National Institute for Health and Care Excellence

Health Technology Evaluation

Low-dose atropine eye drops for treating myopia in people 3 to 14 years [ID6517]

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	Association of Optometrists	The AOP supports the single technology appraisal route for low-dose atropine eye drops.	Thank you for your comment.
	British & Irish Paediatric Ophthalmology and Strabismus Association (BIPOSA)	Its relevant and a growing problem. The issue is lack of data in Caucasian children, (most data is on Chinese or East Asia) and some concern that very low dose is ineffective.	Thank you for your comment. The committee will consider the evidence and its generalisability during the appraisal process.
	College of Optometrists	The prevalence of myopia is increasing globally, including the UK, with estimates as high as 50% of the population by 2050. As a result there is an increasing proportion of patients with high myopia; and a greater risk of myopia related complications with sight threatening potential. There are various licensed optical interventions available to slow down the rate	Thank you for your comment.

Section	Stakeholder	Comments [sic]	Action
		of axial length and myopic progression; but evidence for the certainty of treatment effects are limited. Recent meta-analyses and systemic reveiws have suggested that low-dose atropine (LDA) is among the most effective treatments, but no licensed pharmaceutical product is currently avaialble in the UK (or US). Although myopia is readily detectable through provision of sight testing, there is no NHS funding available to provide any myopia management interventions, including follow-up/monitoring services – meaning access is limited to those able to pay privately. We therefore welcome the proposed evaluation to potentially enable NHS funded evidence based myopia management treatment.	
	Macular Society	STA is an appropriate evaulation route.	Thank you for your comment.
	Neonatal and Paediatric Pharmacy Group (NPPG)	N/A	N/A
	Royal College of Ophthalmologists	This is an appropriate topic for evaluation by NICE. The prevalence and the severity of myopia in children are increasing, and the incidence of sight-threatening complications from myopia in adulthood is increasing. New interventions to delay myopia onset and slow its progression in childhood have become available and have demonstrated efficacy and safety in phase 3 clinical trials. These interventions include low-concentration atropine (0.01 to less than 0.10%), and it is timely to evaluate its use in the UK as a form of secondary prevention to reduce the number of people suffering complications, and potentially in the future as primary prevention to delay the onset of myopia. The proposed evaluation route of a single technology appraisal is suboptimal, as optical solutions (peripheral-plus and diffusion optics spectacle lenses, dual-focus and orthokeratology contact lenses) are already available on the UK market, on private prescription by	Thank you for your comment. No other optical solutions have been referred to NICE for technology appraisal, therefore we consider the single technology appraisal route appropriate.

Section	Stakeholder	Comments [sic]	Action
		optometrists. A multiple technology appraisal would be desirable. However, to provide a timely assessment of low-concentration atropine, a single technology appraisal is justified, and could be followed by other technology appraisals in the future.	
	Santen	It is appropriate to evalaute this technology through a Single technology appraisal	Thank you for your comment.
Wording	Association of Optometrists	Yes, the wording of the remit reflects the issue(s). Please see above for edits recommended to the wording. However, the prevalence of certain eye diseases in relation to the presence of myopia and its consequent management needs to be considered further within the targeted group. The AOP recommends the following edits to the draft remit: “To appraise the clinical and cost effectiveness of low-dose atropine eye drops within its marketing authorisation for treating the progression of myopia in people 3 to 14 years.”	Thank you for your comment. The remit has been updated from “treating myopia” to “slowing the progression of myopia”.
	British & Irish Paediatric Ophthalmology and Strabismus Association (BIPOSA)	Didn’t see much on cost. This will depend on price point, and likely effectiveness. Data on Chinese population suggests that 0.01% reduces (but not eliminates) myopia progression from about 0.8D per year to 0.5D per year. 0.025% reduces the progression to 0.046 per year. Reference LAMP study Ophthalmology 2019;126(1):113 Data from Repka suggests this treatment effect is lost in USA population. More effect is demonstrated with 0.05% solution – but Santen have not produced a product with this %. 0.03% will be more effective and similar to 0.025 as above.	Thank you for your comment. In line with the draft remit, NICE will consider both the clinical and cost effectiveness of the technology. The price of the technology is set by the company (Santen). The appraisal committee will consider the evidence for the

Section	Stakeholder	Comments [sic]	Action
			formulation covered by the marketing authorisation.
	College of Optometrists	It is not clear what is meant by “within it’s marketing authorisation” under remit/evaluation objective – the technology (SYD-101) does not currently have a product license and the associated clinical trial (STAR; NCT 03918915) has not been published.	Thank you for your comment. NICE only issue guidance for technologies with a licence/marketing authorisation in the UK. The exact dates for this are considered confidential by the company.
	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.
	Neonatal and Paediatric Pharmacy Group (NPPG)	N/A	N/A
	Royal College of Ophthalmologists	Yes, it reflects the issues of clinical and cost effectiveness. The age range of 3-14 years covers the age where myopia progression is fastest. It is possible that low-concentration atropine will be used in age groups older than 14 years, but the main clinical need is in the age group from 3-14 years.	Thank you for your comment.

Section	Stakeholder	Comments [sic]	Action
	Santen	To appraise the clinical and cost effectiveness of low-dose atropine eye drops within its marketing authorisation for treating myopia in **paediatric patients** aged 3-14 years	Thank you for your comment. The current wording is considered to be clear and in line with NICE style, no updates have been made to the scope.
Timing issues	Association of Optometrists	Low urgency. The technology is not urgent as it does not relate to an intervention that preserves or extends life, instead this technology is intended to slow down the progression of myopia.	Thank you for your comment.
	British & Irish Paediatric Ophthalmology and Strabismus Association (BIPOSA)	Low – but it's a long game. Treatment probably needs to be continued for the duration of childhood – meaning ? to 18 years of age	Thank you for your comment. Low-dose atropine eye drops will be appraised in line with the marketing authorisation.
	College of Optometrists	There is no currently available NHS funded myopia management intervention; meaning it is only accessible privately by those able to afford treatment. There is risk that a significant proportion of children from lower socio-economic groups will not recieve treatment, particularly those from Asian/East Asian ethnicities who are more likely to be myopic and have higher levels of myopia. Thus, there is urgent need to provide equitable access for myopia management throught NHS funding.	Thank you for your comment. Subgroups by ethnicity have been included in the final scope.
	Macular Society	Non urgent	Thank you for your comment.

