This Patient Group Direction (PGD) must only be used by registered pharmacists who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

PATIENT GROUP DIRECTION (PGD)

For use in the community pharmacy extended care service

Supply of Chloramphenicol Eye Ointment 1% and Eye Drops 0.5% in patients aged 3 months to 2 years for the treatment of Acute Bacterial Conjunctivitis in NHS England Midlands Region

Version Number 6.0 / 2023

Change History	
Version and Date	**Change details**
2.0 / 2022	Existing PGD incorporated into national template
3.0 /2022	FINAL draft following clinical review
4.0 / 2022	FINAL following system review
5.0 / 2023	Annual review
6.0 / 2023	FINAL PGD following system review

This Patient Group Direction (PGD) must only be used by registered pharmacists who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

PGD DEVELOPMENT GROUP

Date PGD comes into effect:	31st March 2023
Review date	January 2024
Expiry date:	31st March 2024

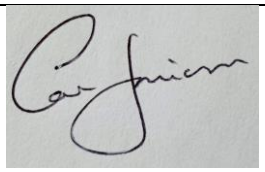
The template for this PGD has been peer reviewed by the Antimicrobial PGDs Short Life Working Group in accordance with their Terms of Reference and approved by the NHSE AMR Programme Board.

This section MUST REMAIN when a PGD is adopted by an organisation.

Name	Designation

The PGD is not legally valid until it has had the relevant organisational approval - see below.

CLINICAL AUTHORISATION OF PGD

Name	Job title and organisation	Signature	Date
Dr Jessica Sokolov	Medical Director, NHSE Midlands		14/03/2023
Richard Seal	Regional Chief Pharmacist, NHSE Midlands		10/03/2023
Andrew Pickard ***(Lead author)***	Regional Pharmacy Advisor, NHSE Midlands		09/03/2023
Dr Conor Jamieson	Regional Antimicrobial Stewardship Lead, NHSE Midlands		10/03/2023

ORGANISATIONAL AUTHORISATION OF PGD

Name	Job title and organisation	Signature	Date
Rebecca Woods	Head of Primary Care Commissioning, NHSE Midlands		**14.03.23**

1. Characteristics of staff

Qualifications and professional registration	• The community pharmacist must be registered with the General Pharmaceutical Council. • The community pharmacist must be accredited by NHS England Midlands to provide the Pharmacy Extended Care (Tier1) Service.
Training requirements	• The community pharmacist authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patient leading to diagnosis of the conditions listed in this PGD in accordance with local policy. • Undertaken appropriate training and successfully completed the competencies for the identification of sepsis • Undertaken appropriate training and successfully completed the competencies for safeguarding children • Individuals operating under this PGD should follow national guidance for diagnosis and management of acute bacterial conjunctivitis Conjunctivitis - infective | Health topics A to Z | CKS | NICE • Individuals operating under this PGD must be familiar with the product and alert to changes in the Summary of Product Characteristics (SPC) • The community pharmacist must provide the service in accordance with the requirements of the associated Service Specification – Pharmacy Extended Care (Tier1) Service
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for the recognition and management of acute bacterial conjunctivitis. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring that they remain up to date with the use of all medicines and guidance 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 (eg. superintendent pharmacist or line manager) and further training provided as required.
The decision to supply any medication rests with the individual registered pharmacist who must abide by the PGD and any associated organisational policies.	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Treatment of Acute Bacterial Conjunctivitis in patients aged 3 months to 2 years. Acute inflammation of the conjunctiva (membrane covering the white of the eye and the inside of the eyelid) of the eye that is indicative of a bacterial infection. This is characterised by irritation, itching, a sensation of grittiness in the eye, watering or sticky discharge, and/or blurred vision due to the discharge that clears with blinking.
Criteria for inclusion	Informed consent must be obtained prior to continuing with the consultation. Children aged 3 months up to 2 years where there are features indicative of a bacterial infection and symptoms have worsened within 3 days of onset, or moderate to severe infections where the parent/guardian considers the symptoms to be distressing, or they are judged to be severe from clinical experience and rapid resolution is required.
Criteria for exclusion	• Patients must be excluded if informed consent is not given. • Children under 3 months of age • Children aged 2 years and over • Mild infections and/or where onset has been less than 3 days before presentation • Users of other prescribed eye drops or ointment • Dry eye syndrome • Glaucoma • Keratitis • Iritis • Atypical symptoms of conjunctivitis • Suspected foreign body in the eye • Eye injury • Photophobia • Where vision has been affected • Severe pain within the eye / swelling around the eye / restricted eye movement • Unusual looking pupils or cloudy cornea • Eye surgery / laser treatment in the previous 6 months • Recent trip abroad • Patient feels generally unwell • Recurrent conjunctivitis (>2 episodes in previous 6 months) • Hypersensitivity to chloramphenicol or any of the components within the formulation • Pupil fixed and mid-dilated or distorted from previous attacks • Headache • Family history of blood dyscrasias • Patients who have experienced myelosuppression during previous exposure to chloramphenicol • Copious discharge that re-accumulates after being wiped

