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 Prescribing Clinical Network on NICE Technology Appraisals: Local implementation

NICE TA Guidance	Adalimumab and dexamethasone for treating non-infectious uveitis NICE TA 460 (**please note** that dexamethasone is commissioned by clinical commissioning groups, adalimumab is commissioned by NHS England – this paper focuses therefore on dexamethasone)		
Available at	https://www.nice.org.uk/guidance/ta460		
Date of issue	26th July 2017	**Implementation deadline**	26th October 2017

Medicine details	
Name, brand name	Dexamethasone (Ozurdex®)
Manufacturer	Allergan
Licensed indication	Dexamethasone intravitreal implant is indicated 'for the treatment of adult patients with inflammation of the posterior segment of the eye presenting as non-infectious uveitis.'
Formulation	intravitreal implant
Usual dosage	The recommended dose of dexamethasone intravitreal implant is 1 implant, containing 700 micrograms of dexamethasone, to be administered intravitreally to the affected eye. Administration to both eyes concurrently is not recommended. Repeat doses should be considered when a patient experiences a response to treatment followed subsequently by a loss in visual acuity and in the clinician's opinion may benefit from retreatment without being exposed to significant risk.
Disease and potential patient group	
Brief description of disease	Uveitis is an inflammation of the uveal tract of the eye, which consists of the iris, the ciliary body and the choroid. The majority of uveitis diagnoses are non-infectious and the disease is usually caused by an underlying autoimmune disorder or trauma to the eye. However, in some people the cause is unknown. Uveitis is classified according to the location of inflammation. Anterior uveitis is inflammation of the iris. Intermediate uveitis affects the posterior part of the ciliary body and the vitreous. Posterior uveitis affects the back of the eye, including the retina and the choroid.
Potential patient numbers per 100,000	NICE state: We do not expect this guidance to have a significant impact on resources; that is, it will be less than £5m per year in England (or £9,100 per 100,000 population). This is because the eligible population size is small (around 450 people per year for adalimumab and around 380 people per year for dexamethasone) due to the optimisations made to the recommendations during development of the guidance.

SUMMARY

NICE recommendation

1.1 Adalimumab is recommended as an option for treating non-infectious uveitis in the posterior segment of the eye in adults with inadequate response to corticosteroids, only if there is:

- active disease (that is, current inflammation in the eye) and
- inadequate response or intolerance to immunosuppressants and
- systemic disease or both eyes are affected (or 1 eye is affected if the second eye has poor visual acuity) and
- worsening vision with a high risk of blindness (for example, risk of blindness that is similar to that seen in people with macular oedema).

1.2 Stop adalimumab for non-infectious uveitis in the posterior segment of the eye in adults with inadequate response to corticosteroids if there is 1 of the following:

- new active inflammatory chorioretinal or inflammatory retinal vascular lesions, or both or
- a 2-step increase in vitreous haze or anterior chamber cell grade or
- worsening of best corrected visual acuity by 3 or more lines or 15 letters.

1.3 Dexamethasone intravitreal implant is recommended as an option for treating non-infectious uveitis in the posterior segment of the eye in adults, only if there is:

- active disease (that is, current inflammation in the eye) and
- worsening vision with a risk of blindness.

1.4 These recommendations are not intended to affect treatment with adalimumab and dexamethasone that was started in the NHS before this guidance was published. Adults having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

Cost implications

Cost of product: each dexamethasone intravitreal implant costs £870.00

NICE: The committee heard from clinical experts that adalimumab would generally be used in people with bilateral or systemic disease or both, but dexamethasone is generally used in people with unilateral disease

Costing information/100,000 population:
Potential additional cost from NICE: £9,100 per 100,000 population (note this is for both products adalimumab and dexamethasone)

Availability of homecare service (if appropriate):
Does not apply to dexamethasone intravitreal implant

Local cost impact: nil anticipated as dexamethasone already available in line with PCN policy statement 33-2012

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

Other NICE recommended products:

The committee heard from the clinical experts that there are 3 main reasons for treating non-infectious uveitis in clinical practice: vitreous haze, macular oedema and worsening vision. The committee also heard from the clinical experts and the assessment group that there is no nationally agreed pathway for treating non-infectious uveitis. The assessment group advised that in clinical practice, systemic steroids are usually used as a first-line treatment and 1 or 2 immunosuppressants, such as mycophenolate mofetil, are either used alone or with steroids as second-line treatment. This general treatment pathway was agreed by the clinical experts, although it was noted that treatment in clinical practice depends on whether disease is:

- active (that is, current inflammation in the eye) or inactive (that is, limited inflammation, usually because of treatment with corticosteroids or immunosuppressants)
- systemic (when disease is not only in the eye) or non-systemic (when disease is limited to the eye)
- unilateral (when 1 eye is affected) or bilateral (when both eyes are affected).

It heard from clinical experts that adalimumab would generally be used as a third-line treatment option in people with bilateral or systemic disease or both, but dexamethasone is generally used in people with unilateral disease. The committee concluded that the treatment pathway reflected current practice.

Impact to patients

The clinical and patient experts stated that treatment options are currently restricted and there was a significant unmet need for both adalimumab and dexamethasone intravitreal implant. The committee heard from the clinical and patient experts that adalimumab and dexamethasone allow corticosteroid sparing, which is important not just for patients' short-term quality of life but also to avoid glaucoma, diabetes, stroke and heart attack. The committee recognised that patients and their carers would greatly value a new treatment which prevented or delayed sight loss, particularly if it reduced the significant side effects associated with current treatments.

Within NWS CCG dexamethasone intravitreal implant has been available for uveitis in line with PCN policy statement 33-2012

PCN 33-2012 Ozurdex for the treat

Treatment protocol for the use of Ozurde

Impact to primary care prescribers

Dexamethasone implant is a PbRe drug and is commissioned by CCGs for use in secondary

care. There should be no prescribing in primary care.
Primary care prescribers should be aware that their patient is receiving dexamethasone implant in order to be alert to potential side-effects, contraindications and interactions with other medicines prescribed in primary care.

Impact to secondary care

The current treatment protocol for the use of Ozurdex® (dexamethasone intravitreal implant) in the management of uveitis agreed by the PCN in 2012 will be replaced by the recommendations in NICE.
The Blueteq forms will be updated accordingly

Impact to CCGs

Dexamethasone is commissioned by clinical commissioning groups, adalimumab is commissioned by NHS England
As dexamethasone was commissioned locally following a PCN decision in 2012 there is limited impact anticipated for CCGs
Local information:

CCG	Number of patients	Number of doses
East Surrey	1	1
Guildford & Waverley	6	16
North West Surrey	2	2
Surrey Downs	0	0
Surrey Heath	2	4

Implementation

NICE TA implementation must be within 90 days of publication
Blueteq forms to be updated

Recommendation to PCN

PbRe: Yes

Recommended traffic light status
RED

Additional comments:
The current treatment protocol for the use fo Ozurdex (dexamethasone intrvitreal implant) needs to be replaced by the recommendations in NICE TA 460

References:
NICE TA 460: Adalimumab and dexamethasone for treating non-infectious uveitis
https://www.nice.org.uk/guidance/ta460

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Declaration of Interest: None **Date:** Sept 2017

VERSION CONTROL SHEET

Version	Date	Author	Status	Comment
v.1	*Sept 2017*	*Linda Honey*	*Draft*	*Sent out for consultation prior to Oct 2017 PCN*

Sent out for consultation 12th September 2017, no comments received