NHS Somerset Clinical Commissioning Group

# Patient Group Direction: For the supply of Chloramphenicol 0.5% eye drops and Chloramphenicol 1.0% eye ointment by Community Pharmacists in Somerset to patients for the treatment of acute superficial bacterial eye infections under the Somerset Minor Ailments Scheme (PGD MAS 1 Version 3.2)

**Staff involved in the development of this PGD:**

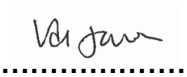
| | Name | Signature | Date |
|---|---|---|---|
| Physician | Dr Andrew Tresidder Somerset CCG Prescribing and Medicines Management Group Chair |  | 19.7.2021 |
| Pharmacist | Hels Bennett Medicines Manager, Somerset CCG |  | 15.07.2021 |

**Name of original authors: Steve DuBois, Medicines Manager, Somerset CCG and Dr Robert Baker, Consultant Microbiologist, Taunton and Somerset NHS Foundation Trust.**

**Expiry Date: 31st July 2023**

**Authorised for use across NHS Somerset CCG by:**

**Val Janson, Director of Quality and Nursing for NHS Somerset CCG (Acting as Clinical Governance Lead)**

**Signed:**  **Date:**21.07.2021.....

Date of Implementation: 1st August 2021

**TO BE COMPLETED BY PHARMACY AUTHORISING MANAGER:**

**I, ……, as authorising manager for**

**…… pharmacy, have read and approved this PGD for use by appropriate healthcare professionals employed at my pharmacy. I understand that I am responsible for ensuring that pharmacy staff have adequate training to ensure that**

**CHLORAMPHENICOL 0.5% EYE DROPS and CHLORAMPHENICOL 1.0% EYE OINTMENT**

**is supplied to patients in strict accordance with this PGD**

**Signed……..Dated……**

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**Expiry Date: 31st July 2023**

**The healthcare professionals named below are authorised to supply Chloramphenicol 0.5% eye drops and Chloramphenicol 1.0% eye ointment as specified under this Patient Group Direction, being employees of …… …… (INSERT PHARMACY NAME)**

In signing this document I confirm the following:

- I have read and understood the above mentioned PGD.
- I agree to practice only within the bounds of my own competence and in accordance with my Code of Professional Conduct.
- I have the qualifications required under the staff characteristics detailed in the PGD
- I am competent to operate under this PGD.
- I agree to administer/supply the above preparations in accordance with this PGD

| NAME *(please print)* | TITLE | SIGNATURE | AUTHORISING MANAGER *(please print)* | MANAGER'S SIGNATURE | DATE |
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- **Complete additional pages as necessary.**
- **Retain original signed pages (1) and (2) with authorising manager.**

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**N.B. You must be authorised by name, under the current version of this PGD before you attempt to work in accordance with it.**

## 1. Clinical Condition

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| **Definition of condition/situation** | • The treatment of acute superficial bacterial eye infections including conjunctivitis, blepharitis, or stye. |
| **Criteria for inclusion** | Adults and children aged one month and older where all the following criteria are met:<br>• Valid consent from patient or person with parental responsibility has been obtained. Consider the ethical and legal implications if the biological parent or the child representative is known or suspected to have no parental responsibility for the child;<br>• Patient is registered with a General Practitioner (GP) in the United Kingdom and gives permission to share relevant information with other healthcare professionals and agencies;<br>• Individuals exhibiting one or more of the following symptoms characteristic of superficial bacterial eye infections:<br>  ○ Diffuse conjunctival infection; usually progressing from unilateral to bilateral symptoms<br>  ○ Purulent discharge;<br>  ○ Discomfort (e.g. burning or gritty sensation);<br>  ○ Minimal pruritis;<br>  ○ Mild photophobia;<br>  ○ Eye-lid inflammation (blepharitis);<br>  ○ Infected meibomian cyst (chalazion);<br>  ○ Stye;<br>  ○ History of close contact with another individual with a bacterial eye infection.<br>• Symptoms have been present for two weeks or less;<br>• Treatment of acute superficial bacterial eye infection(s) is required.<br>• Pharmacists should advise patients of self-care options before supplying chloramphenicol. |

