GIG CYMRU NHS WALES
Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Patient Group Direction (PGD) must only be used by registered Nurses 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. Health professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version.

Patient Group Direction

for the supply and/or administration of

Chloramphenicol 1% Eye Ointment and / or 0.5% Eye Drops

by registered nurses to

Adults and Children aged over 2 years

for the treatment of bacterial conjunctivitis or to provide antibiotic prophylaxis following the removal of surface corneal foreign bodies

in Powys Teaching Health Board Minor Injury Units

Version number: PGD0035F

Reference Number: PGD0035F
Valid from: 24/07/2024
Review date: 24/07/2026
Expiry date: 23/07/2027

Change history

Version number	Change details	Date
PGD0035	Initial issue- not made operational	01/06/2008
PGD0035A	Review issue, change of clinical situation- foreign bodies only	01/04/2011
PGD0035B	Not made operational	
PGD0035C	Review and re-issue	30/09/2018
PGD0035D	Review and re-issue in new PTHB PGD template	16/12/2019
PGD0035E	Review and re-issue, in line with updated Powys template. Removal of references to Fusidic acid and tetracaine eyedrop PGDs, which are no longer in existence. PGD title amended to include the indication. Updated off-label information and dosage information.	21/10/2022
PGD0035F	Review in line with updated PTHB PGD template and changes to Appendix A. Changes to dosage/frequency/treatment period in line with NICE CKS and/or All Wales Medicines Strategy Group Primary Care Antimicrobial Guidelines and local microbiologist advice. Age of PGD changed to include individuals aged over 2 years. Chloramphenicol eye drops no longer to be used for prophylaxis following removal of foreign bodies	24/07/2024

PGD authorisation

Name	Job title and organisation	Signature	Date
Senior Doctor **Dr Richard Stratton**	Lead doctor for PTHB	DocuSigned by: A4AB87B5EE40479...	7/17/2024
Chief Pharmacist **Jacqui Seaton**	Chief Pharmacist for PTHB	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	7/17/2024
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB- Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	7/17/2024
Senior Representative of Professional Group using the PGD **Marie Davies**	Deputy Director of Nursing for PTHB	DocuSigned by: 3B113D283631403...	7/17/2024

Appendix A provides a staff accreditation sheet. Individual practitioners must be authorised by name to work to this PGD.

Those using this PGD must ensure that it is organisationally authorised and signed by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

The final authorised copy of this PGD should be kept by PTHB for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 25 years after the PGD expires.

[1] This includes any relevant amendments to legislation

Training and competence of registered health professionals	Requirements of registered health professionals working under the PGD
Qualifications and professional registration	Practitioners must only work under this PGD where they are competent to do so. Practitioners working under this PGD must also be a registered professional with the following body: • nurses currently registered with the Nursing and Midwifery Council (NMC) The NMC registered nurse should have a current contract of employment with Powys Teaching Health Board. The practitioners must also fulfil the training and additional requirements detailed below. Check *Appendix A – Staff accredited to use the Patient Group Direction* to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Initial training	• The administration/supply of chloramphenicol and knowledge of its uses, contraindications and adverse effects. Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it • 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 completed Patient Group Directions training available via ESR at https://my.esr.nhs.uk or eLearning for Healthcare (e-LfH) at http://www.e-lfh.org.uk/programmes/patient-group-directions/ • must be familiar with the product(s) and alert to changes in the BNF and Summary of Product Characteristics • must have undertaken training appropriate to this PGD as required by local policy including current guidelines for the management of eye injuries

