NHS England

# CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR OTITIS EXTERNA.
# Clioquinol and Flumetasone EAR DROPS
# (Flumetasone pivalate 0.02% w/v and Clioquinol BP1.0%)

## Version Control

This document is only valid on the day it was printed

The current version of this document will be found on the services page of South Staffordshire, Nottinghamshire and Derbyshire LPCs websites;

## Revision History

Date of this revision: March 2018

Date of next revision: Sept 2019 (or in response to new local/national guidelines)

| Version | Date | Author | Change description |
|---|---|---|---|
| 1.2/2018 | March 2018 | Andrew Pickard / Gordon Heeley | Minimal changes aligning to local antimicrobial guidelines |

## Authorisation

This document requires authorisation by the following individuals:

| **Management** | |
|---|---|
| PGD Author | Andrew Pickard, Pharmacy Advisor - NHS England North Midlands Staffordshire and Shropshire |

| **Authorisation** | | | |
|---|---|---|---|
| **Name and Designation** | **Organisation** | **Signature** | **Date** |
| Dr Anne-Marie Houlder – Deputy Medical Director | NHS England North Midlands | | 21/03/2018 |
| Rebecca Woods – Head of Primary Care (Staffordshire/ Shropshire) | NHS England North Midlands | R Woods | 21/03/2018 |
| Andrew Pickard - Pharmacy Advisor | NHS England North Midlands | A. Pickard | 21/03/2018 |
| Joanne Lunn – Head of Primary Care (Derbyshire / Nottinghamshire) | NHS England North Midlands | | 23/03/2018 |

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# CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR OTITIS EXTERNA LOCORTEN-VIOFORM EAR DROPS (Flumetasone pivalate 0.02% w/v and Clioquinol BP1.0%)

| Staff Characteristics | |
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| 1. Professional qualifications to be held by staff undertaking PGD | • Community pharmacists accredited by NHS England North Midlands to provide the Pharmacy First Extended Care Service (Pilot) |
| 2. Competencies required to be held by staff undertaking this PGD | • Has a clear understanding of the legal requirements to operate a PGD.<br>• Competent to follow and administer PGD showing clear understanding of indications for treatment (and subsequent actions to be taken) and the treatment itself.<br>• Has a clear understanding of the drug to be administered including side effects and contraindications.<br>• All clinicians operating within the PGD have a personal responsibility to ensure their on-going competency by continually updating their knowledge and skills. |
| 3. Specialist qualifications, training, experience and competence considered relevant to the clinical condition treated under this PGD | • The community pharmacist must be registered with the General Pharmaceutical Council and have attended the CPPE training workshop - **Advanced training in assessment and management of urgent cases** as approved by NHS England |

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| Clinical Details | |
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| **Indication** | Management of Otitis Externa where a secondary infection is suspected |
| **Inclusion Criteria** | Adults and children aged 2 years and over. |
| **Exclusion Criteria** | • Children under 2 years old<br>• Hypersensitivity to any component of the formulation or iodine<br>• Primary bacterial, viral or fungal infections of the outer ear<br>• There is unremitting pain, otorrhoea, fever or malaise.<br>• There is granulation tissue at the bone-cartilage junction of the ear canal or exposed bone in the ear canal.<br>• The facial nerve is paralysed (drooping of the face on the side of the lesion).<br>• Raised temperature — over 39°C.<br>• Unilateral hearing loss – if this persists once an obvious cause is removed e.g. wad, it may be a type of brain tumour called an acoustic neuroma<br>• Mastoiditis<br>• Skin lesions on the helix – may be a skin cancer i.e. squamous cell carcinoma<br>• Signs of infection on pinna (perichondritis)<br>• Malignant or fungal otitis externa<br>• Cholesteatoma<br>• Evidence of foreign body in the ear canal<br>• Perforation of the tympanic membrane<br>• Pregnancy<br>• Breastfeeding<br>• Ear canal is too swollen or painful to instil drops into canal |
| **Management of excluded clients** | If patient meets exclusion criteria refer to medical practitioner<br><br>Record the reason for exclusion and any action taken on PharmOutcomes. |
| **Management of patients requiring referral** | If patient declines treatment or advice ensure the following details are recorded on PharmOutcomes;<br>• The advice given by the clinician<br>• Details of any referral made<br>• The intended actions of the patient (including parent or guardian). |

