Surrey Heartlands Integrated Care System
Area Prescribing Committee (APC)

Integrated Care Partnership - Surrey Downs, Guildford & Waverley, North-West Surrey, and East Surrey Places & associated partner organisations.

NICE Technology Appraisals (TA) briefing paper for local implementation

NICE TA Guidance name and number	Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema (NICE TA953)		
Available at	https://www.nice.org.uk/guidance/ta953		
Date of issue	13 March 2024	**Implementation deadline**	30 days (24th April 2024)

Medicine details[1]	
Name and brand name	Fluocinolone acetonide (Iluvian)
Manufacturer	Alimera Sciences
Mode of action	Intravitreal Implant
Licenced indication	www.medicines.org.uk Iluvien is indicated for the treatment of vision impairment associated with chronic diabetic macular oedema, (DMO) considered insufficiently responsive to available therapies.
Formulation	Intravitreal implant
Dosage	www.medicines.org.uk **Posology** The recommended dose is one ILUVIEN implant in the affected eye. Administration in both eyes concurrently is not recommended Each ILUVIEN implant releases fluocinolone acetonide for up to 36 months. **Diabetic Macular Oedema** An additional implant may be administered after 12 months if the patient experiences decreased vision or an increase in retinal thickness secondary to recurrent or worsening diabetic macular oedema. Retreatments should not be administered unless the potential benefits outweigh the risks. Only patients who have been insufficiently responsive to prior treatment with laser photocoagulation or other available therapies for diabetic macular oedema should be treated with ILUVIEN.

Comparison of NICE TA with Summary of Product Characteristics (SmPC)[2]	Recommended treatment is in line with SmPC This is the current dose considered by NICE as part of this NICE evaluation. Subsequent changes in the licence following NICE publication will need to be considered by the Area Prescribing Committee and will not be routinely funded by local commissioners, as the incremental cost per QALY would not have been considered.

NICE TA recommendations[2]

Recommendations

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) – **Fluocinolone not recommended (November 2019)**
- 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) – **Fluocinolone recommended (November 2013)**

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

Decision making framework (DMF)

National guidance and priorities

As well as the deadline, indication will be given here on whether the appraisal was given 90 days or fast-tracked to 30 days for implementation.
The ICS has a legal obligation to commission this medicine in line with the NICE TA.

- This NICE TA has been assigned an implementation deadline of 30 days.
- The implementation deadline is 24th April 2024

Clinical effectiveness

- 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.

Patient safety

- The product should be used within its product licence.

- MHRA/CHM advice: Corticosteroids: rare risk of central serous chorioretinopathy with local as well as systemic administration (August 2017)
- NHS Improvement Patient Safety Alert: Steroid Emergency Card to support early recognition and treatment of adrenal crisis in adults (August 2020)
- **Contraindicated** in patients with
    - active or suspected ocular infection (in adults);
    - active or suspected peri-ocular infection (in adults);
    - pre-existing glaucoma (in adults)
- **Caution**
    - Raised baseline intra-ocular pressure (in adults)

Patient factors

- An additional treatment option in patients with phakic lenses would be valued by patients. NICE have already (NICE TA301 – November 2013) recommended use of fluocinolone in patients with pseudophakic lenses.
- Suitable for patients unable to get to the hospital to have frequent injections, their carers cannot bring them, or the hospital is too far away.

Environmental impact

- Patients will be required to attend a clinic setting to receive the injection.
- NICE committee was aware that some people with diabetic macular oedema may require help from a carer to travel to appointments. (carbon footprint)

Equality & diversity

- Not licensed for use in the paediatric population

Note 1: Drugs approved by NICE for adult conditions will be commissioned in children at specialised paediatric centres if the patient meets the NICE criteria and there is evidence to suggest that the drug is safe and clinically appropriate to use in children as per the NHS England Medicines for Children Policy (see https://www.england.nhs.uk/publication/commissioning-medicines-for-children-specialised-services/ and a Blueteq form is available.

Place in therapy relative to available treatments

www.nice.org.uk

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 4-6 months. So, fluocinolone acetonide intravitreal implant needs to be replaced less frequently than dexamethasone intravitreal implant.

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.

Current Pathway

Anti VEGF treatment

- Ranibizumab biosimilar (anti-VEGF)
- Aflibercept (anti-VEGF)
- Brolucizumab (anti-VEGF)
- Faricimab (anti-VEGF)

Intravitreal Corticosteroids

- Dexamethasone Intravitreal implant (Ozurdex®) – for use when DMO does not respond to non-corticosteroid treatment, or such treatment is unsuitable.
- Fluocinolone acetonide intravitreal implant (Iluvien®) - for use when DMO is insufficiently responsive to available therapies.

In the DMO pathway fluocinolone is placed after dexamethasone.

Stakeholder views

Comments to be included in the front sheet.

Cost-effectiveness

The drug cost per Place according to NICE resources does not exceed £100,000/place.

Section 1: cost of the technology

List price of fluocinolone is £5,500 per prolonged release intravitreal implant every 36 months.

Patient numbers: Since 2014 the Ophthalmologists have treated 75 patients with this treatment with 28 of those patients having a least 1 further treatment.

