

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/oral suspension/oral solution for the treatment of acute otitis media (AOM) under the NHS England commissioned Pharmacy First service**

Version Number 1.0

<b>Change History</b>	
<b>Version and Date</b>	<b>Change details</b>
Version 1.0 January 2024	New template

**ORGANISATIONAL AUTHORISATIONS**

Name	Job title and organisation	Signature	Date
<b>Senior doctor</b> <b>Professor Sir</b> <b>Stephen Powis</b>	National Medical Director, NHS England		11.12.23
<b>Senior pharmacist</b> <b>David Webb</b>	Chief Pharmaceutical Officer, NHS England		08.12.23
<b>Specialist in</b> <b>microbiology</b> <b>Professor Mark</b> <b>Wilcox</b>	National Clinical Director for AMR & IPC, NHS England		11.12.23
<b>Person signing on</b> <b>behalf of <u>authorising</u></b> <b><u>body</u></b> <b>David Webb</b>	Chief Pharmaceutical Officer, NHS England		08.12.23

**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

<b>Qualifications and professional registration</b>	Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
<b>Initial training</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> </ul>
<b>Competency assessment</b>	<ul style="list-style-type: none"> <li>• 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 <a href="#">Appendix A</a>).</li> <li>• Individuals operating under this PGD are advised to review their competency using the <a href="#">NICE Competency Framework for health professionals using patient group directions</a></li> </ul>
<b>Ongoing training and competency</b>	<ul style="list-style-type: none"> <li>• 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.</li> </ul>
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

<b>Clinical condition or situation to which this PGD applies</b>	Acute otitis media in children aged 1 year and over and young people (under 18 years of age)
<b>Criteria for inclusion</b>	<ul style="list-style-type: none"> <li>• Informed consent</li> <li>• Individuals aged 1 year and over and under 18 years of age:           <ul style="list-style-type: none"> <li>○ Individuals under 2 years of age with bilateral (in both ears) acute otitis media <b>AND</b> <ul style="list-style-type: none"> <li>▪ Symptoms for &gt; 3 days <b>OR</b></li> <li>▪ Severe symptoms based on clinical global impression</li> </ul> </li> <li><b>OR</b></li> <li>○ Individuals under 18 years of age with acute otitis media and otorrhea (discharge after eardrum perforation)</li> </ul> </li> <li>• Signs and symptoms of acute otitis media using the appropriate <a href="#">NICE CKS guidance</a>:           <ul style="list-style-type: none"> <li>○ In older children: earache</li> <li>○ 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)</li> </ul> </li> </ul> <p><b>AND</b> (on otoscopic examination):</p> <ul style="list-style-type: none"> <li>○ Distinctly red, yellow or cloudy tympanic membrane <b>OR</b></li> <li>○ Moderate-severe bulging of the tympanic membrane, with loss of normal landmarks and an air-fluid level behind the tympanic membrane <b>OR</b></li> <li>○ Perforation of the tympanic membrane and/or sticky discharge in the external auditory canal.</li> </ul>
<b>Criteria for exclusion</b>	<ul style="list-style-type: none"> <li>• Consent refused and documented in the individual's clinical notes</li> <li>• Individuals under 1 year of age or 18 years of age and over</li> <li>• Pregnancy or suspected pregnancy in individuals under 16 years of age</li> <li>• Severely immunosuppressed individuals as defined in <a href="#">Chapter 28a Green book</a>:           <p><b>Individuals with primary or acquired immunodeficiency states due to conditions including:</b></p> <ul style="list-style-type: none"> <li>• acute and chronic leukaemias, and clinically aggressive lymphomas (including Hodgkin's lymphoma) who are less than 12 months since achieving cure</li> <li>• 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)</li> <li>• immunosuppression due to HIV/AIDS with a current CD4 count of below 200 cells/<math>\mu</math>l.</li> <li>• primary or acquired cellular and combined immune deficiencies – those with lymphopaenia (&lt;1,000 lymphocytes/<math>\mu</math>l) or with a functional lymphocyte disorder</li> <li>• 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</li> <li>• those who have received a stem cell transplant more than 24 months</li> </ul> </li> </ul>

