GIG CYMRU NHS WALES
Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board]

GIG CYMRU NHS WALES

National reference: CYM-25005

Local reference: PGD 0194B

Community Pharmacy Common Ailments Service

Sore Throat

Patient Group Directions for the Supply of Antibiotics (phenoxymethylpenicillin, amoxicillin, clarithromycin and erythromycin)

in [**Powys Teaching Health Board**]

Operational from: 03 June 2025

Review date: 01 December 2027

Expiry date: 02 June 2028

Version number: v2.0

PGDs for the supply of antibiotics for the treatment of sore throat by pharmacists delivering the Common Ailments Service component of the Clinical Community Pharmacy Service.

Reference:	Sore throat amoxicillin, clarithromycin, erythromycin and phenoxymethylpenicillin PGDs
Version no:	2.0
Valid from:	03 June 2025
Review date:	01 December 2027
Expiry date:	02 June 2028

Welsh Medicines Advice Service has developed these PGDs for local authorisation.

Those using these PGDs must ensure that it is authorised by the Local Health Board in which they are operating and signed in section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with the Human Medicines Regulations 2012 (HMR2012)[1]. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH HMR2012 SCHEDULE 16 Part 2.**

Authorising organisations must not *alter, amend* or *add* to the *clinical* content of this document such action will invalidate the *clinical sign-off* with which it is provided.

As operation of these PGDs is the responsibility of service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGDs.

INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THESE PGDs BEFORE WORKING ACCORDING TO IT.

Practitioners and organisations must check that they are using the current version of these PGDs. Amendments may become necessary prior to the published expiry date.

Any queries regarding the clinical content of a PGD should be addressed to: welshmedicines.information@wales.nhs.uk

[1] this includes any relevant amendments to legislation (e.g. 2013 No.235, 2015 No.178 and 2015 No.323).

Change history:

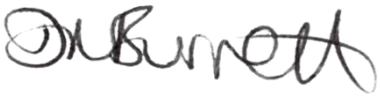
Version number	Change details	Date
1.0	Original PGD template developed.	1st November 2022
1.2	Clarification of age exclusion criteria for phenoxymethylpenicillin and clarithromycin PGDs.	30th November 2022
1.3	Addition of amoxicillin capsules and suspension. Information about off-label crushing and dispersion of solid dose forms. Addition of medicines in pregnancy reference.	8th December 2022
2.0	Formatting and structural changes made to all PGDs to align with National PGD template and processes. Rewording of symptoms and signs as per the CKS reviewed sore throat topic. Green book advice added for typhoid and antibacterial to drug interaction sections. Exclusion criteria aligned to updated CAS sore throat monograph approved by AWPAG December 2024. Lower age changed from 6 years to 5 years. For each antibiotic the clinical content for the oral solution/suspension PGDs reviewed and combined into the appropriate reviewed content for the tablet/capsule PGDs. Breastfeeding removed as an exclusion for clarithromycin.	18 January 2025

1. PGD development

These PGDs have been developed by the following health care professionals on behalf of NHS Wales.

This section MUST REMAIN when these PGDs are adopted by an organisation.

PGD Development

Name	Designation	Signature
Expert Reviewer – Jennifer Ellis	Lead GP Urgent Primary Care Centre, West. Betsi Cadwaladr UHB	
Main author – Dianne Burnett	National Lead Pharmacist Medicines Advice. Welsh Medicines Advice Service, Cardiff and Vale UHB	
Professional group reviewer for amoxicillin – Amy David	Primary Care Pharmacist, Swansea Bay UHB	
Professional group reviewer for phenoxymethylpenicillin, clarithromycin and erythromycin – Jason Carroll	Pharmacist Team Leader, Cwm Taf Morgannwg UHB	

These PGDs have been peer reviewed by the Community Pharmacy Clinical Advisory Group (CPCAG) in accordance with the WMAS PGD Policy and ratified by the All-Wales PGD Advisory Board.

Expert Panel – Community Pharmacy Clinical Advisory Group

Name	Designation
Adam Mackridge	Strategic Lead Pharmacist for Community Pharmacy, Betsi Cadwaladr UHB
Louise Allen	Head of Community Pharmacy, PCIC, Cardiff and Vale UHB
Amy David	Primary Care Pharmacist, Swansea Bay UHB
Meryl Davies	Lead Antimicrobial Pharmacist Primary and Community Care, Health Protection Team, Public Health Wales
Emlyn Pritchard	Head of Primary Care Medicines Management, Powys LHB
Rachel James	Advanced Pharmacist Medicines Management, Hywel Dda UHB
Richard Evans	Community Pharmacy Lead, Aneurin Bevan UHB
Anna Burgess	Digital Lead Pharmacist, Welsh Medicines Advice Service, Cardiff and Vale UHB
Jason Carroll	Pharmacist Team Leader, Cwm Taf Morgannwg UHB
Carys James	Community Pharmacy facilitator, Cwm Taf Morgannwg UHB
Emma Hinks	Deputy Chief Pharmaceutical Officer, Welsh Government
Debra Roberts	Head of Programme Development, Associate Dean, HEIW
Dianne Burnett	National Lead Pharmacist Medicines Advice. Welsh Medicines Advice Service, Cardiff and Vale UHB

Date CPCAG approval of PGDs: 21 February 2025

Date All Wales PGD Advisory Board ratification: 03 March 2025

2. Contents

3. Organisational Authorisations

These PGDs are not legally valid until they have had the authorisation of the Local Health Board in which the community pharmacy using it operates.

It is the responsibility of the Local Health Board, to ensure that all legal and governance requirements are met. The Local Health Board accepts governance responsibility for the appropriate use of these PGDs.

IPowys Teaching Health Board authorises these PGDs for use by community pharmacies within its area that have been commissioned to provide the sore throat component of the Common Ailments Service. This authorisation is limited to those pharmacists that meet the requirements set out within the PGDs.

