University Hospitals of Derby and Burton NHS Foundation Trust

PROTOCOL

Administration of Triadcortyl Ointment (substitute) By Registered Nurses in ENT services at UHDB

Documentation details

Reference no:	UHDB143
Version no:	1
Valid from:	21/02/2022
Review date:	21/08/2024
Expiry date:	20/02/2025

Change history

Version number	Change details	Date
1.0	NewUHDB format and moved from PGD to protocol (requiring PSD/prescription)	14/01/2022

Glossary

Abbreviation	Definition

1. Protocol template development (Protocol Working Group)

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

Name	Designation
Adrian Thompson	Lead Consultant
Hayley Mills	Senior 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 Protocol is not valid until it has had the relevant organisational authorisation.

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

Authorised for use by the following organisation and/or services
ENT Outpatients for QHB, RDH and Outreach sites operated by UHDB staff
Limitations to authorisation
Nil
Agreed rationale for protocol use in place of a PGD (Patient Group Direction)
Prescription (Patient Specific Direction from a prescriber) required to administer. As an unlicensed medication Tri-adcortyl (or substitute/import with the same ingredients) cannot be administered under a PGD. As such any administration must be authorised, in writing, by a prescriber on an individual patient basis. Authorisation may be given either by prescribing (using relevant EPMA system) or by documenting clearly in the patient's medical notes. Once authorisation has been granted administration may continue as detailed within this protocol.

Organisational Authorisation			
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			
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	**25/01/2022**

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

Section 7 provides a healthcare worker authorisation sheet. Individual healthcare workers must be authorised by name to work to this PROTOCOL.

3. Characteristics of staff

Qualifications and professional registration	• Registered Nurse with a current NMC registration
Initial training	• Completion of all Essential-to-role training • Individual has read and understood full content of this protocol and signed authorisation (section 7) • It is the responsibility of the individual Registered Nurse to remain updated, with evidence of continued professional development. • Have undertaken appropriate training for the 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 Individuals operating under this protocol are personally responsible for ensuring they remain up to date with the use of all medicines included in the protocol - if any training needs are identified these should be discussed with the either authorising manager (section 7) or the manager within the protocol 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 protocol. Organisation medication training as required by employing Trust/organisation.
The decision to administer or supply any medication rests with the individual healthcare worker operating under this protocol who must abide by the protocol and any associated organisation policies.	

4. Clinical condition or situation to which this Protocol applies

Clinical condition or situation to which this Protocol applies	Topical treatment of Otitis Externa - known to respond to topical steroid therapy, complicated by bacterial or fungal infection. Post-operative local use in surgery to 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 • **Written authorisation from a prescriber must be gained prior to administration of this product.**
Criteria for exclusion	• Consent not gained • Children under 16 years of age • Pregnancy and breastfeeding • Hypersensitivity to any of the ingredients • Previous local or systemic reactions to the medicine
Cautions including any relevant action to be taken	• May stain clothing/bed linen • Avoid prolonged use • Monitor for sensitivity reactions • Contact the prescriber if irritation occurs • 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	Triadcortyl Ointment (or substitute/import with ingredients below): • Chlortetracycline hydrochloride 3.09 w/w and triamcinolone acetonide 0.1 w/w (Aureocort) • Gramicidin 0.25mg/g, Neomycin base 2.5mg/g, Triamcinolone Acetonide 1mg/g and Nystatin sulphate 100,000 units/g
Legal category	POM (unlicensed)
Route / method of administration	• Topical to ear • Can be inserted to an ear when assessed by a Nurse or a Dr via an ointment syringe or dry mopping.

Indicate any unlicensed or off-label use (if relevant)	Unlicensed product: as part of the consent process, inform the individual/parent/carer that the drug is being offered in accordance with local guidance but that the product is not licensed in the UK.
Dose and frequency of administration	• Prescriber will clinically decide on dose/frequency • Drug is not to be given to patient for home use.
Duration of treatment	• Application in hospital/clinic only.
Quantity to be supplied (leave blank if protocol is administration ONLY)	*N/A – Clinic use only*
Storage	• Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: • Stock to be kept in a locked drugs cupboard • Once opened, use within 30 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	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: • Itching • Burning • Skin irritation • Skin rash • Ringing in ear • Balance issues 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 administration must be recorded in the patient's health records (electronic or paper) and in a drug record stock book kept in the ENT Clinic. State "administered under local protocol" with name and signature of authorised nurse. A second check should be obtained from a qualified healthcare practitioner before administration. Either the system holding the record, or the healthcare practitioner working under the Protocol, 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 Protocol 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 Protocol should also be in the clinical area for audit purposes

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/* • Aureocort 3.09% ww 0.1% ww Ointment - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) *https://www.medicines.org.uk/emc/product/11919*

7. Registered health professional authorisation sheet

Protocol [version]: Triadcortyl (substitute) [v1/0] Protocol ref: UHDB143

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 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 protocol.

The decision to administer or supply any medication rests with the individual healthcare worker operating under this protocol who must abide by the protocol and any associated organisation policies.

I confirm that I have read and understood the content of this Protocol and that I am willing and competent to work to it.			
Name	**Designation**	**Signature**	**Date**

Authorising manager / Assessor

I confirm that those named above have declared themselves suitably trained and competent to work under this Protocol. I give authorisation on behalf of University Hospitals of Derby & Burton NHS Foundation Trust for the above named healthcare workers who have signed the Protocol to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of healthcare workers to prevent additions post managerial authorisation.

This authorisation sheet must be retained by a manager in the clinical department where the Protocol is in-use to serve as a record of those authorised to work under this Protocol.