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| **Exclusion criteria** | • Baby aged less than one month;<br>• Known or suspected gonococcal conjunctivitis, viral conjunctivitis, fungal conjunctivitis, corneal ulcer, or keratitis (refer to relevant specialist);<br>• Known or suspected ophthalmia neonatorium (gonococcal/ chlamydial conjunctivitis in first three months of life - urgently refer);<br>• Known or suspected endophthalmitis (medical emergency: urgently refer to an appropriate specialist);<br>• Known or suspected trachoma (chronic infection with *Chlamydia trachomatis*);<br>• Known, or suspected, shingles - *Herpes zoster* infection - urgently refer;<br>• Severe or recurrent superficial bacterial eye infections;<br>• Visual disturbances (except those due to purulent discharge) e.g. reduced visual acuity (blurred vision) with, or without, red eye (urgently refer);<br>• Moderate or severe photophobia (urgently refer);<br>• Eye pain from within the eye ball (urgently refer);<br>• Abnormal pupils (urgently refer);<br>• The eye looks cloudy (urgently refer);<br>• Foreign body (urgently refer);<br>• Severe inflammation (urgently refer)<br>• Eye inflammation associated with a rash on the scalp or face (urgently refer);<br>• Eye or laser surgery within the last 6 months (urgently refer);<br>• Concurrent myelotoxic drug therapy;<br>• Previous use of chloramphenicol for prolonged periods (may increase the likelihood of sensitisation and resistance);<br>• Known hypersensitivity to chloramphenical or any component of chloramphenicol 0.5% eye drops or 1% eye ointment<br>• Myelosuppression during previous exposure to chloramphenicol.<br>• Known personal or family history of blood dyscrasias including aplastic anaemia.<br><br>For full details see SPC, link in references |
| **Caution** | • If patient is taking any other medications consult the British National Formulary (BNF) Appendix 1 for any potential interactions<br>• Pregnancy;<br>• Lactation/breast feeding;<br>• Eye drops should be used in preference to ointment if other eye drops are being used concurrently (e.g. for glaucoma). |
| **Action if excluded** | • Document reason for exclusion and any action taken or advice given in the clinical records<br>• Refer to GP or, for urgent medical attention, as appropriate. |
| **Action if patient refuses medication** | • Refer to GP or for urgent medical attention, as appropriate |

## 2. Characteristics of Staff

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| **Professional qualification to be held by staff working under this Patient Group Direction** | Pharmacist registered with the General Pharmaceutical Council (GPhC) and competent to work with this patient group direction (PGD), including familiarity with NICE guidance on PGDs (see references). |
| **Additional requirements** | • Must have completed initial training and/or be familiar with the current service level agreement for Somerset Minor Ailments Service.<br>• Must only use this PGD in conjunction with the Somerset Minor Ailments Service.<br>• Must have access to a current copy of the BNF<br>• Consultation room available for discussion<br>• The individual pharmacist's competence with respect to their practice under this PGD will be assessed by their mentor/manager on a regular basis.<br>• It is the responsibility of the pharmacist to keep up-to-date with their continued professional development, in line with GPhC requirements;<br>• The pharmacist must be alert to changes in Summaries of Product Characteristics, and Drug Safety Updates from MHRA. |

## 3. Description of Treatment

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| **Name of Medicine** | • Chloramphenicol 0•5%w/v eye-drops;<br>• Chloramphenicol 1•0%w/w eye ointment. |
| **Legal Class** | POM (Prescription Only Medicine) |
| **Storage** | • The eye-drops should be stored at between 2ºC and 8 ºC.<br>• The eye ointment should be stored at room temperature (below 25 ºC); |
| **Method or route of administration** | • Topical ophthalmic |