Local Health Board approval (legal requirement) as per health board policy			
Role	**Name**	**Sign**	**Date**
Lead Doctor for PTHB	Dr Kate Wright	DocuSigned by: Kate Wright 1F267952823F473...	5/6/2025
Clinical Governance Lead for PTHB	Amanda Edwards	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	5/13/2025
Senior Pharmacist Lead for Community Pharmacies, PTHB	Emlyn Pritchard	DocuSigned by: Emlyn Pritchard EB776BA7283F49B...	5/1/2025
Senior Representative of Professional Group using PGD/Prescribing Advisor	Matthew Hicks	Signed by: Matthew Hicks 01F017E1634D479...	5/7/2025

Local enquiries regarding the use of these PGDs may be directed to:
[welshmedicines.information@wales.nhs.uk]

Appendix B provides a practitioner listing sheet. Individual practitioners must be listed by name to work to these PGDs. Alternative practitioner listing sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement or a multiple practitioner listing sheet as included at the end of these PGDs.

Retention statement

The final authorised copy of this PGD should be kept by the authorising organisation completing section 3 for 8 years after the PGD expires if the PGD relates to adults only, and for 25 years after the PGD expires if the PGD relates to children only or adults and children.

Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

4. Characteristics of Staff

Qualifications and professional registration	This PGD is for use by pharmacists currently registered with the General Pharmaceutical Council (GPhC).
Additional requirements	Pharmacists must: ➢ be employed by or providing services on behalf of a pharmacy listed in the All-Wales Pharmacy Database (AWPD) for the Common Ailments Service component of the Clinical Community Pharmacy Service. ➢ be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it by completing appendix B. ➢ be familiar with the medicine and alert to changes in the Summary of Product Characteristics (SmPC). ➢ have access to the Patient Group Direction and associated resources (including the service specification and the clinical guidance document supporting the PGD) and must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs). ➢ be named in the All-Wales Pharmacy Database for the Sore Throat component of the Common Ailments Service. ➢ have met the training requirements for the service as published by HEIW (Health Education and Improvement Wales). ➢ be familiar with the British National Formulary (BNF) and SmPC entries for amoxicillin, clarithromycin, erythromycin and phenoxymethylpenicillin. ➢ have awareness of the adverse drug reactions associated with amoxicillin, clarithromycin, erythromycin and phenoxymethylpenicillin. **The pharmacist must be listed by name, under the current version of this PGD that has been issued by the Local Health Board in which area they are operating before working under its authority.**
Ongoing training and competency	Pharmacists must: ➢ undertake regular CPD and maintain own level of competence and knowledge in this clinical area to provide the service. ➢ be aware of any updates made to the products in SmPC and BNF. ➢ be aware of any updates to relevant national and local guidelines. ➢ as registered professionals, be professionally accountable and must work within their competence. A record of any training and competency assessments undertaken must be maintained.

PGD for the supply of phenoxymethylpenicillin 250 mg tablets, 125 mg / 5mL and 250 mg / 5 mL oral solution and phenoxymethylpenicillin 125 mg / 5mL and 250 mg / 5 mL sugar free oral solution

1. Clinical Condition

Clinical condition or situation to which this PGD applies	First line treatment for painful, inflamed throat which makes swallowing difficult, in accordance with the community pharmacy sore throat component of the Common Ailments Service.
Inclusion criteria	Phenoxymethylpenicillin can be given to: Adults and children aged 5 years and over presenting with symptoms of acute uncomplicated sore throat **AND** ➢ a FeverPAIN score of 2 or above **OR** ➢ a Centor score of 3 or above **AND** ➢ a positive result from a throat swab Rapid Antigen Diagnostic Test (RADT) for Streptococcus A infection. ➢ they have no contraindications to penicillin and penicillin type antibiotics. ➢ informed consent has been given. in accordance with the All Wales Common Ailments Service Formulary 2025.
Exclusion criteria[2] (continued over page)	Phenoxymethylpenicillin should not be given to individuals **in the presence of the following red flag symptoms – advise the individual to phone 999 or attend A&E immediately:** ➢ life-threatening symptoms such as stridor, breathing difficulty, drooling, difficulty swallowing or opening the mouth. ➢ severe symptoms getting worse quickly. ➢ signs of marked systemic illness or sepsis (including signs of changes in cognitive function, behaviour or mental state e.g. confusion, drowsiness or slurred speech). ➢ systemically unwell and at risk of immunosuppression. ➢ coughing up blood (**more** than just a few spots or streaks of blood present in the phlegm). ➢ skin changes e.g. very cold, or a strange colour or a rash. ➢ crushing central chest pain. ➢ severe headache and vomiting. ➢ suspected peri-tonsillar abscess or cellulitis, parapharyngeal abscess, retropharyngeal abscess or Lemierre's syndrome (risk of airway compromise or rupture of the abscess). (severe neck pain, neck stiffness, visible neck swelling).

[2] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required.

Exclusion criteria (continued)	➢ if they are dehydrated, unable to take fluids or passing little or no urine, and or have dry mucous membranes). ➢ Kawasaki disease. Presents with a high temperature lasting 5 days or more and with one or more of the following symptoms: rash, swollen neck glands, dry, red, cracked lips, swollen bumpy red tongue (strawberry tongue), red inside the mouth and back of the throat, swollen and red hands and feet, red eyes. **Advise the individual to see a GP, call NHS 111 or see a community pharmacist independent prescriber (PIP) as appropriate for same day assessment if any of the following are present:** ➢ known immunosuppression (accompanied by other clinical symptoms of blood disorders), including for example: o a patient who is on chemotherapy, radiotherapy, has known or suspected leukaemia, asplenia, aplastic anaemia or HIV/AIDS, or is taking an immunosuppressive drug following a transplant. o a patient who is taking a disease-modifying anti-rheumatic drug (DMARD), e.g. sulfasalazine, azathioprine, methotrexate. o a patient who is taking a medicine that can cause blood disorders (e.g. neutropenia, agranulocytosis, thrombocytopenia) leading to infection and acute sore throat including cytotoxic drugs, carbimazole, clozapine and sulfasalazine. ➢ abnormal breathing pattern (but not struggling for breath). ➢ a rash, flushed cheeks and swollen tongue (scarlet fever). ➢ a persistent high temperature over 38°C uncontrolled by paracetamol or ibuprofen. ➢ oral mucositis. ➢ coughing up small amounts of blood (**no more** than a few spots or streaks of blood present in the phlegm). ➢ a suspected bacterial infection despite negative antigen test. ➢ moderate, severe or end stage renal failure (eGFR less than 60 mL / min) or patients with renal disease where renal function cannot be confirmed. ➢ high risk of serious complications because: o of significant heart, lung, kidney, liver, or neuromuscular disease (including patients with a history of valvular heart disease, rheumatic fever, post-streptococcal glomerular nephritis and cystic fibrosis). o they are immunocompromised. ➢ diabetes, if, in the opinion of the pharmacist: o there are concerns regarding their individual diabetic control. o the individual is at increased risk of detrimental symptoms associated with poorly controlled diabetes; symptoms can include thirst, blurred vision, fatigue, increased frequency of urination. o the individual is unsure how to manage their diabetes.

