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 of Otigo® (phenazone 40mg/lidocaine hydrochloride 10mg/g) ear drops, solution for the symptomatic relief of pain due to acute otitis media (AOM) under the NHS England commissioned Pharmacy First service

Version Number 1.1

Change History	
Version and Date	**Change details**
Version 1.0 January 2024	New template
Version 1.1 January 2025	TARGET TYI RTI leaflet information updated

Version: 1.1
Reference Number: 7a
Valid from: 31/01/2024
Review date: 30/07/2026
Expiry date: 30/01/2027

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor	Prof. Sir Stephen Powis National Medical Director		29.04.25
Senior pharmacist	David Webb Chief Pharmaceutical Officer		29.04.25
Specialist in microbiology	Prof. Mark Wilcox National Clinical Director, IPC/AMR		29/04/25
Person signing on behalf of authorising body	David Webb Chief Pharmaceutical Officer		29.04.25

PGD DEVELOPMENT GROUP

Date PGD comes into effect:	31/01/2024
Review date	30/07/2026
Expiry date:	30/01/2027

This PGD has been peer reviewed by the Upper Respiratory Tract Infection (URTI) antimicrobial national PGD Short Life Working Group in accordance with their Terms of Reference. It has been reviewed by The Advisory Committee on Antimicrobial Prescribing, Resistance and Healthcare Associated Infection (APRHAI) to the Department of Health and Social Care (England) in November 2023.

Name	Designation
Dr Diane Ashiru-Oredope	Lead Pharmacist, HCAI, Fungal, AMR, AMU & Sepsis Division, UK Health Security Agency
Dr Imran Jawaid	GP and RCGP AMR representative
Dr Jeeves Wijesuriya	GP and Clinical Advisor to NHS England Primary Care Team and Vaccination and Screening Team
Jackie Lamberty	Medicines Governance Consultant Lead Pharmacist, UK Health Security Agency
Jo Jenkins	Lead Pharmacist Patient Group Directions and Medicines Mechanisms, Medicines Use and Safety Division, Specialist Pharmacy Service
Liz Cross	Advanced Nurse Practitioner QN
Dr Martin Williams	Consultant in Microbiology and Infectious Diseases
Temitope Odetunde	Head of Medicines Management
Nigel Gooding	Consultant Paediatric Pharmacist. Neonatal and Paediatric Pharmacist Group (NPPG) representative.
Kieran Reynolds (SLWG co-ordinator)	Specialist Pharmacist – Medicines Governance, Medicines Use and Safety Division, Specialist Pharmacy Service
Laura Whitney	NHS England Regional Antimicrobial Stewardship lead for the London region
Ms Wendy Smith	Consultant ENT Surgeon
Ghulam Haydar	Senior Policy Lead, Primary Care, Community Services and Strategy Directorate, NHS England

Characteristics of staff

Qualifications and professional registration	Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
Initial training	• The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and be competent to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with the specification. • To deliver this service, the registered healthcare professional should have evidence of competence in the clinical skills and knowledge covered in the Centre for Pharmacy Postgraduate Education (CPPE) Pharmacy First Service self-assessment framework. • Before commencement of the service, the pharmacy contractor must ensure that pharmacists and pharmacy staff providing the service are competent to do so, including in the use of an otoscope (except for contractors entering the NHS England pharmaceutical list under a distance-selling exemption) and be familiar with the clinical pathways, clinical protocol and PGDs. This may involve completion of training.
Competency assessment	• Individuals operating under this PGD must be assessed as competent or complete a self-declaration of competence to operate under this PGD (see an example authorisation record sheet in Appendix A). • Individuals operating under this PGD are advised to review their competency using the NICE Competency Framework for health professionals using patient group directions.
Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance 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.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Local symptomatic relief of pain from acute otitis media (AOM) in children aged 1 year and over and young people (under 18 years of age).

