University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Supply & Administration of GENTAMICIN AND HYDROCORTISONE EAR DROPS By Registered Nurses in ENT services at UHDB

Documentation details

Reference no:	UHDB 131
Version no:	V1
Valid from:	21/02/2022
Review date:	21/08/2024
Expiry date:	20/02/2025

Change history

Version number	Change details	Date
1	Update for Burton/Derby ENT Outpatients	13th May

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
Adrian Thompson	Lead Consultant
Hayley Mills	Sister, ENT Outpatients – QHB
Natasha Lucas	Aural Care Nurse Practitioner – RDH
Suzanne Smith	Divisional Lead Pharmacist – Surgery

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
n/a	n/a	n/a

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
ENT Outpatients at QHB, RDH and outreach sites operated by UHDB staff
Limitations to authorisation
Nil

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	**21/02/2022**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Divisional Lead Pharmacist - Surgery *Clinical Pharmacist from PGD working group*	**Suzanne Smith**	Signed copy held in Pharmacy	**18/02/2022**
Lead Consultant/Clinical Director for ENT *Doctor*	**Adrian Thompson**	Signed copy held in Pharmacy	**19/01/2022**
Sister- Outpatients at QHB *Registered Professional representing users of the PGD*	**Hayley Mills**	Signed copy held in Pharmacy	**19/01/2022**

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	• Registered Nurse with a current NMC registration
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) • It is the responsibility of the individual Registered Nurse to remain updated, with evidence of continued professional development. • Staff can undertake appropriate training to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in the PGD. • Have undertaken appropriate training for working under Patient Group Directions for the supply and administration of medicines, undertaken the Aural Care Training Course, The National Diploma in Primary Care for Practitioners and the Trust Drug Assessment.
Competency assessment	• Supervision/Assessment from The ENT Sister/Lead • Supervision/Assessment from The Aural Care Practitioner • 12 month Aural Care Competency book • 7 days course – The National Diploma in Primary Care for Practitioners • Trust Drug 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	Has undertaken appropriate training to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in the PGD. Has undertaken appropriate training for working under Patient Group Directions for the supply and administration of medicines, undertaken the Aural Care Training Course or attended The National Diploma in Primary Care for Practitioners Organisation PGD or medication training as required by employing Trust/organisation.
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	• Eczematous inflammation or infection in Otitis Externa (2nd line of treatment) • For prophylaxis against Otitis Externa following trauma • For post-operative local use in surgery to treat infected mastoid cavities.
Criteria for inclusion	• Consent gained – verbal or written • Any person aged 16 years or over presenting with any of the conditions above
Criteria for exclusion	• Consent not gained • Under 16 years of age • Previous local or systemic reactions to the medicine or any of the ingredients • Myasthenia Gravis • Pregnancy and lactation • Known or suspected perforation • Patent Grommet
Cautions including any relevant action to be taken	• Avoid prolonged use. Prolonged use may lead to skin sensitisation and the emergence of resistant organisms • Monitor for sensitivity reactions Staff Advice - Consult medical advice if an adverse event occurs. Document in medical notes. All serious adverse reactions must be reported under the National yellow card system.
Action to be taken if the patient is excluded	• Refer to medical staff for review and prescribing of alternative agent if appropriate. • Document reason for exclusion
Action to be taken if the patient or carer declines treatment	• Document refusal • Action taken and advice given in nursing documentation • Refer to medical staff if appropriate • Advise patient on alternative treatment
Arrangements for referral for medical advice	Monday to Friday 0900 – 5:30pm ENT Outpatients at QHB or RDH Outside these hours: ENT on call at QHB or RDH

5. Description of treatment

Name, strength & formulation of drug	Gentamicin 0.3% w/v and Hydrocortisone acetate 1% w/v ear drops (Gentisone HC)
Legal category	POM
Route / method of administration	Topical to ear
Indicate any off-label use (if relevant)	Doses above the SPC license are used as below (supported by BNF)
Dose and frequency of administration	Apply 2-4 drops, 4-5 times a day (including a dose at bedtime)
Duration of treatment	7 days

Quantity to be supplied (leave blank if PGD is administration ONLY)	1 bottle for each infected ear *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 to be kept in a locked drugs cupboard • Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: • Once opened, use within 28 days – label with date, time and initials of who has dispensed it. Add in SPC specific conditions hers. Available from the electronic Medicines Compendium website: www.medicines.org.uk
Drug interactions	The following interactions have been identified and should be considered where it is known a patient is on the following medicines: • None relevant to topical use 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	The following side effects are common: • Local reaction 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. • If anaphylaxis management may be required include this information here (e.g. adrenaline to be held/resuscitation team details)
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	• Inform the individual/carer of possible side effects and their management. • The individual/carer should be advised to seek medical advice in the event of an adverse reaction. • 3-4 week follow up in the Nurse Led Clinic

Records	Details of the supply must be recorded in the patient's health records and in a drug record stock book kept in the ENT Clinic. State "administered under PGD" with name and signature of authorised nurse. A second check should be obtained from a qualified healthcare practitioner before administration. For EPMA: Document the utilisation of the medicine under PGD by ordering the appropriate drug order item against the correct patient record in Nursing notes, Cito or V6. 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	Update and include for each revision. In most cases a link to specific records in the examples below will be appropriate • 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]: ENT OPD – Gentisone [v1] PGD ref: UHDB 131

Valid from: 21/02/2022 Expiry date: 20/02/2025

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.