(continued over page)	➢ if they are children under 5 years.
Exclusion criteria (continued)	➢ if they are frail and or elderly over 75 years old. ➢ if they are systemically very unwell and there are no features indicating urgent referral to A&E. ➢ persistent alteration in voice, hoarseness, lasting longer than 3 weeks or is present with no other symptoms. ➢ if they present with additional symptoms atypical of acute sore throat that could indicate another infectious cause of sore throat including: o ulceration in the mouth, sloughing or bleeding of the mucous membranes of the pharynx. o presence of a mass or unilateral swelling. o skin, genital or eye lesions or a rash. o abdominal symptoms. o hand or foot symptoms. o grey/green oropharyngeal membranes. o severe pain. **Advise the individual to see a GP for routine appointment an individual:** ➢ with a history of repeated episodes (more than 2 previous episodes) of Streptococcus A infection in the previous 6 months or a lower threshold if other concerns. ➢ with persistent symptoms that haven't improved after 7 days. A sore throat after 7 days with lethargy may indicate glandular fever, especially if they are aged 15-24 years old. **Phenoxymethylpenicillin is not suitable for individuals:** ➢ with a known hypersensitivity to penicillin and penicillin type antibiotics e.g. amoxicillin, co-amoxiclav and flucloxacillin – see SmPC. ➢ with a known hypersensitivity to cephalosporins, e.g. cefalexin – see SmPC. ➢ with known hypersensitivity to any of the excipients – see SmPC. ➢ with known or suspected hepatic impairment. ➢ with gastrointestinal disease that causes persistent nausea, vomiting, gastric dilation, cardio-spasm, intestinal hyper motility or diarrhoea because absorption may be reduced. ➢ who have suffered severe diarrhoea following previous treatment with phenoxymethylpenicillin. ➢ with symptoms of diarrhoea and they have received an antibiotic within the previous 3 months. ➢ who are also receiving long-term phenoxymethylpenicillin treatment. ➢ requiring the tablets, if they have a rare hereditary problem of galactose intolerance, the Lapp lactase deficiency or glucose -galactose malabsorption.
(continued over page)	

Exclusion criteria (continued)	➢ requiring the oral solution, if they have a rare hereditary problem of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency. ➢ who are taking contraindicated medicines (see drug interactions section for further detail) including: o methotrexate. o bacteriostatic antibiotics, e.g. tetracyclines, erythromycin, chloramphenicol and sulphonamides. o recent typhoid vaccination (oral). o probenecid. ➢ if informed consent has not been given by the individual, parent, guardian or carer; where individuals or their parent, guardian or carer do not agree to share relevant clinical information or there is no valid consent. ➢ if the pharmacist is unable to undertake an appropriate assessment, to determine the need for the medicine and that it would be appropriate for the patient to use it. ➢ to individuals who are unable to administer or use the product effectively themselves or who do not have a parent, guardian or carer to administer or apply the medication for them.
Cautions (including relevant actions to be taken) (continued over page)	Please refer to the SmPC for phenoxymethylpenicillin for full details of special warnings and precautions for use. **History of allergy** ➢ Phenoxymethylpenicillin should be given with caution to patients with a history of allergy, especially to other drugs. ➢ If the patient experiences an allergic reaction, phenoxymethylpenicillin should be discontinued and treatment with the appropriate agents initiated (e.g. adrenaline and other pressor amines, antihistamines and other corticosteroids). ➢ Caution should be exercised in supplying phenoxymethylpenicillin to patients with significant allergies, allergic diathesis or with asthma. **Colitis** Caution should be used when treating patients with a history of antibiotic-associated colitis and other risk factors for *Clostridioides difficile* infection (CDI) (see Risk factors | Background information | Diarrhoea - antibiotic associated | CKS | NICE). Sustained severe diarrhoea should prompt suspicion of pseudomembranous colitis during or after treatment with an antibiotic. As this condition may be life threatening, phenoxymethylpenicillin should be withdrawn immediately. Pseudomembranous colitis has been reported with nearly all antibacterial agents and may range in severity from mild to life-threatening.

