# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Final draft guidance consultation

# Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema in phakic eyes (review of TA613)

## 1 Recommendations

1.1 Fluocinolone acetonide intravitreal implant is recommended, as an option for treating visual impairment caused by chronic diabetic macular oedema in adults, only if:

- their condition has not responded well enough to available treatments, and
- the implant will be used in an eye with a natural lens (phakic eye), and
- the company provides it according to the commercial arrangement (see section 2).

1.2 If people with the condition 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 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). Fluocinolone acetonide intravitreal implant is already recommended as an option for treating visual impairment caused by chronic diabetic macular oedema in people with a pseudophakic (artificial) lens in NICE technology appraisal guidance on fluocinolone



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intravitreal implant for treating chronic diabetic macular oedema after an inadequate response to prior therapy (TA301). Following the resolution of any appeals on the final draft guidance for this review, the final recommendations and relevant discussion will be merged with TA301, and reissued as updated guidance.

Usual treatment for visual impairment caused by diabetic macular oedema that has not responded well enough to available treatments in people with a natural 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.

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. So fluocinolone acetonide intravitreal implant is recommended.

For all evidence see the 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.

# 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 (simple discount patient access scheme). 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.

# 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 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 chronic diabetic macular oedema in a phakic eye 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.

# 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.

**Cara Gibbons**
Technical lead

**Mary Hughes**
Technical adviser

**Louise Jafferally**
Project manager

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