Section	Stakeholder	Comments [sic]	Action
	Neonatal and Paediatric Pharmacy Group (NPPG)	N/A	N/A
	Royal College of Ophthalmologists	This is not an emergency topic, but timely processing will benefit children and reduce the impact of a rapidly increasing public health problem.	Thank you for your comment.
	Santen	No NHS funded medicine is available to treat these patients	Thank you for your comment.
Additional comments on the draft remit	Association of Optometrists	N/A	N/A
	British & Irish Paediatric Ophthalmology and Strabismus Association (BIPOSA)	Yes – the remit is ok its just that your draft does not consider cost – unless I have missed it!	Thank you for your comment. In line with the draft remit, NICE will consider both the clinical and cost effectiveness of the technology. The price of the technology is set by the company (Santen).
	College of Optometrists	Is low-dose atropine used in clinical practice for the treatment of myopia? If so what is the benefit of SYD-101 over currently available preparations of low-dose atropine? There is evidence that low-dose atropine (LDA) treatment may slow the rate of myopia progression (by reducing refractive change and axial elongation) in children[1]. Despite limited certainty of the treatment effect and optimal dose, it is considered among the most effective interventions	Thank you for your comment.

Section	Stakeholder	Comments [sic]	Action
		available[1]. However, in the UK, LDA preparations are unlicensed and are therefore used clinically off-label[2]. These are produced by compounding licensed preparations (atropine 1%) in specialist pharmacies to the relevant dose for myopia management. This means they can only be prescribed by clinicians with the legal ability to prescribe unlicensed medicines (i.e. medical doctors) so their use in the UK is restricted to private ophthalmology led services providing myopia management or clinical trials. As preparations are compounded, there is a lack of control over formulation quality with respect to dose, drug stability and preservative concentration; which not only has implications for storage and shelf-life but also drug safety and efficacy[3]. Ocular side effects of atropine include transient stinging, conjunctival inflammation, light sensitivity and near vision blur which can impact treatment compliance[1, 2]. According to product literature, SYD-101 is produced to pharmaceutical quality standards (currently undergoing US Food and Drug Administration approval) includes an agent to stabilise pH of the formulation to physiological levels, which aims to improve user comfort and tolerability[4]. Although two different doses are undergoing a phase III multicentre clinical trial (STAR, NCT 03918915)[5] there are currently no published reports on safety or efficacy of this intervention. 1. Lawrenson JG, Huntjens B, Virgili G, Ng S, Dhakal R, Downie LE, Verkicharla PK, Kernohan A, Li T, Walline JJ. Interventions for myopia control in children: a living systematic review and network meta-analysis. Cochrane Database of Systematic Reviews 2025, Issue 2. Art. No.: CD014758. DOI: 10.1002/14651858.CD014758.pub3. 2. Jawaid, I., Saunders, K., Hammond, C.J. *et al.* Low concentration atropine and myopia: a narrative review of the evidence for United Kingdom based practitioners. *Eye* 38, 434–441 (2024). https://doi.org/10.1038/s41433-023-02718-2	

Section	Stakeholder	Comments [sic]	Action
		3. Richdale, Kathryn O.D., Ph.D.; Tomiyama, Erin S. O.D., Ph.D.; Novack, Gary D. Ph.D.; Bullimore, Mark A. M.C.Optom., Ph.D.. Compounding of Low-Concentration Atropine for Myopia Control. Eye & Contact Lens: Science & Clinical Practice 48(12):p 489-492, December 2022. | DOI: 10.1097/ICL.0000000000000932 4. Safe and Effective Low-Dose Atropine Can Be Stable and Comfortable Too - Review of Myopia Management 5. Study Details | The Safety and Efficacy of SYD-101 in Children With Myopia | ClinicalTrials.gov	
	Macular Society	N/A	N/A
	Neonatal and Paediatric Pharmacy Group (NPPG)	N/A	N/A
	Royal College of Ophthalmologists	N/A	N/A
	Santen	N/A	N/A

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Association of Optometrists	The background information would benefit from further research/context which can be provided by academic experts within the field. For instance, the mention of complications of “lazy eye” and “squint” are misplaced and would make more sense with the correct context supporting it.	Thank you for your comment. The scope aims to give a brief introduction to the

Section	Consultee/ Commentator	Comments [sic]	Action
			condition, current management and the technology. As part of the appraisal process, the company and other stakeholders will provide detailed and comprehensive evidence submissions which routinely include published literature and expert testimony. These will be considered by the External Assessment Groups and the appraisal committee. No changes have been made to the scope.
	British & Irish Paediatric Ophthalmology and Strabismus Association (BIPOSA)	Poor – you need to review a lot more data -Under Background: Para 3. I would not use the word “slightly”. The increased risk of visual impairment once over -6.00 is x87 (CI 34-222) as per “The Complications of Myopia: IOVS;2020:61(4):49 -Under this - I would put Myopic Macular Degeneration first, as the most significant risk factor for visual impairment, followed by retinal detachment, glaucoma and cataract -Under the paragraph “The Technology” it is mentioned that there is one paper to support low dose atropine. Reference is Clinical trials.gov. The Safety and Efficacy of SYD-101 in Children With Myopia (STAR)	Thank you for your comment. The scope aims to give a brief introduction to the condition, current management and the technology. As part of the appraisal process, the company and other stakeholders will provide detailed and

