in the draft scope: *People with geographic atrophy may have difficulty in reading, judging distance and seeing in dark conditions and so may encounter a loss of mobility and independence, and a reduction in quality of life.*	Attendee at the workshop also discussed equality issues and considered pegcetacoplan would not be dependent on age. No change to scope required.

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		The effect of vision loss in patients will have a significant impact on carers and family members due to the lack of mobility, loss of independence and reduction in quality of life as the lesion growth continues, which is independent of age. **What is established clinical management for geographic atrophy?** There is no clinical intervention to slow the progression of photoreceptor loss within the current geographical atrophy (GA) clinical management pathway (Khan et al. 2023; NICE, 2018) Depending on the visual acuity of both eyes, the Royal College of Ophthalmologists currently recommended that refraction, low vision aids, or a certificate of visual impairment are considered for patients (RCOphth, 2021). **Which outcomes are most relevant to measure intervention effectiveness in geographic atrophy?** Geographic atrophy (GA) lesion growth rate as measured by fundus autofluorescence (FAF) is the current standard imaging technology used for the morphological assessment of GA (Sadda et al. 2016). It is an objective and reproducible technique for the assessment of GA progression and is considered clinically meaningful when assessing efficacy (Sadda et al. 2016; Csaky et al, 2018). In addition, optical coherence tomography (OCT) is another technology widely used in conjunction with FAF and can identify individual cell layers such as photoreceptors (Schall et al, 2016, Schmidt-Erfurth et al, 2023; Mai et al, 2023). There is a high correlation between retinal images captured by FAF and OCT (Mai et al, 2023). It is worth noting that FAF is currently established as the standard imaging modality for	Comment noted. No change to scope required. Comment noted. Attendees at the scoping workshop considered change in geographic atrophy lesion size and visual acuity, were appropriate outcomes. It was noted that microperimetry is currently being assessed in research. So, it has not been fully

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		evaluating GA progression in clinical trials, while OCT is commonly utilised in clinical practice due to its wider availability (Mai et al, 2023). Currently available functional endpoints for GA, such as best-corrected visual acuity (BCVA) and the Functional Reading Independence (FRI) index may not be sensitive enough to detect vision change associated with anatomical changes. There is an unmet need for a precise and sensitive functional endpoint that correlates strongly with GA lesion growth (Heier et al. 2020). The preservation of vision is critical to maintain independence and a good quality of life. A critical treatment goal for GA is slowing the progression of lesion growth in the non-subfoveal region before it reaches the fovea (a region with highest density of photoreceptors in the retina) and impacts patient vision, and to slow subfoveal lesion progression (when the lesion reaches the fovea). The reduction in lesion growth rate and preservation of the photoreceptor loss over time with both non-subfoveal and subfoveal ingression by extension preserves the photoreceptor-dense region in the macular (the fovea) and central vision. BCVA is a measurement of the highest possible resolution of a person's sight when looking at a chart, using corrective lenses if required (Jolly et al, 2019). It provides a baseline measurement of sight for patients, but the gold standard logMAR and ETDRS charts used can be challenging for patients with visual field loss (Jolly et al, 2019). Patients with visual field loss such as GA patients often have difficulty tracking the letters on the chart and as the disease continues to impact the visual field, this difficulty reading the chart continues to worsen as the disease progresses (Jolly et al, 2019). The photoreceptor cell loss begins prior to and exceeds retinal pigment epithelium (RPE) cell loss (Riedl et al, 2022; Cobbs, 2022). In addition to this, FAF imaging, which is most commonly used to monitor GA, is unable to show the detailed photoreceptor loss (Heier et al, 2020); therefore, the initial damage to	validated. It was considered that this would not be an appropriate outcome**.** No further changes to scope needed.

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		the retina may have taken place before it is visible to clinician using this imaging method. BCVA results may also be impacted by patient fatigue or practice. The location of the GA lesion, phenotype and focality can all have an impact on the lesion growth rate (Shen et al, 2020), and thus may have an impact on the results obtained from standardised visual function measurements, such as BCVA. This is why more comprehensive assessments are required as key outcome metrics for GA progression, such as change in FAF imaging to monitor efficacy of treatment over time. Additional outcomes currently available for GA assessment, such as microperimetry, should also be considered (Csaky et al. 2019). Microperimetry measures retinal sensitivity in specific areas by presenting visual stimuli directly onto the retina using real-time tracking of the retinal movements to provide spatially registered measurements of retinal sensitivity on a fundus image of the retina (Csaky et al. 2019). It is a measure to assess the topographic correlation between atrophic areas and corresponding photoreceptor functional abnormality; it therefore has the potential to evaluate the relationship between structural and functional changes in GA in a specific area of the retina (Schmidt-Erfurth et al, 2023). **Would pegcetacoplan be a candidate for managed access?** Pegcetacoplan has demonstrated that it can significantly reduce geographic atrophy (GA) lesion growth rate in its clinical trial programme, compared to sham treatment. Furthermore, there is evidence that the treatment effect associated with pegcetacoplan may increase over time. [redacted]	Comment noted. Thank you. Comment noted. These may be considered by the committee, if