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| **Dose to be used (including criteria for use of differing doses)** | • *If eye drops are used alone*: Initially apply **one drop every two hours** whilst awake then reduce frequency of application to **four times a day** as infection is controlled and continue for 48 hours after infection has been eradicated; *or*<br>• *If eye ointment is used alone*: Initially apply four times a day, and as the infection clears continue applying three to four times a day, and continue for 48 hours after infection has been eradicated; *or*<br>• *If severe infection use eye-drops in conjunction with eye ointment applied once daily at night*: Initially apply **one drop** of the eye drops **every two hours,** while awake, then reduce frequency of application to **three times a day,** continuing to apply the eye ointment at night, as infection is controlled and continue for 48 hours after infection has been eradicated. |
| **Frequency** | • Maximum of seven days treatment.<br>• If symptoms do not start to resolve within three to four days of initiating treatment, the patient should seek further medical advice. |
| **Total dose and number of times drug to be given. Details of supply (if supply made)** | • One 10ml bottle of chloramphenicol 0·5%$^{w}/_{v}$ eye-drops; *or*<br>• One 4g tube of chloramphenicol 1·0%$^{w}/_{w}$ eye ointment; *or*<br>• One 10ml bottle of chloramphenicol 0·5%$^{w}/_{v}$ eye-drops and one 4g tube of chloramphenicol 1·0%$^{w}/_{w}$ eye ointment in severe infections<br>Any further supply is outside the scope of this PGD and must be supplied by patient-specific direction (i.e. an NHS FP10 prescription) from an appropriate prescriber.<br>• **Use of chloramphenicol 1% eye ointment and 0.5% eye drops in children under 2 years is 'off-licence' but is authorised for use within this PGD.**<br>• **All Prescription Only Medicines (POMs) must be labelled in accordance with the *Medicines Act 1968* as amended**<br>• Dispensing considerations:<br>  ○ 'Pharmacy-Only' packs of chloramphenicol eye-drops or ointment are not licensed for use for more than five days, or in children less than two years therefore cannot be supplied under this PGD.<br>  ○ Take care to select the correct formulation of chloramphenicol drops i.e. not to be confused with ear drops. |

**Advice and information to patient/carer including follow-up**

- Advise patient on self-management strategies for superficial eye-infections:
  - Infective conjunctivitis is a self-limiting illness that usually settles without treatment within one to two weeks;
  - Remove contact lenses until all symptoms and signs of infection have completely resolved, and any treatment has been completed for 24 hours;
  - Advise patient to urgently seek medical attention if they develop marked eye pain or photophobia, loss of visual acuity or marked redness of the eye.
  - Lubricant eye drops may reduce eye discomfort; these are available over the counter;
  - Clean away infected secretions from eyelids and lashes with cotton wool soaked in water;
  - Wash hands regularly, particularly after touching infected secretions, and avoid sharing pillows and towels.
- If the patient uses other eye-drops/eye ointments:
  - In the case of eye-drops, wait at least 10 minutes after use before administering chloramphenicol;
  - In the case of eye ointments, wait as long as possible before administering chloramphenicol;
- Application of the eye-drops and/or eye ointment may temporarily blur the patient's vision. Individuals should not drive or operate machinery until their vision is clear;
- Advise the patient on the importance of regular application and course completion (i.e. continue treatment for 48 hours after infection has cleared up to a maximum of seven days treatment);
- Inform of the main possible side-effects and their management (see SPC, current BNF and "Adverse reactions" section below);
- Advice the patient or carer of person to read the Patient Information Leaflet (PIL) before using the medicine and that the pharmacy can be contacted if any queries arise (any written PIL not produced by the manufacturer must not to be confused with the *manufacturer's* PIL for legal and consent purposes);
- Transient stinging, burning, blurring of vision or irritation may occur after application of eye-drops or eye ointment;
- The chloramphenicol 0·5%$^{w}/_{v}$ eye-drops or chloramphenicol 1·0%$^{w}/_{w}$ eye ointment supplied is for use of the patient only. It must not be shared with anyone else;
- Patients must dispose of topical ophthalmic preparations containers 28 days after opening even if they are not empty;
- All medicines should be disposed of in an appropriate manner i.e. unwanted and out of date medicines should be returned to a pharmacy for appropriate disposal.

