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)

Supply/Administration of Neomycin/dexamethasone/acetic acid Ear spray (Otomize®) for moderate/severe acute otitis externa in BNSSG Community Pharmacies

Documentation details

Reference no:	Comm Pharm Otomize PGD
Version no:	2
Valid from:	April 2025
Review date:	November 2027
Expiry date:	March 2028

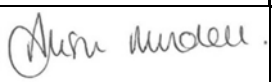
Change history

Version number	Change details	Date
2	Updated PGD written by Alison Mundell and checked by Michelle Jones & Elizabeth Jonas	March 2025

Glossary

Abbreviation	Definition

1. PGD template development

Developed by:	Name	Signature	Date
Pharmacist	Michelle Jones, Principal Medicines Optimisation Pharmacist, BNSSG ICB		18/03/2025
Doctor	Dr Bryn Bird Prescribing lead, BNSSG ICB		
Registered Professional representing users of the PGD	Alison Mundell, ICB Community Pharmacy Clinical Lead		11/03/2025

PGD Working Group membership

Name	Designation
Alison Mundell	Community Pharmacy Clinical Lead, BNSSG ICB
Elizabeth Jonas	Principal Medicines Optimisation Pharmacist, BNSSG ICB
Michelle Jones	Principal Medicines Optimisation Pharmacist, BNSSG ICB
Bryn Bird	GP Clinical Lead for Prescribing, BNSSG ICB
Richard Brown	Chief Officer, Community Pharmacy Avon

2. Organisational authorisations *(may require amendment depending on how the service using the PGD is being commissioned/the organisation who is responsible for authorising the PGD – not all fields may be applicable)*

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.

Bristol, North Somerset and South Gloucestershire ICB authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
All community pharmacies contracted to provide the BNSSG ICB Community Pharmacy PGD Service for Minor Ailments
Limitations to authorisation
None

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Deputy Chief Medical Officer, Bristol, North Somerset and South Gloucestershire ICB	Dr Geeta Iyer		26/03/2025
Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Chief Pharmacist and Director of Medicines Optimisation Bristol, North Somerset and South Gloucestershire ICB	Debbie Campbell		26/03/2025

Local enquiries regarding the use of this PGD may be directed to bnssg.medicines-optimisation@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/templates may be used where appropriate in accordance with local policy.

3. Characteristics of staff

Qualifications and professional registration	Pharmacists currently registered with the General Pharmaceutical Council (GPhC)
Initial training	• must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it • Has undertaken appropriate training and declared themselves competent to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this PGD • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using patient group directions) • must have access to the Patient Group Direction and associated online resource • should fulfil any training requirements defined by BNSSG ICB **The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate training and successfully completed the competencies to undertake clinical assessment of patient leading to diagnosis of the conditions listed.**
Competency assessment	*Complete the self-declaration for this PGD on PharmOutcomes* *Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions* ***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. An additional training course organised by BNSSG ICB must be completed prior to delivering this PGD. If an alternative course has been undertaken this must be approved by the ICB.***
Ongoing training and competency	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to management of otitis externa, with evidence of appropriate Continuing Professional Development (CPD) Pharmacists will be required to complete an annual Declaration of Competence via 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.	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	• **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 lymphadenitis (less common).

Criteria for exclusion	• No valid consent • Children under the age of 2 years • Hypersensitivity to neomycin sulfate, dexamethasone, glacial acetic acid or to any of the excipients • Individuals with compromised immunity, severe infection, high risk of severe infection or systemically unwell consider referral as oral antibiotics may be indicated • Individuals should be referred, and oral antibiotics considered if cellulitis spreads outside 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 occluded - refer for specialist advice • Individuals with extreme pain or discomfort – refer to GP/OOH GP

	• 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 and breast-feeding
	• 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 immunosupressed and diabetic individuals) **- urgent hospital admission should be arranged**
	  • **Typical symptoms:**
	  ○ Unremitting disproportionate ear pain, headache, purulent otorrhoea, fever, or malaise.
	  ○ Vertigo.
	  ○ Profound conductive hearing loss.
	  • **Typical signs:**
	  ○ 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 drops or spray for people aged 12 year and over. Otomize contains methyl and propyl hydroxybenzoates (E218 and E216) which may cause allergic reactions (possibly delayed). Otomize contains stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

	<u>Visual disturbance</u> 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 in patient notes • 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 • Give safety netting advice
Action to be taken if the patient or carer declines treatment	• Document advice given and the decision reached • 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 • Give safety netting advice
Arrangements for referral for medical advice	Refer to the appropriate practitioner in the care pathway

5. Description of treatment

Name, strength & formulation of drug	**Neomycin/dexamethasone/acetic acid ear spray (Otomize®)**
Legal category	**POM**
Route / method of administration	Topically in the ear
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 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	Seven to fourteen days.
Quantity to be supplied	Supply one original pack of 5ml
Storage	Store upright in a carton. Do not store above 25°C. Do not freeze.

	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
Drug interactions	None known This list is not exhaustive. 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	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.** This list is not exhaustive. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk 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 individuals 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 organisation incident policy.
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the product. Provide advice on sources of information and support, such as: • The patient.info leaflet Ear infection (otitis externa). • The NHS patient leaflet Ear infections.
Patient advice / 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. • 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 Otomize 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 of breathing very fast)
Records	Record: • 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 and brand of medication supplied/administered • date of supply/administration • dose, form and route of supply/administration • quantity supplied/administered • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • supplied via Patient Group Direction (PGD) • referral arrangements (including self-care) • label the pack being supplied appropriately 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.

6. Key references

Key references	• Electronic Medicines Compendium, Otomize Ear Spray http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline “Patient Group Directions” https://www.nice.org.uk/guidance/mpg2 • BNSSG Primary Care Antimicrobial Guidelines accessed 18/3/25 • Clinical Knowledge Summaries (NICE) at: Otitis externa | Health topics A to Z | CKS | NICE

7. Registered health professional authorisation sheet

PGD Name: Comm Pharm Otomize v2 Valid from: 1/04/25 Expiry: 31/3/28

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

Registered health professional

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 Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager (if applicable)

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation for the aboved named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

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