

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Netarsudil-latanoprost for previously treated primary open-angle glaucoma or ocular hypertension

Final scope

**Remit/evaluation objective**

To appraise the clinical and cost effectiveness of netarsudil-latanoprost within its marketing authorisation for treating primary open-angle glaucoma or ocular hypertension.

**Background**

Glaucoma refers to a group of eye conditions characterised by progressive damage to the optic nerve. It can lead to impaired peripheral vision and eventually total loss of sight, if it is not detected and treated early. Glaucoma is usually associated with an increase in pressure within the eye. This can be caused by either the production of too much aqueous humour by the ciliary body or decreased outflow (drainage) of the fluid.

Primary, or chronic, open-angle glaucoma (POAG) accounts for over 70% of all glaucoma cases.<sup>1</sup> It develops slowly over many years and doesn't cause any noticeable symptoms until irreversible damage has occurred to the optic nerve. The peripheral vision is affected first, and without treatment, central vision may also be lost resulting in loss of visual acuity.

Ocular hypertension (OHT) is the term used to describe elevated intraocular pressure (IOP; OHT is IOP greater than 21 mmHg) in the absence of optic nerve damage or visual field loss. It can be present for many years without the development of glaucoma, however sustained elevation of IOP causes damage to the optic nerve head and is a major risk factor for the development of glaucoma. Lowering OHT has been shown to lower the risk of developing glaucoma.

POAG has an estimated UK prevalence of 2% of people over the age of 40.<sup>2</sup> Using the 2020 ONS population projections this would be more than approximately 560,000 people in England.<sup>3</sup> The overall risk of developing primary open-angle glaucoma increases substantially with increasing IOP and with age.

OHT is estimated to affect 3-5% of people over the age of 40, which could be over 1 million people in England.<sup>1,3</sup> However, the number of people requiring treatment is expected to be much lower than this.

NICE's guidance on the diagnosis and management of glaucoma (NG81) recommends a generic prostaglandin analogue as ongoing treatment for people with IOP of 24 mmHg or more if they are at risk of visual impairment within their lifetime. For those who cannot tolerate their current treatment, an alternative generic prostaglandin analogue should be offered, and if this is not tolerated, a beta-blocker. If none of these options are tolerated (or not reducing IOP sufficiently), non-generic prostaglandin analogues, carbonic anhydrase inhibitors, sympathomimetics, miotics or a combination of treatments should be offered. People whose IOP cannot be

reduced sufficiently with pharmacological treatment should be referred to a consultant ophthalmologist to discuss other options.

A generic prostaglandin analogue is offered to people with confirmed POAG. For people with advanced POAG, surgery with pharmacological augmentation is offered (with interim treatment with a generic prostaglandin analogue while listed for surgery). If adherence and eye drop instillation technique are satisfactory but IOP has not been reduced sufficiently to prevent the risk of progression to sight loss despite pharmacological treatment, or the drug is not tolerated, a drug from another therapeutic class can be offered (beta-blocker, carbonic anhydrase inhibitor or sympathomimetic), and topical drugs from different therapeutic classes may be needed at the same time to control IOP. Alternatively, laser trabeculoplasty or other glaucoma surgery can be offered.

**The technology**

Netarsudil-latanoprost (Roclanda, Santen) is an eye drop that combines a fixed dose of netarsudil 0.02% (Rhokiinsa, Santen) with latanoprost 0.005%. Netarsudil-latanoprost has a marketing authorisation for the reduction of elevated IOP in adult patients with primary open-angle glaucoma or ocular hypertension for whom monotherapy with a prostaglandin or netarsudil provides insufficient IOP reduction.

