

This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

PATIENT GROUP DIRECTION (PGD)

Administration of

Betamethasone 0.1% and Clioquinol 3% Ointment

for the Treatment of

Otitis Externa

(In Adults and Children Aged 2 Years and Over)

by Registered Pharmacists, as part of the

**Doncaster Clinical Commissioning Group
Ear Care Service**

Version Number 1.0

Change History	
Version and Date	Change details
1.0 June 2021	New PGD

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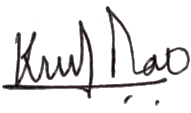

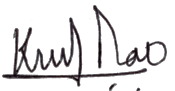
PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	01/07/2021
Review date	31/05/2023
Expiry date:	31/05/2024

This PGD has been developed by the individuals named below. This PGD has been approved by the authorised signatories detailed in the Organisational Authorisations section of this document, on behalf of Doncaster CCG.

Name	Designation
Richard Neilson	Locality Lead Pharmacist, Doncaster CCG Medicines Management

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor	Rao Kolusu Prescribing Lead GP NHs Doncaster CCG		Jun 16, 2021
Senior pharmacist	Alex Molyneux Chief Pharmacist NHs Doncaster CCG		15/06/2021
Senior representative of professional group using the PGD			Jun 16, 2021
Person signing on behalf of authorising body	Rao Kolusu Prescribing Lead GP NHs Doncaster CCG		Jun 16, 2021

GLOSSARY

PGD	Patient Group Direction
GPhC	General Pharmaceutical Council
OOH	Out of Hours Clinic
DoCs	CPPE Declaration of Competence Documents
CPD	Continuing Professional Development
CKS	Clinical Knowledge Summary
SmPC	Summary of Product Characteristics
AOM	Acute Otitis Media
OE	Otitis Externa
PIL	Patient Information Leaflet

1. Characteristics of Staff

Qualifications and professional registration	Qualified pharmacist registered with the General Pharmaceutical Council (GPhC).
Initial training	<p>Competent to work under Patient Group Directions, including satisfactory completion of training to assess patients and supply in accordance with this Patient Group Direction.</p> <p>Working as a community pharmacist and completed ear care training through the Rotherham Primary Earcare & Audiology service.</p> <p>All references in Section 4, and any subsequent updates, must be read and understood by the clinician prior to using this PGD.</p>
Competency assessment	<p>CPPE Declaration of Competence Documents (DoCs). See Minor ailments (cppe.ac.uk).</p> <p>Pharmacists operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions.</p> <p>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 senior individual responsible for authorising individuals to act under the PGD and further training provided as required.</p>
Ongoing training and competency	<p>Commitment to undertake training updates and revalidation according to the accreditation requirements of the commissioning organisation.</p> <p>Commitment to keep up to date with clinical developments in this area or changes to the recommendations for the medicine listed, as part of their Continuing Professional Development (CPD).</p> <p>Competent to follow, and supply medicines using, a PGD.</p> <p>Be able to demonstrate understanding of the indications for the treatment and the correct posology with appropriate advice given.</p> <p>Commitment to keep up to date Safeguarding training at a minimum of Level 2.</p> <p>The pharmacist must keep up to date with current legislation, including the Equality Act and Mental Capacity Act.</p>
<p>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.</p>	

2. Clinical Condition or Situation to which this PGD Applies

Clinical condition or situation to which this PGD applies	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Patients presenting with: <ul style="list-style-type: none"> Symptoms of otitis externa unresponsive to less potent corticosteroids Inflamed mastoid cavity Dry, flaky, red, and inflamed auricle Seborrhoeic dermatitis, eczema, or psoriasis of the auricle Itchy ears Adults and children aged 2 years and over The pharmacist is able to make a safe diagnosis of otitis externa The parent/carer of a child under 16 years of age agrees to treatment under this PGD
Criteria for exclusion	<ul style="list-style-type: none"> Infants under 2 years of age No consent obtained from the parent/carer if the patient is under 16 years of age Hypersensitivity to any of the active ingredients or excipients Primary cutaneous viral infections, e.g. herpes, and chicken pox Acne vulgaris affecting any part of the ear Rosacea Any unremitting ear pain Any signs of otitis media, with effusion ('glue ear') or without Patients that are already using this ointment or a pharmaceutically similar topical preparation for otitis externa Any recent treatment for the same presentation within the last 4 weeks There is granulation tissue at the bone-cartilage junction of the ear canal, or exposed bone in the ear canal Any signs of facial paralysis such as drooping of one side of the face - refer to NHS 111 immediately Any systemic symptoms such as malaise or fever (temperature of 38°C or above) Unilateral hearing loss - if this persists once an obvious cause is removed, for example, removal of earwax, refer to a GP for further investigation to rule out more serious issues such as an acoustic neuroma Any sign of mastoiditis - refer to a GP or NHS 111 immediately Skin lesions on the helix - refer to a GP for further investigation to rule out more serious issues such as a squamous cell carcinoma Signs of infection of the pinna (perichondritis) Malignant otitis externa Visible cholesteatoma Evidence of foreign body in the ear canal Perforation of the tympanic membrane Patients with a grommet (tympanostomy tube) inserted in the tympanic membrane within the last 12 months Pregnancy or breastfeeding
Cautions including any relevant action to be taken	<ul style="list-style-type: none"> Visual disturbance may be reported with systemic and topical corticosteroid use If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist (via the patient's usual GP) for evaluation of possible causes which may include cataract,