Section	Consultee/ Commentator	Comments [sic]	Action
		NCT03918915. Accessed 11 February 2025. This may be so in the UK – but there are many papers - mostly from East Asia – summarised in 2023. Comparison of efficiency and safety of atropine for myopia control: A meta analysis. Frontiers of Pharmacology 2023; 14: 1227787. DOI 10.3389/fpar.2023.1227787. this sites 44 studies. There is also Efficacy and Safety of Low-dose Atropine on Myopia Prevention in Premyopic Children: Systematic review and meta-analysis. J of Clin Medicine 2024;13:1506. DOI 10.3390/jcm13051506. This selected 4 studies -In the sentence starting “Higher dose…” there is a typo – occular – should be ocular You should consider Repka et al. JAMA 2023; 141(8):756 – an RCT which demonstrated no treatment effect with 0.01% Atropine in a mixed race US population	comprehensive evidence submissions which routinely include published literature and expert testimony. These will be considered by the External Assessment Groups and the appraisal committee. The following changes have been made in response to the comments provided: “Slightly increased chance” has been replaced by “high risk”. The ordering of complications has been revised as suggested. Clarification that STAR is the key phase 3 trial has been added.

Section	Consultee/ Commentator	Comments [sic]	Action
			The typo has been corrected.
	College of Optometrists	While the majority of people with myopia do not experience further complications, they require life-long visual correction (spectacles, contact lenses) and with higher levels an increased dependence on visual correction, which tend to poorer cosmesis (increased lens thickness and weight). Higher levels of myopia also result in worse unaided vision, less favourable refractive surgery outcomes, and are less likely to pass occupational vision standards. Complications of higher levels of myopia include glaucoma – which is the same as raised intraocular pressure and not necessarily the result of raised intraocular pressure. Suggest to state “glaucoma” alone. Myopia is not an established risk factor for macular degeneration, but for a specific pathology called myopic maculopathy. In children, “squint” should be labelled as strabismus and “lazy eye” as amblyopia. Amblyopia can occur in both eyes, not just one. The cited study under “the technology” is a reference to the clinical trial registration only. There is no published report of the study in the peer reviewed literature. Higher doses of atropine have been studied (including at 1%), but while results show a dose-dependent response, this is countered by the expected clinical effects on the eye at higher doses (blurred vision, photophobia); and the increased risk of adverse events (such as CNS disturbances). Further, lower doses of atropine have varying rates of effectivness dependent on ethnicity, with children of Asian and East Asian descent exhibiting lower treatment responses. Thus, there is currently no established optimal dose.	Thank you for your comments. The scope aims to give a brief introduction to the condition, current management and the technology. The wording of the complications in both adults and children has been revised. “Glaucoma” is now included separately from “raised pressure in the eye”. As part of the appraisal process, the company are required to provide an evidence submission including full details of the key clinical trial, its results, and other relevant evidence identified through systematic literature

Section	Consultee/ Commentator	Comments [sic]	Action
			review. Although the trial is not currently published, it is expected that results will be published online once the UK marketing authorisation has been granted. The committee will consider all clinical evidence presented during the appraisal process. The dose/formulation appraised by NICE will be in line with the marketing authorisation.
	Macular Society	The background somewhat underplays the impact of sight loss in later life due to the development of complications, such as myopic macular degeneration. It is predicted that 49.8% of the world population will have myopia and 9.8% will have high myopia by 2050 (1). Individuals with myopia are at a greater risk of developing complications such as MMD. Studies have shown this risk to be significantly greater for those with high myopia, especially in early age. A recent systematic review and meta-analysis has estimated the prevalence of MMD in people with high myopia to be 47.4% (1).	Thank you for your comments. The wording has been amended to state “people with severe myopia have a high risk of developing other eye conditions in later life” aligned with the information provided. The scope aims to give a brief introduction to the condition, current

Section	Consultee/ Commentator	Comments [sic]	Action
		MMD is a serious condition that can lead to legal blindness if not managed properly. Approximately 2.1% of the global population is currently affected by MMD (1). Without effective interventions, the number of people with visual impairment due to MMD is expected to rise significantly. By 2050, it is estimated that 55.7 million people globally could be affected by MMD, 18.5 million of whom will be blind (2). The complications arising from myopia, such as MMD, not only result in central vision loss, distorted vision, and blind spots, making it significantly more challenging to perform daily tasks requiring detailed vision. They also have severe emotional and psychological impacts alongside an added financial burden. The loss of vision can lead to profound feelings of frustration, anxiety, and depression, as well as a devastating loss of independence (3). The physical, emotional, and financial burdens underscore the urgent need for effective treatment and management strategies. 1. Zou, M., Wang, S., Chen, A., Liu, Z., Young, C.A., Zhang, Y., Jin, G. and Zheng, D., 2020. Prevalence of myopic macular degeneration worldwide: a systematic review and meta-analysis. British Journal of Ophthalmology, 104(12), pp.1748-1754. 2. Fricke, T.R., Jong, M., Naidoo, K.S., Sankaridurg, P., Naduvilath, T.J., Ho, S.M., Wong, T.Y. and Resnikoff, S., 2018. Global prevalence of visual impairment associated with myopic macular degeneration and temporal trends from 2000 through 2050: systematic review, meta-analysis and modelling. British Journal of Ophthalmology, 102(7), pp.855-862. 3. Sankaridurg, P., Tahhan, N., Kandel, H., Naduvilath, T., Zou, H., Frick, K.D., Marmamula, S., Friedman, D.S., Lamoureux, E., Keeffe, J. and	management and the technology.

