NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Dexamethasone intracanalicular insert for treating inflammation and pain after cataract surgery

Draft scope (pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of dexamethasone intracanalicular insert within its marketing authorisation for treating inflammation and pain after cataract surgery.

Background

A cataract is any opacity in the crystalline lens of the eye. Cataracts most commonly affect adults as a result of biological ageing (age-related cataracts) and may be classified according to the area of the lens that is affected (nuclear sclerotic, cortical or posterior subcapsular cataracts). The changes to the transparency and refractive index of the lens result in different levels of visual impairment. Cataracts may occur secondary to hereditary factors, trauma, inflammation, metabolic or nutritional disorders, and exposure to radiation. In addition, lifestyle factors such as tobacco smoking and high alcohol intake are associated with an increased risk of developing age-related cataracts.[1]

Surgical removal is the only effective treatment for cataracts[2], although if the cataract does not impair daily activities, then a change of glasses and brighter reading lights may help.[3] Incisions made during cataract surgery can cause inflammation in the eye. Inflammation is a common cause of patient discomfort, delayed recovery and reduced visual outcome. Untreated or persistent post-operative inflammation can lead to pain, uveitis, elevated intraocular pressure, glaucoma and leaking of fluid into the eye (cystoid macular oedema, CMO).[4]

Inflammation should be treated immediately with postoperative sunconjunctival steroids with or without orbital floor steroids. Post operatively, intensive treatment with topical steroids and cycloplegic agents should be given.[2] NICE draft Cataracts guideline recommends the prophylactic use of topical steroids and/or non-steroidal anti-inflammatory drugs (NSAIDs) after cataract surgery to prevent inflammation and CMO.

Cataract surgery is the commonest elective surgical procedure in the UK and accounts for a large proportion of the surgical workload of ophthalmologists.[2] Proxy data on the frequency of cataract surgery indicate that, in 2012/13, a total of 340,809 operations were performed in England.[5] Incidence rates of post-cataract surgery inflammation range from 1.5% and 2% but does not

take into account people with diabetes.[6] Patients on prostaglandin treatment for glaucoma or hypertension and patients with dry eye syndrome are at an increased risk of post-ocular surgery inflammation.[4]

The technology

Dexamethasone intracanalicular insert (Dextenza [OTX-DP], Ocular Therapeutix) delivers a sustained release of dexamethasone onto the eye to treat inflammation associated with cataract surgery. Corticosteroids reduce inflammation by inhibiting the production of prostaglandins and leukotrienes in the inflammatory cyclo-oxygenase and lipoxygenase pathways.[4]

Dexamethasone intracanalicular insert does not have a UK marketing authorisation for treating inflammation and pain after cataract surgery. Its effects on inflammation and pain have been studied in clinical trials compared with placebo in adults with cataracts who are expected to undergo clear corneal cataract surgery with phacoemulsification and implementation of posterior chamber lens.

Intervention(s)	Dexamethasone intracanalicular insert
Population(s)	Adults undergoing cataract surgery
Comparators	Established clinical management without dexamethasone intracanalicular insert (including but not limited to topical non-steroidal anti-inflammatory drugs [NSAIDs] and topical corticosteroids)
Outcomes	The outcome measures to be considered include: • Pain • Inflammation • Visual function • 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 and NICE Pathways	Guidelines in development Cataracts in adults: management NICE guideline. Publication expected October 2017. Related Interventional Procedures: Implantation of multifocal (non-accommodative) intraocular lenses during cataract surgery (2008) NICE interventional procedures guidance 264 Implantation of accommodating intraocular lenses for cataract (2007) NICE interventional procedures guidance 209 Related NICE Pathways: Eye conditions (2017) NICE pathway
Related National Policy	None.

Questions for consultation

Is the population appropriately defined? In particular:

- Will dexamethasone intracanalicular insert only be used after cataract surgery or after any other eye surgeries?

- Will dexamethasone intracanalicular insert be used for prevention or treatment of inflammation following eye surgery?

What are the relevant comparators for dexamethasone intracanalicular insert? Which treatments are considered to be established clinical practice in the NHS for inflammation after cataract surgery? In particular, are postoperative subconjunctival steroids an appropriate comparator?

Are the outcomes listed appropriate?

Are there any subgroups of people in whom dexamethasone intracanalicular insert is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Where do you consider dexamethasone intracanalicular insert will fit into the existing NICE pathway, Eye conditions?

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 dexamethasone intracanalicular insert 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.

Do you consider dexamethasone intracanalicular insert to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of dexamethasone intracanalicular insert can result in any potential significant and 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 Appraisal Committee to take account of these benefits.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/article/pmg19/chapter/1-Introduction).

References

1. National Institute for Health and Care Excellence. Final scope: Cataracts in adults: management. Clinical guideline in development GID-CGWAVE0741. Expected April 2018.

2. The Royal College of Ophthalmologists. Cataract surgery guidelines. London; September 2010.

3. NHS Choices. Cataract surgery. http://www.nhs.uk/conditions/Cataractsurgery/Pages/Introduction.aspx Accessed 3 May 2017.

4. Dua HS, Attre R. (2012) Treatment of post-operative inflammation following cataract surgery – a review. European Ophthalmic Review 6(2):98–103.

5. RNIB. Surgery deferred. Sight denied. London; July 2013. https://www.rnib.org.uk/sites/default/files/Surgery%20deferred%20sight%20denied%20Campaign%20report.pdf Accessed 3 May 2017.

6. Alio JL, Bodaghi B, Tassignon M-J. (2008) Guidelines for managing post-cataract surgery inflammation. Can we reach a consensus? Ophthalmology Times Europe. http://ophthalmologytimes.modernmedicine.com/sites/default/files/images/OphthalmologyTimesEurope/PDF/Guidelines-for-managing-post-cataract-surgery-inflammation.pdf Accessed 3 May 2017.