| Drug Details | |
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| **Name, form & strength of medicine** | Clioquinol and Flumetasone Ear Drops<br>(Flumetasone pivalate 0.02% w/v and Clioquinol BP1.0%) |
| **Legal classification** | Prescription Only Medicine (POM) |
| **Route/Method** | Topical |
| **Dosage/Frequency/ Duration of Treatment** | Instil 2 or 3 drops directly into the auditory canal of the affected ear TWICE daily<br><br>Treatment should be limited to 7 days |
| **Quantity to supply/administer** | 1 x 7.5ml or if unavailable 1 x 10ml bottle |
| **Storage** | Do not store above 25°C |
| **Cautions** | • Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects<br>• Clioquinol in urine may give a false positive with the ferric chloride test for phenylketonuria<br>• Long-term continuous topical therapy should be avoided since this can lead to adrenal suppression. Refer patients seeking continuation therapy to a medical practitioner<br>• Topical application of clioquinol-containing preparations may lead to a marked increase in protein-bound iodine (PBI). The results of thyroid function tests, such as PBI, radioactive iodine and butanol extractable iodine, may be affected. However, other thyroid function tests, such as the $T_3$ resin sponge test or $T_4$ determination, are unaffected.<br><br>• Visual disturbance related to systemic and topical corticosteroid use<br><br>**Please refer to current BNF http://bnf.org/bnf/ and SPC for full details http://www.medicines.org.uk/emc/** |

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| **Side Effects** | • Clioquinol and Flumetasone ear drops are generally well tolerated, but occasionally at the site of application, there may be signs of irritation such as a burning sensation, itching or skin rash<br>• Hypersensitivity reactions may also occasionally occur. Treatment should be discontinued if patients experience severe irritation or sensitisation<br>•Clioquinol may cause hair discoloration.<br><br>Use the Yellow Card System to report adverse drug |

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| | reactions directly to the MHRA. http://yellowcard.mhra.gov.uk/ |
| **Advice to patients** | • The ear drops combine the anti-fungal and anti-bacterial properties of clioquinol with the anti-inflammatory activity of flumetasone pivalate<br>• Lie with affected ear uppermost, put two to three drops in the ear and lie in this position for one or two minutes<br>• Press the cartilage at the front of the ear canal a few times to push the drops deep into the ear canal<br>• The ear drops should not be allowed to come into contact with the eye (conjunctiva)<br>• Recommend the use of simple analgesia such as Paracetamol or Ibuprofen to help relieve pain if required<br>• Offer reassurance that oral antibiotics are not usually needed because they are likely to make little difference to symptoms, may have adverse effects (for example diarrhoea, vomiting and rash) and can contribute to antibiotic resistance.<br>• Ensure that any precipitating or aggravating factors are removed<br>• If earwax is a problem, the person should seek professional advice and have it removed safely to avoid damaging the ear canal.<br>• Cotton buds or other objects should not be used to clean the ear canal.<br>• Keep the ears clean and dry by using ear plugs and or a tight fighting cap when swimming — people with acute otitis externa should abstain from water sports for at least 7 to 10 days.<br>• Using a hair dryer (at the lowest heat setting) to dry the ear canal after hair washing, bathing or swimming.<br>• Keeping shampoo, soap and water out of the ear when bathing and showering.<br>• If the person is allergic or sensitive to ear plugs, hearing aids, or earrings they should avoid them, or use alternatives if available (for example hypoallergenic hearing aids).<br>• If the person has a chronic skin condition (for example eczema or psoriasis) they should ensure that this is well controlled if possible.<br>• There are no known interactions with other medical products when administered via this topical route<br>• Clioquinol may stain skin and clothing. Any stained clothing should be washed immediately or |

