NHS
Somerset
Integrated Care Board

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 4.0)

Staff involved in the development of this PGD:

	Name	Signature	Date
Physician	Dr Andrew Tresidder NHS Somerset Medicines Programme Board Chair	Andrew Tresidder	21.06.2023
Pharmacist	Hels Bennett Medicines Manager, NHS Somerset ICB	H.M. Bennett	21.06.2023

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

Authorised for use across NHS Somerset ICB by:

Shelagh Meldrum, Chief Nursing Officer for NHS Somerset ICB (Acting as Clinical Governance Lead)

Signed: Shelagh meldrum **Date:** 21 June 2023

Date of Implementation: 1st August 2023
Expiry Date: 31st July 2025

TO BE COMPLETED BY PHARMACY AUTHORISING MANAGER:

I, ……, as authorising manager for …… pharmacy, have read and approved this PGD for use by appropriate registered pharmacists working 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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The registered pharmacists named below are authorised to supply Chloramphenicol 0.5% eye drops and Chloramphenicol 1.0% eye ointment as specified under this Patient Group Direction, while working at: …… …… (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 will provide the service in accordance with this PGD

NAME *(please print)*	TITLE	SIGNATURE	AUTHORISING MANAGER *(please print)*	MANAGER'S SIGNATURE	DATE

- **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

Definition of condition/situation	• The treatment of acute superficial bacterial eye infections: conjunctivitis or blepharitis.
Criteria for inclusion	**Adults and children aged one month and older** where all the following criteria are met: • Valid informed consent • Patient is registered with a GP in the United Kingdom and gives permission to share relevant information with the GP and other healthcare professionals and agencies; • Individuals exhibiting one or more of the following symptoms: **Acute bacterial conjunctivitis:** - **Where symptoms have been present for less than 2 weeks** - Yellow purulent discharge and/or eyelid(s) stuck together in the morning - Swelling of the eyelid(s) - Irritated, itchy, red or watery eye(s) and/or burning or gritty sensation in eye(s) **Blepharitis:** - **Where no improvement despite optimal non-pharmacological treatment i.e. lid hygiene** - Sore eyelids - Itchy eyes - Gritty sensation in the eyes - Flakes or crusts around the roots of the eyelashes - Eyelids stuck together in the morning • Treatment of acute superficial bacterial eye infection(s) is required. • Pharmacists should advise patients of self-care options before supplying chloramphenicol. ****Off-label use**** **Use of chloramphenicol 1% eye ointment and 0.5% eye drops in children under 2 years is 'off-label' but is authorised for use within this PGD.** MHRA Drug Safety Update - 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.

Exclusion criteria	- Valid informed consent not obtained - Baby aged less than one month - Likely viral infection - Known hypersensitivity to chloramphenicol or any component of chloramphenicol 0.5% eye drops or 1% eye ointment - Recent eye infection, including conjunctivitis - Recent use of chloramphenicol - Previous use of chloramphenicol for prolonged periods (may increase the likelihood of sensitisation and/or resistance) - Recurrent or chronic superficial bacterial eye infections - Myelosuppression during previous exposure to chloramphenicol. - Known personal or family history of blood dyscrasias including aplastic anaemia - Concurrent myelotoxic drug therapy e.g. azathioprine, chemotherapy - Glaucoma - Severe dry eye syndrome - Blepharitis with only one eye affected, eyelids not the same shape, loss of eyelashes, difficulty closing eyelids, sudden onset of symptoms, severe symptoms or diagnosis uncertain - **Urgently refer** if: - Signs of symptoms which could indicate severe/life-threatening infection or sepsis e.g. lethargy, fever, chills, rigors, confusion, cyanosis of skin, lips or tongue, vomiting – **urgently refer to A&E – THINK SEPSIS** - Eye pain from within the eye ball - Painful eye movements - Marked redness of eye(s) - Orbital/peri-orbital cellulitis - Known or suspected endophthalmitis (swelling of internal eye tissue) - Photophobia - always consider serious systemic conditions such as meningitis in a person presenting with photophobia. - History of trauma (mechanical, chemical or ultraviolet) or possible foreign body. - Head injury - Severe headache - Known or suspected herpes infection. - Known or suspected gonococcal or chlamydial infection - Known or suspected fungal infection - Corneal ulcer or keratitis - Known or suspected corneal involvement associated with soft contact lens use - Visual disturbances (except those due to purulent discharge) e.g. reduced visual acuity (blurred vision) with, or without, red eye - Known or suspected ophthalmia neonatorium (conjunctivitis within first 30 days of life) - Eye looks cloudy - Abnormal pupil(s) - Severe inflammation - Eye inflammation associated with a rash on the scalp or face - Eye surgery or laser treatment within the last 6 months - Conjunctivitis associated with a severe systemic condition such as rheumatoid arthritis or immunocompromised. - Known or suspected conjunctivitis due to Molluscum contagiosum

