Patient Group Direction (PGD) for the Administration of

Betamethasone valerate 0.1% and clioquinol 3% ointment

by Specialist Ear Care Nurses or Registered Nurses, with a Diploma in Primary Ear Care (or equivalent) employed or contracted by the Rotherham NHS Foundation Trust working within clinic or at the home of the patient who have successfully undertaken approved training and have been assessed as competent

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Discipline:	Primary Ear Care and Audiology Services
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Patient Group Directions are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.

The majority of clinical care should be provided on an individual, patient-specific basis. The supply and administration under a PGD should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety), and where it is consistent with appropriate professional relationships and accountability.

- Each PGD has a unique identifier allocated by the pharmacist responsible for the management of Patient Group Directions for the organisation.

- Once a PGD has been given approval, the date on which the PGD comes into effect will be inserted by the pharmacist prior to submission onto the Rotherham NHS Foundation Trust intranet.

- The PGD must be reviewed within three years of authorisation

- PGDs that have failed to be reviewed and re-ratified ***must not*** be used past their expiry date and patient specific direction (prescriptions) must be used to authorise supply of medicines.

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1. Clinical Condition or situation to which the direction applies

Drug Name: **Betamethasone 0.1% and Clioquinol 3% ointment**

Clinical Indications	• Severe inflammatory skin disorders such as eczema and psoriasis unresponsive to less potent corticosteroids • Acute or chronic otitis externa which is confirmed by otoscopy and is believed to be either a bacterial and/or fungal infective cause.
Criteria for Inclusion	• Informed consent of patient prior to examination • Children aged one to seventeen years and adults 18 years and older without occlusive dressing Patients presenting with any of the following: • Symptoms of otitis externa unresponsive to less potent corticosteroids • Inflamed mastoid cavity • Dry/flaky, red and inflamed meatus/pinna • Seborrhoeic dermatitis, eczema, or psoriasis of the meatus or pinna • Itchy ears
Criteria for Exclusion	• Patients with hypersensitivity to any component of the product or to iodine • Children aged under one year • Use with an occlusive dressing • Children who have had this treatment for 5 days • Adults who have had this treatment for 7 days without clinical improvement • Pregnancy and breastfeeding • Primary cutaneous viral infections, e.g. herpes, chicken pox • Acne vulgaris affecting the pinna • Rosacea • Fungal Infections

Action if Excluded	• If patient is allergic to betamethasone valerate/clioquinol ointment or iodine, treat with second line agent, Synalar N® ointment, according to the Patient Group Direction • Refer to specialist ear care nurse independent prescriber • Refer to medical practitioner or ENT consultant • Document in patient's clinical record
Action if Patient declines Treatment	• Explain rationale for compliance to patients who do not wish to receive the medication • Inform/refer to specialist ear care nurse independent prescriber • Inform/refer to medical practitioner or ENT consultant • Document in patient's clinical record
Notes, Drug Interactions and Adverse Effects	• Use of potent/very potent topical corticosteroids can rarely cause adrenal suppression and Cushing's syndrome • Staining of hair, skin clothes • Use of potent/very potent corticosteroids in psoriasis can result in rebound relapse, development of generalised pustular psoriasis, and local and systemic toxicity • Other adverse effects include hypersensitivity reactions, skin thinning, striae atrophicae and telangiectasia, contact dermatitis, acne, mild depigmentation, hypertrichosis, burning sensation, rash, urticaria. • This list is not exhaustive. Refer to current BNF or Summary of Product Characteristics (SPC) for full details www.medicines.org.uk/emc

2. Description of treatment

Name, strength and formulation of drug	Betamethasone 0.1% and Clioquinol 3% ointment
Legal status	POM
Storage	Standards must be consistent with the Summary of Product Characteristics. All medication must be stored in a secure locked environment away from the direct patient care area below 30ºC. Do not use after expiry date

Dose/dose range	• Apply sparingly into the external auditory meatus/pinna • If applying to face do not use for more than five days • If using in children do not use for more than 5 days • If using in adults do not use for more than 7 days without clinical improvement
Method /route	Following aural toilet, paint the ointment onto the affected area using cotton wool wound round a Jobson Horne probe All ear treatments must be carried out under direct vision using a light source
Frequency of administration	A 'one-off' application is frequently sufficient. Alternatively can be repeated in 48 hours. If the meatus is inflamed and there is no improvement after 48 hours, consider taking a swab for culture and sensitivities and treat accordingly
Total dose number	In children aged one to seventeen years of age courses should be limited to 5 days. In adults 18 years and older do not continue for more than 7 days in the absence of clinical improvement.

3. Records

1. The following records must be kept either on paper or computer based. Records should be kept locally and appropriate information passed to patient and relevant physicians.

- Patient's name, address, date of birth and consent given
- Name of medication
- Dose given.
- Brand, Batch Number and Expiry Date
- Signature & name of staff who administered or supplied the medication
- Route and site of administration (record all sites of administration to allow any reactions to be related to the site of the injection
- Information & advice given to patient (including side effects)
- Details of any adverse drug reaction and actions taken, including documentation in the patient's clinical record. Any adverse reaction must be notified to relevant physicians.
- Referral arrangements (including self care)
- Date administered / supplied
- Any serious adverse events and any that may be attributable to black triangled drugs ▼ should be reported via Trust procedure and then to the MHRA using the yellow card system. www.yellowcard.mhra.gov.uk

2. Audit Trail Data Collection

- A record of all individuals receiving treatment under this Patient Group Direction should be kept for audit purposes.