Section	Consultee/ Commentator	Comments [sic]	Action
		Walline, J.J., 2021. IMI impact of myopia. Investigative ophthalmology & visual science, 62(5), pp.2-2.	
	Neonatal and Paediatric Pharmacy Group (NPPG)	N/A	N/A
	Royal College of Ophthalmologists	Please amend the sentence: “This means that the vision does not generally become any worse after the mid- to late twenties”. It should say that myopia does not generally progress after the mid- to late twenties. The term “vision” is too vague here. The sentence “around one in six children in the UK are currently affected by myopia” – please specify the age – is these 0 to 16 years? Or to 18 years? What is the lower age limit? The sentence “people with severe myopia have a slightly increased chance of developing other eye conditions…” is not correct. People with severe myopia (more than -5 or -6 diopters) have a high risk of sight-threatening complications and a 39% risk of permanent sight loss by the age of 75 years (doi: 10.1001/jamaophthalmol.2016.4009). However, the largest number of complications happens in people with moderate myopia, as there are more people with moderate than high myopia (modelled for the US: doi: 10.1038/s41598-023-42108-y). It is also not correct that the optic nerve damage is only due to raised pressure in the eye – people with myopia also have an increased risk of low-tension glaucoma, where the pressure is normal. It may be preferable	Thank you for your comments. These have now been addressed in the scope. For comment 1, the wording has been added in line with the suggestion provided. For comment 2, the age range considered in the prevalence estimate has been added and reference updated. For comment 3, “slightly increased chance” has now been amended to “high risk” in line with the suggestion here and

Section	Consultee/ Commentator	Comments [sic]	Action
		to refer to this as “myopia-associated optic neuropathy”, or “damage to the optic nerve because of myopia”. Macular degeneration should be specified as “Myopic macular degeneration”, to distinguish it from age-related macular degeneration, which typically manifests in the 80s, whereas MMD can manifest from the 50s onward. Complications in children can include a squint: correct this to “where one eye points outward, or less commonly, inward”, and “amblyopia (‘lazy eye’) – where vision is weaker in one eye”. The reason for this comment is that families take great offence about the term “lazy eye”, as neither the child nor the eye are lazy. With high myopia, children can also suffer a detached retina, though this is rare. Short-sightedness is not treatable with standard glasses or contact lenses, as neither stops or slows the progressive elongation of the eye. It would be more accurate to say that “The blurred vision in short-sightedness can be corrected with glasses or contact lenses, so people can see distance objects more clearly. Glasses and contact lenses are suitable for adults and children.” High-dose atropine (1%) is also used in children for the treatment of amblyopia.	from other stakeholders. For comments 4 and 5, the wording of the complications has been revised for both adults and children. For comment 6, wording has been amended to state “common complications in children”. For comment 7, the wording has been clarified to state that glasses and contact lenses manage, rather than treat, myopia.

Section	Consultee/ Commentator	Comments [sic]	Action
	Santen	Rapidly progressing myopia (greater than or equal -0.5D per year) can progress to high myopia. Patients with high myopia have increased chance of developing other eye conditions in later life. Use of the word “treated” with regards to glasses and lenses is not strictly true. Short sightedness can be managed with glasses and lenses. The underlying disease progression is not impacted with the use of glasses or contact lenses	Thank you for your comments. The wording has been clarified to state that glasses and contact lenses manage, rather than treat, myopia.
Population	Association of Optometrists	The target population could be extended to include children aged 3 to 18 years old as myopia progression may occur across this age range.	Thank you for your comment. The technology will be appraised in line with its marketing authorisation.
	British & Irish Paediatric Ophthalmology and Strabismus Association (BIPOSA)	*Is the population defined appropriately?* Yes I think so – children from 3 to 14	Thank you for your comment.
	College of Optometrists	Most studies those with high or pathological myopia, or history of other ocular disease and surgery. However, these exclusion criteria do not significantly affect enrolment as they are not common among children. Most studies recruit children between ages 6-13, but sime include upto 18 years of age – this is important as faster rates occur in younger children and slows in older teenagers. Myopia is a progressive condition and stabilisation is usually reached around age 15; but it is unclear how long treatment should continue due to	Thank you for your comment. The technology will be appraised in line with its marketing authorisation.

Section	Consultee/ Commentator	Comments [sic]	Action
		risk of rebound effects and some children show progression into early adulthood	
	Macular Society	*Is the population defined appropriately?* Yes	Thank you for your comment.
	Neonatal and Paediatric Pharmacy Group (NPPG)	Although the age range of 3-14 years fits in with the marketing authorisation, does the review by NICE need to be extended to 18 years of age? The document Myopia Control in Children American Academy of Ophthalmology (accessed via https://www.aao.org/eye-health/diseases/myopia-control-in-children) discusses use of low-dose atropine up to 18 years of age.	Thank you for your comment. The technology will be appraised in line with its marketing authorisation.
	Royal College of Ophthalmologists	Yes, the population is defined appropriately.	Thank you for your comment.
	Santen	*Is the population defined appropriately?* Yes	Thank you for your comment.
Subgroups	Association of Optometrists	There are subgroups that need to be considered further. For example, existing research shows that the prevalence of myopia amongst children of Asian (East Asian children specifically) descent is greater than in a Caucasian population, these children are also at a greater risk of more rapid progression. Additional evidence and insight should be obtained from the experts in the field (please see our recommendations below).	Thank you for your comment. Subgroups by ethnicity have been included in the final scope.
	British & Irish Paediatric Ophthalmology and Strabismus	Are there groups within the population that should be considered separately? For example, are there subgroups in which the technology is expected to be more clinically or cost effective? Yes - Chinese > Asian > Caucasian	Thank you for your comment. Subgroups by ethnicity have been

Section	Consultee/ Commentator	Comments [sic]	Action
	Association (BIPOSA)		included in the final scope.
	College of Optometrists	Subgroups analysis should include differentiation by ethnicity as well as age. Children of Asian/East Asian descent and younger children in general exhibit faster rates of myopic progression and are less likely to respond to lower doses of atropine. Children of European/Caucasian descent appear to respond better to lower doses, but treatment effects are greater with relatively higher doses. This means different drug concentrations may be needed depending on age and ethnicity of the child.	Thank you for your comment. Subgroups by age and ethnicity have been included in the final scope.
	Macular Society	Are there groups within the population that should be considered separately? For example, are there subgroups in which the technology is expected to be more clinically or cost effective? No	Thank you for your comment.
	Neonatal and Paediatric Pharmacy Group (NPPG)	N/A	N/A
	Royal College of Ophthalmologists	The technology will have the greatest effect in children under 13 years, so the age range 3-14 years is appropriate. There is an evidence gap about the subpopulation of children who develop myopia secondary to other eye conditions. It is currently not clear how well the technology will work in these.	Thank you for your comment. The technology will be appraised in line with its marketing authorisation.
	Santen	Subgroups suggested are appropriate	Thank you for your comment.
Comparators	Association of Optometrists	Comparators such as glasses and contact lenses are appropriate for the target group. But others like laser eye treatment, refractive lens exchange are typically not performed on children hence not appropriate. In that regard	Thank you for your comment.