Criteria for inclusion	• Informed consent
	• Individuals aged 1 year and over and under 18 years of age
	• Signs and symptoms of acute otitis media using the appropriate NICE CKS guidance:
	  ○ In older children: earache
	  ○ In younger children: holding, tugging or rubbing of the ear(s) (also non-specific symptoms: fever, crying, poor feeding, restlessness, behavioural changes, cough or rhinorrhoea may also be present)
	AND (on otoscopic examination):
	  ○ Distinctly red, yellow or cloudy tympanic membrane **OR**
	  ○ Moderate-severe bulging of the tympanic membrane, with loss of normal landmarks and an air-fluid level behind the tympanic membrane.
	• Pain not adequately controlled with regular doses of (over the counter) paracetamol or ibuprofen, using a dosing schedule appropriate for the age and weight of the child. (For further information see: Mild to moderate pain and NSAIDs-prescribing issues).
	• Individuals with moderate – severe symptoms.

Criteria for exclusion	• Consent refused and documented in the individual's clinical notes
	• Individuals under 1 year of age or over 18 years of age
	• Pregnancy or suspected pregnancy in individuals under 16 years of age
	• Severely immunosuppressed individuals as defined in Chapter 28a Green book):
	Individuals with primary or acquired immunodeficiency states due to conditions including:
	  • *acute and chronic leukaemias, and clinically aggressive lymphomas (including Hodgkin's lymphoma) who are less than 12 months since achieving cure*
	  • *individuals under follow up for a chronic lymphoproliferative disorders including haematological malignancies such as indolent lymphoma, chronic lymphoid leukaemia, myeloma, Waldenstrom's macroglobulinemia and other plasma cell dyscrasias (N.B: this list not exhaustive)*
	  • *immunosuppression due to HIV/AIDS with a current CD4 count of below 200 cells/µl.*
	  • *primary or acquired cellular and combined immune deficiencies – those with lymphopaenia (<1,000 lymphocytes/ul) or with a functional lymphocyte disorder*
	  • *those who have received an allogeneic (cells from a donor) or an autologous (using their own cells) stem cell transplant in the previous 24 months*
	  • *those who have received a stem cell transplant more than 24 months ago but have ongoing immunosuppression or graft versus host disease (GVHD)*

Individuals on immunosuppressive or immunomodulating therapy including:

- *those who are receiving or have received in the past 6 months immunosuppressive chemotherapy or radiotherapy for any indication*
- *those who are receiving or have received in the previous 6 months immunosuppressive therapy for a solid organ transplant*
- *those who are receiving or have received in the previous 3 months targeted therapy for autoimmune disease, such as JAK inhibitors or biologic immune modulators including B-cell targeted therapies (including rituximab but for which a 6 month period should be considered immunosuppressive), monoclonal tumor necrosis factor inhibitors (TNFi), T-cell co-stimulation modulators, soluble TNF receptors, interleukin (IL)-6 receptor inhibitors., IL-17 inhibitors, IL 12/23 inhibitors, IL 23 inhibitors (N.B: this list is not exhaustive)*

Individuals with chronic immune mediated inflammatory disease who are receiving or have received immunosuppressive therapy

- *moderate to high dose corticosteroids (equivalent ≥20mg prednisolone per day) for more than 10 days in the previous month*
- *long term moderate dose corticosteroids (equivalent to ≥10mg prednisolone per day for more than 4 weeks) in the previous 3 months*
- *any non-biological oral immune modulating drugs e.g. methotrexate >20mg per week (oral and subcutaneous), azathioprine >3.0mg/kg/day; 6-mercaptopurine >1.5mg/kg/day, mycophenolate >1g/day) in the previous 3 months*
- *certain combination therapies at individual doses lower than stated above, including those on ≥7.5mg prednisolone per day in combination with other immunosuppressants (other than hydroxychloroquine or sulfasalazine) and those receiving methotrexate (any dose) with leflunomide in the previous 3 months*

Individuals who have received a short course of high dose steroids (equivalent >40mg prednisolone per day for more than a week) for any reason in the previous month.

