NHS
Doncaster
Clinical Commissioning Group

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

Amoxicillin Capsules or Amoxicillin Suspension

for the Treatment of

Acute Otitis Media (In Adults and Children Aged 1 Year and Over)

by Registered Pharmacists, as part of the

Doncaster Clinical Commissioning Group Minor Ailments Service

Version Number 1.0

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

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

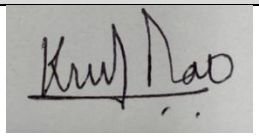
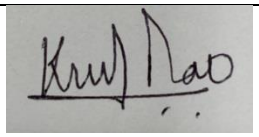
PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	01/06/2021
Review date	01/06/2022
Expiry date:	01/06/2024

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
Chioma Nnamdi	Locality Lead Pharmacist, Doncaster CCG Medicines Management
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		27/05/2021
Senior pharmacist	Alex Molyneux, Head of Medicines Mangement, NHS Doncaster CCG		21/05/2021
Senior representative of professional group using the PGD			
Person signing on behalf of authorising body	Rao Kolusu, Prescribing Lead GP, NHS Doncaster CCG		27/05/2021

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

1. Characteristics of Staff

Qualifications and professional registration	Qualified pharmacist registered with the General Pharmaceutical Council (GPhC).
Initial training	Competent to work under Patient Group Directions, including satisfactory completion of training to assess patients and supply in accordance with this Patient Group Direction. Working as a community pharmacist and accredited to provide the Minor Ailments Service.
Competency assessment	CPPE Declaration of Competence Documents (DoCs). See Minor ailments (cppe.ac.uk). Pharmacists 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.
Ongoing training and competency	Commitment to undertake training updates and revalidation according to the accreditation requirements of the commissioning organisation. 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). Competent to follow and supply medicines using a PGD. Be able to demonstrate understanding of the indications for the treatment and the correct posology with appropriate advice given. Commitment to keep up to date Safeguarding training at a minimum of Level 2. The pharmacist must keep up to date with current legislation, including the Equality Act and Mental Capacity Act.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

2. Clinical Condition or Situation to which this PGD Applies

Clinical condition or situation to which this PGD applies	• Acute otitis media Without antibiotic treatment, symptoms will improve within 24 hours in 60% of children with acute otitis media (AOM), and will settle spontaneously within 3 days in 80% of children. Consider a delayed antibiotic prescribing strategy. Advise that antibiotics should be started if symptoms are not improving within 4 days of the onset of symptoms or if there is a significant worsening of symptoms at any time. Note that amoxicillin is first line oral antibiotic treatment for otitis media. Clarithromycin is second line oral antibiotic treatment and for those with an allergy or hypersensitivity to any penicillin antibiotics. Refer to the Clarithromycin PGD if amoxicillin is not suitable for the patient.
Criteria for inclusion	• Adults and children aged 1 year 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	• Infants and neonates under 1 year of age • No consent obtained from the parent/carer of the patient is under 16 years of age • Hypersensitivity to amoxicillin, any other penicillin antibiotic, or to any of the excipients • Primary bacterial, viral or fungal infections of the outer ear • Any otorrhoea (drainage of the ear, often due to a perforated ear drum) • Any other current or recent infection of the ear • Any recent course of treatment for the same presentation (3-4 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 for further investigation • Any systemic symptoms such as malaise or fever (temperature of 38ºC 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 on pinna (perichondritis) • Malignant otitis externa • Visible cholesteatoma • Any potential meningitis symptoms, for example, photophobia, a non-blanching rash, stiff neck, or sudden malaise or tiredness • Evidence of foreign body in the ear canal • Perforation of the tympanic membrane • Pregnancy or breastfeeding

Cautions including any relevant action to be taken	• Refer to Summary of Product Characteristics for the product supplied http://www.medicines.org.uk/emc/
Action to be taken if the patient is excluded	• 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 • Telephone 999 immediately for anyone attending who has life-threatening symptoms such as suspected meningitis or who is systemically unwell
Action to be taken if the patient or carer declines treatment	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. You must: • Document advice given • Advise patient on alternative treatment • Refer to a prescriber if appropriate
Arrangements for referral for medical advice	Supply the patient with a referral note to hand to the prescriber indicating the reasons for the referral.

