

## Briefing Paper for Prescribing Clinical Network on NICE Technology Appraisal (Number): December 2015

<b>NICE TA Guidance</b>	Ciclosporin for treating dry eye disease that has not improved despite treatment with artificial tears (TA369)
<b>Date of issue</b>	16 <sup>th</sup> December 2015
<b>Available at</b>	<a href="http://www.nice.org.uk/guidance/ta369/resources/ciclosporin-for-treating-dry-eye-disease-that-has-not-improved-despite-treatment-with-artificial-tears-82602737172421">http://www.nice.org.uk/guidance/ta369/resources/ciclosporin-for-treating-dry-eye-disease-that-has-not-improved-despite-treatment-with-artificial-tears-82602737172421</a>

<b>Medicine details</b>	
<b>Name, brand name and manufacturer</b>	Ciclosporin (Ikervis) Santen Pharmaceuticals
<b>Licensed indication, formulation and usual dosage</b>	<p><a href="http://www.medicines.org.uk">www.medicines.org.uk</a> <b>Ikervis patient information leaflet</b> IKERVIS contains the active ingredient, ciclosporin. Ciclosporin belongs to a group of medicines known as immunosuppressive agents that are used to reduce inflammation. IKERVIS is used to treat adults with severe keratitis (inflammation of the cornea, the transparent layer in the front part of the eye). It is used in those patients who have dry eye disease, which has not improved despite treatment with tear substitutes (artificial tears).</p> <p><b>Formulation:</b> Ikervis (Ciclosporin eye drops 1mg/ml) <b>Recommended dose:</b> 1 drop into the affected eye once daily at bedtime</p>

<b>Disease and potential patient group</b>	
<b>Brief description of disease</b>	<p><a href="http://www.rnib.org.uk">www.rnib.org.uk</a> Dry eye is an eye condition caused by a problem with tears. Dry eye can make your eye feel dry, scratchy, irritated and uncomfortable. About dry eye Dry eye often affects both eyes but sometimes one eye is affected more than the other. It can make you feel you have something in your eye, like an eyelash or a piece of grit, even when there is nothing there. Dry eye can make your vision slightly blurry, though usually only for short periods of time. The blurriness usually gets better on its' own or when you blink. Dry eye doesn't usually cause long term problems with your sight but it is important to let someone know if your eyes are feeling dry, gritty and sore. Your GP may be able to help or they may recommend that you have your eyes examined either by an optometrist (optician) or an eye specialist (ophthalmologist). In most cases, dry eye just results in mild discomfort but in more severe cases it can become very painful and the dryness can cause permanent damage to the front of the eye. The severity of the problem depends very much on the cause of the dry eye. Once you have dry eye you tend to always be prone to it, but it can be treated. Usually there are times when it is better than others. Medically, dry eye is known as keratoconjunctivitis sicca</p>
<b>Potential patient numbers per 100,000</b>	<p><a href="http://www.nice.org.uk">www.nice.org.uk</a> NICE Assumptions (Costing template information)</p> <ul style="list-style-type: none"> <li>• People with dry eye disease <ul style="list-style-type: none"> <li>○ <b>1,793/100,000 population</b></li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>• People with severe keratitis with severe dry eye disease <ul style="list-style-type: none"> <li>○ <b>108/100,000</b></li> </ul> </li> <li>• People with severe keratitis with dry eye disease that has not improved despite treatment with artificial tears <ul style="list-style-type: none"> <li>○ <b>108/100,000 population</b></li> </ul> </li> </ul> <p>NICE estimates future practice <b>81/100,000 population</b> will be treated with Ikervis (ciclosporin eye drops 0.1%) and artificial tears and/or corticosteroids.</p> <p>This is NICE making the assumption that patients would be treated with the licensed product (Ikervis) rather than the unlicensed products Restasis (ciclosporin eye drops 0.05%) or Optimimmune (ciclosporin eye ointment 0.2%) in the future.</p>
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## SUMMARY

### Guidance

#### 1. Guidance

- 1.1. Ciclosporin is recommended as an option, within its marketing authorisation, for treating severe keratitis in adult patients with dry eye disease that has not improved despite treatment with tear substitutes.

