Appendix B

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Polihexanide eye drops for treating acanthamoeba keratitis in people 12 years and over

Final scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of polihexanide within its marketing authorisation for treating acanthamoeba keratitis in adults and children from 12 years of age.

Background

Acanthamoeba keratitis (AK) is a rare but serious infection of the cornea that can result in permanent visual impairment or blindness. The infection is caused by a microscopic amoeba called Acanthamoeba that is found in air, water, dust, soil or sewage. Risk factors for developing AK include eye trauma, swimming in contaminated water or poor contact lens hygiene. Symptoms of AK include eye pain, redness and blurred vision. Early diagnosis is essential for effective treatment of AK as if left untreated can lead to severe pain and vision loss. Diagnosis is made by testing samples of fluid or tissue from the eye, or by seeing signs of the infection using slit-lamp microscopy or using a confocal microscope.[12] If AK is suspected, urgent referral to a specialist is advised.

The estimated incidence of AK is 2.35 cases per million people in the UK, with 87% of cases being in contact lens users.[3]

Current treatment in the NHS includes antiseptic eyedrops such as polihexanide 0.2mg/mL (PHMB), chlorhexidine, propamidine or hexamidine. These treatments may be administered as a monotherapy or dual therapy. Eye drops need to be taken hourly for the first few days (including during the night) and then reduced to 2-hourly and so on as treatment progresses. Anti-inflammatories and painkillers may be prescribed to manage pain. Antibiotics may be prescribed if there is a concurrent bacterial infection.[45] Patients with severe inflammation or scleritis (inflammation of the white part of the eye) are sometimes prescribed steroid eye drops and their use needs to be carefully managed. A corneal transplant (penetrating keratoplasty) may be recommended to eliminate the infection if other treatment is unsuccessful or to improve vision if it is badly affected after treatment.

Polihexanide eye drops (0.2mg/mL), chlorhexidine eye drops and hexamidine eye drops are all unlicensed products. Propamidine eye drops are licensed for treating minor eye infections. However, the dosing regimen used to treat AK differs from the dosing regimen specified in the summary of product characteristics (off-label use).

The technology

Polihexanide 0.8mg/ml eye drops, (AKANTIOR, SIFI S.p.a.) does not currently have a marketing authorisation in the UK for the treatment of acanthamoeba keratitis. It

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has been studied in a clinical trial in adults and children from 12 years of age compared with 0.2mg/ml polihexanide and 0.1mg/ml propamidine in combination.

Intervention(s)	Polihexanide 0.8mg/ml
Population(s)	Adults and children from 12 years of age with acanthamoeba keratitis
Comparators	Use individually or in combination. • Polihexanide 0.2mg/ml • Chlorhexidine • Propamidine • Hexamidine
Outcomes	The outcome measures to be considered include: • Clinical resolution rate • Time to cure • Visual acuity • Reduction of symptoms (for example: pain, swelling, redness) • 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	None

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1 Fanselow, N., Sirajuddin, N., Yin, X. T., Huang, A. J. W., & Stuart, P. M. (2021). Acanthamoeba Keratitis, Pathology, Diagnosis and Treatment. Pathogens (Basel, Switzerland), 10(3), 323.

2 Azzopardi, M., Chong, Y. J., Ng, B., Recchioni, A., Logeswaran, A., & Ting, D. S. J. (2023). Diagnosis of Acanthamoeba Keratitis: Past, Present and Future. Diagnostics (Basel, Switzerland), 13(16), 2655. https://doi.org/10.3390/diagnostics13162655

3 Jasim, H., Grzeda, M., Foot, B., Tole, D., & Hoffman, J. J. (2024). Incidence of Acanthamoeba Keratitis in the United Kingdom in 2015: A Prospective National Survey. Cornea, 43(3), 269–276

4 The College of Optometrists (2024). Clinical guidelines. Accessed: December 2024.

5 Moorfields Eye Hospital NHS Foundation Trust (2019). Acanthamoeba keratitis. Accessed: December 2024.