Appendix B

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Bimatoprost implant for treating open angle glaucoma or ocular hypertension in people who are unsuitable for topical treatments

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of bimatoprost slow-release biodegradable implant within its marketing authorisation for people with open angle glaucoma or ocular hypertension who are unsuitable for topical intraocular pressure lowering treatments

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 (COAG) accounts for over 70% of all glaucoma cases.[1] 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; that is IOP greater than 21 mmHg[2]) 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 IOP has been shown to lower the risk of developing glaucoma.

Open-angle glaucoma had an estimated UK prevalence of approximately 2% of people over the age of 40 years.[3] Using the 2020 ONS population projections this would be more than approximately 560,000 people in England.[4] The overall risk of developing glaucoma increases substantially with increasing IOP and with age.[3] Open angle glaucoma is also more prevalent in people from Black African or Caribbean family backgrounds.[5] OHT is estimated to affect 3-5% of people over the age of 40 years.[1]

NICE's guidance on the diagnosis and management of glaucoma (NG81) recommends offering 360° selective laser trabeculoplasty (SLT) to people with newly diagnosed, non-advanced COAG (excluding cases associated with pigment dispersion syndrome). NG81 also recommends offering 360° SLT to people with newly diagnosed OHT with IOP of 24 mmHg or more (excluding cases associated with pigment dispersion syndrome) if they are at risk of visual impairment within their lifetime. However, NG81 states that treatment should not be offered to people with suspected COAG and IOP of less than 24 mmHg. NG81 recommends offering glaucoma surgery with pharmacological augmentation to people with advanced COAG.

The technology

Bimatoprost slow-release biodegradable implant (Durysta, AbbVie) does not currently have a marketing authorisation in the UK for treating open angle glaucoma or ocular hypertension. It has been studied in clinical trials compared with SLT in people with open-angle glaucoma or ocular hypertension that requires IOP lowering treatment.

Intervention(s)	Bimatoprost slow-release biodegradable implant
Population(s)	People with open-angle glaucoma or ocular hypertension who are unsuitable for topical intraocular pressure lowering treatments.
Subgroups	If the evidence allows the following subgroups will be considered. These include: • People with advanced open-angle glaucoma
Comparators	For people with non-advanced open-angle glaucoma or people with ocular hypertension: • 360° selective laser trabeculoplasty For people with advanced open-angle glaucoma: • glaucoma surgery with pharmacological augmentation
Outcomes	The outcome measures to be considered include: • mean intraocular pressure • visual acuity • visual field test • evaluation of anterior and posterior segment parameters • structural integrity of the optical nerve • 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. 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 NICE guidelines:** Glaucoma: diagnosis and management (2017) NICE guideline NG81 **Related interventional procedures:** Repetitive short-pulse transscleral cyclophotocoagulation for glaucoma (2021) NICE interventional procedures guidance 692 High-intensity focused ultrasound for glaucoma (2019) NICE interventional procedures guidance 661 Microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma (2018) NICE interventional procedures guidance 612 Ab externo canaloplasty for primary open-angle glaucoma (2017) NICE interventional procedures guidance 591 Trabecular stent bypass microsurgery for open-angle glaucoma (2017) NICE interventional procedures guidance 575 Trabeculotomy ab interno for open angle glaucoma (2011) NICE interventional procedures guidance 397 **Related quality standards:** Serious eye disorders (2019) NICE quality standard 180
Related National Policy	NHS England (2019) The NHS long term plan NHS England (2018) Manual for prescribed specialised services 2018/19 Chapter 12 (Adult specialist ophthalmology services) NHS England. 2013/14 NHS Standard Contract for Specialised Ophthalmology (Adult). D12/S/a. NHS England (2019) Transforming elective care services ophthalmology NHS England (2022) Open-angle glaucoma decision tool

Questions for consultation

Is the population appropriate?

What treatment would people with OHT with an intraocular pressure of between 21 mmHg and 24 mmHg receive?

Will bimatoprost slow-release biodegradable implant be used to treat advanced open-angle glaucoma?

Is glaucoma surgery with pharmacological augmentation a relevant comparator in this appraisal?

Are the subgroups listed appropriate?

Where do you consider bimatoprost slow-release biodegradable implant will fit into the existing care pathway for open-angle glaucoma and ocular hypertension?

Would bimatoprost slow-release biodegradable implant be a candidate for managed access?

Do you consider that the use of bimatoprost slow-release biodegradable implant 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 bimatoprost slow-release biodegradable implant 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. King A, Azuara-Blanco A, Tuulonen A (2013) Glaucoma. The British Medical Journal 346: f3518. Accessed June 2023.

2. The College of Optometrists (2022) Ocular hypertension (OHT). Accessed June 2023.

3. Imrie C, Tatham A (2016) Glaucoma: the patient's perspective. British Journal of General Practice 66 (646): e371-373. Accessed June 2023.

4. Office of National Statistics (ONS) 2020 Mid-year population projections. Accessed July 2023.

5. Nagar A, Myers S, Kozareva D, et al. (2022) Cascade screening for glaucoma in high-risk family members of African-Caribbean glaucoma patients in an urban population in London. British Journal of Ophthalmology 106: pg376–380

