NHS
Cornwall and Isles of Scilly

Patient group direction for the supply of dexamethasone 0.1%, neomycin 0.5%, and acetic acid 2% ear spray by community pharmacists for the management of moderate to severe acute otitis externa

Documentation details

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Change history

Version number	Date	Details
1.0	12/05/2026	New PGD

Patient group direction development

Date template comes into effect: June 2026
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Patient group direction clinical working group

Name and role	Job title	Organisation
Amanda Fidelis Pharmacist (Author)	Senior clinical pharmacist/community pharmacy clinical lead	NHS Cornwall and Isles of Scilly Integrated Care Board (ICB)
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This patient group direction (PGD) was developed by a working group involving pharmacists from NHS Cornwall and Isles of Scilly integrated care board (CIOS ICB) and GP clinical lead from CIOS ICB and virtually approved via the Quality Assurance Group Meeting (QAM)

Based on a version authored by Alison Mundell and commissioned by NHS BNSSG.

Organisational authorisations

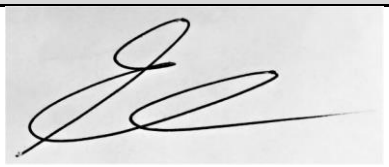
The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

CIOS ICB authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services: Community pharmacies contracted to provide the CIOS ICB community pharmacy PGD service for minor ailments.

Limitations to authorisation: None.

Approved by	Name	Signature	Date of email approval
Chief Pharmacist NHS Cornwall and Isles of Scilly Integrated Care Board	Marco Motta		17/06/2026
Chief Medical Officer &Chief Place and Transformation Officer NHS Devon, Cornwall and Isles of Scilly Integrated Care Board	Dr Chris Reid		23/6/2026
Chief Nursing Officer & Chief Clinical Officer NHS Devon, Cornwall and Isles of Scilly Integrated Care Board	Susan Bracefield		17/06/2026

Local enquiries regarding the use of this PGD may be directed to ciosicb.prescribing@nhs.net

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD. Alternative authorisation sheets and templates may be used where appropriate in accordance with local policy.

Characteristics of staff

Qualifications and professional registration

Registered professional with one of the following bodies:

- Pharmacists registered with the General Pharmaceutical Council (GPhC)

Initial training

- Must be authorised by name as an approved practitioner under the current terms of this PGD before working to it.
- Has undertaken appropriate training and been assessed and declared competent to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this PGD.
- Must be competent in the use of PGDs (see NICE competency framework for health professionals using PGDs).
- Must have access to the PGD and associated online resources.

Competency assessment

All pharmacists operating under this PGD are required to complete a declaration of competence for minor ailments via the Centre Pharmacy Postgraduate Education (CPPE) website and complete the declaration of competence on PharmOutcomes.

Staff operating under this PGD are encouraged to review their competency using the NICE competency framework for health professionals using PGDs.

Staff operating under this PGD are encouraged to attend specific commissioning organised training events on minor ailments and complete the CPPE common clinical conditions e-learning.

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.

Ongoing training and competency

Practitioners must ensure they are up to date with relevant issues and clinical skills relating to the management of otitis externa, with evidence of appropriate continued professional development (CPD).

Pharmacists will be required to complete an annual declaration of competence via the CPPE website and PharmOutcomes.

The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.

Clinical condition or situation to which this PGD applies

Condition or situation: Otitis externa / inflammatory conditions of the external ear canal, where a secondary infection is suspected.

Criteria for inclusion

- Valid Informed consent
- Children (under 16) should demonstrate competence under Gillick competency rules, or consent for treatment must be given by an adult with parental responsibility

Adults and children aged 2 years and over with moderate/severe symptoms not managed by conservative treatment (see cautions)

At least one typical symptom (usually rapid onset within 48 hours):

- Itch of the ear canal.
- Ear pain and tenderness of the tragus and/or pinna (often severe), with possible jaw pain.
- Ear discharge.
- Hearing loss due to ear canal occlusion (less common)

AND at least two typical signs:

- Tenderness of the tragus and/or pinna.
- The ear canal is red and oedematous, and there may be debris and ear discharge contributing to swelling and canal occlusion.
- Tympanic membrane erythema (may be difficult to visualize if the ear canal is narrowed or filled with debris).

- Conductive hearing loss (less common).
- Tender regional lymphadenopathy (less common).
- Cellulitis of the pinna and adjacent skin.