Section	Consultee/ Commentator	Comments [sic]	Action
		there is some confusion between reducing myopia progression and any associated risks and alleviating myopia via laser eye surgery.	
	British & Irish Paediatric Ophthalmology and Strabismus Association (BIPOSA)	No – I would add axial length measurements	Thank you for your comment, this has been added as an outcome.
	College of Optometrists	Yes. Children with myopia are provided with conventional visual correction (through spectacles and contact lenses) to overcome myopic refractive error and restore normal visual acuity. While this enables children to see clearly, this does not slow myopic progression. There are currently no NHS funded treatments available to slow down myopic progression.	Thank you for your comment. The wording has been amended to reflect this.
	Macular Society	We appreciate that the comparators are treatments currently used in the NHS but it should be noted that there are a variety of treatments available to slow myopia progression which are available privately through opticians, such as orthokeratology and specialised spectacle and contact lenses.	Thank you for your comment. Whilst there are other options available privately, NICE can only consider treatments available on the NHS as comparators for technology appraisal.
	Neonatal and Paediatric Pharmacy Group (NPPG)	N/A	N/A

Section	Consultee/ Commentator	Comments [sic]	Action
	Royal College of Ophthalmologists	Single-vision glasses are the current standard of care in the NHS. Single-vision contact lenses are available for children and young people on a private basis, not paid for by the NHS.	Thank you for your comment. It is our understanding from other stakeholder comments that contact lenses may be supplied on the NHS under the NHS voucher system. Therefore, contact lenses have not been removed as a comparator.
	Santen	*Are the comparators listed considered to be the standard treatments currently used in the NHS with which the technology should be compared?* Yes	Thank you for your comment.
Outcomes	Association of Optometrists	The outcomes should include an evaluation of the prevalence of disease in later life that may be associated with myopia.	Thank you for your comment. “Long-term complications of myopia” has been added as an outcome.
	British & Irish Paediatric Ophthalmology and Strabismus Association (BIPOSA)	Difficult – the primary outcome is reduced myopia progression – which in an individual is not known at presentation. The long term health benefit is over a lifetime	Thank you for your comment. “Long-term complications of myopia” has been added as an outcome.

Section	Consultee/ Commentator	Comments [sic]	Action
	College of Optometrists	Myopic progression should be clearly defined. Clinical trials utilise both axial elongation measures and myopic progression to determine treatment effects. Care should be taken when reviewing results, with studies often reporting relative changes expressed as a percentage rather than absolute differences to determine effect size. Further, many report statistically significant differences but the greatest treatment effects typically occur early in the trial (usually around 12 months) and in younger particpants; and overall clinical effects on the level of myopia are considered modest at best. This means selection of an appropriate clinically significant difference is critical; as it may vary with duration of treatment and age. More recently, clinical trials have reported the proportion of children who have been deemed not to progress significantly by the study endpoint as a primary outcome; with several using <0.50D at 3 years as a response to therapy.	Thank you for your comment. Axial length/elongation has now been added as an outcome.
	Macular Society	*Are the outcomes listed appropriate?* Yes	Thank you for your comment.
	Neonatal and Paediatric Pharmacy Group (NPPG)	N/A	N/A
	Royal College of Ophthalmologists	Myopic progression, i.e. the increase in spectacle prescription or “spherical equivalent refraction” is a less precise outcome measure than axial elongation, i.e. the progressive increase in the length of the eyeball which typically underlies increasing myopia. Axial elongation should be the first outcome on the list, followed by myopic progression. The other points are appropriate.	Thank you for your comment. Axial elongation has been added as the first outcome, followed by myopic progression.

Section	Consultee/ Commentator	Comments [sic]	Action
	Santen	*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.
Equality	Association of Optometrists	The current draft remit and scope are not exclusionary at this stage.	Thank you for your comment.
	British & Irish Paediatric Ophthalmology and Strabismus Association (BIPOSA)	Can't see any problem with these statements	Thank you for your comment.
	College of Optometrists	None identified. This is the current situation that is leading to inequality of opportunity bettween people with protected charastertics and others. As there is no currently available NHS funded myopia management intervention, a significant proportion of children from lower socio-economic groups will not recieve treatment, particularly those from Asian/East Asian ethnicities who are more likely to be myopic and have higher levels of myopia. There is an urgent need to provide equitable access for myopia management throught NHS funding.	Thank you for your comment. The issues raised here have been recorded in the equalities impact assessment and will be considered by the committee during the evaluation.
	Macular Society	No changes to suggest.	Thank you for your comment.
	Neonatal and Paediatric	N/A	N/A

Section	Consultee/ Commentator	Comments [sic]	Action
	Pharmacy Group (NPPG)		
	Royal College of Ophthalmologists	There is some evidence that myopia disproportionately affects children from global majority populations (doi: 10.1167/iovs.10-5528). There is also evidence that children in more deprived areas are less likely to receive glasses than those in more affluent areas (doi: 10.1111/opo.13399). The draft remit and scope do not exclude these populations, but consideration should be given to how they will access the technology, i.e. engagement with health care professionals. Education campaigns may support myopia awareness in different populations. The technology is not anticipated to have adverse effects on people with a particular disability.	Thank you for your comment. The issues raised here have been recorded in the equalities impact assessment and will be considered by the committee during the evaluation.
	Santen	No comment	N/A
Other considerations	Association of Optometrists	N/A	N/A
	British & Irish Paediatric Ophthalmology and Strabismus Association (BIPOSA)	Consider two measurements a year apart to assess baseline – of axial length plus cycloplegic refraction?	Thank you for your comment. Axial length/elongation has been added as an outcome to the scope. The outcomes in the scope are general and not exhaustive – the outcomes included in the appraisal will be