Cautions (including relevant actions to be taken) (continued)	*Clostridioides difficile*-associated diarrhoea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhoea to fatal colitis. **Diabetes** Individuals with diabetes can be supplied with treatment if, in the opinion of the pharmacist, there are no concerns or symptoms suggestive of poor control, for example, thirst, blurred vision, fatigue etc. Provided there are no features, signs or symptoms, treatment can be supplied. Individuals should be reminded of the diabetes sick day rules (see patient or carer advice). **Oral hypoglycaemic agents/insulin** – careful monitoring of glucose is recommended. **Epilepsy** Convulsions may occur in individuals with predisposing risk factors e.g. history of seizures, treated epilepsy or meningeal disorders. **Effect on laboratory tests** During treatment with phenoxymethylpenicillin, non-enzymatic glucose tests may be false-positive. **Potassium** Some phenoxymethylpenicillin tablets and oral solution preparations may contain potassium, which may be harmful to people on low potassium diets and may cause stomach upset, diarrhoea and hyperkalaemia. High doses should be used with caution in patients receiving potassium-containing drugs or potassium sparing-diuretics. **Sucrose** ➢ Phenoxymethylpenicillin oral solution may contain sucrose. This should be taken into consideration in individuals with diabetes mellitus. ➢ May be harmful to the teeth. **Oral anticoagulants** There is a risk of serious haemorrhage and significant elevations in International Normalized Ratio (INR) and prothrombin time when phenoxymethylpenicillin is co-administered with warfarin. INR and prothrombin times should be frequently monitored while patients are receiving phenoxymethylpenicillin and oral anticoagulants concurrently. **Advise the individual to contact their clinic responsible for INR monitoring within 3 days of starting phenoxymethylpenicillin treatment**. Caution should be exercised when phenoxymethylpenicillin is co-administered with direct acting oral anticoagulants such as dabigatran, rivaroxaban, apixaban and edoxaban particularly to patients at high risk of bleeding.

(continued over page)

Cautions (including relevant actions to be taken) (continued)	**Pregnancy** ➢ Not known to be harmful. ➢ Phenoxymethylpenicillin has been in extensive clinical use and suitability in human pregnancy has been well documented in clinical trials. However, as with other drugs, caution should be exercised when supplying to pregnant patients. ➢ A patient information leaflet is available (PIL) to support an individual in their decision to use antibiotics during pregnancy. bumps - best use of medicine in pregnancy (medicinesinpregnancy.org). **Breastfeeding** Penicillins pass into breast milk in very small amounts and are unlikely to be harmful. It can cause some babies to have mild stomach upsets. Individuals should contact their health visitor, midwife or general practitioner if their baby: ➢ is not feeding as well as usual. ➢ is unsettled after feeding. ➢ develops diarrhoea and or vomiting. ➢ develops a rash. ➢ is unusually sleepy. ➢ has oral thrush. **Crushing and dispersing** Only to be considered if liquid not available or suitable and would be off-label. There is a risk of sensitisation. Advise the individual to always wear gloves and mask, and use a closed system where possible, e.g. disperse tablet in the barrel of a syringe. See off-label section and Welsh Medicines Advice Service guidance to support provision of antibiotic solid dosage forms when liquid preparations are not available for further advice.
Action to be taken if the individual is excluded or declines treatment	➢ If individual meets the exclusion criteria, refer to a medical practitioner or PIP as appropriate. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination. ➢ Explain the reasons for exclusion to the individual and document in the consultation record. ➢ If the individual declines, advise of the consequences of not receiving treatment and document the advice given and details of any referral made and their (patient, parent/carer or guardian) intended actions. ➢ If appropriate, individuals may be offered a suitable alternative antibiotic or provided with advice and symptomatic treatment from the All Wales Common Ailments Service Formulary. Alternatively, refer the individual to a GP or PIP if appropriate.

Further advice	If there is any doubt about the administration of the medication or the individual's fitness or suitability to receive the medication, a doctor or appropriate PIP should be consulted. ➢ Refer to SmPC, BNF and the All Wales Common Ailments Service.

2. Description of Treatment

Name, strength & formulation of drug	Phenoxymethylpenicillin 250 mg tablets. Phenoxymethylpenicillin oral solution 125 mg / 5mL, 250 mg / 5mL. Phenoxymethylpenicillin oral solution sugar free 125 mg / 5mL, 250 mg / 5mL.
Legal category	POM – Prescription Only Medicine.
Black triangle▼	No.
Off-label use	Yes. If the individual is unable to swallow tablets AND the oral solution is unavailable or unsuitable, the tablets may be dispersed in water OR crushed and mixed with liquid or soft food. Please follow the guidance to support provision of antibiotic solid dosage forms when liquid preparations are not available. It is important to note the following: ➢ Administration in this way is off-label (used outside of the product licence). ➢ When crushing tablets caution should be exercised on handling the antibiotic powder produced to avoid contact sensitisation or inhalation; safety measures that should be used include: o using a closed system e.g. dispersing a tablet in the barrel of a syringe. o wearing gloves to reduce contact with the skin, and a mask to prevent dust inhalation. o sensitisation is a risk with all the antibiotics but may be of particular concern with penicillins. ➢ Parents/carers with penicillin allergy should avoid involvement in preparing and administering the tablets this way.
Route / method of administration	Oral. **Tablets**: Each tablet should be swallowed whole with water, at least 30 minutes before food, or 2 hours after food. If supplied because the liquid formulation is not available or unsuitable, see Welsh Medicines Advice Service guidance to support provision of antibiotic solid dosage forms when liquid preparations are not available for advice on dispersing or crushing and mixing with liquid or soft food. **Oral solution**: Follow the instructions for reconstitution. Each dose should be taken at least 30 minutes before food, or 2 hours after food.

Dose and frequency of administration	**Children aged 5 years**: 125 mg FOUR times a day for TEN days. Where an individual is unable to comply with four times a day dosing regime, the dose can be given as: 250 mg TWICE daily for TEN days. **Children aged 6 to 11 years**: 250 mg FOUR times a day for TEN days. Where an individual is unable to comply with four times a day dosing regime, the dose can be given as: 500 mg TWICE daily for TEN days. **Adults and children aged 12 years and over**: 500 mg FOUR times a day for TEN days. Where an individual is unable to comply with four times a day dosing regime, the dose can be given as: 1000 mg TWICE a day for TEN days.
Duration of treatment	TEN days. This PGD only allows for the duration stated in the dosage schedule above.
Quantity to be supplied (continued over page)	The best value product available at the time to meet the clinical need should be appropriately labelled and supplied to provide treatment for TEN days: **Children aged 5 years**: **2 x 100 mL** (125 mg / 5 mL) at a dose of: 5 mL FOUR times a day **or** 10 mL TWICE a day. **If 125 mg / 5 mL unavailable** **1 x 100 mL** (250 mg / 5 mL) at a dose of: 2.5 mL FOUR times a day **or** 5 mL TWICE a day. **Children aged 6 to 11 years**: **40 x 250 mg** tablets at a dose of: ONE tablet FOUR times a day **or** TWO tablets TWICE a day. **OR**