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  $\geq 20$ mg prednisolone per day) for more than 10 days in the previous month
- long term moderate dose corticosteroids (equivalent to  $\geq 10$ mg prednisolone per day for more than 4 weeks) in the previous 3 months
- any non-biological oral immune modulating drugs e.g. methotrexate  $>20$ mg per week (oral and subcutaneous), azathioprine  $>3.0$ mg/kg/day; 6-mercaptopurine  $>1.5$ mg/kg/day, mycophenolate  $>1$ g/day) in the previous 3 months
- certain combination therapies at individual doses lower than stated above, including those on  $\geq 7.5$ mg 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  $>40$ mg 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.
- Known hypersensitivity to amoxicillin, any penicillin or any of the components within the formulation -see [Summary of Product Characteristics](#). **Acceptable sources of allergy information include individual/carer/parent/guardian or National Care Record.**  
**OR**
- History of severe immediate hypersensitivity reaction (e.g. anaphylaxis) to another beta-lactam antibiotic (e.g. cephalosporin, carbapenem or monobactam). **Acceptable sources of allergy information include individual/carer/parent/guardian or National Care Record.**
- Inability to absorb oral medications and/or inability to swallow oral dosage formulations (i.e. capsules or oral suspension (or oral solution))

	<ul style="list-style-type: none"> <li>• Current long-term use of amoxicillin (or amoxicillin containing preparation) (e.g. for prophylaxis)</li> <li>• Individuals following a <a href="#">ketogenic diet</a></li> <li>• Failed previous antibiotic for this episode of acute otitis media</li> <li>• Individuals with evidence of, or suspected, foreign body in the ear canal</li> <li>• 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</li> <li>• 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)</li> <li>• <a href="#">Otitis Media with visible effusion (glue ear)</a></li> <li>• Individuals with a temperature over 39°C</li> <li>• Individuals with suspected <a href="#">meningitis</a> (neck stiffness, photophobia, mottled skin)</li> <li>• Individuals with suspected <a href="#">mastoiditis</a> (pain, soreness, swelling, tenderness behind the affected ear(s))</li> <li>• Individuals with suspected <a href="#">intracranial (brain) abscess</a> (severe headache, confusion or irritability, muscle weakness)</li> <li>• Individuals with suspected <a href="#">sinus thrombosis</a> (headache behind or around the eye(s))</li> <li>• Individuals with facial nerve paralysis (drooping of the face)</li> <li>• Individuals with <a href="#">cholesteatoma</a></li> <li>• Any individual identified with symptoms of <a href="#">severe/life-threatening infection or systemic sepsis</a>: refer urgently via ambulance.</li> <li>• Possible cancer:       <ul style="list-style-type: none"> <li>○ Bloody/blood stained discharge from ear(s)</li> </ul> </li> <li>• Known Chronic Kidney Disease (CKD) stages 4 or 5 (eGFR &lt;30ml/min/1.73m<sup>2</sup>)</li> <li>• Less than 3 days before receiving, or within 3 days after receiving, oral typhoid vaccine</li> <li>• Concurrent use of any interacting medicine as listed in <a href="#">Drug Interactions</a> section of this PGD</li> </ul>
<p><b>Cautions including any relevant action to be taken</b></p>	<ul style="list-style-type: none"> <li>• Breastfeeding individuals: amoxicillin can be used in breastfeeding individuals; monitor nursing infant for gastro-intestinal disturbances, oral candida infection, rashes, irritability and drowsiness.</li> <li>• Caution should be exercised when supplying amoxicillin capsules or oral suspension (or oral solution) to individuals who should avoid the following excipients:       <ul style="list-style-type: none"> <li>○ <b>Lactose, sucrose, fructose and sorbitol:</b> Individuals with rare hereditary problems of galactosaemia, galactose intolerance, total lactase deficiency, glucose-galactose malabsorption, sucrase-isomaltase deficiency, fructose-1,6-bisphosphatase deficiency (also known as hereditary fructose intolerance): check the individual list of excipients available in the <a href="#">SPC</a> before supplying.</li> <li>○ <b>Aspartame:</b> Individuals with <a href="#">phenylketonuria</a> (PKU) must not use medicines containing aspartame. Check the individual list of</li> </ul> </li> </ul>