- Immunosuppressed individuals: individuals who are immunosuppressed or are currently taking immunosuppressants (including systemic corticosteroids*) or immune modulators, but who do not meet the definition of severe immunosuppression (see above). [For equivalent doses in children, see Chapter 6 Green Book]
  * does not include:
  - replacement corticosteroids for individuals with adrenal insufficiency
  - corticosteroid inhalers or corticosteroids applied topically (e.g. to the skin, ears, eyes, nasal cavity)
  - intra-articular, -bursal or -tendon corticosteroid injections.
- Hypersensitivity to the active substances or to any of the excipients within the formulation (see Summary of Product Characteristics for further details). **Acceptable sources of allergy information include individual/carer/parent/guardian or National Care Record**.
- Individuals with mild symptoms: Ask the individual to return to Community Pharmacy within 3-5 days if no improvement for pharmacist reassessment.

	• Known perforation (infectious or traumatic) of the tympanic membrane (i.e. perforated or "burst" eardrum) (including otorrhea, myringotomy, presence of a grommet or other ventilation tube) of the affected ear(s)
	• Individuals with evidence of, or suspected, foreign body in the ear canal of the affected ear(s)
	• Individuals with recurrent infection - defined as three or more documented and separate acute otitis media episodes (with an absence of middle ear disease between episodes) in the preceding 6 months, or four or more episodes in the preceding 12 months with at least one episode in the past 6 months
	• Individual is at high risk of complications due to pre-existing co-morbidity (e.g. children with significant heart, lung, kidney, liver or neuromuscular disease, severe immunosuppression or immunosuppression, cystic fibrosis and young children who were born prematurely)
	• Individuals most likely to benefit from an oral antibiotic (see separate PGDs):
	  ○ Individuals under 18 years of age with acute otitis media and otorrhea (ear discharge after tympanic membrane perforation)
	  ○ Individuals under 2 years of age with bilateral (in both ears) acute otitis media.
	• Otitis Media with visible effusion (glue ear)
	• Individuals with a temperature over 39°C.
	• Individuals with suspected meningitis (neck stiffness, photophobia, mottled skin)
	• Individuals with suspected mastoiditis (pain, soreness, swelling, tenderness behind the affected ear(s))
	• 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
	• Any individual identified with symptoms of severe/life-threatening infection or systemic sepsis: refer urgently via ambulance
	• Possible cancer:
	  ○ Bloody/blood stained discharge from ear(s)
	• Individuals with haemoglobinopathies or Glucose-6-phosphate dehydrogenase (G6PD) deficiency (or other risk factors for methemoglobinaemia).

Cautions including any relevant action to be taken	Individuals who are **subject to anti-doping tests** should be advised against using Otigo® as this medicinal product contains an active substance which may give positive results in anti-doping tests.
Specific information for suspected infection to be provided	Provide the Treating Your Infection Respiratory Tract Infection (TYI-RTI) patient information leaflet (TARGET RTI leaflet) (TARGET RTI leaflets in other languages are also available). Advise that acute otitis media mainly affects children, can last for

	around 1 week and most children will get better within 3 days without antibiotics.

Action to be taken if the individual is excluded	• Record reasons for exclusion in the appropriate clinical record.
	
	Individuals where treatment is not indicated:
	• Provide TARGET RTI leaflet (TARGET RTI leaflets in other languages are also available).
	• Provide self-care advice including:
	  ○ Advise regular doses of paracetamol or ibuprofen (over the counter and where appropriate) for pain, using a dosing schedule appropriate for the age and weight of the child. (For further information see: Mild to moderate pain and NSAIDs-prescribing issues).
	  ○ Explain that evidence suggests decongestants and antihistamines (over the counter) do not help with symptoms.
	• Advise individual/carer/parent/guardian to seek medical advice if symptoms worsen rapidly or significantly or the individual becomes systemically very unwell.
	
	Refer urgently to a prescriber for further assessment if:
	• Individual is systemically very unwell, but not showing signs or symptoms of sepsis
	• Individual has signs of a more serious illness
	• Individual is at high risk of complications due to pre-existing co-morbidity (e.g. children with significant heart, lung, kidney, liver or neuromuscular disease, severe immunosuppression or immunosuppression, cystic fibrosis and young children who were born prematurely)
	• Possible cancer suspected:
	  ○ Bloody/blood stained discharge from ear(s)
	• Individuals where treatment under this PGD is not indicated/permitted but upper respiratory symptoms are present and require further assessment.
	
