BNSSG Shared Care Guidance
Please complete all sections

Section 1: Heading

Drug	Ciclosporin (Ikervis) 1mg/ml eye drops, emulsion
Amber ***three months***	
Indication	Ciclosporin (Ikervis) is indicated for the treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes Ciclosporin (Ikervis®) treatment must be initiated by an ophthalmologist or a healthcare professional qualified in ophthalmology
Speciality / Department	Ophthalmology
Trust(s)	Bristol Eye Hospital
	Click here to enter details
	Click here to enter details

Section 2: Treatment Schedule

Usual dose and frequency of administration	Recommended therapy is one eye drop in the affected eye(s) once daily. If one dose is missed, treatment should continue with the next dose as planned. The dose should not exceed one drop in the affected eye(s) daily.
Route and formulation	Ocular use, 1 mg/mL eye drops, emulsion
Duration of treatment	12 months

Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

Baseline tests - where appropriate

Nil
Subsequent tests - where appropriate
Specialist: Monitor the patient after initiation to ensure no side effects and to check for efficacy. Reassess patient at minimum 12 monthly intervals GP: Monitor for any side effects or lack of efficacy

Section 4: Side Effects

Please list the most common side effects and management. Please provide guidance on when the GP should refer back to the specialist.

Side effects and management	The most common adverse reactions with ciclosporin are eye pain, eye irritation, lacrimation, ocular hyperaemia and eyelid erythema which were usually transitory and occurred during instillation. This medicinal product may induce temporary blurred vision or other visual disturbances which may affect the ability to drive or use machines. Patients should be advised not to drive or use machines until their vision has cleared.
Referral back to specialist	Drop in vision, signs of acute infection

Section 5: Drug Interactions

Please list clinically significant drug interactions (eMC link please click here)

Significant Drug Interactions	Co-administration with eye drops containing corticosteroids could potentiate the effects of ciclosporin on the immune system Patients with glaucoma, especially with beta blocker treatment as these are known to reduce tear secretion Ikervis contains cetalkonium chloride which may cause eye irritation
Reminder to ask patient about specific problems	Click here to enter details

Section 6: Contra-indications, Cautions and Special Recommendations

Please list

1. Hypersensitivity to the active substance or to any of the excipients listed (refer to SPC)
2. Active or suspected ocular or peri-ocular infection
3. Pregnancy and breast feeding
4. Patients with a history of ocular herpes simplex
5. Patients wearing contact lenses have not been studied. Careful monitoring of patients with severe keratitis is recommended. Contact lenses should be removed before instillation of the eye drops at bedtime and may be reinserted at wake-up time of patients
6. Ciclosporin is not recommended in women of childbearing potential not using effective contraception

Section 7: Advice to the patient

Advice for prescribing clinician to inform patient

1. Ask the consultant / specialist or primary care prescriber for information, if any aspects of treatment are not fully understood
2. Share any concerns in relation to treatment with consultant
3. Attend follow-up appointments with the consultant / specialist
4. Read the patient information leaflet included with your medication and report any side effects or concerns you have to the consultant/specialist or GP or Primary Care Prescriber
5. The patient may also choose to report any adverse drug reaction direct to the MHRA on a Yellow Card , available at pharmacies, GPsurgeries or from the Yellow Card hotline (freephone 0808 100 3352 during business hours). The form can also be downloaded from www.mhra.gov.uk/yellowcard

Section 8: Responsibilities for Secondary Care

Core responsibilities

1. Initiating treatment and prescribing for the first three months
2. Undertaking the clinical assessment and monitoring for the first three months.
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Refer patients to GP and provide information of further action where appropriate e.g. blood test is due.
5. To provide advice to primary care when appropriate.
6. Review concurrent medications for potential interaction prior to initiation of ciclosporin (Ikervis).
7. Stopping treatment where appropriate or providing advice on when to stop.
8. Reporting adverse events to the MHRA.
9. Reminder to ask patients about particular problems see section 5.

Other specific to drug

1. To initiate therapy (prescribe by brand) by prescribing an initial 2 month trial and reassess the patient prior to the end of the trial period. Trial for an additional 1 month if appropriate. Consultant to send GP a letter informing them of initiation of the 2 month trial
2. Inform GP if treatment is to continue or not and request GP to take over the prescribing
3. Review the patient in the ophthalmic clinic at least 12 monthly to monitor disease
4. To confirm with the patient's GP that if the patient has intolerance to ciclosporin (Ikervis®) treatment at any time, the specialist will accept the patient back into clinic to consider further treatment options

Section 9: Responsibilities for Primary Care

Core responsibilities

1.Responsible for taking over prescribing after the first three months
2. Responsible for the clinical assessment and monitoring after the first three months
3. Review of any new concurrent medications for potential interactions.
4. Reporting adverse events to the MHRA.
5. Refer for advice to specialist where appropriate.
6. Reminder to ask patients about particular problems see section 5.

Other specific to drug

1. Subsequent prescribing of ciclosporin (by brand) at the dose recommended when requested by specialist after trial period

Section 10: Contact Details

Name	Organisation	Telephone Number	E mail address
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Section 11: Document Details

Date prepared	December 2017
Prepared by	Kieren Darcy
Date approved by JFG	January 2018
Date of review	January 2020
Document Identification: Version	V1

Section 12: Collaboration

Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. Click here to enter details

Section 13: References

Please list references

1. Summary of Product Characteristics Ikervis® 1 mg/mL eye drops, emulsion Santen UK Ltd Last updated on eMC 13/10/2016 http://www.medicines.org.uk/emc/medicine/30584
2. NICE TA 369 Ciclosporin for treating dry eye disease that has not improved despite treatment with artificial tears 16/12/2015 https://www.nice.org.uk/Guidance/ta369
3. BNF January 2017 Ciclosporin Accessed via https://www.medicinescomplete.com/mc/bnf/current/