Quantity to be supplied (continued)	**2 x 100 mL** (250mg / 5 mL) at a dose of: 5 mL FOUR times a day **or** 10 mL TWICE a day. **If 250 mg / 5 mL unavailable** **4 x 100 mL** (125 mg / 5 mL) at a dose of: 10 mL FOUR times a day **or** 20 mL TWICE a day. **Adults and children aged 12 years and over**: **80 x 250 mg** tablets at a dose of: TWO tablets FOUR times a day **or** FOUR tablets TWICE a day. **OR** **4 x 100 mL** (250 mg / 5mL) at a dose of: 10 mL FOUR times a day **or** 20 mL TWICE a day. **If 250 mg / 5 mL unavailable** **8 x 100 mL** (125 mg / 5 mL) at a dose of: 20 mL FOUR times a day **or** 40 mL TWICE a day.
Storage	Medicines must be stored securely and in accordance with product SmPC.
Disposal	Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.
Drug interactions (continued over page)	The following list is not exhaustive. A detailed list of drug interactions can be found in the SmPC and the BNF. **Contraindicated** ➢ Methotrexate – use of phenoxymethylpenicillin while taking methotrexate can cause reduced excretion of methotrexate thereby increasing the risk of toxicity. ➢ Typhoid vaccine (oral) – antibacterial agents may inactivate oral typhoid vaccine if ingested concomitantly. The Green Book advises that the vaccine should not be commenced within three days of completing any antibacterial agent and similarly antibacterial therapy should not commence within 3 days after the last dose of vaccine. ➢ Aminoglycosides – neomycin is reported to reduce the absorption of phenoxymethylpenicillin.

Drug interactions (continued)	➢ Bacteriostatic antibiotics – certain bacteriostatic antibiotics such as chloramphenicol, erythromycin, tetracyclines and sulphonamides have been reported to antagonize the bactericidal activity of penicillins and concomitant use is not recommended. ➢ Uricosuric drugs like probenecid and sulfinpyrazone can reduce the excretion of phenoxymethylpenicillin resulting in increased plasma levels and prolonged action. **Cautions** Phenoxymethylpenicillin should be used in caution in patients also prescribed: ➢ guar gum – slows the speed of absorption of phenoxymethylpenicillin. ➢ coumarin anticoagulants – penicillins may interfere with anticoagulant control (see cautions). ➢ phenindione – penicillins may interfere with anticoagulant control (see cautions). ➢ potassium-containing drugs or potassium sparing-diuretics (see cautions). ➢ oral contraceptives – phenoxymethylpenicillin does not reduce their efficacy but if it makes the individual sick or have severe diarrhoea for more than 24 hours, they may not be protected from pregnancy. Advise the individual to follow the instructions in their pill packet. More advice is available from What if I'm on the pill and I'm sick or have diarrhoea? - NHS (www.nhs.uk).
Identification & management of adverse reactions (continued over page)	Advise the patient that if any of the following side effects occur, discontinue treatment immediately and contact the emergency department or dial 999: ➢ allergic reactions such as sudden difficulty with breathing, speaking and swallowing. ➢ extreme dizziness or fainting. ➢ severe itchy skin rash especially if blistering, soreness of the eyes, mouth or genital organs. The following side effects have been reported by patients taking phenoxymethylpenicillin tablets or oral solution. **Very common to uncommon** (affecting between 1 in 10 and 1 in 1000 patients): ➢ nausea, vomiting, soft stools, diarrhoea, abdominal pain. ➢ allergic reactions, hypersensitivity, skin reactions (urticarial, erythematous or morbilliform rash, pruritis). ➢ nephropathy (usually associated with high doses of parenteral penicillin).

Identification & management of adverse reactions (continued)	**Rare or very rare adverse effects** (affecting between 1 in 1000 and 1 in 10,000 patients): ➢ changes in blood counts, including thrombocytopenia, neutropenia, leucopenia, eosinophilia and haemolytic anaemia. ➢ hepatitis and cholestatic jaundice. ➢ severe allergic reactions causing angioedema, laryngeal oedema and anaphylaxis. ➢ interstitial nephritis. ➢ exfoliative dermatitis. N.B. detailed lists of adverse reactions are available in the SmPC, and the BNF. Prior to issuing medication, please refer to these resources to check that there has been no change to the potential adverse reactions listed above.
Patient or carer advice/follow up (continued over page)	Supply the marketing authorisation holder's patient information leaflet (PIL). Supply an appropriate information leaflet from the TARGET: Respiratory tract infection resource suite: Patient facing materials (rcgp.org.uk) as a discussion tool and provide a copy if possible. Supply the information for parents and carers leaflet if they cannot swallow tablets and the liquid is unavailable or unsuitable. A patient information leaflet is available (PIL) to support an individual in their decision to use antibiotics during pregnancy. bumps - best use of medicine in pregnancy (medicinesinpregnancy.org). Inform the individual or their carer: ➢ the tablets should be swallowed whole with water, if the individual can't swallow tablets and the liquid is unavailable or unsuitable, the tablets can be dispersed in liquid or crushed and mixed with liquid or soft food; see Welsh Medicines Advice Service guidance to support provision of antibiotic solid dosage forms when liquid preparations are not available. ➢ the oral solution should be kept in the fridge. ➢ the oral solution should be shaken well before each dose. ➢ to take the dose at least 30 minutes before food or 2 hours after food. ➢ taking simple analgesics like paracetamol or ibuprofen at regular intervals will help temperature and discomfort. ➢ adults and older children may find sucking ice cubes, flavoured frozen desserts (e.g. ice lollies) or hard sweets provides symptomatic relief. ➢ they may wish to try medicated lozenges (containing a local anaesthetic, a nonsteroidal anti-inflammatory drug [NSAID] or an antiseptic) which may provide temporary relief from throat pain, but their benefit is likely to be small; it is unclear if throat sprays containing an antiseptic plus local anaesthetic or benzydamine gargles help symptoms. ➢ to avoid smoking and smoky environments.