	excipients available in the <a href="#">SPC</a> before supplying.
<b>Specific information for suspected infection to be provided</b>	<p>Provide <a href="#">TARGET Treating Your Infection Respiratory Tract Infection (TYI-RTI) leaflet</a> (TARGET RTI leaflet)</p> <p>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.</p>
<b>Action to be taken if the individual is excluded</b>	<ul style="list-style-type: none"> <li>Record reasons for exclusion in the appropriate clinical record</li> </ul> <p><b>Individuals where treatment is not indicated:</b></p> <ul style="list-style-type: none"> <li>Provide <a href="#">TARGET RTI leaflet</a>.</li> <li>Provide <a href="#">self-care advice</a> including:           <ul style="list-style-type: none"> <li>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: <a href="#">Mild to moderate pain</a> and <a href="#">NSAIDs-prescribing issues</a>).</li> <li>Explain that evidence suggests decongestants and antihistamines (over the counter) do not help with symptoms.</li> </ul> </li> <li>Advise individual/carer/parent/guardian to seek medical advice if symptoms worsen rapidly or significantly or the individual becomes systemically very unwell or if symptoms do not start to improve within 3 days.</li> </ul> <p><b>Refer urgently to a prescriber for further assessment if:</b></p> <ul style="list-style-type: none"> <li>Individual is systemically very unwell, but not showing signs or symptoms of <a href="#">sepsis</a></li> <li>Individual has signs of a more serious illness</li> <li>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)</li> <li>Possible cancer suspected:           <ul style="list-style-type: none"> <li>Bloody/blood stained discharge from ear(s)</li> </ul> </li> <li>Individuals where treatment under this PGD is not indicated/permitted but upper respiratory symptoms are present and require further assessment.</li> </ul> <p><b>Refer urgently to A&amp;E for further assessment if:</b></p> <ul style="list-style-type: none"> <li>Signs or symptoms of serious complications (including <a href="#">meningitis</a>, <a href="#">mastoiditis</a>, <a href="#">intracranial (brain) abscess</a>, <a href="#">sinus thrombosis</a> or facial nerve paralysis (drooping of the face)) suspected.</li> </ul> <p><b>If <a href="#">sepsis</a> is suspected refer the individual urgently to A&amp;E</b></p> <p><b>For children:</b> see <a href="#">Healthier Together guidance (otitis media (earache))</a> for further information on appropriate signposting and parent information sheets.</p>
<b>Action to be taken if the individual/carer/parent/guardian declines</b>	<ul style="list-style-type: none"> <li>Document advice given</li> <li>Provide safety netting advice and advise individual/carer/parent/guardian of alternative treatment available using <a href="#">TARGET RTI leaflet</a>.</li> <li>Refer to a prescriber if appropriate</li> </ul>



<b>treatment</b>	
<b>Arrangements for referral for medical advice</b>	Refer to the appropriate medical practitioner in the care pathway

### Description of treatment

<b>Name, strength &amp; formulation of drug</b>	<p>Amoxicillin 250mg capsules          Amoxicillin 500mg capsules          Amoxicillin 125mg/5mL oral suspension (or oral solution) x 100mL          Amoxicillin 125mg/5mL sugar free oral suspension (or oral solution) x 100mL          Amoxicillin 250mg/5mL oral suspension (or oral solution) x 100mL          Amoxicillin 250mg/5mL sugar free oral suspension (or oral solution) x 100mL          Amoxicillin 500mg/5mL sugar free oral suspension (or oral solution) x 100mL</p>
<b>Legal category</b>	POM
<b>Route / method of administration</b>	Orally, taken with food or water. Capsules should be swallowed whole.
<b>Off-label use</b>	<p><b>Temperature variations</b>          Medicines should be stored according to the conditions detailed in the <a href="#">Storage</a> 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.</p> <p>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.</p> <p>The responsibility for the decision to release the affected medicines for use lies with the pharmacist.</p> <p><a href="#">Manipulating solid dosage forms</a>          In the event of an individual being unable to swallow solid oral dosage formulations, and alternate liquid formulations not being readily available provide advice on how to give doses by opening capsules. Use in this way may be outside the product licence and is thus off-label.</p> <p>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.</p> <p><b>Opening and dispersing</b>          Amoxicillin capsules can be opened and the contents tipped out and mixed with liquid or soft food. However, this <b>should not</b> be undertaken</p>