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		Do you consider that the use of pegcetacoplan can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation? Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits. Yes. The loss of vision over time leads to a greater reliance on caregivers (Sarda et al. 2021). Whilst caregivers provide important support to patients, this can come with negative impacts on their own health (Kuriakose et al. 2017). The health-related quality of life of caregivers should be considered within the economic evaluation of pegcetacoplan. It is imperative that the utilisation of costly social services for patients with sight loss and the loss of work for family carers is considered over and above the quality-adjusted life year (QALY) calculation. The impact of poor vision on A&E visits, trips, falls and hip replacements in this elderly population, in addition to GP visits and overall health deterioration may not be adequately captured by a QALY calculation; therefore, these factors would need to be considered (Amoaku et al, 2023). People with AMD are also at an increased risk of depression (Casten & Rovnere, 2013). Identifying and managing depression in accordance with the NICE guidelines could have an impact on the system, which is not factored for within the QALY calculation. Recent studies have found that older individuals experiencing vision loss may have an increased susceptibility to cognitive decline or the development of dementia, which should be considered (Fang et al, 2021; Elyashiv et al, 2014; Lee et al, 2020; Nagarajan et al, 2022). The MOSAIC study was conducted to characterise the clinical, humanistic and economic burden of GA on patients and carers. This is a non-interventional cross-sectional burden of illness study among patients with GA	appropriate, at the time of the appraisal.

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		and their caregivers across six countries, including the United Kingdom. Results were recently presented at conferences in May 2023 (Sarda et al, 2023; Amoaku et al, 2023). References: Amoaku W, et al. Presented at Royal College of Ophthalmologists Annual Congress, Birmingham, UK; May 22–25, 2023. Casten RJ & Rovnere BW. Curr Opin Ophthalmol, 2013;24(3):239–246. Csaky KG, et al. Invest Ophthalmol Vis Sci, 2018;58(9):3456–3463. Csaky KG, et al. Surv Ophthalmol. 2019;64(3): 353–364. Chiang et al. The Association for Research in Vision and Ophthalmology Annual Meeting. New Orleans, USA, 2023. Elyashiv SM, et al. Br J Ophthalmol, 2014;98(1):129–132. Fang IM, et al. Nat Sci Rep, 2021;11(1):17593. Heier JS, et al. Ophthalmol Ret, 2020;4(7):673–688. Jolly K, et al. Br J Ophthalmol, 2019104(7):924–931. Khan H, et al. Clin Ophthalmol 2023;17:221–327. Kuriakose R, et al. Int Ophthalmol, 2017;37(3):767–777. Lee ATC, et al. J Gerontol A Biol Sci Med Sci, 2020;75(11):2162–2168. Mai J, et al. Nat Sci Rep, 2023;13:7028.	

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		Nagarajan N, et al. BMJ, 2022;12(1):e047929. NICE, 2018. NG82: Age-related macular degeneration. Available at: https://www.nice.org.uk/guidance/ng82/resources/agerelated-macular-degeneration-pdf-1837691334853 Riedl SR, et al. Ophthalmology Retina, 2022;6(11):1009–1018. RCOphth. Commissioning Guidance, 2021. Available at: https://www.rcophth.ac.uk/wp-content/uploads/2021/08/AMD-Commissioning-Guidance-Full-June-2021.pdf Sadda SR, et al. Retina, 215;36(10):1806–1822. Sarda SP, et al. Clin Ophthalmol, 2021;15:4629–4644. Sarda SP, et al. Presented at ISPOR, Boston, MA, USA; May 7–10, 2023. Schaal KB, et al. Ophthalmology, 2016;123(5):1060–1079. Schmidt-Erfurth U, ARVO Annual Meeting, Vienna, Austria, Waltham, MA, USA, 2023. Shen LL, et al. IOVS, 2020;61(1):1–14. Wilde C, et al. Eye (Lond), 2021;35(6):1697–1704.	
	Macular Society	**Where do you consider pegcetacoplan will fit into the existing care pathway for geographic atrophy?** People with GA are not currently recommended to be referred to hospital eye care services except in a few specific circumstances e.g. to obtain a Certificate of Visual Impairment. There will therefore need to be a process established for referral from primary care to secondary care, in a similar way to that for wet AMD but without the same	Comment noted. No change to scope required.

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		level of urgency. As improvements in the triage or referrals for wet AMD are brought into play to manage the pressure on eye clinics, referrals for suspected GA will need to be included and managed alongside those for wet AMD. **Would eligibility to receive pegcetacoplan be dependent on age?** No, it should be dependent on a diagnosis of GA and clinical judgement of the benefit of treatment to the patient. **Which outcomes are most relevant to measure intervention effectiveness in geographic atrophy?** See earlier response under Outcomes. There should be a focus on what matters to patients. They will want to maintain the vision they have at the start of treatment as far as possible and be able to continue to do the things that they enjoy, such as driving, reading, art, sport etc. as well as maintain their overall independence. The wider impact of vision loss, such as an increased likelihood of falls, deterioration in mental health, isolation and loneliness are all consequences which could be impacted positively by effective intervention. **Would pegcetacoplan be a candidate for managed access?** Managed access could be an option if it enabled some people with GA to be treated with pegcetacoplan and it supported building the evidence for cost effectiveness ahead of full access.	Comment noted. Thank you. Comment noted. Thank you. Comment noted. Thank you.
	Fight for Sight	No additional comment.	Noted. Thank you.
Additional comments on the draft scope	Apellis (company)	No additional comments.	Noted. Thank you.
	Macular Society	None.	Noted. Thank you.

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	Fight for Sight	No additional comment.	Noted. Thank you.

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

Royal College of Pathologists

Royal National Institute for the Blind