- **Reconciliation**: Stock balances should be reconcilable with Receipts, Administration, Records and Disposals on a patient-by-patient basis

- **Storage**: Standards must be consistent with the Summary of Product Characteristics. All medication must be stored in a secure locked environment away from the direct patient care area

4. Anaphylaxis - Emergency Treatment

Before administering any medication the possibility of anaphylaxis must be discussed and documented with the patient/carer prior to administration of any medication, which may produce an anaphylactic reaction.
When giving any medication the following should always be readily available:

- Access to the patients notes
- Adrenaline (Epinephrine) 1 in 1000 for intramuscular (i.m.) injection for use in emergency (NB: **check expiry dates** regularly)
- Syringes and needles of **suitable size** and capacity for dose.
- Access to a telephone

Adrenaline (Epinephrine) 1 in 1000 (1mg/ml)	**For intramuscular injection**	
Age	Dose	Volume
Children under 6 years	150 micrograms	0.15ml
Children 6 – 12 years	300 micrograms	0.3ml
Adults and adolescents	500 micrograms	0.5ml
These doses may be repeated if necessary at 5-minute intervals according to blood pressure, pulse and respiratory function.		
Special cautions: see BNF 3.4.3	Epinephrine/ Adrenaline	

BNF Current Edition section 3.4.3

5. Professional Responsibility All practitioners

- The Lead Person and the practitioner will ensure he/she has the relevant training and is competent. He/she will attend training updates as appropriate.
- The practitioner will have due regard for the their Professional Conduct and Guidelines for the Administration / Supply of Medicines
- It is the responsibility of the individual practitioner to ensure that he/she has appropriate knowledge of the product prior to proceeding. Refer to the Summary of Product Characteristics (SPC) or current BNF for further details on the product.
- Each individual must have received a personal copy of the PGD and signed on the list of individual professionals who may work within this PGD (kept with master copy of this PGD)
- Must be competent in the recognition and management of anaphylaxis.
- Must have access to all relevant DOH advice, including the relevant CMO letters or training and be competent in all aspects of immunisation including contraindications
- Must have access to a current copy of the BNF and *Immunisation against infectious disease* (The 'Green book') and comply with its recommendations (available on DH website – www.dh.gov.uk/greenbook) where appropriate.
- Annual attendance at the The Rotherham NHS Foundation Trust or workplace update on resuscitation skills and the management of anaphylaxis.
- Maintenance of own level of updating with evidence of continued professional development
- Regular updates in immunisation and vaccination where appropriate with particular reference to changes and national directives.
- **Such practitioners that meet the above criteria for training have The Rotherham NHS Foundation Trust's approval to administer/supply Betamethasone 0.1% and Clioquinol 3% ointment in accordance with this PGD without a doctor's prescription, and with the patient's informed consent.**
- Storage and handling of medicines should be carried out accordance with The Rotherham NHS Foundation Trust's Medicines Management Policy.
- The EC Labelling and Leaflet Directive 92/27 applies to all supplies of medicine, including those supplied under Patient Group Directions and all products other than those immediately administered must be labelled for supply to patients.

Sources: HSC 200/026 Patient Group Directions; Current BNF; Current Summary of Product Characteristics.
Refer to The Rotherham NHS Foundation Trust Procedure for Emergency Treatment of Anaphylactic Reactions and the UK Resuscitation Council Guidelines

The original signed copy of this Patient Group Direction is held in the Pharmacy department. A copy of the signed document is held on file by the Lead Person.

6. Management of Patient Group Direction

This patient group direction is to be read, agreed to and signed by all healthcare professionals to whom it applies. One copy should be given to each practitioner with a copy being kept by the Lead Person with responsibility for PGDs within the organisation.

Developed by:-	**Name & Title**	**Signature**	**Date**
Lead doctor			
Lead pharmacist	Christina Dezelak Medicines Information Pharmacist		
Lead health professional from group who will administer/supply medicine			

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The Administration of Betamethasone 0.1% and Clioquinol 3% Ointment
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This Patient Group Direction is authorised by us			
Title	**Name (& Role if not stated)**	**Signed**	**Date**
Local clinical manager e.g. nurse manager			
Responsible Consultant/ Clinician			
Chair of Drugs & Therapeutic Group	Osman Chohan Chief Pharmacist		

The Registered Nurses named below, being employed or contracted by The Rotherham NHS Foundation Trust working within clinic or at the home of the patient have successfully undertaken approved training and have been assessed as competent and are authorised to supply/administer

Betamethasone 0.1% and Clioquinol 3% Ointment

as specified under this Patient Group Direction

Register of Staff Trained and Assessed to Administer or Supply this Medicine:
(additional sheets may be attached)

"I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct".

Name of authorised practitioner	Signature of authorised practitioner	Clinical manager	Signature of clinical manager	Date