

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

Formulary Extension Briefing Paper for Prescribing Clinical Network

Medicine details – Consideration for the increased frequency of Ozurdex implants in patient with DMO for whom 6-monthly implants are insufficient	
Name, brand name	Dexamethasone Intravitreal implant (Ozurdex)
Manufacturer	Allergan
Licensed indication	• visual impairment due to diabetic macular oedema (DME) who are pseudophakic or who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy
Formulation	One implant contains 700 micrograms of dexamethasone
Usual dosage	<p>The recommended dose is one OZURDEX implant to be administered intravitreally to the affected eye. Administration to both eyes concurrently is not recommended</p> <p><u>DME</u></p> <p>Patients treated with OZURDEX who have experienced an initial response and in the physician's opinion may benefit from retreatment without being exposed to significant risk should be considered for retreatment.</p> <p>Retreatment may be performed after approximately 6 months if the patient experiences decreased vision and/or an increase in retinal thickness, secondary to recurrent or worsening diabetic macular oedema.</p> <p>There is currently no experience of the efficacy or safety of repeat administrations in DME beyond 7 implants.</p>

Disease and potential patient group	
Brief description of disease	<p>Diabetic eye disease is a leading cause of blindness registration among working age adults in England and Wales. It is caused by changes to the tiny blood vessels of the retina (the light sensitive layer at the back of the eye). In diabetic macular oedema, blood vessels leak fluid into the retina. Vision loss occurs when the fluid reaches the macula (the centre of the retina that provides sharp vision) and builds up, causing swelling. Over time, diabetic macular oedema can cause central vision to become blurred. A healthy macula is essential for good vision.</p>
Potential patient numbers per 100,000	To be discussed at the ophthalmology network meeting

SUMMARY

Reason for formulary extension
<p>DME – Diabetic macular oedema</p> <ul style="list-style-type: none"> • agree place in therapy and funding of Ozurdex who require treatment more frequently than 6-monthly (not more than 4-monthly)

- agree a view on the SPC statement that 'There is currently no experience of the efficacy or safety of repeat administrations in DME beyond 7 implants'

NICE usually only considers licensed indications, and the retreatment intervals have been interpreted from the SPC and reflected in the Blueteq forms as allowing **TWO** treatments per year from the description 'Retreatment may be performed after approximately 6 months'

This has been challenged as there has been the recognition that some patients need to be retreated after 4 months, requiring a change of funding approval to **THREE** treatments per year.

NICE TA [349](#), Jul-2015, 'Dexamethasone intravitreal implant for treating diabetic macular oedema', states that:

'Dexamethasone intravitreal implant is given as an injection into the eye. Each implant delivers 700 micrograms dexamethasone to the back of the eye over a period of 6 months or more'

'The summary of product characteristics states that, after initial treatment, re-treatment can be performed after approximately 6 months if the patient experiences decreased vision with or without an increase in retinal thickness with recurrent or worsening diabetic macular oedema'

'BEVORDEX compared dexamethasone 700 micrograms with bevacizumab 1.25 mg in 88 eyes. Dexamethasone intravitreal implant was not given more than every 4 months'

'The Committee noted that dexamethasone intravitreal implant is licensed for use every 6 months in line with the MEAD trials but heard that **it is often given more frequently than this in practice (every 4 months)**'

Tick one box – Allow funding for up to ONE additional Oxurdex implant per year

Addition to formulary product/s

Replacement of originator

product/s.....

Name of

Evidence as necessary

As included in the detail of the NICE technology appraisal

Cost implications

Cost of product:

Annual cost per patient: Additional £870.00 plus procedure tariff

Costing information/100,000 population and per CCG:

Availability of PAS and details (if appropriate): Yes - Confidential

Availability of homecare service (if appropriate): Not appropriate

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

Ozurdex – £1,740 - £2,610

Ranibizumab – £4,408 - £6,612

Aflibercept - £6,520

Notes – The above are the list prices, NHS prices are confidential

When considering Ozurdex, NICE has included the cost of cataract surgery in phakic patients


When considering Ozurdex , the treatment of intraocular pressure needs to be considered

Bevacizumab – approx. £600

Impact to patients

Would require fewer procedures per year than for VEGF therapies, with possibly fewer appointments (depending on intraocular pressure)

Phakic patients would require earlier cataract surgery due to adverse effects

Impact to primary care
Secondary treatment, may require GPs to prescribe treatment for intraocular pressure
Impact to secondary care
May require an additional appointment for injection. However this treatment has been requested for patients for whom the 6-monthly treatment is insufficient and therefore already requiring further appointments
Impact to CCGs
May require an additional appointment for injection. However this treatment has been requested for patients for whom the 6-monthly treatment is insufficient and therefore already requiring further appointments
Implementation
Minor change to Ophthalmology Manual and Blueteq form
Recommendation to PCN
<p>PbRe: Y</p> <div style="text-align: right;">  Colour classification guidelines </div> <p>Recommended traffic light status (see attached guidelines): RED</p> <p>Additional comments: Blueteq form</p>

References:

1. NICE TA [349](#), Jul-2015, 'Dexamethasone intravitreal implant for treating diabetic macular oedema'
2. MIMS database for prices, accessed 6th March 2018

Prepared by:

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Declaration of Interest:

None

Date: 6th March 2018

Reviewed by:

Name, Designation, Organisation

Declaration of Interest:

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Date: XXXX

VERSION CONTROL SHEET

Version	Date	Author	Status	Comment
<i>v.1</i>	6/3/2018	<i>Carina Joanes</i>		<i>Out for consultation to PCN Ophthalmology Network</i>
<i>v.2</i>				