University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Supply / Administration of Cyclopentolate 1% eye drops By Registered Practitioner working for University Hospitals of Derby and Burton

Documentation details

Reference no:	UHDB 115
Version no:	2.2
Valid from:	19/09/2024
Review date:	19/03/2027
Expiry date:	18/09/2027

Change history

Version number	Change details	Date
2.1	Addition of Orthoptist to PGD working group	20.05.24
2.2	Hyperaemia listed as criteria for exclusion instead of caution. Specified single-use formulation (minims). Storage information updated to discard single dose unit after use. Information added to support use of 1% in 12-17 year olds.	12.09.24

Glossary

Abbreviation	Definition

1. PGD template development (PGD Working Group)

PGD Working Group Membership (minimum requirement of consultant, pharmacist and a registered professional who can work under a PGD (or manages the staff who do). If this is a review of existing PGD, replace previous names with the individuals involved for this version

Name	Designation
VICKI MEREDITH	SENIOR SISTER OUTPATIENTS QHB
PARAMJIT KAUR	SENIOR SISTER OUTPATIENTS RDH
MR ANIL KUMAR	CONSULTANT OPHTHALMOLOGIST
SUZANNE SMITH	PHARMACIST
ANDREW CASTLE	ORTHOPTIST

Where an antimicrobial is included, confirm the name, designation and date of the antimicrobial pharmacist who has reviewed this version

Name of antimicrobial pharmacist	Designation	Date Reviewed

2. Organisational authorisations

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

University Hospitals of Derby & Burton NHS Foundation Trust authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
All UHDB sites and in clinics operated by UHDB staff at peripheral community sites
Limitations to authorisation
Supply applies only to paediatric clinics supplying drops for pre-procedural instillation at home. ED: adult use only for alleviation of pain due to injury or foreign body.

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Pharmacist *Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)*	**Ellie Gunner**	Signed copy held by Pharmacy	19/09/2024

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Pharmacist	**SUZANNE SMITH**	Signed copy held by Pharmacy	**13/09/2024**
Assistant Clinical Director (Ophthalmology)	**LOLA LAWUYI**	Signed copy held by Pharmacy	**13/09/2024**
Senior Sister Outpatients	**VICKI MEREDITH**	Signed copy held by Pharmacy	**13/09/2024**
Senior Sister Outpatients	**PARAMJIT KAUR**	Signed copy held by Pharmacy	**18/09/2024**

Local enquiries regarding the use of this PGD may be directed to UHDB.PGDgovernance@nhs.net

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD.

3. Characteristics of staff

Qualifications and professional registration	- Qualified NMC Registered Nurse - HCPC Registered Orthoptist - Health Care Professionals (who can legally operate under PGDs) who have undergone additional training to administer drug outlined in this PGD and been assessed as competent.
Initial training	- Completion of all Essential-to-role training as outlined in the UHDB PGD policy. - Individual has read and understood full content of this PGD and signed authorisation (section 7) - The Registered Healthcare Professional will undertake training and will ensure he/she is competent in all aspects of this treatment.
Competency assessment	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 either the authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be provided as required.
Ongoing training and competency	- Health care professionals must complete annual basic life support and anaphylaxis training to administer drugs under this PGD.
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	To produce mydriasis prior to ocular examination, cataract or retinal surgery. To facilitate refraction and laser treatment To produce mydriasis to alleviate pain in cases of large corneal abrasion, arc eye and after removal of large longstanding foreign bodies where inflammation is present
Criteria for inclusion	➢ Adults and children over 3 months requiring ophthalmic examination ➢ Children under the age of 16 years old require consent to be given by parent or legal guardian. ➢ Adult patients undergoing laser treatment.
Criteria for exclusion	➢ Consent not gained ➢ previous local or systemic reactions to the medicine ➢ Known or suspected hypersensitivity to any of the ingredients ➢ Pregnancy or breastfeeding ➢ Shallow anterior chamber ➢ Angle closure glaucoma ➢ Where examination of the pupil reactions are necessary eg: RAPD and Horners ➢ Neonates and infants less than 3 months old. ➢ Patients with hyperaemia as systemic absorption could be increased
Cautions including any relevant action to be taken	• Darkly pigmented iris is more resistant to pupillary dilation and caution should be exercised to avoid over dosage. • Ensure emergency drugs and equipment, including adrenaline, are available for the treatment of anaphylaxis and emergencies, according to local policy.
Action to be taken if the patient is excluded	➢ Record reasons for exclusion in patient notes ➢ Inform doctor ➢ Advise patient on alternative treatment
Action to be taken if the patient or carer declines treatment	➢ Document advice given ➢ Inform doctor ➢ Advise patient on alternative treatment
Arrangements for referral for medical advice	Inform doctor or suitably qualified specialist in ophthalmology. Discuss potential consequences/referral/records to be kept. The practitioner is expected to use their own clinical judgement and refer patients to OOHs GP/ A&E / Minor Injuries unit / Walk-in centre as they see fit. Provide appropriate details e.g. Eye casualty opening times.