	away • Patient taking bone marrow suppressant drugs • Enlarged lymph nodes in front of the ears (associated with Chlamydia / adenoviral type) • Eye inflammation associated with a rash on the scalp or face. • Immunocompromised patients • More than two episodes of acute bacterial conjunctivitis treated under this PGD within previous 12 months.
Deferred treatment	If clinically appropriate, and the individual agrees to defer treatment, the pharmacist should determine that they could be treated under the service PGDs if they do return. If the individual then returns after waiting the appropriate amount of time, the pharmacist can then supply the medication once an appropriate follow-up assessment under the PGD is undertaken. The pharmacist making the assessment may refer to the original consultation notes, but must fully reassess the individual for suitability for treatment. The supply should be recorded in the Deferred Treatment Module within PharmOutcomes.
Cautions including any relevant action to be taken	No specific cautions for this age group, although the safety alert with regards to chloramphenicol eye drops containing borax or boric acid buffers should be taken into consideration before making a supply Chloramphenicol eye drops containing borax or boric acid buffers: use in children younger than 2 years - GOV.UK (www.gov.uk) or BNF British National Formulary - NICE for full details
Specific information for suspected infection to be provided	Acute bacterial conjunctivitis is generally a self-limiting condition that does not routinely require treatment with antibiotics with 65% resolving within 5-7 days without treatment. In all cases, the following advice should be given; - bath/clean eyelids with cotton wool dipped in sterile saline or boiled (cooled) water, to remove crusting - use one cotton wool pad per eye - wash hands thoroughly and avoid sharing towels / facecloths as eye infection is highly contagious - apply a cool compress to soothe the eye Medical advice should be sought if there is no improvement in the condition after 2 days of treatment, or if symptoms worsen at any time
Management of excluded clients	• If the patient is aged under 3 months refer to a Primary Care Clinician. • If the patient is aged 2 years or over where chloramphenicol is considered appropriate, patient/parent should be advised to purchase OTC as per the guidance below. • Do not refer to General Practice unless there is a clinical reason to do so. Contractors may consider referring the

	patient to primary eye care services if available or appropriate. - Primary Eyecare provides NHS-funded eyecare services via local opticians NHS England » Conditions for which over the counter items should not routinely be prescribed in primary care: Guidance for CCGs Record the reason for exclusion and any action taken on PharmOutcomes. Advise individual/carer on alternative non antibiotic treatment if an antibiotic is not indicated and provide safety netting advice.
Management of patients requiring referral	If patient declines treatment or advice, ensure the following details are recorded on PharmOutcomes; • The advice given by the clinician • Details of any referral made • The intended actions of the patient (including parent or guardian). Discuss potential consequences of not undertaking treatment and provide safety netting advice.

3. Description of treatment

Name, strength & formulation of drug	Chloramphenicol Eye Ointment 1% Chloramphenicol Eye Drops 0.5%
Legal category	Prescription Only Medicine (POM)
Route of administration	Topical
Off label use	Not applicable
Dose and frequency of administration	• Chloramphenicol 1% eye ointment; or • Chloramphenicol 0.5% eye drops Eye ointment - • Apply three to four times a day for 48 hours, then twice daily Eye drops - • Instil 1 drop every 2 hours then reduce frequency as infection is controlled and continue for 48 hours after healing, frequency dependent on the severity of the infection. • For less severe infection 3–4 times daily is generally sufficient.
Quantity to be supplied	Supply 1 x 4g tube of ointment for one treatment episode Or 1x 10ml bottle of eye drops for one treatment episode Maximum of two treatment courses to be supplied in any 12 month period