	• must have received training and be competent in the recognition, management of, and reporting of recognised adverse reactions, including anaphylaxis. Must be competent in the administration of adrenaline and have up to date Intermediate Life Support (ILS) skills • must have access to the Patient Group Direction and associated online resources • should fulfil any additional requirements defined by local policy • must have undertaken and completed at least level 3 Safeguarding of Children, Young people and Vulnerable adults – Training and Competency passport, as applicable to the role **THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**
Competency assessment	Evidence of ongoing PGD training to be submitted to Line Manager annually – this should include an annual completion certificate of PGD e-learning or a dated screenshot of the PGD e-learning assessment results as proof of completion. Practitioners must: • Be aware of any updates made to the product in its SmPC or BNF entries • As registered professionals, be professionally accountable and must work within their competence. A record of training and competence must be maintained (see Appendix A). The individual must complete a self-declaration of competency in their Personal Appraisal and Development Review (PADR)- the **personal development plan** (yellow) section of the PADR booklet should be used to record completion of Statutory and Mandatory training, including annual PGD e-learning.
Ongoing training and competency	Updating at least every 2 years on the use of PGDs and chloramphenicol. Practitioners must ensure they are up to date with relevant issues and clinical skills and management of anaphylaxis, ILS, with evidence of appropriate Continued Professional Development (CPD). Evidence of appropriate Continued Professional Development (CPD) must be retained and made available on request. Compliance with all mandatory NHS training.

	It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD. The decision to administer or supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.

Clinical condition or situation to which this PGD applies	
Clinical condition or situation to which this PGD applies	1. To provide antibiotic prophylaxis following the removal of surface corneal foreign bodies in accordance with "Minor Injury and Minor Illness Guidelines", or 2. Treatment of bacterial conjunctivitis in accordance with PTHB "Minor Injury and Minor Illness Guidelines". This PGD should be used with reference to NICE CKS Conjunctivitis- Infective. NICE recommend "treat with topical antibiotics if severe or circumstances require rapid resolution. A delayed treatment strategy may be appropriate". This PGD should also be used in conjunction with the "Minor Injury & Minor Illness Guidelines (Including Treatment Protocols & Care Pathways)" and with Fluorescein Sodium 1% PGD and/or Proxymetacaine hydrochloride 0.5% w/v eye drops (minims) PGD where applicable. **It is the responsibility of the administering/ supplying nurse to ensure that the patient is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the treatment. If there is any reason for concern, seek medical advice.**
Inclusion Criteria	• Individuals aged 2 years and older. • Medical and drug history taken, no reason for exclusion • Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained prior to administration/ supply and recorded appropriately. NB Refer to PTHB Consent to Treatment and Examination Policy.

	• Assessment of visual acuity performed and recorded, in accordance with "Minor Injury and Minor Illness Guidelines" • Meets the clinical situations criterion • In case of any doubt, contact medical team
Exclusion criteria (Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required)	• Conditions outside of the clinical situations criteria • Individuals for whom valid consent, or 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained or received. Refer to sections "action to be taken if the patient is excluded" and "action to be taken if the patient or carer declines treatment". • Head injury. • Severe pain within the eye • Disturbed vision • Photophobia • Glaucoma • Eye surgery or laser treatment in the past six months • Using over the counter chloramphenicol/already using other eye ointments or drops • Pupil looks unusual • Eye looks cloudy • Associated pain or swelling around the eye or face • The patient has had conjunctivitis in the recent past – refer to ophthalmology or an optometrist • The patient has dry eye syndrome • Children aged under 2 years • Known hypersensitivity to chloramphenicol or any of the excipients in the medicinal product(s) – refer to prescriber for further advice • Myelosuppression during previous exposure to chloramphenicol)- refer to a prescriber for further advice • Pregnancy or breastfeeding - refer for further advice • A known personal or family history of blood dyscrasias including aplastic anaemia - refer for advice • Eye inflammation associated with a rash on the scalp or face • Indications for an immediate referral to A & E or an Ophthalmologist or Ophthalmology Outpatient Department, or optometrist as listed in Powys Minor Injury and Minor Illness Guidelines • Red flags as identified by NICE CKS

	• Infective conjunctivitis associated with contact lens wear should be reviewed in eye casualty, due to the risk of corneal involvement • Suspected penetrating eye injury or intraocular foreign body, all chemical injuries
Cautions /reasons for seeking further advice from a prescriber	Seek further advice where appropriate if patient is excluded from the PGD. Prolonged or frequent intermittent treatment with chloramphenicol should be avoided as it may increase the likelihood of sensitisation and emergence of resistant organisms. **Treatment should be continued for a maximum of 7 days.** If any new infection appears during treatment discontinue the chloramphenicol and seek a medical opinion. Bone marrow hypoplasia, including aplastic anaemia and death, has been reported following topical use of chloramphenicol. Whilst the hazard is a rare one, it should be borne in mind when assessing the benefits expected from the use of the compound. Patients with complex multiple pathologies, polypharmacy or multiple allergies. Check for any other medications that the patient is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. Refer to a prescriber if patient taking any other medication which is likely to depress the bone marrow function. (Refer to BNF/SPC for full list) Since systemic absorption can follow topical application, the possibility of interactions should be borne in mind. Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the Minor Injury Unit guidelines followed, along with PTHB safeguarding policies. Consider discussing with GP.

	Any safeguarding concerns need to be directed to Safeguarding Hub: • To generic email address: PowysTHB.Safeguarding@wales.nhs.uk And • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 Advice can also be sought from local Safeguarding Leads
Arrangements for referral for medical advice	Contact GP/Optician for advice or refer to DGH if applicable. Document advice given.
Action to be taken if patient excluded	Explain reason to patient / carer. Record reason for exclusion and any action taken and seek medical advice. If appropriate, refer to GP / A & E/ DGH /NHS111/Optician, offer alternative management if appropriate.
Action to be taken if patient declines treatment	Explain consequences of refusing treatment. Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for administration and recorded appropriately. The patient information leaflet should be available to inform consent. Where a person lacks capacity, in accordance with the Mental Capacity Act 2005, a decision to treat may be made in the patients best interests. Make patient or their representative aware of alternative sources of treatment (A & E, DGH, Optometrist or GP/Optician as appropriate). Offer alternative management if appropriate. Document refusal and any advice given. Complete a Discharge Against Advice Form if appropriate. Inform or refer to GP/follow local procedures as appropriate. Complete the letter on the WPAS system and send over to the GP immediately.

Details of the medicine	
Name, form and strength of medicine	Chloramphenicol 1% Eye Ointment Chloramphenicol 0.5% Eye Drops
Legal category	POM/P
Off-label use	The SPC therapeutic indication is for treatment of bacterial conjunctivitis caused by chloramphenicol susceptible organisms. Different SPCs recommend different doses, and the duration ranges from 5 days total, to at least 48 hours after eye appears normal. The BNF recommends one drop may be applied every 2 hours initially, then reduce frequency as infection is controlled and continue for 48 hours after healing. The BNF states it is generally sufficient for 3-4 times daily for less severe infection. Dosage and treatment period in the PGD may differ from the SPC but is in line with NICE CKS. It is outside the terms of the SPC for antibiotic prophylaxis following the removal of surface corneal foreign bodies. NICE CKS recommends that if there is a risk of infection, a topical broad-spectrum antibiotic prescribed for at least 5 days is appropriate. Medicines should be stored according to the conditions detailed in the Storage section in this document. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with pharmacy/Medicines Management. Where the medication is recommended off-label consider, as part of the consent process, informing the individual/carer that it is being offered in accordance with national guidance/ justified by best

	clinical practice but that this is outside the product license.
Route/method of administration	**Ointment**: Apply to the inside of the lower lid. **Drops:** Place ONE drop into the conjunctival sac. Compress the lacrimal sac at the medial canthus for one minute during and after instillation of the drop. This reduces systemic absorption and is especially important in children.
	DOSE: **Ointment:** Apply approximately 1cm of eye ointment. **Drops:** Apply ONE drop into the conjunctival sac. **FREQUENCY:** **Bacterial Conjunctivitis** - **Ointment** – Apply to affected eye four times a day (if ointment to be used alone). - **Drops-** Apply 1 drop to the affected eye every 2 hours (whilst awake) for 2 days, then reduce to four times daily. Continue treatment until 48 hours after symptom resolution. Do not use after 7 days. **Antibiotic prophylaxis following removal of surface corneal foreign bodies** - **Ointment -** Apply to affected eye four times a day for 7 days Note- if chloramphenicol eye drops are required for antibiotic prophylaxis following removal of surface corneal foreign bodies this is outside the remit of this PGD and another form of authorisation will be required. **Combined treatment for bacterial conjunctivitis** Usually application of drops throughout the day (as above) and application of eye ointment at night only.