Patient or carer advice/follow up (continued)	➢ to drink plenty of cool or warm fluid and avoid very hot drinks that could irritate the throat; eat cool and soft foods. ➢ adults can try a warm saline mouthwash or gargle (half a teaspoon of salt in a glassful of warm water at frequent intervals), but do not swallow the mouthwash – this is not suitable for young children. ➢ the condition is self-limiting and is likely to get better within 7 days, with or without antibiotic treatment and to seek further medical advice from a GP if symptoms worsen or do not improve within 3-4 days of antibiotic treatment, for example: o pain does not improve. o it becomes difficult to swallow saliva or liquids. o if any difficulty in breathing develops. o one sided neck or throat swelling develops. ➢ if they take oral contraceptives – phenoxymethylpenicillin does not reduce their efficacy but if it makes the individual sick or have severe diarrhoea for more than 24 hours, they may not be protected from pregnancy. Advise the individual to follow the instructions in their pill packet. More advice is available from What if I'm on the pill and I'm sick or have diarrhoea? - NHS (www.nhs.uk). ➢ if they are breastfeeding, they can continue; penicillins can cause some babies to have mild stomach upsets. If their baby is not feeding as well as usual or they are unsettled after feeding, if they have diarrhoea and or vomiting, if they develop a rash or are unusually sleepy, if they have oral thrush, or any concerns, they should contact their health visitor, midwife or general practitioner. ➢ if they have diabetes, their blood sugars may be higher or lower than usual whilst they are unwell. They should follow their diabetes sick day rules; see Diabetes and being ill | Managing when you're sick | Diabetes UK. ➢ if they get any side effects, to talk to their doctor, or pharmacist or nurse and report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme. This includes any possible side effects not listed in the PIL. ➢ in the event of a severe adverse reaction to discontinue treatment immediately and to seek medical advice if their condition deteriorates and/or they become systemically unwell. ➢ if they develop severe diarrhoea, which may contain blood and mucus, stomach pain and fever, they should seek medical attention immediately. ➢ to return any unused medicines to a pharmacy for disposal: do not dispose of medicines in the bin, down the sink or toilet. ➢ to read the PIL before taking the medication. ➢ to visit the NHS website on phenoxymethylpenicillin for more information.
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Patient or carer advice/follow up (continued)	➢ to visit the NHS 111 Wales site for further information on sore throat. ➢ reinforce messages around preventing infections e.g. wash hands frequently, avoid sharing glasses or utensils with people who are ill, cough or sneeze into a tissue and dispose of it in the bin.
Records	The consultation details including any medication supplied under the PGD must be recorded in Choose Pharmacy at the time of the consultation. Where the Choose Pharmacy platform is not available, temporary records must be made using the paper-based consultation record. Paper based records must be transferred onto the Choose Pharmacy Sore Throat module as soon as practically possible following the consultation. If the patient is excluded, and any specific advice that has been given, a record of the reason for exclusion must be documented within the consultation notes. For pregnant women record the antibiotic supplied in the hand-held maternity record (if available).

PGD for the supply of amoxicillin 250 mg or 500 mg capsules, amoxicillin 250 mg / 5 mL and 500 mg / 5 mL oral suspension and amoxicillin 250 mg / 5 mL and 500 mg / 5 mL oral suspension sugar free

1. Clinical Condition

Clinical condition or situation to which this PGD applies	For the treatment of painful, inflamed throat, which makes swallowing difficult, AND phenoxymethylpenicillin is unavailable#, in accordance with the community pharmacy sore throat component of the Common Ailments Service.
Inclusion criteria	Amoxicillin can be given to: Adults and children aged 5 years and over, presenting with symptoms of acute uncomplicated sore throat **AND** phenoxymethylpenicillin is unavailable# **AND** ➢ a FeverPAIN score of 2 or above **OR** ➢ a Centor Score of 3 or above **AND** ➢ a positive result from a Rapid Antigen Diagnostic Test (RADT) for Streptococcus A infection **AND** ➢ have no contraindications to amoxicillin and penicillin type antibiotics. ➢ informed consent has been given. in accordance with the All Wales Common Ailments Service Formulary 2025. **# amoxicillin should only be issued when the preferred antibiotic (phenoxymethylpenicillin) cannot be obtained within a reasonable time frame. Phenoxymethylpenicillin is the preferred antibiotic because it is a narrow spectrum penicillin with a lower risk of causing resistance than amoxicillin and see cautions regarding amoxicillin use in possible concurrent glandular fever infection. Advise the individual that amoxicillin is not the recommended first line treatment and document in the record.**
Exclusion criteria[3] (continued over page)	Amoxicillin should not be given to individuals **in the presence of the following red flag symptoms – advise the individual to phone 999 or attend A&E immediately:** ➢ life-threatening symptoms such as stridor, breathing difficulty, drooling, inability to swallow or open the mouth. ➢ severe symptoms getting worse quickly. ➢ signs of marked systemic illness or sepsis including signs of changes in cognitive function, behaviour or mental state e.g. confusion, drowsiness, slurred speech. ➢ systemically unwell and at risk of immunosuppression.

[3] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required.