Criteria for exclusion

- No valid consent
- Children under the age of 2 years
- Hypersensitivity to dexamethasone, neomycin sulfate, glacial acetic acid and any other excipients in the formulation or any drugs of the same class.
- Individuals with compromised immunity, severe infection, high risk of severe infection or systemically unwell - refer as oral antibiotics may be indicated
- Cellulitis outside of the ear canal
- Individuals with perforation of the tympanic membrane – acute or chronic or suspected tympanic perforation
- Patients with a suspected fungal ear infection (creamy white debris in the external ear canal, black or white fungal spores)
- Individuals with a patent grommet
- Ear canal is significantly occluded such that there may be difficulty using topical treatment effectively
- Individuals with suspected mastoiditis (pain, soreness, swelling, tenderness behind the affected ear(s)
- Individuals with considerable discharge or extensive swelling of the auditory canal, and microsuction or ear wick insertion is required
- Individuals with a previous episode in the last three months
- Individuals with current episode where treatment with antibiotics has not been effective in managing their symptoms.
- Individuals presenting with mild symptoms or signs which would respond to appropriate analgesia and an over-the-counter preparation
- Pregnancy or any suspected pregnancy
- Individuals with suspected meningitis (neck stiffness, photophobia, mottled skin)
- Individuals with suspected intracranial (brain) abscess (severe headache, confusion or irritability, muscle weakness)
- Individuals with suspected sinus thrombosis (headache behind or around the eye(s))
- Individuals with facial nerve paralysis (drooping of the face)
- Individuals with cholesteatoma
- Individuals with evidence of, or suspected, foreign body in the ear
- Individuals with known mitochondrial mutations or a family history of ototoxicity. Aminoglycosides (gentamicin, amikacin, tobramycin, and neomycin): increased risk of deafness in patients with mitochondrial mutations - GOV.UK

- Chronic otitis externa – inflammation or symptoms which have lasted for more 3 months

Malignant otitis externa or a serious complication is suspected – refer to GP/OOH GP

Red flags

- **Signs of sepsis** (signs include acting confused, slurred speech or not making sense; blue, pale or blotchy skin, lips or tongue; a rash that does not fade when you roll a glass over it; difficulty breathing, breathlessness of breathing very fast) – call 999 or direct the patient to go to A&E
- **Patients with suspected malignant otitis** (more likely in immunosuppressed and diabetic individuals) **- urgent hospital admission should be arranged**.

  Typical symptoms of malignant otitis include:
  - Unremitting disproportionate ear pain, headache, purulent otorrhoea, fever, or malaise.
  - Vertigo.
  - Profound conductive hearing loss.

  Typical signs of malignant otitis include:
  - Systemically unwell, high fever.
  - Granulation tissue seen on the floor of the ear canal and at the bone-cartilage junction; exposed bone in the ear canal.
  - Ipsilateral facial nerve palsy.

Cautions including any relevant action to be taken

Ear swabs for microbiology are rarely helpful in primary care and not indicated for non-complicated otitis externa.

The PGD is not intended to replace self-care and purchase of OTC medicines but offers an alternative or additional option where clinically appropriate.

First line treatment is analgesia for pain relief, keeping the ears clean and dry and consider offering use of over-the-counter acetic acid 2% (Ear Calm) ear drops or spray for people aged 12 year and over.

Dexamethasone 0.1% / neomycin 0.5% / acetic acid 2% ear spray contains methyl and propyl hydroxybenzoates (E218 and E216) which may cause allergic reactions (possibly delayed).It also contains stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

Visual disturbance

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 referred.

Action to be taken if the patient is excluded

- Record reasons for exclusion and any action(s) taken.
- Advise patient on alternative treatment including OTC acetic acid 2% ear spray (for people aged 12 years and over)
- Refer to a prescriber if appropriate (for example emergency department, GP, or NHS 111 or out of hours (OOH) service).
- Give safety-netting advice.
- If severe infection or complication is suspected, immediately refer to the appropriate clinical team

Action to be taken if the patient or carer declines treatment

- Document advice given and the decision reached.
- Advise patient on alternative treatment if appropriate including OTC acetic acid 2% ear spray (for people aged 12 years and over)
- Refer to a prescriber if appropriate.
- Give safety-netting advice.

Arrangements for referral for medical advice

Advise people with otitis externa, and their parents or carers if appropriate, to seek medical help if symptoms worsen at any time, or symptoms persist after completing a course of treatment.

Description of treatment

Name, strength and formulation of drug

Dexamethasone 0.1% / neomycin 0.5% / acetic acid 2% ear spray.

Legal category

Prescription only medicines (POM).

Route and method of administration

Topical (for outer ear use only).

Indicate any off-label use (if relevant)

Not applicable

Dose and frequency of administration

One metered dose three times a day into the affected ear(s) until two days after symptoms have disappeared up to a maximum of 14 days. Discontinue treatment if no clinical improvement after 7 days.

Shake the bottle well before use. Before first use, press actuator down several times to obtain a fine spray. Each press then delivers one metered dose. Do not inhale the spray.
Administer spray directly by gently placing nozzle tip into ear opening and pressing down once on the actuator.
Any unused medicine should be returned to pharmacy for disposal.