	<p>glaucoma, or rare diseases such as central serous chorioretinopathy (CSCR), which have been reported after use of systemic and topical corticosteroids</p> <ul style="list-style-type: none"> • Use of potent topical corticosteroids may rarely cause adrenal suppression and Cushing's syndrome • Refer to Summary of Product Characteristics for the product supplied: www.medicines.org.uk/
Action to be taken if the patient is excluded	<ul style="list-style-type: none"> • Record reasons for exclusion in patient notes • Record the reason for exclusion and any action taken on PharmOutcomes • Advise patient on alternative treatment if suitable • Refer to a prescriber such as the patient's usual GP or NHS 111 if appropriate
Action to be taken if the patient or carer declines treatment	<p>Refer to the patient's usual GP or NHS 111 if the patient is not able to see their GP or is not registered with an NHS GP practice. Offer the patient details of relevant local services such as walk-in centres and OOH services if applicable.</p> <p>You must:</p> <ul style="list-style-type: none"> • Document advice given • Advise patient on alternative treatment • Refer to a prescriber if appropriate
Arrangements for referral for medical advice	<p>Supply the patient with a referral note to hand to the prescriber indicating the reasons for the referral.</p>

3. Description of Treatment

Name, strength & formulation of drug	Betamethasone valerate 0.1% and clioquinol 3% ointment.
Legal category	POM
Route / method of administration	<p>Topical ointment.</p> <p>Following aural toilet, paint the ointment onto the affected area using cotton wool wound round a Jobson Horne probe.</p> <p>All ear treatments must be carried out under direct vision using a light source.</p>
Dose and frequency of administration	<ul style="list-style-type: none"> • Apply sparingly into the external auditory meatus, and auricle • 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 <p>A 'one-off' application is frequently sufficient. The application can be repeated in 48 hours if limited improvement is seen.</p> <p>If the external auditory meatus is inflamed and there is no improvement after 48 hours, consider referring the patient to their GP for a swab for culture and sensitivities, and any ongoing treatment.</p>
Duration of treatment	Single topical treatment.
Quantity to be administered	A topical application during the consultation. No supply is to be made.

Storage	<p>This ointment must be stored in ambient storage conditions, usually within the range of 8-25°C.</p> <p>One tube of ointment may be used on several patients providing that all necessary hygiene techniques have been adhered to.</p> <p>Once opened, the cream must be labelled with the date of opening and discarded within 12 weeks.</p> <p>Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk.</p>
Drug interactions	<p>General information about interactions between betamethasone and other medicinal products is available in the BNF: Betamethasone Interactions. You must refer to this reference along with the interactions stated in the SPC before supplying the ointment.</p> <p>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk/</p>
Identification & management of adverse reactions	<p>The following side effects may be seen with betamethasone valerate and clioquinol ointment:</p> <ul style="list-style-type: none"> • Staining of hair, skin, and clothes • Use of 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, and urticaria <p>Advise the patient that if they notice any adverse reactions, they must contact a pharmacist or their GP immediately.</p> <p>The above list of side effects is not exhaustive. A detailed list of adverse reactions is available in the SPC for the product used, which is available from the electronic Medicines Compendium website: www.medicines.org.uk</p>
Management of and reporting procedure for adverse reactions	<ul style="list-style-type: none"> • 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 • Report via the pharmacy's policy for reporting adverse reactions
Written information to be given to patient or carer	<p>Give the marketing authorisation holder's patient information leaflet (PIL) with the product supplied every time.</p>
Patient advice / follow up treatment	<ul style="list-style-type: none"> • Discuss side effects and administration with the patient's parent/carer and provide the manufacturer's patient information leaflet • If there is little improvement after 5 days treatment, the patient must book an appointment with their GP at the earliest opportunity • Recommend the use of simple analgesia such as paracetamol or ibuprofen to help relieve pain if required • Ensure that any precipitating or aggravating factors are removed

	<ul style="list-style-type: none"> • If earwax is a problem, the person should seek professional advice and have it removed safely to avoid damaging the ear canal • Cotton buds or other objects should not be used to clean the ear canal • Keep the ears clean and dry by using ear plugs and or a tight fitting cap when swimming - people with acute otitis externa should abstain from water sports for at least 10 days • For external use only • Advise the parent/carer that the infection can spread, therefore need to wash hands after use and between applications if using the ointment in both ears • Advise the parent/carer about personal hygiene and not to share towels, face cloths, etc. • Advise patient to dispose of the ointment by returning unused supplies to a community pharmacy for safe destruction after completing the course • Patients or parents/carers must consult a GP if new symptoms occur, or current symptoms worsen • Patient information is available on the NHS website https://www.nhs.uk
<p>Records</p>	<p>Record:</p> <ul style="list-style-type: none"> • That valid informed consent was given • 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) • Advice given, including advice given if excluded or declines treatment • Details of any adverse drug reactions and actions taken • That the medicine is supplied via a PGD • In discussion with the client enter consultation details onto the relevant module within PharmOutcomes at the time of the consultation if possible and always within 24 hours • Details of the supply must also be made in the pharmacy's patient medication record (PMR) <p>All records should be clear, legible, and contemporaneous.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>

4. Key References

<p>Key references</p>	<ul style="list-style-type: none"> • Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines Practice Guideline MPG2 for Patient Group Directions https://www.nice.org.uk/guidance/mpg2 • Common Conditions and Minor Ailments https://www.cppe.ac.uk/learningdocuments/pdfs/common_clinical_conditions_and_minor_ailments.pdf • CPPE Minor Ailments and Declaration of Competence
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	<p>https://www.cppe.ac.uk/gateway/minor</p> <ul style="list-style-type: none">• Clinical Knowledge Summary Otitis Externa https://cks.nice.org.uk/topics/otitis-externa/• NHS Conditions – Ear Infections https://www.nhs.uk/conditions/ear-infections/
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Betamethasone_Clioquinol_Oint_OE_PGD_DC CG_finals

Final Audit Report

2021-06-16

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