Exclusion criteria (continued)	➢ coughing up blood (**more** than just a few spots or streaks of blood present in the phlegm). ➢ skin changes e.g. very cold or a strange colour or a rash. ➢ crushing central chest pain. ➢ severe headache and vomiting. ➢ suspected peri-tonsillar abscess or cellulitis, parapharyngeal abscess, retropharyngeal abscess or Lemierre's syndrome (risk of airway compromise or rupture of the abscess). (severe neck pain, neck stiffness, visible neck swelling). ➢ if they are dehydrated, unable to take fluids or passing little or no urine, and or have dry mucous membranes). ➢ Kawasaki disease. Presents with a high temperature lasting 5 days or more and with one or more of the following symptoms: rash, swollen neck glands, dry, red, cracked lips, swollen bumpy red tongue (strawberry tongue), red inside the mouth and back of the throat, swollen and red hands and feet, red eyes. **Advise the individual to see a GP, call NHS 111 or see a community PIP as appropriate for same day assessment if any of the following are present:** ➢ known immunosuppression (accompanied by other clinical symptoms of blood disorders), including for example: o a patient who is on chemotherapy, radiotherapy, has known or suspected leukaemia, asplenia, aplastic anaemia or HIV/AIDS, or is taking an immunosuppressive drug following a transplant. o a patient who is taking a disease-modifying anti-rheumatic drug (DMARD), e.g. sulfasalazine, azathioprine, methotrexate. o a patient who is taking a medicine that can cause blood disorders (e.g. neutropenia, agranulocytosis, thrombocytopenia) leading to infection and acute sore throat including cytotoxic drugs, carbimazole, clozapine and sulfasalazine. ➢ abnormal breathing pattern (but not struggling for breath). ➢ a rash, flushed cheeks and swollen tongue (scarlet fever). ➢ persistent high temperature over 38°C uncontrolled by paracetamol or ibuprofen. ➢ oral mucositis. ➢ coughing up small amounts of blood (**no more** than a few spots or streaks of blood). ➢ a suspected bacterial infection despite negative antigen test. ➢ moderate, severe or end stage renal failure (eGFR less than 60 mL / min) or patients with renal disease where renal function cannot be confirmed.

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Exclusion criteria (continued)	➢ high risk of serious complications because: o of significant heart, lung, kidney, liver, or neuromuscular disease (including patients with a history of valvular heart disease, rheumatic fever, post-streptococcal glomerular nephritis and cystic fibrosis). o they are immunocompromised. ➢ diabetes, if, in the opinion of the pharmacist: o there are concerns regarding their individual diabetic control. o the individual is at increased risk of detrimental symptoms associated with poorly controlled diabetes; symptoms can include thirst, blurred vision, fatigue, increased frequency of urination. o the individual is unsure how to manage their diabetes. ➢ if they are children under 5 years. ➢ if they are frail and or elderly over 75 years old. ➢ if they are systemically very unwell and there are no features indicating urgent referral to A&E. ➢ persistent alteration in voice, hoarseness, lasting longer than 3 weeks or is present with no other symptoms. ➢ if they present with additional symptoms atypical of acute sore throat that could indicate another infectious cause of sore throat including: o ulceration in the mouth, sloughing or bleeding of the mucous membranes of the pharynx. o presence of a mass or unilateral swelling. o skin, genital or eye lesions or a rash. o abdominal symptoms. o hand or foot symptoms. o grey/green oropharyngeal membranes. o severe pain. **Advise the individual to see a GP for routine appointment an individual:** ➢ with a history of repeated episodes (more than 2 previous episodes) of Streptococcus A infection in the previous 6 months or a lower threshold if other concerns. ➢ with persistent symptoms that haven't improved after 7 days. A sore throat after 7 days with lethargy may indicate glandular fever, especially if they are aged 15-24 years old. **Amoxicillin is not suitable for individuals:** ➢ with a known hypersensitivity to amoxicillin and penicillin type antibiotics e.g. co-amoxiclav and flucloxacillin – see SmPC. ➢ with a known hypersensitivity to cephalosporins, e.g. cefalexin – see SmPC. ➢ with a known hypersensitivity to any of the excipients – see SmPC.
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Exclusion criteria (continued)	➢ with known or suspected hepatic impairment. ➢ who have suffered severe diarrhoea following previous treatment with amoxicillin. ➢ with symptoms of diarrhoea and they have received an antibiotic within the previous 3 months. ➢ who are taking concurrent antibiotic treatment. ➢ with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency and the oral suspension is required. ➢ who are taking contraindicated medicines (see drug interactions section for further detail) including: o methotrexate. o bacteriostatic antibiotics, e.g. tetracyclines, erythromycin, chloramphenicol and sulphonamides. o recent typhoid vaccination (oral). o probenecid. ➢ if informed consent has not been given by the individual, parent, guardian or carer; where individuals or their parent, guardian or carer do not agree to share relevant clinical information or there is no valid consent. ➢ if the pharmacist is unable to undertake an appropriate assessment, to determine the need for the medicine and that it would be appropriate for the patient to use it. ➢ to individuals who are unable to administer or use the product effectively themselves or who do not have a parent / guardian / carer to administer or apply the medication for them.
Cautions (including relevant actions to be taken) (continued over page)	Please refer to the SmPC for amoxicillin for full details of special warnings and precautions for use. **History of allergy** ➢ Amoxicillin should be given with caution to patients with a history of allergy, especially to other drugs. If the patient experiences an allergic reaction, amoxicillin should be discontinued and treatment with the appropriate agents initiated (e.g. adrenaline and other pressor amines, antihistamines and other corticosteroids). **Colitis** Caution should be used when treating patients with a history of antibiotic-associated colitis and other risk factors for *Clostridioides difficile* infection (CDI) (see Risk factors | Background information | Diarrhoea - antibiotic associated | CKS | NICE). Sustained severe diarrhoea should prompt suspicion of pseudomembranous colitis during or after treatment with an antibiotic. As this condition may be life threatening, amoxicillin should be withdrawn immediately.