**Adverse effects:** Any serious adverse reaction should be documented e.g. in the consent forms, patient's medical record and the GP should also be informed. Unusual /persistent side effects should be followed up with a medical practitioner.

Any **serious** adverse events that may be attributable to chloramphenicol eye drops or ointment should be reported to the MHRA using the yellow card system (https://yellowcard.mhra.gov.uk/) and also follow the local incident reporting procedure.

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| | See the Summary of Product Characteristics (SPC) (http://www.medicines.org.uk/emc/) and the current edition of the BNF for full details and updates. |

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| **Specify method of recording supply /administration including audit trail** | It is a legal requirement to keep auditable records of administration and supply of medication via a PGD.<br><br>Information entered into a patient clinical record should include:<br><br>• Patient's name, address and date of birth<br>• Consent given<br>• Indication<br>• Name strength form and pack size of medication supplied<br>• Date supplied<br>• Information and advice given to the patient.<br>• Signature/name and GPhC number of pharmacist who supplied the medication, and name and address of pharmacy<br>• Details of any drug interactions experienced<br>• Details of any adverse reactions experienced<br>• Any patient decline or reason for exclusion<br>• Record that medicine supplied via Patient Group Direction<br><br>The GP practice should be informed of the consultation and supply of medication.<br><br>A computer or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes within each pharmacy. Check with employer which method of recording is to be used.<br><br>Data must be stored in accordance with Caldicott guidance and the Data Protection Act. |

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| **References used in the development of this PGD**: | • BNF SPC References for chloramphenicol 0.5% eye drops and 1% eye ointment. Latest versions on electronic Medicines Compendium accessed 30/03/2021 www.medicines.org.uk<br>• Current edition of British National Formulary (BNF)<br>• General Pharmaceutical Council standards<br>• 'National Institute for Health and Care Excellence. Medicines Practice Guidelines, 'Patient Group Directions' last updated March 2017. https://www.nice.org.uk/Guidance/MPG2<br>• NHS Choices http://www.nhs.uk/conditions/conjunctivitis-infective/pages/introduction.aspx<br>• MHRA Drug Safety Update Volume 14 Issue 12 July 2021 https://www.gov.uk/drug-safety-update/chloramphenicol-eye-drops-containing-borax-or-boric-acid-buffers-use-in-children-younger-than-2-years |

**Please refer to the summary of product characteristics for full information**

**This Patient Group Direction is operational from 1st August 2021 and expires 31st July 2023**

## Version History

| Version | Date | Brief Summary of Change | Owner's Name |
|---|---|---|---|
| 0.0 | 19/6/2017 | **NHSE PGD from Sue Mulvenna reviewed and put into CCG Format** | Catherine Henley |
| 1.0 | 21/6/2017 | **Reviewed by Somerset CCG Prescribing and Medicines Management Group** | Catherine Henley |
| 2.0 | 3/5/2019 | **PGD reviewed and amended with current references** | Catherine Henley |
| 2.1 | 8/5/2019 | **Reviewed and approved by Somerset CCG Prescribing and Medicines Management Group** | Catherine Henley |
| 3.0 | 30/03/2021 | **PGD reviewed & updated due to change in chloramphenicol 0.5% eye drops SPC (contraindicated in under 2yr olds). CCG logo updated.** | Hels Bennett |
| 3.1 | 31/03/2021 | **Updated that 'off-licence' use of chloramphenicol 1% eye ointment in under 2yr olds is authorised under PGD.** | Hels Bennett |
| 3.2 | 12/07/2021 | **Updated following MHRA Drug Safety Update stating that chloramphenicol 0.5% eye drops containing borax or boric acid can be safely administered to children under 2 years old where antibiotic eye drop treatment is indicated.**<br>**Approved by Somerset CCG Prescribing & Medicines Management Group** | Hels Bennett |