PATIENT GROUP DIRECTION (PGD)

Supply/Administration of chloramphenicol
For the treatment of severe bacterial conjunctivitis

Documentation details

Reference no:	Comm Pharm Chloramphenicol PGD
Version no:	V1.4
Valid from:	December 2024
Review date:	December 2025
Expiry date:	December 2026

Change history

Version number	Change details	Date
1.0	Adapted from the BCH UCC Chloramphenicol PGD	November 2019
1.1	Removal of Chloramphenicol drops	April 2021
1.2	Written by BNSSG CCG, adapted for BSW and checked by Marco Yeung and Paul Clarke	December 2021
1.3	Removed OTC chloramphenicol as an option if patient or career declines treatment. Fixed how to give eye drops link.	January 2022
1.4	Reviewed, with minor typographical updates by Emma Shah	November 2024

Glossary

Abbreviation	Definition

1. PGD template development

Developed by:	Name	Signature	Date
Pharmacist	Michelle Jones, Senior Medicines Optimisation Pharmacist, BNSSG CCG		10.02.2020
Doctor	Dr Shaba Nabi, GP Prescribing lead, BNSSG CCG		13.02.2020
Registered Professional representing users of the PGD	Helen Wilkinson, Principal Medicines Optimisation Pharmacist, BNSSG CCG		12.02.2020

PGD Working Group Membership

Name	Designation
Helen Wilkinson	Principal Medicines Optimisation Pharmacist, BNSSG CCG
Elizabeth Jonas	Senior Medicines Optimisation Pharmacist , BNSSG CCG
Michelle Jones	Senior Medicines Optimisation Pharmacist , BNSSG CCG
Judith Poulton	Pharmacist, Avon Local Pharmaceutical Committee
Dr Shaba Nabi	GP Prescribing Lead, BNSSG CCG
Richard Brown	Pharmacist, Avon Local Pharmaceutical Committee

2. Organisational authorisations *(may require amendment depending on how the service using the PGD is being commissioned/the organisation who is responsible for authorising the PGD – not all fields may be applicable)*

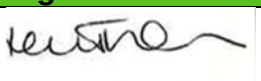
The PGD is not legally valid until it has had the relevant organisational authorisation.

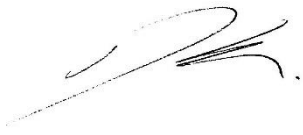
It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

Bath and North East Somerset, Swindon and Wiltshire ICB authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
Community Pharmacies contracted to provide the BSW ICB Community Pharmacy PGD Service for Minor Ailments
Limitations to authorisation
None

Organisational approval (legal requirement)			
Senior Doctor			
Role	**Name**	**Sign**	**Date**
Deputy Chief Medical Officer, BSW ICB	Dr Barry Coakley		**03/12/24**

Senior Pharmacist			
Role	**Name**	**Sign**	**Date**
Community Pharmacy Clinical Lead, BSW ICB	Helen Wilkinson		**03/12/24**

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Director (Medicines Optimisation), BSW CCG	Nadine Fox		**04/12/24**

Local enquiries regarding the use of this PGD may be directed to bswccg.prescribing@nhs.net
Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD. Alternative authorisation sheets/templates may be used where appropriate in accordance with local policy.

3. Characteristics of staff

Qualifications and professional registration	• Pharmacists registered with the General Pharmaceutical Council (GPhC)
Initial training	• must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it • Has undertaken appropriate training and declared themselves assessed competent to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this PGD • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using patient group directions) • must have access to the Patient Group Direction and associated online resource • should fulfil any additional requirements defined by local policy ***The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate training and successfully completed the declaration of competence to undertake clinical assessment of patient leading to diagnosis of the conditions listed.***
Competency assessment	*Complete the self-declaration for this PGD on PharmOutcomes* *Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions* ***Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.***
Ongoing training and competency	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to this PGD and should be aware of any change to the recommendations for the medicines listed. It is the responsibility of the individual to keep up-to-date with Continued Professional Development (CPD).
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	**Severe Bacterial conjunctivitis**
Criteria for inclusion	• Children over 30 days of age and under 24 months • Valid informed consent from parent/guardian • Infective bacterial conjunctivitis that is severe, or likely to become severe. Main signs are purulent, sticky discharge with red eye. • It would seem reasonable to consider infective conjunctivitis to be severe, when the person considers the symptoms to be distressing or signs are judged to be severe from clinical experience.