Cost per year since 2014 has been approximately £25,000 across Surrey Heartlands patients.

The fluocinolone license does note that another treatment can be administered within 12 months of the previous treatment and we have seen treatment intervals of 12-24 months months in 50% of the patients treated with further injections.

Cost in comparison to dexamethasone

- Cost of intravitreal dexamethasone is £870. Given every 4-6 months (local decision – made at APC in 2018)

a. Availability of CAP/PAS price:
Yes

Resource impact statement

NICE has recommended fluocinolone acetonide intravitreal implant 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.

The recommendation for its use in eyes with phakic lenses was a review of TA613.

We expect the resource impact of implementing the recommendations in England for treating chronic diabetic macular oedema in eyes with phakic lenses will be less than £5 million per year (or approximately £8,800 per 100,000 population, based on a population for England of 56.6 million people).

This is because the fluocinolone acetonide intravitreal implant is a further treatment option and the overall cost of treatment will be similar for this patient group.

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.

This resource impact statement is supported by a resource impact template to help estimate potential resource and capacity impacts.

Fluocinolone acetonide intravitreal implant has a discount that is commercial in confidence. For enquiries about the patient access scheme contact medicalinformation@alimerasciences.com

Treatments for people with diabetic macular oedema are commissioned by integrated care boards. Providers are NHS hospital trusts.

The payment mechanism for the technology is determined by the responsible commissioner and depends on the technology being classified as high cost.

This page was last updated: 13 March 2024

The Surrey Heartlands Director of Pharmacy and Medicines Optimisation has delegated authority to enable the Committee to be a decision-making committee providing the impact of any single decision does not exceed £100,000 within an individual Place per annum. Decisions with a cost impact of over £100,000 within an individual Place per annum require authorisation from Surrey Heartlands Health & Care Professionals Committee at their next meeting. Exception to this will be for any decision made in relation to a NICE Technology Appraisal (which are subject to requiring mandatory funding by commissioners) and other urgent items. The exceptions will be taken to the next Executive Meeting (which meets weekly) for authorisation.

Traffic light recommendation to APC

NHS Payment Scheme (NHSPS) excluded high-cost drug: see NHS England » 2023-25 NHS Payment Scheme
Yes

Recommended traffic light status and rationale:

- **RED** – Specialist ONLY drugs - treatment initiated and continued by specialist clinicians.

Implementation

NICE TA implementation must be within 30 days of publication.

a. Primary care

- This is a National Tariff excluded high-cost drug and is commissioned by ICSs for use in secondary care. There should be no prescribing in primary care.
- Primary care prescribers should be aware that their patient is receiving this medicine and ensure that this is recorded in the patient's notes in order to be alert to potential side-effects and interactions with other medicines prescribed in primary care. This will also ensure that GP records, which are accessed by other healthcare providers, are a true and accurate reflection of the patient's medication.

b. Secondary care

- Providers are NHS hospital trusts.
- Fluocinolone is already on the hospital formularies for us in line with NICE TA301 (patients with pseudophakic lens)
- The initiation, administration and on-going treatment is managed by secondary care.
- Specialists will be required to notify the high-cost drugs teams of initiation using the Blueteq® system.
- Homecare arrangements will be managed by the trust.

c. ICS

- This technology is commissioned by integrated care systems.
- Pathway does not need to be updated in line with this guidance as there is no reference made in the pathway to the type of lens used.

d. PAD and Joint Formulary

- PAD will be updated to reflect new published guidance
- Removal
    - PAD narrative – October 2018 (updated from November 2022)
    - PAD policy statement APC 369-2018 (Updated from November 2022)

• Add
  ○ Link to NICE TA953
  ○ Briefing paper for NICE TA953
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Proposed tick box forms
Blueteq® form for initiation has been developed.

References:

1 Summary of Product Characteristics. emc. Available at: www.medicines.org.uk Accessed <26/03/2024>

2 NICE Technology Appraisal Guidance: . Available at: www.nice.org.uk Accessed <27/03/2024>

3 NICE Resource Impact Report: . Available at: www.nice.org.uk Accessed <27/03/2024>

Blueteq® form:

FLUOCINOLONE acetonide - INITIAL treatment for Chronic Diabetic Macular Oedema	
Please indicate whether patient meets the following NICE criteria:	**Please tick**
1. This patient is aged 18 or over	Yes No
2. Patient has visual impairment caused by chronic diabetic macular oedema?	Yes No
3. Patient has not responded well enough to available treatments? (Please check YES if you agree with this statement)	Yes No
6. Information only **1 dose of Fluocinolone will be approved if all the criteria above are met. If further doses are required a repeat form will be required to be completed** Summary of Product Characteristics (accessed 4th April 2024) - Each ILUVIEN implant releases fluocinolone acetonide for up to 36 months. An additional implant may be administered after 12 months if the patient experiences decreased vision or an increase in retinal thickness secondary to recurrent or worsening diabetic macular oedema. The safety and efficacy of ILUVIEN administered to both eyes concurrently have not been studied. It is recommended that an implant is not administered to both eyes at the same visit. Concurrent treatment of both eyes is not recommended until the patient's systemic and ocular response to the first implant is known.	