3. Description of Treatment

Name, strength & formulation of drug	• Amoxicillin capsules 250mg or 500mg • Amoxicillin oral suspension SF 125mg/5ml or 250mg/5ml
Legal category	POM
Route / method of administration	Oral
Indicate any off-label use (if relevant)	This POM product must be supplied for use within its licenced posology and method of administration for the purpose of this PGD.
Dose and frequency of administration	Use the following dosage regimen based on patient age: • Child 1-4 years: 250mg three times a day • Child 5-17 years: 500mg three times a day • Adults aged 18 years and above: 500mg three times a day Wherever possible, adults should be treated with solid dosage forms and liquids only reserved for those who are genuinely unable to swallow capsules. Higher doses are licensed but are beyond the scope of this PGD. Refer serious and recurrent infections to the patient's GP or NHS 111.
Duration of treatment	5 days
Quantity to be supplied	15 capsules if supplying either 250mg or 500mg capsules. Oral suspension in multiples of 100ml to provide 5 days of treatment, with instructions to discard the remainder after the 5-day course.

Storage	Amoxicillin capsules must be stored in ambient storage conditions, usually within the range of 8-25ºC. Amoxicillin suspension, once reconstituted, should be stored in the refrigerator within the range of 2-8ºC for up to 7 days. Prior to reconstitution, the product requires ambient storage conditions. Offer the patient's parent/carer appropriate advice about the correct storage conditions. 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	**Allopurinol** - Concomitant use of allopurinol and amoxicillin may increase the incidence of skin rashes. Concomitant use need not be avoided for this reason. **Vitamin K antagonists** (e.g. warfarin) - Prolongation of prothrombin time has been reported in people taking one of the penicillin group of antibiotics and warfarin concurrently. **Methotrexate** – The penicillin group of antibiotics may reduce the excretion of methotrexate. The interaction is not usually serious and risk factors are unknown but advise patients on signs and symptoms of methotrexate toxicity. **Oral hormonal contraception** - Additional contraceptive precautions are NOT required during or after courses of the penicillin group of antibiotics. However, advise women about the importance of correct contraceptive practice if they experience vomiting or diarrhoea. **Probenecid** - Decreases the renal tubular secretion of amoxicillin. Concomitant use of probenecid may result in increased and prolonged levels of amoxicillin and should be avoided. 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	The following side effects may be seen with amoxicillin: • Diarrhoea • Nausea • Vomiting • Skin rash Advise the patient that if they notice any adverse reactions, they must contact a pharmacist or their GP. A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Management of and reporting procedure for adverse reactions	• 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	Give the marketing authorisation holder's patient information leaflet (PIL) with the product supplied every time.
Patient advice / follow up treatment	• Discuss side effects and administration with the patient's parent/carer and provide the manufacturer's patient information leaflet • Consider a delayed antibiotic prescribing strategy for adults and children aged 2 years and over - advise that antibiotics should be started if symptoms are not improving within 4 days of the onset of symptoms or if there is a significant worsening of symptoms at any time • 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 • 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 • Advise the patient or parent/carer that the course should be completed • 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
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 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) 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.

4. Key References

Key references	• Electronic Medicines Compendium 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 • 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 https://www.cppe.ac.uk/gateway/minor • Clinical Knowledge Summary Otitis Externa https://cks.nice.org.uk/topics/otitis-externa/ • NHS Conditions – Ear Infections https://www.nhs.uk/conditions/ear-infections/ • NHS Medicines – Amoxicillin https://www.nhs.uk/medicines/amoxicillin/

5. Registered Pharmacist Authorisation Sheet

Before signing this PGD, check that the document has had the necessary authorisations in Section 1. Without these, this PGD is not lawfully valid.

Registered Pharmacist

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**