Duration of treatment	Continue treatment for 48 hours after symptoms have resolved up to a maximum of 7 days.
Storage	Eye Ointment - Store below 25°C or in accordance with the manufacturers Summary of Product Characteristics (SPC), which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF Eye Drops – Store between 2°C and 8°C or in accordance with the manufacturers Summary of Product Characteristics (SPC), which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF Discard within 28 days of opening
Drug interactions	Concomitant administration of chloramphenicol with other drugs liable to depress bone marrow function should be avoided. Please refer to SPC Home - electronic medicines compendium (emc) or BNF British National Formulary - NICE for full details.
Identification & management of adverse reactions	Local sensitivity reactions such as transient irritation, burning, stinging and itching may occur Blurred vision following administration of eye ointment or drops.
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse drug reactions (ADR's) to the Medicines and Healthcare products Regulatory Agency (MHRA) using the using the Yellow Card System to reporting scheme on: http://yellowcard.mhra.gov.uk • Record all ADR's in the patient's medication record. • It is considered good practice to notify the individual's GP in the event of an adverse reaction
Further advice to be supplied to individuals	• Take and read patient information leaflet. • Provide Medicines for Children leaflet - Chloramphenicol for eye infections – Medicines For Children • Advise that the risk of a serious complication from untreated infective conjunctivitis is low. **Self -care** • Bathe/clean eyelids with cotton wool dipped in sterile saline or boiled (cooled) water, to remove crusting. Use one cotton wool pad per eye • Remove contact lenses, if worn, until all symptoms and signs of infection have completely resolved, and any treatment has been completed for 24 hours. • Parents/guardians should be advised to contact their child's optometrist to get their contact lens checked.

	Treatment • Advise on correct administration of ointment or drops • Wash hands thoroughly and avoid sharing towels / facecloths as eye infection is highly contagious • Course of treatment is for 48 hours after symptom resolution up to a maximum of 7 days. • Medical advice should be sought if there is no improvement in the condition after 2 days of treatment, or if symptoms worsen at any time. • Patients may experience a transient burning or stinging sensation with treatment • Hypersensitivity reactions possible though rare • A cold compress may soothe the eye • Store the eye drops in a refrigerator • Discard product after completing the course FOLLOW UP – Individuals must be contacted within 7 days of the initial consultation to ascertain success of treatment, and arrange referral to an appropriate clinician if symptoms have not resolved, and the individual has not already sought additional advice. Please refer to SPC Home - electronic medicines compendium (emc) or BNF British National Formulary - NICE for full details. If patient experiences severe side effects, discontinue treatment immediately and refer to Primary Care Clinician
Records	In discussion with the parent/guardian enter consultation details onto the relevant module within PharmOutcomes. All consultations must be entered onto PharmOutcomes on the day that the consultation takes place. The record itself must include the following: - that valid informed consent was given where applicable - name of individual, address, date of birth and GP with whom the individual is registered (if relevant) - any known medication allergies - name of registered health professional operating under the PGD - name of medication supplied - batch number and expiry date - date of supply - dose, form and route of administration - quantity supplied

	- advice given, including advice given if excluded or declines treatment - details of any adverse drug reactions and actions taken - administered via Patient Group Direction (PGD) • Details of the supply must also be made in the patients (PMR) record. • All supplies of chloramphenicol ointment or drops must be labelled in accordance with the labelling requirements for a dispensed medicine as stated within Schedule 5 of The Medicines (Marketing Authorisations etc) Regulations 1994. No 3144 as amended. In addition to the above, the label must also state the words "Supplied under a PGD" to help with audit purposes. • Electronic patient records should be retained until the child is 25 years old. • If the client is excluded, a record of the reason for exclusion must be documented within PharmOutcomes, and any specific advice that has been given. • In every case when a supply of chloramphenicol eye ointment or drops is made in accordance with this PGD, the Pharmacist must inform the patient's GP of the supply within two working days. This will be done through secure nhs.net email accounts via PharmOutcomes once the consultation data has been recorded within the specified module. On the occasions where no nhs.net account is available to PharmOutcomes, the Pharmacist will be informed by the system and must make alternative arrangements to send the information (within two working days).

4. Key references

Key references	Children's BNF – Current Version BNFC (British National Formulary for Children) | NICE Clinical knowledge summaries – Conjunctivitis (infective) 2022 https://cks.nice.org.uk/conjunctivitis-infective Home - electronic medicines compendium (emc) NICE ANTIMICROBIAL SUMMARY GUIDANCE for conjunctivitis https://www.bnf.org/news/2021/07/29/bnf-hosts-antimicrobial-summary-guidance-on-behalf-of-nice-and-phe/ Principles of Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use https://www.nice.org.uk/guidance/ng15

Appendix A - Registered pharmacist authorisation sheet

Supply of Chloramphenicol Eye Ointment 1% and Eye Drops 0.5% in patients aged 3 months to 2 years for the treatment of Acute Bacterial Conjunctivitis.

Version: 6.0/2023 Valid from: 31st March 2023 Expiry: 31st March 2024

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

Registered pharmacist

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

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 pharmacists 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 pharmacists to prevent additions post managerial authorisation.

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

Add details on how this information is to be retained according to organisation PGD policy.