NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

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

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of low-dose atropine eye drops within its marketing authorisation for treating myopia in people 3 to 14 years.

Background

Myopia (also known as short-sightedness or near-sightedness) occurs when light coming from distant objects is 'overfocused', so that the point of focus is in front of the retina. It occurs because either the eyeball is too long or, less commonly, because the cornea is too curved. People with myopia can see close objects clearly but distant objects appear more blurry as their light rays do not focus properly in the eye.[1]

Myopia tends to start in childhood and early teenage years. The younger it starts, the more severe it is likely to become. By the time early adulthood is reached, the condition has usually reached its peak. This means that the vision does not generally become any worse after the mid to late twenties.[1] Around one in six children in the UK are currently affected by myopia.[2]

Most people with myopia have no additional problems. However, people with severe myopia have a slightly increased chance of developing other eye conditions in later life. Complications in adults include[1]:

- Raised pressure in the eye (glaucoma)
- A detached retina
- Cataracts
- Macular degeneration

Complications in children include[3]:

- A squint – where the eyes point in different directions
- A lazy eye – where sight in 1 eye does not develop properly

Short-sightedness can usually be treated with glasses or contact lenses which help the eyes focus correctly, so people can see distant objects more clearly. Glasses are suitable for adults and children and contact lenses are suitable for adults and some children.

The technology

Low-dose atropine eye drops (SYD-101, Ryjunea, Santen) do not currently have a marketing authorisation in the UK for treating myopia in children aged 3 to 14 years, Low-dose atropine eye drops have been studied in a clinical trial in children aged 3 to 14 years with myopia, astigmatism or ansiometropia; at 2 different doses compared with placebo (vehicle).[4]

Higher-dose (1%) atropine eye drops are currently available and used for other ocular indications as a topical mydriatic and cycloplegic. They are used in the treatment of iritis and uveitis to immobilise the iris and ciliary muscle and to prevent or break down adhesions. They are also used for induction of mydriasis and/or cycloplegia in adults and for cycloplegic refraction in children. Since they are a powerful cycloplegic, they are used in the determination of refraction in children below six years and children with convergent strabismus.

Intervention	Low-dose atropine eye drops (SYD-101)
Population	Children aged 3 to 14 years with myopia
Subgroups	Subgroups by severity
Comparators	• glasses • contact lenses
Outcomes	The outcome measures to be considered include: • myopic progression • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The cost effectiveness analysis should include consideration of the benefit in the best and worst seeing eye.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation.Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations	**Related technology appraisals:** Ranibizumab for treating choroidal neovascularisation associated with pathological myopia (2013 updated 2024) NICE technology appraisal guidance 298 **Related interventional procedures:**

	Laser correction of refractive error following non-refractive ophthalmic surgery (2011) NICE interventional procedures guidance 385 Intraocular lens insertion for correction of refractive error, with preservation of the natural lens (2009) NICE interventional procedures guidance 289 Photorefractive (laser) surgery for the correction of refractive errors (2006) NICE interventional procedures guidance 164

Questions for consultation

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?

Would the intervention be used instead of or alongside glasses and contact lenses?

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):

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?

For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would low-dose atropine eye drops be a candidate for managed access?

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?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

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:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which low-dose atropine eye drops will be licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

References

1. Patient UK. Myopia (short-sightedness). Health advice. Accessed 11 February 2025.

2. Global Myopia Awareness Coalition. United Kingdom. Accessed 11 February 2025.

3. NHS UK. Short-sightedness (myopia). Accessed 11 February 2025.

4. Clinical trials.gov. The Safety and Efficacy of SYD-101 in Children With Myopia (STAR) NCT03918915. Accessed 11 February 2025.