Criteria for exclusion	• No valid informed consent
	• Infants in the first 30 days of life
	• Children 24 months old and over and adults (OTC sale may be considered)
	• Likely viral infection, cough, cold, runny nose, bilateral red eyes.
	• **Red flags** which indicate the need for urgent ophthalmological assessment include:
	  ○ Signs of sepsis e.g. persistent high temperature, irritability, drinking less than 50% of usual, lethargy
	  ○ Severe eye pain, headache or 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.
	  ○ Copious rapidly progressive discharge — may indicate gonococcal infection.
	  ○ Infection with a herpes virus.
	  ○ Soft contact lens use with corneal symptoms – photophobia and watering.
	  ○ Reduced visual acuity.
	• People with a personal or family history of blood dyscrasias, including aplastic anaemia
	• Known hypersensitivity to chloramphenicol or excipients
	• Patients who have experienced bone marrow suppression during previous exposure to chloramphenicol.
	• Patients taking bone marrow depressant drugs such as azathioprine or receiving chemotherapy
	• When chloramphenicol treatment has already been used and there is suspicion that the infection is caused by a non-susceptible organism to chloramphenicol (e.g. fungal or viral infection)
	• Eye surgery or laser treatment in the last 6 months
	• The eye looks cloudy
	• The pupil looks unusual
	• People with persistent fever (5 days or longer consider Kawasaki disease)
	• Glaucoma
	• Dry eye syndrome

Cautions including any relevant action to be taken	• First line for treatment of conjunctivitis: bath/clean eyelids with cotton wool dipped in sterile saline or boiled (cooled) water to remove crusting. • Only treat if severe as most viral or self-limiting. • Bacterial conjunctivitis is usually unilateral and self-limiting. It is characterised by red eye with mucopurulent, not watery, discharge. • MHRA DSU July 2021 concluded that the balance between the benefits and risks of chloramphenicol eye drops containing borax or boric acid remains positive for children aged 0 to 2 years. Chloramphenicol eye drops can be safely administered to children aged 0 to 2 years where antibiotic eye drop treatment is indicated.
Action to be taken if the patient is excluded	• Record reasons for exclusion and any action(s) taken in patient notes • Document advice given and the decision reached • Advise patient on alternative treatment. This may include OTC chloramphenicol eye drops/ointment where this is indicated and appropriate • Refer to a GP/NHS 111/OOH services for urgent ophthalmological assessment if appropriate
Action to be taken if the patient or carer declines treatment	• Record reasons for decline and any action(s) taken in patient notes • Document advice given and the decision reached • Advise patient on alternative treatment • Refer to a GP or for urgent ophthalmological assessment if appropriate
Arrangements for referral for medical advice	• Contact GP or arrange referral to eye hospital if necessary • Clinical information should be sent to the patient's GP in accordance with local protocols

5. Description of treatment

Name, strength & formulation of drug	Chloramphenicol 1% eye ointment Chloramphenicol 0.5% drop 10ml
Legal category	Prescription-only medicine (POM) or Pharmacy only medicines (P)
Route / method of administration	Topical administration to the eye
Indicate any off-label use (if relevant)	Use of the 'P' eye ointment/drop in children under 2 is off label.
Dose and frequency of administration	**Chloramphenicol 1% eye ointment** Apply small amount (approximately 1cm) of ointment into the space between the lower eye lid four times a day **Chloramphenicol 0.5% eye drop** Apply ONE drop 4 times daily to the affected eye(s)
Duration of treatment	FIVE days
Quantity to be supplied	*1x chloramphenicol 1% eye ointment or 1x chloramphenicol 0.5% drop 10ml* *Increasing to 2 if bilateral*