Section	Consultee/ Commentator	Comments [sic]	Action
			dependent on the evidence base.
	College of Optometrists	N/A	N/A
	Macular Society	The complications arising from myopia, such as MMD, not only result in central vision loss, distorted vision, and blind spots, making it significantly more challenging to perform daily tasks requiring detailed vision. They can also have severe emotional and psychological impacts alongside an added financial burden. The loss of vision can lead to profound feelings of frustration, anxiety, and depression, as well as a devastating loss of independence (1). The physical, emotional, and financial burdens underscore the urgent need for effective treatment and management strategies. 1. Sankaridurg, P., Tahhan, N., Kandel, H., Naduvilath, T., Zou, H., Frick, K.D., Marmamula, S., Friedman, D.S., Lamoureux, E., Keeffe, J. and Walline, J.J., 2021. IMI impact of myopia. Investigative ophthalmology & visual science, 62(5), pp.2-2.	Thank you for your comment. As part of the appraisal process, stakeholders will be given the opportunity to provide evidence and testimony, which will be considered by the appraisal committee.
	Neonatal and Paediatric Pharmacy Group (NPPG)	N/A	N/A
	Royal College of Ophthalmologists	This section is appropriate.	Thank you for your comment.
	Santen	N/A	N/A

Section	Consultee/ Commentator	Comments [sic]	Action
Questions for consultation	Association of Optometrists	Appendix B Q) Where do you consider low-dose atropine eye drops will fit into the existing care pathway for children with myopia? A) Currently, the NHS has a pathway for the management of myopia via spectacles and contact lenses supplied through the NHS voucher system. B) The atropine eye drops would sit within the early stages of the existing pathway to target the rate at which myopia progresses in children.	Thank you for your comment.
	British & Irish Paediatric Ophthalmology and Strabismus Association (BIPOSA)	Questions for consultation (answers in capitals) Is low-dose atropine used in clinical practice for the treatment of myopia? If so what is the benefit of SYD-101 over currently available preparations of low-dose atropine? NO THERE IS NO COMMERCIALLY AVAILABLE PRODUCT. PATIENTS/PARENTS HAVE TO SOURCE A PRODUCT FROM OVERSEAS. Would the intervention be used instead of or alongside glasses and contact lenses? ALONGSIDE Where do you consider low-dose atropine eye drops will fit into the existing care pathway for children with myopia?	Thank you for your comments.

Section	Consultee/ Commentator	Comments [sic]	Action
		ALONGSIDE. PATIENTS STILL REQUIRE OPTICAL TREATMENT. GLASSES WITH PERIPHERAL DEFOCUS MAY ALSO BE USED Please select from the following, will low-dose atropine eye drops 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): OPTION B – ALTHOUGH CONSIDER FOLLOW UP IN PRIMARY CARE TO MEAN IN HIGH STREET OPTOMETERTRISTS OPTION A MIGHT ALSO BE A CONSIDERATION IF OPTOMETRISTS FELT THIS WAS WITHIN THEIR SKILL SET. Have all relevant comparators for low dose atropine eye drops (SYD-101) been included in the scope? Should laser eye treatment, refractive lens exchange or other surgery be considered relevant comparators for children aged 3-14? Q1:NO, Q2: NO, Q3: NO For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention. YES – SEE ABOVE Would low-dose atropine eye drops be a candidate for managed access?	

Section	Consultee/ Commentator	Comments [sic]	Action
		YES – COULD CONSIDER CRITERIA TO QUALIFY FOR NHS TREATMENT Do you consider that the use of low-dose atropine eye drops can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation? NO Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits. THERE IS A LOT OF DATA - SEE REFERENCES ABOVE NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope: CAN'T IMAGINE ANY CONFLICT WITH THIS STATEMENT Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts. SEE REFERENCES ABOVE	
	College of Optometrists	Would the intervention be used instead of or alongside glasses and contact lenses? As the mechanism of action of atropine treatment is based on minimising choroidal and scleral thinning to slow axial elongation, refractive correction through traditional spectacles or contact lenses would be required to be	Thank you for your comments.

Section	Consultee/ Commentator	Comments [sic]	Action
		worn concurrently improve visual acuity. In some children who experience ocular side effects of light sensitivity (photophobia) or near vision blur, they may be prescribed photochromic/tinted lenses for use outdoors or in other bright light conditions and progressive addition lenses (PALs, or varifocals) or both. LDA would, however, be considered first or second-line intervention for myopia management as studies have shown it produces greater treatment effects compared to licensed (UK) optical interventions (specially designed spectacle and contact lens-based myopia management treatments)[1, 6] 6. Dahlmann-Noor AH, Ghorbani-Mojarrad N, Williams KM, Ghoneim A, Allen PM, Beach ML, et al. 2024 UK and Ireland modified Delphi consensus on myopia management in children and young people. *Ophthalmic Physiol Opt*. 2024; 44: 1368–1391. https://doi.org/10.1111/opo.13381 Where do you consider low-dose atropine eye drops will fit into the existing care pathway for children with myopia? Myopia is readily detectable and the vast majority of currently available licensed optical interventions for myopia management are provided and followed up privately in primary care optometry practice. As these interventions are based on specially designed spectacles and contact lenses, all optometrists can prescribe them. However, prescription of a LDA preparation would only be able to be provided by optometrists with independent prescribing (IP) status provided it also has license as a medicine. There are over 2,000 IP optometrists (who are also granted SP status) across the UK, so assuming this product is licensed, they can be prescribed and followed up in primary care – either directly by IP optometrists or in collaboration with non-IP optometrists. Other existing mechanisms of supply of a licensed LDA would be through exemption legislation which grants optometrists with supplementary prescribing (SP)	

