East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG, Surrey Heath CCG, Crawley CCG, Horsham & Mid-Sussex CCG

Briefing Paper for Surrey & North West Sussex Area Prescribing Committee (APC) on NICE Technology Appraisals: Local implementation

NICE TA Guidance	Fluocinolone acetonide intravitreal implant for treating recurrent non-infectious uveitis (TA590)		
Available at	https://www.nice.org.uk/guidance/ta590		
Date of issue	31 July 2019	**Implementation deadline**	31st October 2019

Medicine details	
Name, brand name	Fluocinolone acetonide (*Iluvien*)
Manufacturer	Alimera Sciences
Licensed indication	Fluocinolone acetonide intravitreal implant (*Iluvien*, Alimera Sciences) is indicated for 'prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye'. July 2019
Formulation	Intravitreal implant
Usual dosage	Fluocinolone acetonide intravitreal implant is administered through intravitreal injection. Each implant contains 0.19 mg of fluocinolone acetonide and releases fluocinolone acetonide for up to 36 months. (July 2019)
NICE recommended dosage/schedule	As above

Disease and potential patient group	
Brief description of disease	**Uveitis** is a general term describing inflammation of the part of the eye called the uveal tract. This consists of the iris, ciliary body and choroid - although uveitis can additionally involve other parts of the eye. It can be caused by diseases or problems of the eye alone, or can be a part of conditions affecting other parts of the body. Uveitis is classified according to exactly where in the uvea it occurs, and symptoms also vary with the affected area. Treatment, often with pupil dilators and steroid eye drops, can usually reduce inflammation and ease symptoms. However, the treatment itself can cause complications. If treatment is not started promptly and/or complications occur, uveitis can lead to permanent loss of vision.
Potential patient numbers per 100,000	Posterior uveitis is thought to account for around 1 in 5 of all uveitis cases and affects between 1,500 and 5,000 patients annually in England with a prevalence of ~5 to 10 per 100,000 people.

SUMMARY

NICE recommendation
Fluocinolone acetonide intravitreal implant is recommended, within its marketing authorisation, as an option for preventing relapse in recurrent non-infectious uveitis affecting

the posterior segment of the eye. It is recommended only if the company provides it according to the commercial arrangement.

Why the committee made these recommendations

Treatments for recurrent non-infectious uveitis affecting the posterior segment of the eye include systemic corticosteroids, immunosuppressants and dexamethasone implants. These treatments can be disruptive to daily life, needing frequent hospital visits.

The clinical trial results for the fluocinolone acetonide intravitreal implant compared with limited current practice are difficult to interpret and very uncertain. The trial didn't directly measure health-related quality of life and the number of recurrences reported may be overestimated.

The cost-effectiveness estimates are also uncertain. However, if all the most plausible assumptions had been included in the model, most of the cost-effectiveness estimates would be within the range that NICE normally considers a cost-effective use of NHS resources, so the fluocinolone acetonide implant is recommended.

Author comment

A new option that will compete with dexamethasone implant and adalimumab injection. Iluvien is likely to be less frequent than the dexamethasone implant potentially saving administration costs.

Cost implications*

Cost of product:

£5,500 per implant (excluding VAT, British national formulary online [accessed May 2019]).

Annual cost per patient: £5,500 every 3 years

NICE do not expect this guidance to have a significant impact on resources; that is, the resource impact of implementing the recommendations in England will be less than £5 million per year in England (or £9,000 per 100,000 population). This is because the technology is a further treatment option and the overall cost of treatment will be similar.

Has dose escalation been considered as part of the NICE costing template?

It is not known whether dose escalation (in this case having an implant more often than every 36 months) has been considered, as no NICE costing template has been published.

Recommendation to APC is to ask that if dose escalation is required this is subject to IFR for individual patient, or a service development if a patient cohort is identified.

Costing information/100,000 population and per CCG:

	Est patients / 100,000 (pop)	Cost
NHS Surrey Heath CCG	10 (96,627)	£8,696
NHS Crawley CCG	11 (111,664)	£10,050
NHS East Surrey CCG	18 (184,734)	£16,626
NHS Horsham & Mid Sussex CCG	24 (236,113)	£21,250
NHS North West Surrey CCG	35 (347,747)	£31,297
NHS Surrey Downs CCG	29 (291,545)	£26,239

NHS Guildford and Waverley CCG	21 (208,802)	£18,792
Total	148 (1,477,232)	£132,951

Availability of PAS and details (if appropriate): Yes
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.

Availability of homecare service (if appropriate): Product will need to administered to patient in a "clean room" environment, so homecare is not applicable

**NICE funding requirements are based on Quality Adjusted Life Years (QALY) threshold. If there is evidence that the incremental cost rises above this threshold in the future, the APC may reconsider the commissioning status.*

Alternative treatments and cost per patient (per year / per month as appropriate)

Other NICE recommended products:
Non-infectious uveitis without systemic disease may first be treated with local corticosteroids, followed by systemic corticosteroids or a dexamethasone implant.
Multiple repeated dexamethasone implants may be given.

Bilateral disease or unilateral disease with active systemic disease may first be treated with systemic corticosteroids, followed by immunosuppressants or dexamethasone implants. Treatments may also be used in combination. TNF-alpha inhibitors such as adalimumab may be an option after immunosuppressants

Impact to patients

Iluvien is supposed to last for 3 years in situ – as opposed to alternative uveitis implant (dexamethasone) which is repeated after at least 4 to 6 months. The implant in both cases is administered intravitreally to the patient – assumption is that patients would welcome a treatment option which would mean less frequent administration.

Impact to primary care prescribers

Iluvien will be prescribed and administered exclusively within a secondary or tertiary care setting, or possibly via a private provider.

However, primary care prescribers should ensure that patient medication records include any medicine for which prescribing remains the responsibility of secondary or tertiary care. This will ensure that GP records, which are accessed by other healthcare providers, are a true and accurate reflection of the patient's medication.

Impact to secondary care

Although there is a lack of active enthusiasm for this product by secondary care clinicians in the Ophthalmology Network, they should look to develop a treatment protocol for uveitis which incorporates Iluvien.

Iluvien is already in use in secondary care for other indications, so there is little impact to with regards to implementation.

Impact to CCGs

Iluvien is excluded from the national Tariff and is commissioned by CCGs.

It is possible that there might be some savings seen from patients requiring fewer appointments for repeated implants with Iluvien (compared to dexamethasone).

Implementation

NICE TA implementation must be within 90 days of publication
Blueteq forms to be produced and activated.

Recommendation to APC

PbRe: Yes

Colour classification guidelines

Recommended traffic light status (see attached guidelines):
RED

Recommendation to APC is to ask that if dose escalation (i.e. administration more often than every 3 years) is required, this is subject to IFR for individual patient, or a service development if a patient cohort is identified.

Additional comments:
Blueteq form to be developed and activated.
Possible Uveitis treatment pathway with regards to intravitreal implants to be discussed at regional Ophthalmology Network.

References:

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Prepared by:

Name, Designation, Organisation

Declaration of Interest:

XXXX

Date: XXXX

Reviewed by:

Name, Designation, Organisation

Declaration of Interest:

XXXX

Date: XXXX

VERSION CONTROL SHEET

Version	Date	Author	Status	Comment
v.1				*Out for consultation*
v.2				
v.3	*20/12/2017*	*G.Randall*		*Added requirement to think about dose escalation*