	- Known or suspected trachoma (chronic infection with *Chlamydia trachomatis*) - Severe bacterial eye infection - Contact lenses have been worn in the shower, or the eye with the contact lens has come into possible contact with water
Caution	• Consider drug interactions - refer to BNF and SPC for full details • Pregnancy • Breast feeding – refer to the Specialist Pharmacy Service for guidance Using chloramphenicol during breastfeeding – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice • Bacterial conjunctivitis in infants, particularly premature infants, can often lead to secondary infections such as otitis media or the more serious meningitis or septicaemia. • **Contact lens wearers:** The person should seek advice from an optician, optometrist or doctor before using chloramphenicol. If a practitioner recommends chloramphenicol, the person should be advised: - Not to wear contact lenses until all the signs and symptoms of conjunctivitis have gone - Not to wear contact lenses during, or for at least 24 hours after chloramphenicol use - Reusing old contact lenses can cause re-infection, so re-using lenses is not recommended even after symptoms have resolved - To replace contact lens containers, as continued use can lead to re-infection See also urgent referral in exclusion criteria
Action if excluded	• Document reason for exclusion and any action taken or advice given in the clinical records • Provide advice on alternative non-antibiotic treatment and safety netting advice. • Refer to optician, GP or for urgent medical attention via A&E, as appropriate. • **If sepsis or life-threatening illness is suspected – urgently refer to A&E**
Action if patient refuses medication	• Document on clinical record and refer to optician, GP or for urgent medical attention via A&E as appropriate • Provide advice on alternative non-antibiotic treatment and safety netting advice.

2. Characteristics of Staff

Professional qualification to be held by staff working under this Patient Group Direction	Pharmacist currently registered with the General Pharmaceutical Council (GPhC)
Additional requirements	• Must have undertaken appropriate education and training and declared themselves competent to undertake clinical assessment of patient leading to diagnosis of the condition(s) listed in this PGD. • Must have undertaken appropriate education and training and declared themselves competent for the identification of sepsis. • Must be familiar with NICE guidance on PGDs and competent in the use of PGDs (see NICE competency framework for health professionals using PGDs). Suggested recommended training - eLfH PGD elearning programme • Must have access to the PGD and associated online resources relating to the use of the PGD • Must have access to current BNF (BNF online is recommended) • Consultation room available for discussion • CPPE level 2 Safeguarding children and vulnerable adults (including updates), or equivalent • Must have completed initial training and/or be familiar with the current service level agreement for Somerset Minor Ailments Service. • Must only use this PGD in conjunction with the Somerset Minor Ailments Service. • Individuals operating under this PGD must be assessed as competent or complete a self-declaration of competence to operate under this PGD • Staff operating under this PGD should review their competency using the NICE Competency Framework for health professionals using patient group directions • It is the responsibility of the pharmacist to keep up-to-date with their continued professional development, in line with GPhC requirements; • The pharmacist must be alert to changes in Summaries of Product Characteristics, and Drug Safety Updates from MHRA.