Section	Consultee/ Commentator	Comments [sic]	Action
		status to provide POMs containing atropine via signed order. There are few optometrists with SP status but with an extension to the exemption legislation to include POMs containing atropine for all optometrists this would enable significantly greater access to LDA treatment. However, systems should be implemented to arrange NHS funding for LDA signed-orders to enable equitable access for patients[6]. Please select from the following, will low-dose atropine eye drops 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): D: The clinical management approach for initiating and monitoring myopia management is broadly similar across the available interventions and is based on typical procedures undertaken by optometrists in primary care settings. Under current medicines legislation, assuming product license has been granted, LDA can be prescribed in primary care by IP optometrists or supplied via signed order by SP optometrists in primary care and followed up in primary care (provided myopia management services are within their scope of practice). Non-IP optometrists may refer to an IP or SP optometrist within primary care to manage the patient or work collaboratively through an agreed management plan by all parties. Without product license, patients must be referred to their GP or secondary care by all optometrists to access LDA treatment. GPs may however be reluctant to prescribe LDA as myopia management is very likely outside their current scope of practice and it is reasonable to expect they would not	

Section	Consultee/ Commentator	Comments [sic]	Action
		be prepared to be the patients responsible clinician. In secondary care, treatment would be prescribed by an ophthalmologist and may be monitored in secondary care; or managed under a shared care arrangement between secondary and primary care. Thus, unless this intervention is granted a product license, treatment is likely to be initiated by an ophthalmologist in secondary care. Without a commissioned arrangement to provide subsequent myopia management follow-up/monitoring services in primary care, patients are likely to retained in secondary care, with treatment required for at least 2 years[2]. However, there is lack of certainty on treatment duration and rebound effects as myopia is progressive with stabilisation typically reached at 15 years of age[1, 7]. With NHS eye care services under pressure in secondary care, this would further impact out-patient capacity. 7. COMET Group. Myopia Stabilization and Associated Factors Among Participants in the Correction of Myopia Evaluation Trial (COMET). Invest Ophthalmol Vis Sci. 2013;54:7871–84. Have all relevant comparators for low dose atropine eye drops (SYD-101) been included in the scope? Should laser eye treatment, refractive lens exchange or other surgery be considered relevant comparators for children aged 3-14? Clinical trials of LDA are based on comparison to placebo or untreated control group[1]. There are very few studies which have evaluated direct comparison between LDA and other myopia management interventions (multifocal spectacles, alone or in combination[1, 2]. In all studies, traditional spectacles and/or contact lenses were worn to correct myopic refractive error. It is important to distinguish between licensed optical myopia management interventions, which are based on specially designed and spectacles and contact lenses which provide both therapy and refractive	

Section	Consultee/ Commentator	Comments [sic]	Action
		correction; and traditional spectacles and contact lenses which provide refractive correction alone. Laser refractive correction and refractive lens exchange in very rarely carried out in children aged 3-14 and in most cases is due to clinical need rather than elective refractive correction. Clinical trials of myopia management interventions, including LDA, typically exclude children with ocular comorbidity, previous ocular surgery and high and/or pathological myopia. For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention. Myopia is readily detectable through provision of sight testing and the vast majority of currently available licensed optical interventions for myopia management are provided and followed up privately in primary care optometry practice. Without product license and a commissioned myopia management follow-up/monitoring service in primary care, the intervention is likely only prescribed/available in secondary care. Do you consider that the use of low-dose atropine eye drops can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation? The primary aim of myopia management is to reduce the final level of myopia which reduces the risk of myopia related ocular complications such as myopic maculopathy and retinal detachment. However, lower levels of myopia have other benefits such as improved unaided distance and near vision; reduced dependence on visual correction; better refractive surgery outcomes; increased likelihood of meeting occupational vision standards and improved cosmetic appearance of spectacle lenses (thickness and weight)[8, 9]	

Section	Consultee/ Commentator	Comments [sic]	Action
		8. Jonas JB, Ang M, Cho P, et al. IMI prevention of myopia and its progression. Invest Ophthalmol Vis Sci 2021 62(5):6 9. Bullimore MA, Brennan NA. Myopia Control: Why Each Diopter Matters. Optom Vis Sci 2019 96(6):463-465	
	Macular Society	Is low-dose atropine used in clinical practice for the treatment of myopia? If so, what is the benefit of SYD-101 over currently available preparations of low-dose atropine? SYD-101 is designed to be more stable and consistent than compounded atropine. Compounded formulations can vary in concentration and efficacy due to differences in manufacturing processes The 0.01% formulation of SYD-101 is particularly noteworthy because it has been shown to be effective in slowing myopia progression while minimizing side effects. Higher concentrations of atropine, such as 0.05% or 0.5%, are associated with increased risks of visual disturbances, including glare and difficulty with near vision. The lower concentration in SYD-101 balances efficacy with a reduced likelihood of these adverse effects, making it a more tolerable option for pediatric patients. - https://www.optometrytimes.com/view/inside-the-moa-of-syd-101-the-potential-first-fda-approved-formulation-of-low-dose-atropine - https://www.sydnexis.com/post/first-patients-phase-3 Would the intervention be used instead of or alongside glasses and contact lenses? It would be used alongside them. Glasses and contact lenses correct the refractive error as a result of myopia while SYD-101 aims to slow the progression of myopia itself.	Thank you for your comments.