	<p>by anyone with, or in the vicinity of someone with a penicillin allergy.</p> <p><b>Masking the taste</b></p> <p>The capsule contents will taste bitter so it can be helpful to use a strongly flavoured drink (e.g. blackcurrant cordial) or food (e.g. jam, apple sauce, yoghurt) that the individual likes:</p> <ul style="list-style-type: none"> <li>• Use a small amount of food or drink (e.g. a teaspoonful) so you can be sure the individual eats it all and swallows the whole dose</li> <li>• It might be helpful to use an oral syringe for liquids</li> <li>• After mixing the powder with food or drink, give it straight away.</li> </ul> <p>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.</p>
<b>Dose and frequency of administration</b>	<p><b>Children 1–4 years:</b> 250mg three times a day (every 8 hours)</p> <p><b>Children 5-17 years:</b> 500mg three times a day (every 8 hours)</p>
<b>Duration of treatment</b>	<p>5 days.</p> <p><b>Treatment should be started immediately and 5 days of treatment completed</b></p>
<b>Quantity to be supplied</b>	<p>In line with the Pharmacy First service specification the best value product to meet the clinical need should be supplied from those listed within this PGD.</p> <p><b>Children 1–4 years:</b> Appropriately labelled pack of 1 x 100mL x 500mg/5mL oral suspension (or oral solution) <b>OR</b> appropriately labelled pack of 1 x 100mL x 250mg/5mL oral suspension (or oral solution) <b>OR</b> appropriately labelled pack of 2 x 100mL x 125mg/5mL oral suspension (or oral solution)</p> <p><b>Children 5-17 years:</b> Appropriately labelled pack of 15 x 500mg capsules <b>OR</b> appropriately labelled pack of 30 x 250mg capsules <b>OR</b> appropriately labelled pack of 1 x 100mL x 500mg/5mL oral suspension (or oral solution) <b>OR</b> appropriately labelled pack of 2 x 100mL x 250mg/5mL oral suspension (or oral solution) <b>OR</b> appropriately labelled pack of 3 x 100mL 125mg/5mL oral suspension (or oral solution)</p>
<b>Storage</b>	<p>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: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>
<b>Drug interactions</b>	<p>Where it is known an individual is concurrently taking one of the following medicines, amoxicillin must not be supplied under this PGD and the individual referred to a prescriber:</p> <ul style="list-style-type: none"> <li>• Allopurinol</li> </ul>

	<ul style="list-style-type: none"> <li>• Methotrexate</li> <li>• Probenecid</li> <li>• Typhoid vaccine (oral): see <a href="#">Criteria for exclusion</a></li> </ul> <p>See <a href="#">BNF</a> for all drugs that can interact with amoxicillin.</p> <p>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>
<b>Identification &amp; management of adverse reactions</b>	<p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> and BNF <a href="http://www.bnf.org">www.bnf.org</a></p> <p>The following side effects are listed in the product SPC or BNF as <b>common or very common</b> with amoxicillin (but may not reflect all reported side effects):</p> <ul style="list-style-type: none"> <li>• Diarrhoea</li> <li>• Nausea</li> <li>• Skin rash</li> <li>• Hypersensitivity</li> <li>• Vomiting</li> <li>• Thrombocytopenia (low levels of platelets in the blood)</li> </ul> <p>Severe adverse reactions are rare, but <a href="#">anaphylaxis</a> (delayed or immediate) has been reported and requires immediate medical treatment.</p> <p>In the event of a severe adverse reaction, the individual must be advised to stop treatment immediately and seek urgent medical advice.</p>
<b>Management of and reporting procedure for adverse reactions</b>	<ul style="list-style-type: none"> <li>• 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: <a href="https://yellowcard.mhra.gov.uk">https://yellowcard.mhra.gov.uk</a></li> <li>• Record all adverse drug reactions (ADRs) in the individual's clinical record.</li> <li>• Report and document in accordance with organisation incident policy.</li> <li>• It is considered good practice to notify the individual's GP in the event of an adverse reaction.</li> </ul>
<b>Written or other information to be given to individual/carer/parent/guardian</b>	<ul style="list-style-type: none"> <li>• Provide marketing authorisation holder's information leaflet (PIL) provided with the product.</li> <li>• Provide the <a href="#">TARGET RTI leaflet</a>.</li> <li>• Utilise <a href="#">TARGET antibiotic checklist</a> for counselling individuals/carers/parents/guardians.</li> <li>• Give any additional information in accordance with the service specification.</li> </ul>
<b>Individual advice / follow up treatment</b>	<ul style="list-style-type: none"> <li>• Explain the dose, frequency and method of administration.</li> <li>• The individual/carer/parent/guardian should be advised to read the PIL.</li> <li>• Store reconstituted oral suspension (or oral solution) in accordance</li> </ul>

