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 ID6497

Draft 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 a confocal microscope.[1] 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.[2]

Current treatment in the NHS includes antiseptic eyedrops such as polihexanide 0.2mg/mL (PHMB), chlorhexidine, propamidine or hexamidine. 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.[3][4] 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. If there is much scarring of the cornea following the eventual elimination of the infection, and vision is badly affected, a corneal transplant (penetrating keratoplasty) may be recommended.

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.

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 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.

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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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Questions for consultation

Please describe the current treatment pathway in the NHS for acanthamoeba keratitis?

Where do you consider polihexanide 0.8mg/ml will fit into the existing care pathway for acanthamoeba keratitis?

Are there areas of unmet need with current treatment options?

Are current treatment options widely accessible within the NHS?

Are there delays in accessing the current treatment options following diagnosis?

What are the key outcomes for recovery or improvement when treating acanthamoeba keratitis?

Please select from the following, will polihexanide 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):
For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would polihexanide be a candidate for managed access?

Do you consider that the use of polihexanide 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.

Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.

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 polihexanide 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.

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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).

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 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

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

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