Section	Consultee/ Commentator	Comments [sic]	Action
		- https://www.restorevisionclinic.com/blog/pediatric-myopia-treatment-what-parents-need-to-know-about-syd-101-in-2025 Where do you consider low-dose atropine eye drops will fit into the existing care pathway for children with myopia? Please select from the following, will low-dose atropine eye drops be: A. Prescribed in primary care with routine follow-up in primary care [Yes] 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):	
	Neonatal and Paediatric Pharmacy Group (NPPG)	N/A	N/A
	Royal College of Ophthalmologists	*Is low-dose atropine used in clinical practice for the treatment of myopia?* Only in private practice, not in NHS practice; available concentrations are 0.01 and 0.05% *If so what is the benefit of SYD-101 over currently available preparations of low-dose atropine?* n/a (no NHS formulation) *Would the intervention be used instead of or alongside glasses and contact lenses?* Current standard of care are single-vision glasses (or privately paid contact lenses), which correct visual acuity, but do not slow myopia progression. People with myopia need to wear these corrective lenses to see clearly. Low-concentration atropine cannot replace these lenses and will not be used instead of these. It will be used alongside.	Thank you for your comments.

Section	Consultee/ Commentator	Comments [sic]	Action
		A special case are myopia-control spectacles and contact lenses (paid for by parents/carers). These can be used instead of or in addition to low-concentration atropine to slow myopia progression, i.e. possible treatments to slow myopia progression are: standard glasses plus atropine; myopia-control spectacles/contact lenses only; myopia-control spectacles/contact lenses plus atropine (enhanced effect) *Where do you consider low-dose atropine eye drops will fit into the existing care pathway for children with myopia? Please select from the following, will low-dose atropine eye drops 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):* The prevalence of myopia in children is so high that secondary care does not have the capacity to provide monitoring nor treatment. Low-concentration atropine can be prescribed by general practitioners and by optometrists with independent prescribing qualification. Optometrists are also in the best position to provide ongoing monitoring of treatment effect, i.e. monitor axial length. However, prescribing in primary care by non-medical practitioners will require guidelines for starting, monitoring and discontinuing treatment. *Have all relevant comparators for low dose atropine eye drops (SYD-101) been included in the scope?* Yes, but the concentration(s) of low-concentration atropine should be specified. *Should laser eye treatment, refractive lens exchange or other surgery be considered relevant comparators for children aged 3-14?* No, as none of these slow myopia progression. These interventions aim to improve clarity	

Section	Consultee/ Commentator	Comments [sic]	Action
		of distance vision instead of wearing glasses or contact lenses. They have no effect on myopia progression, axial elongation nor the risk of myopia-associated complications in later life. *For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.* Comparator: glasses – prescribed by optometrists, routine follow-up by optometrists Subsequent treatments: refractive laser, lens implants – private secondary care. Retinal detachment repair, anti-VEGF injections for myopic macular degeneration, management of myopia-associated optic neuropathy, cataract – NHS secondary/tertiary care. *Would low-dose atropine eye drops be a candidate for managed access?* No. The aim of using low-concentration atropine is to reduce the future risk of sight-threatening complications. Once there is an imminent sight-threatening situation, low-concentration atropine will not help. In childhood itself, there are effective alternatives to slow down myopia progression, i.e. peripheral-plus and diffusion optics spectacle lenses, dual-focus and orthokeratology contact lenses. *Do you consider that the use of low-dose atropine eye drops can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?* The problem with QALYs for children is the generic nature of health utility scales for children. Children with myopia can be expected to have “normal” QoL, if they have glasses. Standard tools are therefore likely to miss the impact of myopia-slowing interventions, as the main impact would be captured by measuring reduced QoL in adults losing vision because of myopia-complications. The immediate impact of reducing myopia	

Section	Consultee/ Commentator	Comments [sic]	Action
		progression in children is a lower degree of dependence on glasses, i.e. preservation of better uncorrected vision. This is measured by the SREEQ (doi: 10.1097/OPX.0000000000001804), but this is not a QoL instrument. *Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.*	
	Santen	Unlicensed compounded low dose atropine (LDA) is made and sold privately very little NHS use. LDA used alongside glasses and contact lenses. Combination of secondary and primary care prescribed routinely follow up in primary care. Primary care may need some form of shared care guidance that enables IP optometrists to prescribe LDA in a community setting. Glasses and contact lenses are routinely sold by optometrists making use of NHS optical vouchers. These vouchers are available to hospital eye services for patients attending clinics.	Thank you for your comments.
Additional comments on the draft scope	Association of Optometrists	N/A	N/A
	British & Irish Paediatric Ophthalmology and Strabismus Association (BIPOSA)	N/A	N/A
	College of Optometrists	N/A	N/A

Section	Consultee/ Commentator	Comments [sic]	Action
	Macular Society	N/A	N/A
	Neonatal and Paediatric Pharmacy Group (NPPG)	We suggest that a definition of low-dose atropine be included for clarity as to the concentration the appraisal is considering, though have assumed 0.025% as Ryjunea is the product specified. There seems to be quite a bit of information regarding 0.01% concentration (which does not seem to support benefit).	Thank you for your comments. It is understood that the strength of Ryjunea is 0.1mg/ml (see MHRA marketing authorisation). This has been added to the scope. The appraisal committee will consider the effectiveness and cost effectiveness of this strength only in line with the anticipated marketing authorisation.
	Royal College of Ophthalmologists	The intervention does not specify the concentration of atropine. It would be important to include all concentrations of less than 0.1%. Clinical trials have evaluated 0.01, 0.02, 0.025 and 0.05%, though not necessarily in the formulation currently under appraisal evaluation. Again, for reasons of timeliness it would be acceptable to narrow this HTA down to the specific formulation and concentration in question, and to carry out further appraisals in the future.	Thank you for your comments. It is understood that the strength of Ryjunea is 0.1mg/ml (see MHRA marketing authorisation). This has been added to the scope. The appraisal committee will consider the effectiveness and cost effectiveness of

Section	Consultee/ Commentator	Comments [sic]	Action
			this strength only in line with the anticipated marketing authorisation.
	Santen	N/A	N/A

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

N/A