Dose and frequency	The choice of treatment regimen depends on age, lifestyle, ability to self-administer or availability of a carer to administer. The eye ointment lasts longer in the eye. It can be helpful in preventing the lid from sticking to the cornea during sleep. The ointment may smear causing blurred vision. This makes the drops more practical for daytime use.
Quantity to be administered and/or supplied	Per eye: 1 x 4g tube chloramphenicol 1% eye ointment. 1 x 10ml vial chloramphenicol 0.5% eye drops. If treatment is required for both eyes double the quantity is to be supplied ensuring separate containers for each eye to avoid cross contamination. Label the containers 'Right Eye' and 'Left Eye' For **combined treatment** issue 1 pack each of eye ointment and eye drops for each affected eye.
Maximum or minimum treatment period	Bacterial conjunctivitis:- Duration of treatment- continue treatment until 48 hours after symptom resolution. Maximum treatment period of 7 days. Advise patient to seek further medical assistance if symptoms not resolved within 7 days of starting treatment. Antibiotic prophylaxis following removal of surface corneal foreign bodies:- Duration of treatment- 7 days. Advise patient to seek further medical assistance if symptoms not resolved within 7 days of starting treatment.
Storage	Chloramphenicol 1% eye ointment: • Discard once the course is completed, and within 28 days of opening. • Do not store above 25°C. • Protect from light Chloramphenicol 0.5% eye drops: • Store upright at 2°C to 8°C in a refrigerator. • Discard once the course is completed and within 28 days of opening. • Protect from light. • Do not freeze.

Drug interactions	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 and reporting of Adverse reactions	• Transient stinging, irritation, burning and sensitivity reactions such as itching and dermatitis may occur. • Hypersensitivity reactions e.g. angioedema, anaphylaxis, urticaria, fever, vesicular and macropapular dermatitis have been reported and are causes for immediate discontinuation. Very rarely cases of major adverse haematological events (bone marrow depression, aplastic anaemia and death) have been reported following ocular use of chloramphenicol. This list is not exhaustive. Refer to British National Formulary and / or Summary of Product Characteristics www.medicines.org.uk/emc for complete list. Healthcare professionals and individuals/ parents/ carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme at: http://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store, or completing a Yellow Card (found in the British National Formulary). For established medicines, serious adverse events in adults or all suspected adverse reactions in children that may be attributable to the medication should be reported. Guidance on the yellow card system is available at the back of the BNF or using the above link. Record all adverse drug reactions (ADRs) in the patient's medical record and report any suspected adverse reactions to a doctor. In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use:

	Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone must be available for immediate use. In case of anaphylaxis:- Refer to adrenaline (epinephrine) PGD and anaphylaxis policy • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in patient notes • Ensure all patient records are marked **ALLERGIC TO chloramphenicol**. • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers All significant adverse drug reactions and any administration errors must be recorded via the Once for Wales Reporting System. A written discharge summary of care must be sent to the GP.
Records to be kept	Record consultation details as required by local procedures. In addition, record: • Name, address and date of birth of patient • Name and address of GP • Medical and drug history taken, including any allergies and previous adverse events. • Any reasons for exclusion or referral, including actions taken. • Any advice received from medical cover and advice given to patient / carer. • If the patient has refused treatment, and any advice given in this circumstance. • That valid informed patient consent to treatment was obtained, or a decision to treat made in the individual's best interests in accordance with the Mental Capacity Act 2005. Record name of representative who gave consent if appropriate. • That the drug is being supplied/administered in accordance with a PGD- record PGD title, number and version. • Record any advice given • Date and time of administration (if administered in MIU)