	Refer urgently to A&E for further assessment if:
	• Signs or symptoms of serious complications (including meningitis, mastoiditis, intracranial (brain) abscess, sinus thrombosis or facial nerve paralysis (drooping of the face)) suspected.
	
	If sepsis is suspected refer the individual urgently to A&E
	
	For children: see Healthier Together guidance (otitis media (earache)) for further information on appropriate signposting and parent information sheets.

Action to be taken if the individual/carer/parent/ guardian declines treatment	• Document advice given • Provide safety netting advice and advise individual/carer/parent/guardian of alternative treatment available (e.g. regular oral analgesia) using TARGET RTI leaflet (TARGET RTI leaflets in other languages are also available). • Refer to a prescriber if appropriate
Arrangements for	Refer to the appropriate medical practitioner in the care pathway

referral for medical advice	

Description of treatment

Name, strength & formulation of drug	Otigo® (phenazone 40mg/lidocaine hydrochloride 10mg/g) ear drops, solution
Legal category	POM
Route / method of administration	Topically into the external auditory canal of the affected ear(s) instilled into the affected ear(s) via a dropper applicator (provided with bottle). Advise individual/carer/parent/guardian to warm the bottle between their hands before each use. Further advice re: administration can be found in the patient information leaflet (PIL). Further guidance on how to administer ear drops to children is available from Medicines for Children.
Off-label use	**Temperature variations** Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the pharmacist must ensure the medicine remains pharmaceutically stable and appropriate for use if it is to be issued. Where medicines have been assessed by a pharmacist in accordance with national or specific product recommendations/manufacturer advice as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected medicines for use lies with the pharmacist. Where a drug is recommended off-label consider, as part of the consent process, informing the individual/carer/parent/guardian that the drug is being offered in accordance with national guidance but that this is outside the product licence.
Dose and frequency of administration	**Children over 1 year of age and young people under 18 years of age:** Instil 4 drops up to three times daily into the external auditory canal of the affected ear(s). Further advice re: administration can be found in the patient information leaflet (PIL). Further guidance on how to administer ear drops to children is available from Medicines for Children.
Duration of treatment	Until symptoms have resolved or up to a maximum of 7 days
Quantity to be supplied	**Children over 1 year of age and young people under 18 years of age:** Appropriately labelled 15mL bottle of Otigo® (phenazone

	40mg/lidocaine hydrochloride 10mg/g) ear drops
Storage	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 Store in the original package, in order to protect from light.
Drug interactions	No interaction studies have been performed. Due to the external administration of the product and application of the active ingredients at a low dose, systemic absorption is very unlikely. Therefore, no clinically significant interactions are expected.
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk The following side effects are listed in the product SPC as **rare** (but may not reflect all reported side effects): • Local allergic reactions (itching, maculopapular rash), • Auditory canal hyperaemia (increased blood flow to the auditory canal).
Management of and reporting procedure for adverse reactions	• Healthcare professionals and individuals/carers/ parents/guardians 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 individual's clinical record. • Report and document in accordance with organisation incident policy. • It is considered good practice to notify the individual's GP in the event of an adverse reaction.
Written information to be given to individual/carer/parent/ guardian	• Provide marketing authorisation holder's information leaflet (PIL) provided with the product. • Provide the TARGET RTI leaflet (TARGET RTI leaflets in other languages are also available). • Give any additional information in accordance with the service specification.
Individual advice / follow up treatment	• Explain the dose, frequency and method of administration (use instructions from the PIL provided to aid this). Further guidance on how to administer ear drops to children can be found here. • Without treatment, symptoms should start to improve within 3 days. • Advise individual/carer/parent/guardian that if symptoms do not improve within 3-5 days to return to Community Pharmacy for pharmacist reassessment. • Advise individual/carer/parent/guardian to seek medical attention if symptoms worsen rapidly or significantly at any time. • Advise individual/carer/parent/guardian to seek immediate medical attention (by calling 999 or going to A&E) if the individual develops signs or symptoms of sepsis. • If ear discharge develops during the course of treatment with Otigo®, (which may indicate perforation) advise