### Cost implications

**Cost:** [www.nice.org.uk](http://www.nice.org.uk) £72.00 per 30 single dose containers

**Annual cost per patient:** NICE assumption: 1 pack per month. Annual cost: £864 (excluding VAT)

**Availability of PAS and details (if appropriate):**N/A

**Availability of homecare service (if appropriate):**N/A

### Alternative treatments and cost per patient per year

[www.nice.org.uk](http://www.nice.org.uk)

Unlicensed specials:

- Restasis (0.05% eye drops) £7.40 per single dose container. £2,664/year
- Optimimmune (0.2% ointment) £83.73 per container. £1,005/year 9 (Licensed as an animal medicine but has been manufactured to exactly the same standards as required for licensed human medicines)

### Impact to patients

All patients currently using unlicensed specially compounded eye drops and imported products licensed in other countries, therefore patients will have the advantage of using a licensed product.

### Impact to primary care

These patients will be at the severe end of the spectrum so will have been referred into secondary care for specialist intervention.

Current practice in line with the treatment pathway currently available is for Ciclosporin to be initiated in secondary care and to remain in secondary care as a RED drug.

If recommended at PCN patients will be initiated in secondary care and then prescribing responsibility could potentially be transferred to primary care once the patient is stabilised on treatment

The consultation should seek to establish the interval or indication for specialist review, and whether this will be a lifetime treatment otherwise, when and how the need for continued

treatment will be assessed.

### Impact to secondary care

First licensed Ciclosporin product available for use in this cohort of patients. Currently Ciclosporin eye preparations (unlicensed) are considered as RED within the Dry Eye Management Prescribing Guidelines. Patients will currently be having outpatient appointments to obtain repeat prescriptions.

Changing traffic light status will have a positive impact on outpatient activity for acute providers.

### Impact to CCGs

Ciclosporin eye drops (unlicensed up to this point) have been initiated and have remained in secondary care since the dry eye management guidelines were produced in June 2014. The change of status from RED to Amber\* would be a cost pressure for primary care.

[www.nice.org.uk](http://www.nice.org.uk)

Using the NICE resource impact template, an overall saving is expected to the health economy with a reduction in the use of unlicensed medicines:

CCG	Adult Population	NICE predicted numbers to be treated with Ikervis	Cost per year (£864)	NICE predicted current costs
<b>Horsham and Mid Sussex</b>	175,516	180	£155,520	£253,070
<b>Crawley</b>	83,450	86	£74,304	£120,208
<b>East Surrey</b>	137,822	142	£122,688	£199,292
<b>Surrey Downs</b>	221,273	227	£184,998	£319,501
<b>Guildford and Waverley</b>	163,414	168	£145,152	£236,198
<b>Surrey Heath</b>	74,002	76	£65,664	£106,500
<b>North West Surrey</b>	265,796	273	£235,872	£383,822

### Implementation

#### **Moorfields Eye Hospital NHS Foundation Trust recommendations: (Agreed pre NICE guidance in October 2015)**

North Central London Joint Formulary Committee has agreed that prescribing of Ciclosporin can be initiated only in secondary care by corneal/external diseases specialists and can be continued in primary care according to the agreed protocol to avoid an increase in non-specialist prescribing and subsequent cost impact.

#### **Choice of ciclosporin eye product**

- The licensed ciclosporin 1mg/mL eye drops [emulsion] (Ikervis®) should be used first line; Some patients may not tolerate ciclosporin 1mg/ml eye drops (Ikervis®) due to sensitivity to excipients, therefore ciclosporin 0.2% preservative free eye ointment (unlicensed) may be prescribed;
- Ciclosporin 0.05% eye drops (Restasis) should not be prescribed;
- Ciclosporin 2% and 0.06% eye drops (unlicensed specials) are no longer manufactured and should not be prescribed.

Recommendation in this guidance is that there is an ophthalmic review at least every 6 months.

**Brighton Area Prescribing Committee** considered this paper on 23<sup>rd</sup> February 2016 and considered this drug as BLUE with an information sheet which will be developed and until this has been developed, Ciclosporin will continue to be RED.

### Recommendation to PCN

**PbRe:** No

Traffic light status: RED to Amber\*

**QUESTION: Monitoring requirements for primary care prescribers? Schedule for review/ discontinuation To check with consultants at consultation**

Prescribing Guidelines for Dry Eye Management will be discussed at the PCN in April 2016  
(Review date: June 2016 on current guidelines)

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**Declarations of Interest:** Null

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**Declarations of Interest:** Null

#### VERSION CONTROL SHEET

Version	Date	Author	Status	Comment
V1	12/02/2016	Clare Johns	DRAFT	For consultation with ophthalmologists