NICE National Institute for Health and Care Excellence

NICE guidance

Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema

Technology appraisal guidance
Published: 13 March 2024

www.nice.org.uk/guidance/ta953

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Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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This guidance replaces TA613 and TA301.

1 Recommendations

1.1 Fluocinolone acetonide intravitreal implant is recommended, within its marketing authorisation, as an option for treating visual impairment caused by chronic diabetic macular oedema that has not responded well enough to available treatments in adults. It is recommended only if the company provides it according to the commercial arrangement.

1.2 For people with the condition in an eye with a natural (phakic) lens, if the person and their clinicians consider fluocinolone acetonide intravitreal implant to be 1 of a range of suitable treatments, after discussing the advantages and disadvantages of all the options, use the least expensive. Take account of administration costs, dosage, price per dose, duration of effect and commercial arrangements.

Why these recommendations were made

This evaluation is a review of NICE technology appraisal guidance on fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema in phakic eyes after an inadequate response to previous therapy (TA613). The new recommendation merges the outcome of the review for treating chronic diabetic macular oedema in eyes with a phakic (natural) lens, with the recommendation from NICE technology appraisal guidance on fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema after an inadequate response to prior therapy in people with a pseudophakic (artificial) lens (TA301).

Usual treatment for visual impairment caused by diabetic macular oedema that has not responded well enough to available treatments in eyes with a phakic lens is dexamethasone intravitreal implant. Fluocinolone acetonide and dexamethasone are both corticosteroid treatments. Fluocinolone acetonide intravitreal implant works in a similar way to dexamethasone intravitreal implant, and would be offered to the same population. Fluocinolone acetonide is released from the implant for up to 36 months, whereas dexamethasone is released over 6 months. So, fluocinolone acetonide intravitreal implant needs to be replaced less frequently than dexamethasone intravitreal implant.

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Clinical trial evidence suggests that fluocinolone acetonide intravitreal implant is more effective than a sham (inactive) procedure. Evidence from people having fluocinolone acetonide intravitreal implant in clinical practice supports the trial evidence that it is clinically effective. Fluocinolone acetonide intravitreal implant has not been directly compared in a clinical trial with dexamethasone intravitreal implant. But indirect comparisons suggest that it is likely to work as well as dexamethasone intravitreal implant.

A cost comparison suggests fluocinolone acetonide intravitreal implant has lower costs than dexamethasone intravitreal implant for treating diabetic macular oedema in eyes with a phakic lens. For the evidence for this review, see the TA953 committee papers. To see what NICE did for dexamethasone intravitreal implant see the committee discussion section in NICE's technology appraisal guidance on dexamethasone intravitreal implant for treating diabetic macular oedema.

NICE TA301 recommended fluocinolone acetonide intravitreal implant as an option for treating chronic diabetic macular oedema in eyes with a pseudophakic lens. The cost-effectiveness estimates for eyes with a pseudophakic lens are within the range that NICE considers an acceptable use of NHS resources. For the evidence for TA301, see the TA301 manufacturer's submission and committee papers.

So, fluocinolone acetonide intravitreal implant is recommended for treating visual impairment caused by chronic diabetic macular oedema, irrespective of the type of lens.

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2 Information about fluocinolone acetonide intravitreal implant

Marketing authorisation indication

2.1 Fluocinolone acetonide intravitreal implant (Iluvien, Alimera Sciences) is indicated for 'the treatment of vision impairment associated with chronic diabetic macular oedema, (DMO) considered insufficiently responsive to available therapies'.

Dosage in the marketing authorisation

2.2 The dosage schedule is available in the summary of product characteristics for fluocinolone acetonide intravitreal implant.

Price

2.3 Fluocinolone acetonide intravitreal implant costs £5,500 per 190 microgram implant (excluding VAT; BNF online, accessed December 2023).

2.4 The company has a commercial arrangement. This makes fluocinolone acetonide intravitreal implant available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

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3 Implementation

3.1 Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 3 months of its date of publication. Because fluocinolone acetonide intravitreal implant has been recommended for people with phakic eyes through the cost-comparison process, NHS England and integrated care boards have agreed to provide funding to implement this guidance 30 days after publication.

3.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final draft guidance.

3.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has visual impairment caused by chronic diabetic macular oedema that has not responded well enough to available treatments, and the doctor responsible for their care thinks that fluocinolone acetonide intravitreal implant is the right treatment, it should be available for use, in line with NICE's recommendations.

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4 Evaluation committee members and NICE project team

Evaluation committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by the lead team of committee C, which includes the chair and vice chair.

Committee members are asked to declare any interests in the technology being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

Chair and vice chair

Stephen O'Brien and Richard Nicholas
Chair and vice chair, technology appraisal committee C

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser and a project manager.

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Accreditation

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