3. Description of Treatment

Name of Medicine	• Chloramphenicol 0.5% w/v eye drops • Chloramphenicol 1.0% w/w eye ointment
Legal Class	POM (Prescription Only Medicine)
Storage	• The eye drops should be stored at between 2ºC and 8ºC. • The eye ointment should be stored at room temperature (below 25ºC);
Method or route of administration	• Topical ophthalmic
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* • *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* • *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. • If symptoms do not start to improve within 48 hours of starting 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* • One 4g tube of chloramphenicol 1.0% w/w eye ointment; *or* • 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 infection 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. • **All Prescription Only Medicines (POMs) must be labelled in accordance with the *Medicines Act 1968* as amended** • Dispensing considerations: - '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. - 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	• Ensure that the Patient Information Leaflet (PIL) is provided and advise the patient to read the leaflet before using the medicine • Advise that the pharmacy can be contact if any queries arise • Advise on the correct administration of eye drops and/or ointment – wash hands before use, do not touch eye or lashes with the tip of the bottle/tube to avoid contamination. • 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 - 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 boiled & cooled water (1 piece for each eye) - Wash hands regularly, particularly after touching infected secretions, and avoid sharing pillows and towels - Contact lens wearers should remove contact lenses until all symptoms and signs of infection have completely resolved, and any treatment has been completed for 24 hours - Blepharitis: It is important to highlight to patients that this is a chronic condition and therefore ongoing non-pharmacological treatment will be needed to keep it well controlled. Refer to: Blepharitis - NHS (www.nhs.uk) • Advise patient to seek medical advice if symptoms do not start to improve within 48 hours or if symptoms worsen at any time. • Advise patient to urgently seek medical attention if they develop marked eye pain or photophobia, loss of visual acuity or marked redness or swelling of the eye – see also Exclusion criteria 'Urgently refer'. • 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 • 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: - Blurred vision (which is temporary after using the eye product) – patients should be warned not to drive or operate machinery unless their vision is clear - Transient stinging, irritation or burning sensations - Hypersensitivity reactions, including angioneurotic oedema, anaphylaxis, fever, urticarial and vesicular dermatitis - if a reaction occurs stop treatment and seek medical advice - Rarely, bone marrow hypoplasia, including fatal aplastic anaemia

A detailed list of adverse reactions is available in the SPC www.medicines.org.uk and BNF www.bnf.org

- The chloramphenicol 0.5%w/v eye drops and/or 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: 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.

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.

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. All records should be clear, legible and contemporaneous. All records should be kept in line with national guidance. This includes individual data, master copies of the PGD and lists of authorised practitioners. Information entered into a patient clinical record should include: • Patient's name, address and date of birth • Consent given • Indication • Specify how the individual has/has not met the criteria of the PGD • Name strength form and pack size of medication supplied • Date & time of supply • Relevant past and present medical history • Information and advice given to the patient. • Signature/name and GPhC number of pharmacist who supplied the medication, and name and address of pharmacy • Details of any drug interactions experienced • Details of any adverse reactions experienced • Any patient decline or reason for exclusion • Any referral arrangements (including self-care) • Record that medicine supplied via Patient Group Direction • Recording of any prescription charges / exemptions • Consultation details to be recorded on PharmOutcomes (ideally at time of consultation but must be within 48 hours) The GP practice should be informed of the consultation and supply of medication (this will be done automatically via PharmOutcomes). 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. Data must be stored in accordance with Caldicott guidance and the Data Protection Act.

References used in the development of this PGD:	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • General Pharmaceutical Council standards • 'National Institute for Health and Care Excellence. Medicines Practice Guidelines, 'Patient Group Directions' last updated March 2017. https://www.nice.org.uk/Guidance/MPG2 • NHS Choices http://www.nhs.uk/conditions/conjunctivitis-infective/pages/introduction.aspx • 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 • NICE CKS Conjunctivitis – infective: Last revised Oct 2022 https://cks.nice.org.uk/topics/conjunctivitis-infective/ • NICE CKS Red eye: Last revised May 2021 https://cks.nice.org.uk/topics/red-eye/diagnosis/diagnosis/ • Pregnancy, breastfeeding and fertility while taking chloramphenicol - NHS (www.nhs.uk) • Using chloramphenicol during breastfeeding – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice • Clinical Consultation skills training from RPS & RCGP (rpharms.com) • Chloramphenicol (P medicine) | RPS (rpharms.com) • NICE CKS Blepharitis: Last updated April 2023 https://cks.nice.org.uk/topics/blepharitis/

Please refer to the summary of product characteristics for full information

This Patient Group Direction is operational from 1st August 2023 and expires 31st July 2025

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. Approved by Somerset CCG Prescribing & Medicines Management Group**	Hels Bennett
4.0	02.06.2023	**PGD reviewed and updated and put into ICB format. Inclusion criteria updated. Exclusion criteria updated to include patients with glaucoma & severe dry eye syndrome. Cautions & exclusions added for contact lens wearers Safety netting advice updated. Reviewed & approved by NHS Somerset Medicines Programme Board.**	Hels Bennett Medicines Manager, NHS Somerset ICB