5. Description of treatment

Name, strength & formulation of drug	Cyclopentolate eye drops 1% single dose (minims)
Legal category	Prescription Only Medicine (POM)

Route / method of administration	Instilled into the eye(s) to be examined
Indicate any off-label use (if relevant)	Whilst BNFC and SPC for minims recommends using 0.5% strength in patients aged 12-17 years, use of 1% is accepted clinical practice at UHDB. The SPC for cyclopentolate 1% multi-dose container (Mydrilate) also supports use in this age group.
Dose and frequency of administration	ONE drop of 1% in patients more than 3 months One drop into the eye(s) approximately 20-30 minutes before the examination with further drops at 15-30 minute intervals if necessary
Duration of treatment	Maximum THREE drops per affected eye in Adults and TWO drops for paediatrics
Quantity to be supplied (leave blank if PGD is administration ONLY)	Paediatric orthoptist use only: Supply an individual container for each patient for home use. The patients name and date of issue should be added to an appropriately labelled pack. Labelling must meet the requirements outlined in Trust PGD Policy and associated training. The Pharmacy department over-label packs to meet legal requirements for supply. If you do not hold these appropriately over-labelled packs in stock, then a supply to patients is not appropriate.
Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: • Store below 25°C. Do not freeze. • Protect from light. • Each single dose unit should be discarded after use.
Drug interactions	*The following interactions have been identified and should be considered where it is known a patient is on the following medicines:* • None Known 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	• Stinging on instillation • Blurring of vision for up to 24 hours • Dry mouth • Photophobia • Raised intraocular pressure in pre-disposed patients • Allergic reactions including red eyes with lacrimation and stringy white discharge. • Systemic absorption is unlikely but may manifest as CNS disturbances including hallucinations. Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of the drops. 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. ➢ Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use. ➢ **Anaphylaxis/Emergency Treatment at Derby and main Queens site**: ➢ Call the crash team via switchboard ➢ **Anaphylaxis/Emergency treatment at all other sites:** ➢ Call 999 ➢ Summon help ➢ Maintain airway ➢ CPR ➢ Follow trust resuscitation guidelines
Written information to be given to patient or carer	None routinely required for administration in department. May give copy of marketing authorisation holder's patient information leaflet (PIL) which can be obtained from www.medicines.org.uk if required
Patient advice / follow up treatment	• The patient should be advised to remove contact lenses before use, and these should not be worn during the treatment course. • Advise that stinging and blurring of vision may occur on instillation. • Advise vision may be impaired for up to 24 hours and not to drive or operated hazardous machinery if affected. • The individual/carer should be advised to seek medical advice in the event of an adverse reaction. • The patient should be advised on the reason for administration of the drug and subsequent management if the condition.
Records	Document using the system in place for your clinical area which may include: ePMA; patient notes; Treatment card; Eye casualty card; Ophthalmic care pathway. Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following: ➢ name of individual, address, date of birth and GP with whom the individual is registered (if relevant) ➢ name of registered health professional ➢ name of medication supplied/administered ➢ date of supply/administration ➢ dose, form and route of supply/administration ➢ quantity supplied/administered ➢ batch number and expiry date (if applicable e.g. injections and implants) ➢ advice given, including advice given if excluded or declines treatment ➢ details of any adverse drug reactions and actions taken ➢ Confirm whether supplied and/or administered and that this was done via Patient Group Direction (PGD)

	Records should be signed and dated (or a password controlled e-records). All records should be clear, legible and contemporaneous. If you are not recording in ePMA (or other electronic system which has ability to generate audit reports) then a record of all individuals receiving treatment under this PGD should also be in the clinical area for audit purposes as per UHDB PGD policy.

6. Key references

Key references	➢ *Electronic Medicines Compendium http://www.medicines.org.uk/* ➢ *Electronic BNF https://bnf.nice.org.uk/* ➢ *NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2* ➢ *https://medusa.wales.nhs.uk*

7. Registered health professional authorisation sheet

PGD Name [version]: Ophthalmology – Cyclopentolate 1% V2.2 PGD ref: UHDB 115

Valid from: 19/09/2024 Expiry date: 18/09/2027

Before signing check that the document you have read is published on Koha or is an in-date hard-copy with all necessary authorisations signed in section 2. The Name/Version/Ref of the document you have read MUST match this authorisation form.

Registered health professional
By signing this patient group direction you are indicating that

a) You agree to and understand all content and commit to only work within this framework.
b) You have completed any core PGD e-Learning or training records on My Learning Passport or within your department.
c) You meet the staff characteristics and have completed any additional learning/competency outlined in Section 3 of this PGD.

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 / Assessor

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 University Hospitals of Derby & Burton NHS Foundation Trust 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 must be retained by a manager in the clinical department where the PGD is in-use to serve as a record of those registered health professionals authorised to work under this PGD.