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| <b>Intervention(s)</b> | Netarsudil-latanoprost                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Population(s)</b>   | Adults with POAG or ocular hypertension whose IOP has not improved after treatment with a prostaglandin or netarsudil                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Subgroups</b>       | <p>If the evidence allows the following subgroups will be considered:</p> <ul style="list-style-type: none"> <li>• Adults with POAG whose IOP has not improved after treatment with a prostaglandin or netarsudil</li> <li>• Adults with ocular hypertension whose IOP has not improved after treatment with a prostaglandin or netarsudil.</li> </ul>                                                                                                                                                                                                                                        |
| <b>Comparators</b>     | <ul style="list-style-type: none"> <li>• Topical (eye drops), monotherapy or in combination: <ul style="list-style-type: none"> <li>○ Prostaglandin analogues (such as bimatoprost, latanoprost, tafluprost, travoprost)</li> <li>○ Beta-blockers (such as betaxolol, levobunolol hydrochloride, timolol maleate)</li> <li>○ Carbonic anhydrase inhibitors (such as acetazolamide, brinzolamide, dorzolamide)</li> <li>○ Sympathomimetics (such as apraclonidine, brimonidine tartrate).</li> </ul> </li> <li>• Selective laser trabeculoplasty</li> <li>• Other glaucoma surgery.</li> </ul> |
| <b>Outcomes</b>        | <p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> <li>• mean intraocular pressure</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

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|                                                       | <ul style="list-style-type: none"> <li>• visual acuity</li> <li>• visual field test</li> <li>• evaluation of anterior and posterior segment parameters</li> <li>• structural integrity of the optic nerve</li> <li>• adverse effects of treatment</li> <li>• health-related quality of life.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Economic analysis</b>                              | <p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>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.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.</p> <p>The availability and cost of biosimilar and generic products should be taken into account.</p> <p>Cost effectiveness analysis should include consideration of the benefit in the best and worst seeing eye.</p> |
| <b>Other considerations</b>                           | <p>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.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Related NICE recommendations and NICE Pathways</b> | <p><b>Related NICE guidelines:</b></p> <p><a href="#">Glaucoma: diagnosis and management</a> (2022) NICE guideline NG81.</p> <p><b>Related interventional procedures</b></p> <p><a href="#">Ab interno canaloplasty for open-angle glaucoma</a> (2022) NICE interventional procedures guidance 745.</p> <p><a href="#">Repetitive short pulse transscleral cyclophotocoagulation for glaucoma</a> (2021) NICE interventional procedures guidance 692.</p> <p><a href="#">High-intensity focused ultrasound for glaucoma</a> (2019) NICE interventional procedures guidance 661.</p> <p><a href="#">Microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma</a> (2018) NICE</p>                                                                                                                                   |

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|                                | <p>interventional procedures guidance 612.</p> <p><a href="#">Ab externo canaloplasty for primary open-angle glaucoma</a> (2017) NICE interventional procedures guidance 591.</p> <p><a href="#">Trabecular stent bypass microsurgery for open-angle glaucoma</a> (2017) NICE interventional procedures guidance 575.</p> <p><a href="#">Trabeculotomy ab interno for open angle glaucoma</a> (2011) NICE interventional procedures guidance 397.</p> <p><b>Related Quality Standards</b></p> <p><a href="#">Serious eye disorders</a> (2019) NICE quality standard QS180.</p>                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Related National Policy</b> | <p>The NHS Long Term Plan, 2019. <a href="#">NHS Long Term Plan</a></p> <p>NHS England (2018/2019) <a href="#">Manual for prescribed specialised services 2018/19</a>. Chapter 12 adult specialist ophthalmology services.</p> <p>Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domain 2<br/><a href="https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017">https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017</a></p> <p>Royal College of Ophthalmologists (2016)<br/><a href="#">Commissioning guide: Glaucoma</a></p> <p>NHS England (2014) <a href="#">Improving eye health and reducing sight loss, a 'Call to Action'</a></p> <p>NHS England (2013) <a href="#">Local Eye Health Networks. Improving eye health and services. A Getting Started Guide</a></p> <p>NHS England (2013) <a href="#">NHS standard contract for specialised ophthalmology (adult). Service specification number: D12/S/a</a></p> |

## References

- 1 [King A, Azuara-Blanco A, Tuulonen A \(2013\) Glaucoma](#). The British Medical Journal 346: f3518.
- 2 [Allison K, Patel D, Alabi O \(2020\) Epidemiology of Glaucoma: The Past, Present, and Predictions for the Future](#). Cureus: e11686.
- 3 Office of National Statistics (ONS) [2020 Mid-year population projections](#). Accessed February 2023.