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| | soaked overnight<br>• For external use only<br>• Complete the course.<br><br>**Please refer to current BNF http://bnf.org/bnf/ or SPC for full details http://www.medicines.org.uk/emc/** |

| **Records and Follow Up** | |
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| **Follow up** | • Advise patient that if rash or other signs of hypersensitivity occur, stop taking the medicine and contact their medical practitioner for advice;<br>• Seek medical attention if condition deteriorates or if there is little improvement after 7 days treatment<br>• If visual disturbances occur during or following recent treatment refer to their medical practitioner. |
| **Records/audit trail** | • In discussion with the client enter consultation details onto the relevant module within PharmOutcomes or complete the paper proforma if unable to access PharmOutcomes at the time of the consultation. All consultations must be entered onto PharmOutcomes on the day that the consultation takes place.<br>• Details of the supply must also be made in the patient's (PMR) record.<br>• All supplies must be labelled in accordance with the labelling requirements for a dispensed medicine as stated within Schedule 5 of The Medicines (Marketing Authorisations etc.) Regulations 1994. No 3144 as amended. In addition to the above, the label must also state the words "Supplied under a PGD" to help with audit purposes.<br>• Informed verbal consent should be obtained (for clients aged under 16 years Fraser guidelines should be followed)<br>• Electronic patient records and/or the completed paper proforma should be retained for adults for a period of 10 years after attendance and for children until the child is 25 years old. Electronic patient medication records are recommended to be kept.<br>• If the client is excluded, a record of the reason for exclusion must be documented within PharmOutcomes and any specific advice that |

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| | has been given.<br>• In every case when a supply is made in accordance with this PGD, the Pharmacist must inform the patient's GP of the supply within two working days. This will be done through secure nhs.net email accounts via PharmOutcomes once the consultation data has been recorded within the specified module. On the rare occasion where no nhs.net account is available to PharmOutcomes the Pharmacist will be informed by the system and must make alternative arrangements to send the information (within two working days). |
| **Adverse drug reactions** | All serious adverse reactions must be reported to MHRA via the yellow card system www.yellowcard.gov.uk.<br><br>A client presenting with a suspected serious ADR should be referred to their medical practitioner. |
| **Date last reviewed: March 2018** | **Date for next review: September 2019** |
| **Expiry date: 31st December 2019** | **Version No: 1.2 / 2018** |

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| **References** | BNF – Current Version<br>Clinical knowledge summaries – Acute Diffuse Otitis Externa - 2016<br>Antimicrobial prescribing guidelines in general practice (Staffordshire) – 2016<br>Antibiotic guidance for Shropshire and Powys Primary Care – 2015<br>Electronic Medicines Compendium - SPC<br>Flumetasone/Clioquinol 0.02%w/v / 1%w/v ear drops – 2017<br>Nottinghamshire APC Antimicrobial Guidelines 2017 |
| **Glossary** | BNF – British National Formulary<br>CKS – Clinical Knowledge Summaries<br>SPC – Summary of Product Characteristics<br>PIL – Patient Information Leaflet<br>PGD – Patient Group Direction<br>PMR – Patient Medication Record<br>POM – Prescription Only Medicine<br>MHRA – Medicines and Healthcare Products Regulatory Agency<br>ADR – Adverse Drug Reaction<br>LPC – Local Pharmaceutical Committee |

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**PGD Workgroup**

The following individuals have been involved with the development and production of this PGD;

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| Andrew Pickard MRPharmS | Pharmacy Advisor – NHS England North Midlands |
| Dr Gill Hall FRPharmS | Service Development Officer – South Staffordshire LPC |
| Tania Cork MRPharmS | Chief Operating Officer – North Staffs and Stoke LPC |
| Peter Prokopa MRPharmS | Chief Officer – South Staffordshire LPC |
| Lindsey Fairbrother MRPharmS | Secretary – Shropshire LPC |
| Gordon Heeley MRPharmS | Treasurer – Nottinghamshire LPC |

**Register of practitioners qualified to supply Clioquinol and Flumetasone Ear Drops via PGD**

Operation of this PGD is the responsibility of the commissioner and service providers.

The practitioner must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Contractors who are commissioned to provide the service will be notified of any amendments and provided with updated documentation for use by individual practitioners.

NHS England authorise this PGD for use by accredited Community Pharmacists delivering the service from community pharmacies that meet the requirements as outlined in the service specification and that have been commissioned by NHS England.

This page must be completed and retained by each individual Pharmacist who intends to work in accordance with this PGD.

**Professional Responsibility and Declaration**

- I have successfully completed the relevant training as outlined in the Service Specification and this Patient Group Direction
- I agree to maintain my clinical knowledge appropriate to my practice in order to maintain competence to deliver this service
- I am a registered pharmacist with the General Pharmaceutical Council
- I confirm that indemnity insurance is in place to cover my scope of practice
- I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD

| Name of professional (please print) | Signature | Date of signing |
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**PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY**