University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Administration of APRACLONIDINE 1% eye drops

By Registered Practitioners working at University Hospital of Derby and Burton

Documentation details

Reference no:	UHDB183
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Change history

Version number	Change details	Date

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 Eye Clinic
MR ANIL KUMAR	CONSULTANT OPHTHALMOLGIST
LISA NOCK	PHARMACIST

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 sites
Limitations to authorisation

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer *Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)*	**James Hooley**	Signed copy held in Pharmacy	**12/09/2022**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Pharmacist *Clinical Pharmacist from PGD working group*	**Lisa Nock**	**Signed copy held in Pharmacy**	**13/07/2022**
Consultant Ophthalmologist *Doctor*	**James Tildsley**	**Signed copy held in Pharmacy**	**08/09/2022**
Senior Sister Outpatients *Registered Professional representing users of the PGD*	**Vicki Meredith**	**Signed copy held in Pharmacy**	**27/07/2022**
CD Accountable Officer (CDs only)			

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 Registered Health Care Professionals (who can legally operate under PGD's) who have undergone additional training to administer drops outlined in this PGD and have 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 the either 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	Control or prevent post operative elevations in intra-ocular pressure after anterior segment laser treatment
Criteria for inclusion	Adult patients undergoing laser treatment
Criteria for exclusion	• Consent not gained • Patients with a history of severe or unstable and uncontrolled cardiovascular disease. • Children • Patients with hypersensitivity to any of the substances (clonidine or apraclonidine) or to any of the excipients. • Patients receiving monoamine oxidase inhibitor therapy, systemic sympathomimetic agents, tricyclic antidepressants. • Pregnancy and Breast-feeding
Cautions including any relevant action to be taken	Patients with hyperaemia as systemic absorption could be increased. Patients with a history of: Vasovagal attacks Angina, severe coronary insufficiency recent myocardial infarction, overt cardiac failure Cerebrovascular disease Chronic renal failure Raynaud's disease Thromboangiitis obliterans. Monitoring of depressed patients are advised since apraclonidine has been rarely associated with depression.
Action to be taken if the patient is excluded	• Record reasons for exclusion in patient notes • Advise patient on alternative treatment
Action to be taken if the patient or carer declines treatment	• Document advice given • Advise patient on alternative treatment
Arrangements for referral for medical advice	Inform Ophthalmic consultant refer to medics

5. Description of treatment

Name, strength & formulation of drug	Apraclonidine 1% eye drops
Legal category	Prescription-only medicine (POM).
Route / method of administration	One drop instilled into the eye one hour prior to the laser treatment. A second drop should be instilled into the same eye immediately upon the completion of the laser procedure.
Indicate any off-label use	Not Applicable

(if relevant)	
Dose and frequency of administration	One drop one hour prior to laser, effects last three to five hours.
Duration of treatment	For the procedure only
Quantity to be supplied (leave blank if PGD is administration ONLY)	N/A administration
Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: Store below 25 (degrees). Do not freeze. Protect from light.
Drug interactions	*The following interactions have been identified and should be considered where it is known a patient is on the following medicines:* Interactions appears to be low but there is a possibility of the following: CNS depressants (Alcohol, barbiturates, Opiates, Sedatives, anaesthetics) Tricyclic antidepressants Beta blockers, antihypertensives and cardiac glycosides-risk of hypotension (monitor BP and Pulse) Neuroleptics - hypotension Insulin- response to and identification of hypoglycaemia. Topical sympathomimetics- systemic pressor response- Check BP prior to administration.
Identification & management of adverse reactions	The following side effects are common: Dry mouth Eye lid retraction and mydriasis Immune system disorders Nervous system disorders Eye disorders Cardiac disorders Psychiatric disorders Respiratory,Thoratcic and mediastinal disorders Vascular disorders Gastrointestinal disorders Skin and subcutaneous tissue disorders Musculoskeletal connective tissue and bone disorders General disorders and administration site conditions
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 Queens:

	• Call the crash team via switchboard and 999 for the TC QHB • Anaphyaxis/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	Not routinely required for administration in the department. May be given a copy of the marketing authorisation holder's patient information leaflet (PIL) provided with the product if required.
Patient advice / follow up treatment	Advise may cause dizziness and drowsiness for up to 24 hours and not to drive or operate hazardous machinery
Records	Document using the system in place for your clinical area which may include: EPMA, patients 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 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* Iopidine 1.0% Ophthalmic Solution - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) • *Electronic BNF https://bnf.nice.org.uk/* • *NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2*

7. Registered health professional authorisation sheet

PGD Name [version]: Ophthalmology – Apraclonidine 1% Eye Drops [v1]
PGD ref: UHDB183

Valid from: 12/09/2022 Expiry date: 11/09/2025

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.