	• Administration route – including which eye(s). • Whether chloramphenicol eye ointment or eye drops were administered, strength and expiry date. • Details of any adverse reactions and actions taken. For supply, record: • Date and time of supply • Name, form, strength, dose, route, frequency and quantity of medication(s) supplied • Administration route, including which eye(s). • Manufacturer and expiry date of medicine supplied The record must include the printed name and signature of the nurse responsible for administration/supply. Assess and document visual acuity before and after treatment if possible, in accordance with MIU guidelines. All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this PGD should be kept for audit purposes in accordance with local policy.
Patient information	
Written/verbal information to be given to patient or carer	• Explain the indication, contraindications, cautions and administration technique(s). • If treating conjunctivitis, give appropriate self-care advice, e.g. wash hands regularly, clean away infected secretions from eyelids and lashes with cotton wool soaked in water. Avoid sharing pillows and towels to avoid spreading infection. Advise the person that there is no recommended exclusion period from school, nursery, or childminders for isolated cases but that many nursery and primary schools may nevertheless have an exclusion policy. • When applicable, advise the patient / carer when the subsequent dose is due. • The treatment may cause transient blurring of vision. Do not drive or operate machinery until the vision is clear. • Do not wear contact lenses for the period of treatment and for at least 24 hours after the last

	application and until all symptoms of infection are gone. • Store the eye ointment at room temperature. • Store the eye drops in a refrigerator. • Wash hands thoroughly before and after applying the medication. • Write the patients name, directions, and the date of supply onto the label. • If both eyes are being treated use separate containers (labelled 'Right Eye' and 'Left Eye') and wash hands between applications. • Avoid touching the eye or lashes with the tube or nozzle. This may contaminate the medication. • Discard any unused drops or ointment- give advice on appropriate disposal, e.g. return to community pharmacy. • If symptoms persist or worsen review with own GP. • Provide patient information leaflet. Draw patient's or representative's attention to the label and patient information leaflet. Give appropriate advice if medication is used off-label. • Patient information on Conjunctivitis is available from NHS A-Z at www.nhs.uk. Where applicable, inform the individual or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed in the product's SPC
Follow-up advice to be given to patient or carer	Inform individual of possible side effects and their management. Follow up at 24 and 48 hours in accordance with MIU guidelines. Advise them to seek medical advice immediately if they have any unexpected reaction or other cause for concern, including if symptoms worsen at any time or if there is no improvement within 48 hours, or if they develop marked eye pain or photophobia, loss of visual acuity or marked redness of the eye. Seek further medical assistance if symptoms are not resolved within 7 days of starting treatment. Contact GP via surgery, Optician or NHS 111 Wales out of hours service.

Key references

NICE CKS- conjunctivitis-infective- Last revised October 2022

https://cks.nice.org.uk/conjunctivitis-infective

NICE CKS- corneal superficial injury- Last revised June 2022

https://cks.nice.org.uk/corneal-superficial-injury

SPC- chloramphenicol eye drops 0.5% FDC International Ltd 25/6/24

BNF- accessed 08/04/24

SPC- chloramphenicol 1% eye ointment Martindale Pharma 19 July 2023

SPC- chloramphenicol eye drops 0.5%- Martindale Pharma 10 Dec 2021

PIL- chloramphenicol eye drops 0.5% FDC International Ltd June 2024

SPS Using chloramphenicol in breastfeeding. last updated 12 April 2023

awttc.nhs.wales/files/guidelines-and-pils/primary-care-antimicrobial-guidelines-2022-pdf/- March 2022, updated March 2024

Appendix A: Staff accredited to use the Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board for the named healthcare professionals below who have signed the PGD to work under it.
The authorising manager must use the competency checklist (below).

Practitioner: By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs 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.

Printed name of registered health professional	Signature of registered health professional	Printed name of senior representative authorising health professional	Signature of senior representative authorising health professional	Date

The authorising manager should retain the original signed copy, which will be required for audit purposes. This list should be kept by PTHB for 25 years after the PGD expires.

The healthcare professional should retain a copy of the document after signing.

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

	Name: **Role:**	Sign / Initial	Further training identified (Y/N)	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) _____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to individual's line manager and to the staff member, in conjunction with the PGD Appendix A authorisation sheet. A copy of this form should also be kept by service lead in the training file.