	<p>with the conditions as outlined in the individual product <a href="#">SPC</a> (storage recommendations may vary between different reconstituted oral suspension (or oral solution) products).</p> <ul style="list-style-type: none"> <li>• Without treatment, symptoms should start to improve within 3 days.</li> <li>• Symptoms should start to improve within 72 hours of taking amoxicillin – advise individual/carer/parent/guardian to seek medical advice if symptoms do not improve or worsen within this time.</li> <li>• Advise individual/carer/parent/guardian to seek immediate medical attention (by calling 999 or going to A&amp;E) if the individual develops <a href="#">signs or symptoms of sepsis</a>.</li> <li>• Inform individual/carer/parent/guardian of possible side effects and their management, including advice to take amoxicillin with food to reduce the likelihood of nausea.</li> <li>• Advise individual/carer/parent/guardian to take/give the medication at regular intervals with food or water and to finish the course.</li> <li>• If the individual is affected by dizziness or drowsiness advise them not to drive or operate machinery.</li> <li>• 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.</li> <li>• If a dose is missed advise to refer to PIL supplied with the product</li> <li>• 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.</li> </ul>
<b>Records</b>	<p>Appropriate records must include the following:</p> <ul style="list-style-type: none"> <li>• That valid informed consent has been given</li> <li>• Individual's name, address and date of birth</li> <li>• Name of GP individual is registered with or record where an individual is not registered with a GP</li> <li>• Name and registration number of registered healthcare professional operating under this PGD</li> <li>• Specify how the individual has/has not met the criteria of the PGD</li> <li>• Relevant past and present medical history and medication history</li> <li>• Any known allergies and nature of reaction(s)</li> <li>• Name/dose/form/quantity of medicine supplied</li> <li>• Date and time of supply</li> <li>• Documentation of cautions as appropriate</li> <li>• Advice given, including advice given if individual excluded or declines treatment</li> <li>• Details of any adverse drug reactions and actions taken</li> <li>• Advice given about the medication including side effects, benefits, and when and what to do if any concerns.</li> <li>• Any follow up and/or referral arrangements made.</li> <li>• Any supply outside the terms of the product marketing authorisation</li> <li>• The supply must be entered in the Patient Medication Record (PMR)</li> <li>• That supply was made under a PGD</li> <li>• Any safety incidents, such as medication errors, near misses and suspected adverse events</li> <li>• Any additional requirements in accordance with the service</li> </ul>

	<p>specification:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• All records should be kept in line with <a href="#">national guidance</a>. This includes individual data, master copies of the PGD and lists of authorised practitioners.</li> </ul> <p><b>Records must be signed and dated (or a password controlled e-records).</b></p> <p><b>All records must be clear, legible and contemporaneous.</b></p> <p><b>A record of all individuals receiving treatment under this PGD must also be kept for audit purposes in accordance with the service specification.</b></p>
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### Key references

<p><b>Key references (last accessed November 2023)</b></p>	<ul style="list-style-type: none"> <li>• Electronic Medicines Compendium <a href="http://www.medicines.org.uk/">http://www.medicines.org.uk/</a></li> <li>• Electronic BNF <a href="https://bnf.nice.org.uk/">https://bnf.nice.org.uk/</a></li> <li>• Electronic BNF for children <a href="https://bnfc.nice.org.uk/">https://bnfc.nice.org.uk/</a></li> <li>• Reference guide to consent for examination or treatment <a href="https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653_1_.pdf">https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653_1_.pdf</a></li> <li>• Medicines for Children. Amoxicillin for bacterial infections. <a href="https://www.medicinesforchildren.org.uk/medicines/amoxicillin-for-bacterial-infections/">https://www.medicinesforchildren.org.uk/medicines/amoxicillin-for-bacterial-infections/</a></li> <li>• NICE Medicines practice guideline “Patient Group Directions” <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li> <li>• NHS Specialist Pharmacy Service. Using solid oral dosage form antibiotics in children <a href="https://www.sps.nhs.uk/articles/using-solid-oral-dosage-form-antibiotics-in-children/">https://www.sps.nhs.uk/articles/using-solid-oral-dosage-form-antibiotics-in-children/</a></li> <li>• UK Sepsis Trust. Sepsis e-learning resources. <a href="https://sepsistrust.org/professional-resources/sepsis-e-learning/">https://sepsistrust.org/professional-resources/sepsis-e-learning/</a></li> <li>• TARGET Treating your infection - Respiratory Tract Infection (TYI-RTI) leaflet <a href="https://elearning.rcgp.org.uk/mod/book/view.php?id=12647&amp;chapterid=444">https://elearning.rcgp.org.uk/mod/book/view.php?id=12647&amp;chapterid=444</a></li> <li>• NICE Clinical knowledge summaries. Analgesia –mild-to-moderate pain. <a href="https://cks.nice.org.uk/topics/analgesia-mild-to-moderate-pain/">https://cks.nice.org.uk/topics/analgesia-mild-to-moderate-pain/</a></li> <li>• NICE Clinical knowledge summaries. NASIDs – prescribing issues. <a href="https://cks.nice.org.uk/topics/nsaids-prescribing-issues/">https://cks.nice.org.uk/topics/nsaids-prescribing-issues/</a></li> </ul>
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Version: 1.0  
 Reference Number: 7b  
 Valid from: 31/01/2024  
 Review date: 30/07/2026  
 Expiry date: 30/01/2027

**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 <b>insert name of organisation</b> 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.**

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