Duration of treatment

7 to 14 days.

Quantity to be supplied

5mls

Storage

Stock must be stored in conditions in line with the summary of product characteristics (SmPC).
Do not store above 25°C. Do not freeze.

Drug interactions

None known

The SPC is available from the electronic Medicines Compendium website: summary of product characteristics.

Identification and management of adverse reactions

This medicine is 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. Hypersensitivity reactions may also occasionally occur. Treatment should be discontinued if patients experience severe irritation or sensitisation.
Any adverse reaction to medication should be documented in the patient notes.
Detailed information on adverse reactions is available in the summary of product characteristics.

Use the Yellow Card System to report unexpected adverse drug reactions directly to the MHRA. Guidance on the use of the Yellow Card System and Yellow Cards are available in the current BNF or via www.yellowcard.gov.uk

Management of and reporting procedure for adverse reactions

- Healthcare professionals and patients or carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme .
- Record all adverse drug reactions (ADRs) in the patient's medical record and inform the patient's GP.
- Report via organisation incident policy.

Written information to be given to patient or carer

The marketing authorisation holder's patient information leaflet provided with the product if treatment is to be supplied and advise patient to read the leaflet.

Patient advice and follow up treatment

- Inform the individual/carer of treatment, possible side effects and their management.
- The individual/carer should be advised to seek medical advice in the event of an adverse reaction.
- Advise individual on self-care measures for symptom relief and to reduce risk of recurrent infection.
- Avoid damage to the external ear canal:
  - Troublesome ear wax should be removed safely to avoid damaging the ear canal.
  - Cotton buds or other objects should not be used to clean the ear canal.
- Advise on options for analgesia such as paracetamol, or ibuprofen for symptom relief.
- Keep the ears clean and dry.
  - Avoid swimming and water sports for at least 7–10 days during treatment.
  - Use ear plugs and/or a tight-fighting cap when swimming.
  - Keep shampoo, soap, and water out of the ear when bathing and showering, for example by inserting ear plugs or cotton wool (with petroleum jelly).
  - Consider using a hair dryer (at the lowest heat setting) to dry the ear canal after hair washing, bathing, or swimming.
  - Avoid using hearing aids (if possible) until the condition resolves.
- Advise individual on managing any underlying causes or risk factors including associated skin conditions, where possible

- If the person is allergic or has contact sensitivity to ear drops such as neomycin, ear plugs, hearing aids, or earrings, they should avoid use, or use alternatives where available (such as hypoallergenic hearing aids)
- Advise if they forget to use dexamethasone 0.1% / neomycin 0.5% / acetic acid 2% ear spray not to worry and use it as soon as they remember, then continue as before
- Provide safety netting advice and advise individual to seek advice from healthcare professional if symptoms are not improving within 48-72 hrs of starting treatment or if symptoms have not fully resolved after 2 weeks of starting treatment. Explain they should seek urgent medical advice if they develop signs of sepsis (signs include acting confused, slurred speech or not making sense; blue, pale or blotchy skin, lips or tongue; a rash that does not fade when you roll a glass over it; difficulty breathing, breathlessness or breathing very fast).
- Seek immediate advice if any visual disturbance develops.

Records

- Completion of PGD checklist on PharmOutcomes.
- Completion of patient medication record.
- Label the pack being supplied appropriately:
    - dose, form and route of supply or administration
    - quantity supplied or administered
    - supplied via PGD
- Record details of any adverse drug reactions and actions taken.
- Referral arrangements (including self-care).
- Batch number and expiry date (if applicable).
- Records should be signed and dated (or a password-controlled e-records).
- All records should be clear, legible and contemporaneous.
- A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

Audit trail

- PMR entry.
- Patient's GP should be notified using the notification form on PharmOutcomes within 48 hours of supply for inclusion in the patients notes.

Key references

- CIOS ICB management of infection guidelines
- NICE PGD medicines practice guideline [MPG2]
- Specialist Pharmacy website
- Dexamethasone/ Neomycin sulfate/ Acetic acid 0.1%w/w / 0.5%w/w / 2%w/w Ear Spray - Summary of Product Characteristics (SmPC) - (emc) | 101162
- Electronic BNF https://bnf.nice.org.uk/
- NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2
- Clinical Knowledge Summaries (NICE) at: Otitis externa | Health topics A to Z | CKS | NICE

Registered health professional authorisation sheet

PGD: Supply of dexamethasone 0.1%, neomycin 0.5%, and acetic acid 2% ear spray by community pharmacists for the management of moderate to severe acute otitis externa

Valid from: 1 June 2026
Expiry: 31 May 2028

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

Authorisation

By signing this patient group direction, you are indicating that you agree to its contents and that you will work within it.

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 PGD and that I am willing and competent to work to it within my professional code of conduct.

Name	Designation	Signature	Date

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.