	individual/carer/parent/guardian to stop administering and seek advice from a medical professional. • Inform individual/carer/parent/guardian of possible (although rare) side effects and their management. • Advise individual/carer/parent/guardian to administer the medication at regular intervals. • The individual/carer/parent/guardian should be advised to seek medical advice in the event of an adverse reaction or if any other new symptoms develop. • If a dose is missed advise to refer to PIL supplied with the product (do not double up on a missed dose). • Advise individual/carer/parent/guardian to return any unused medicines to a pharmacy for disposal: do not dispose of medicines in the bin, down the sink or toilet.

Records	Appropriate records must include the following:
	
	• That valid informed consent has been given
	• Individual's name, address and date of birth
	• Name of GP individual is registered with or record where an individual is not registered with a GP
	• Name and registration number of registered healthcare professional operating under this PGD
	• Specify how the individual has/has not met the criteria of the PGD
	• Relevant past and present medical history and medication history
	• Any known allergies and nature of reaction(s)
	• Name/dose/form/quantity of medicine supplied
	• Date and time of supply
	• Documentation of cautions as appropriate
	• Advice given, including advice given if individual excluded or declines treatment
	• Details of any adverse drug reactions and actions taken
	• Advice given about the medication including side effects, benefits, and when and what to do if any concerns.
	• Any follow up and/or referral arrangements made.
	• Any supply outside the terms of the product marketing authorisation
	• The supply must be entered in the Patient Medication Record (PMR)
	• That supply was made under a PGD
	• Any safety incidents, such as medication errors, near misses and suspected adverse events
	• Any additional requirements in accordance with the service specification:
	  • The pharmacy contractor will ensure that a notification of the provision of the service is sent to the patient's general practice on the day of provision or on the following working day. Where possible, this should be sent as a structured message in real-time via the NHS assured Pharmacy First IT system. In the absence of an automated digital solution or if there is a temporary problem with the system, this should be sent via NHSmail or hard copy.
	  • Where an action is required by the General Practice team (such

	as booking the patient in for a follow up or appointment) an action message or alternative form of an URGENT ACTION communication (rather than the standard post event message) must be sent to the practice. • All records should be kept in line with national guidance. This includes individual data, master copies of the PGD and lists of authorised practitioners. **Records must be signed and dated (or a password controlled e-records).** **All records must be clear, legible and contemporaneous.** **A record of all individuals receiving treatment under this PGD must also be kept for audit purposes in accordance with the service specification.**

Key references

Key references (last accessed November 2023)	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • Electronic BNF for children https://bnfc.nice.org.uk/ • Reference guide to consent for examination or treatment https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653__1_.pdf • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2 • NICE Clinical knowledge summaries. Otitis media - acute https://cks.nice.org.uk/topics/otitis-media-acute/ • UK Sepsis Trust. Sepsis e-learning resources. https://sepsistrust.org/professional-resources/sepsis-e-learning/ • TARGET Treating your infection - Respiratory Tract Infection (TYI-RTI) leaflet https://elearning.rcgp.org.uk/mod/book/view.php?id=13511&chapterid=787 • TARGET Treating your infection - Respiratory Tract Infection (TYI-RTI) leaflet (available in other languages) https://elearning.rcgp.org.uk/mod/book/view.php?id=12647&chapterid=444 • NICE Clinical knowledge summaries. Analgesia –mild-to-moderate pain. https://cks.nice.org.uk/topics/analgesia-mild-to-moderate-pain/ • NICE Clinical knowledge summaries. NASIDs – prescribing issues. https://cks.nice.org.uk/topics/nsaids-prescribing-issues/ • Venekamp, Roderick P et al. Acute otitis media in children. *BMJ clinical evidence* vol. 2014 0301. 16 Sep. 2014

Appendix A – example registered health professional authorisation sheet (example – local versions/electronic systems may be used)

PGD Name/Version **Valid from:** **Expiry:**

Before signing this PGD, check that the document has had the necessary authorisations. 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

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of insert name of organisation for the above 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.

Add details on how this information is to be retained according to organisation PGD policy.