Storage	Store ointment below 25ºC
Drug interactions	The concomitant administration of Chloramphenicol with other drugs liable to depress bone marrow function (such as azathioprine or receiving chemotherapy should be avoided. ***A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk***
Identification & management of adverse reactions	Chloramphenicol is absorbed systemically from the eye and toxicity such as bone marrow hypoplasia (e.g. idiosyncratic type of irreversible, fatal aplastic anaemia) has been reported following chronic exposure. Whilst the hazard is rare, it should be borne in mind when assessing the benefits expected from the use of the compound. Transient burning or stinging sensations may occur. More serious side effects include hypersensitivity reactions that may present as angioneurotic oedema, urticaria, anaphylaxis, fever, and vesicular and maculopapular dermatitis. If this happens treatment must be discontinued immediately. Prolonged use should be avoided as it may increase the likelihood of sensitisation and the emergence of resistant organisms. **A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk**
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: ***https://yellowcard.mhra.gov.uk*** • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report via organisation incident policy.
Written information to be given to patient or carer	Give marketing authorisation holder's patient information leaflet (PIL) provided with the product.
Patient advice / follow up treatment	**For patients where no antibiotics are indicated:** • Offer reassurance that antibiotics are not needed because they are likely to make little difference to symptoms, may have adverse effects (for example hypersensitivity), and can contribute to antibiotic resistance. • Infective conjunctivitis is a self-limiting illness that, for most people, settles without treatment within 1-2 weeks. If symptoms persist for longer than 1 week or symptoms worsen, they should re-consult for investigation of the cause. • Bath/clean eyelids with cotton wool dipped in sterile saline or boiled (cooled) water to remove crusting. • Cool compresses applied gently around the eye area. • Advise on the use of over-the-counter lubricating drops or artificial tears to reduce eye discomfort where appropriate.

	• Avoid rubbing the affected eye(s). • Wash their hands with soap and water regularly, particularly after touching infected secretions. • Avoid sharing pillows and towels to avoid spreading infection. • Advise parents that it is not necessary to exclude a child from nursery or childcare if they have infective conjunctivitis, unless there is an outbreak of infective conjunctivitis. However, some nurseries may nevertheless have an exclusion policy. **For patients where chloramphenicol is indicated:** • Explain treatment and course of action and potential side effects. • The individual/carer should be advised to seek medical advice in the event of an adverse reaction. • Advise to use at regular intervals and to complete the 5 day course (unless otherwise directed). • Advise on the correct administration of eye ointment How to give medicines: eye drops and eye ointment – Medicines For Children • Do not touch eye or lashes with the tip of the tube to avoid contamination. • Eye ointment may cause transient blurring of vision. Patients should not drive or operate hazardous machinery unless vision is clear. • Advise to store medicines out of reach of children • At the end of the treatment, take any unused medication to the nearest pharmacy for disposal. • If symptoms persist for longer than five days or symptoms worsen, they should re-consult for investigation of the cause. • Advise to urgently seek medical attention if they develop marked eye pain or photophobia, loss of visual acuity, or marked redness of the eye. • Bath/clean eyelids with cotton wool dipped in sterile saline or boiled (cooled) water to remove crusting/discharge. • Cool compresses applied gently around the eye area. • Advise on the use of over-the-counter lubricating drops or artificial tears to reduce eye discomfort. • Avoid rubbing the affected eye(s) • Wash their hands with soap and water regularly, particularly after touching infected secretions, • Avoid sharing pillows and towels to avoid spreading infection. • Advise parents that it is not necessary to exclude a child from school or childcare if they have infective conjunctivitis, unless there is an outbreak of infective conjunctivitis. However, some nursery and primary schools may nevertheless have an exclusion policy. • Safety netting – failure of treatment after 5 days see a medical practitioner and consider exclusion criteria.
Records	Record: • that valid informed consent was given • name/signature of individual, address, date of birth and GP with whom the individual is registered (if relevant) • History, examination, diagnosis • Drug history including any allergies • name of registered health professional

	• name and brand of medication supplied/administered • date and time of supply/administration • dose, form and route of supply/administration • quantity supplied/administered • batch number and expiry date (if applicable) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • supplied via Patient Group Direction (PGD) • Referral arrangements (including self-care) • Add patient name and date of supply to the pre-labelled pack before issuing. ***Records should be signed and dated (or a password controlled e-records).*** ***All records should be clear, legible and contemporaneous.*** ***A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.***

6. Key references

Key references	• Summary of product characteristics at: http://www.medicines.org.uk/emc/ • Clinical Knowledge Summaries (NICE) at: http://cks.nice.org.uk/conjunctivitis-infective • British National Formulary for Children available at: http://www.medicinescomplete.com • BSW Antimicrobial Prescribing Guidelines available online at Prescribing guidance - Medicines • NHS Choices about conjunctivitis at https://www.nhs.uk/conditions/conjunctivitis/ • MHRA Drug Safety Update On Chloramphenicol eye drops https://www.gov.uk/drug-safety-update/chloramphenicol-eye-drops-containing-borax-or-boric-acid-buffers-use-in-children-younger-than-2-years?UNLID=672501787202111291752 8

7. Registered health professional authorisation sheet

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

Registered health professional

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager (if applicable)

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of INSERT NAME OF ORGANISATION for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.