Cautions (including relevant actions to be taken) (continued)	Pseudomembranous colitis has been reported with nearly all antibacterial agents and may range in severity from mild to life-threatening. *Clostridioides difficile*-associated diarrhoea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhoea to fatal colitis. **Diabetes** Individuals with diabetes can be supplied with treatment if, in the opinion of the pharmacist, there are no concerns or symptoms suggestive of poor control, for example, thirst, blurred vision, fatigue etc. Provided there are no features, signs or symptoms, treatment can be supplied. Individuals should be reminded of the diabetes sick day rules (see patient or carer advice). **Oral hypoglycaemic agents/insulin** – careful monitoring of glucose is recommended. **Epilepsy** Convulsions may occur in individuals with predisposing risk factors e.g. history of seizures, treated epilepsy or meningeal disorders. **Effect on laboratory tests** During treatment with amoxicillin, non-enzymatic glucose tests may be false-positive. **Concurrent infection** Individuals, particularly adolescents with concurrent infection with Glandular fever / Epstein-Barr virus (EBV), have an increased frequency of amoxicillin associated skin rashes. This may lead to confusion and the individual labelled as penicillin allergic. The rash is similar to a penicillin allergy. Advise the individual that if a rash develops to seek medical attention. **Phenylketonuria** Amoxicillin oral suspensions may contain aspartame (E951), a source of phenylalanine. This medicine should be used with caution in patients with phenylketonuria. **Maltodextrin (glucose)** ➢ Amoxicillin oral suspension may contain glucose. This should be taken into consideration in patients with diabetes mellitus. ➢ May be harmful to the teeth. **Oral anticoagulants** There is a risk of serious haemorrhage and significant elevations in International Normalized Ratio (INR) and prothrombin time when amoxicillin is co-administered with warfarin. INR and prothrombin times should be

(continued over page)

Cautions (including relevant actions to be taken) (continued)	frequently monitored while patients are receiving amoxicillin and oral anticoagulants concurrently. **Advise the individual to contact their clinic responsible for INR monitoring within 3 days of starting amoxicillin treatment**. Caution should be exercised when amoxicillin is co-administered with direct acting oral anticoagulants such as dabigatran, rivaroxaban, apixaban and edoxaban particularly to patients at high risk of bleeding. **Pregnancy** ➢ Not known to be harmful. ➢ Penicillins like amoxicillin may be used in pregnancy. Most of the large amount of available data shows no increased risk following maternal exposure. However, as with other drugs, caution should be exercised when supplying to pregnant patients. ➢ A patient information leaflet is available (PIL) to support an individual in their decision to use antibiotics during pregnancy. bumps - best use of medicine in pregnancy (medicinesinpregnancy.org). ➢ The presence of amoxicillin may distort assay results for oestriol in pregnant women. **Breastfeeding** Penicillins pass into breast milk in very small amounts and are unlikely to be harmful. It can cause some babies to have mild stomach upsets. Individuals should contact their health visitor, midwife or general practitioner if their baby: ➢ is not feeding as well as usual. ➢ is unsettled after feeding. ➢ develops diarrhoea and or vomiting. ➢ develops a rash. ➢ is unusually sleepy. ➢ has oral thrush. **Opening capsules and dispersing** Only to be considered if liquid not available or suitable and would be off-label. There is a risk of sensitisation. Advise the individual to always wear gloves and mask, and use a closed system where possible, e.g. disperse capsule contents in the barrel of a syringe. See off-label section and Welsh Medicines Advice Service guidance to support provision of antibiotic solid dosage forms when liquid preparations are not available for further advice.

Action to be taken if the individual is excluded or declines treatment	➢ If individual meets the exclusion criteria, refer to a medical practitioner or PIP as appropriate. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination. ➢ Explain the reasons for exclusion to the individual and document in the consultation record. ➢ If the individual declines, advise of the consequences of not receiving treatment and document the advice given and details of any referral made and their (patient, parent/carer or guardian) intended actions. ➢ If appropriate, individuals may be offered a suitable alternative antibiotic or provided with advice and symptomatic treatment from the All Wales Common Ailments Service Formulary. Alternatively, refer the individual to a GP or PIP if appropriate.
Further advice	If there is any doubt about the administration of the medication or the individual's fitness or suitability to receive the medication, a doctor or appropriate PIP should be consulted. ➢ Refer to SmPC, BNF and the All Wales Common Ailments Service.

2. Description of Treatment

Name, strength & formulation of drug	Amoxicillin 250mg or 500 mg capsules. Amoxicillin 250 mg / 5 mL and 500mg / 5 mL oral suspension. Amoxicillin 250 mg / 5 mL and 500mg / 5 mL oral suspension sugar free.
Legal category	POM – Prescription Only Medicine.
Black triangle▼	No.
Off-label use	Yes. If the individual is unable to swallow the capsules AND the liquid is unavailable or unsuitable, the capsule can be opened and the contents tipped out and mixed with liquid or soft food. Please follow the guidance to support provision of antibiotic solid dosage forms when liquid preparations are not available. It is important to note the following: ➢ Administration in this way is off-label (used outside of the product licence). ➢ When crushing opening capsules, caution should be exercised on handling the antibiotic powder produced to avoid contact sensitisation or inhalation; safety measures that should be used include: o using a closed system e.g. dispersing a tablet in the barrel of a syringe. o wearing gloves to reduce contact with the skin, and a mask to prevent dust inhalation. o sensitisation is a risk with all the antibiotics but may be of particular concern with penicillins. ➢ Parents/carers with penicillin allergy should avoid involvement in preparing and administering the capsules this way.
Route / method of administration	Oral. **Capsules**: Each capsule should be swallowed whole with water. If supplied because the liquid formulation is not available or unsuitable, see Welsh Medicines Advice Service guidance to support provision of antibiotic solid dosage forms when liquid preparations are not available for advice on opening the capsule and tipping the contents into soft food or liquid. **Oral suspension**: Follow the instructions for reconstitution.
Dose and frequency of administration	**Adults and children aged 5 years and over**: 500 mg THREE times a day for TEN days.

Duration of treatment	TEN days. This PGD only allows for the duration stated in the dosage schedule above.
Quantity to be supplied	The best value product available at the time to meet the clinical need should be appropriately labelled and supplied to provide treatment for TEN days: **Capsules**: **30 x 500 mg** capsules at a dose of ONE capsule THREE times a day. **If 500 mg capsules are unavailable**: **60 x 250 mg** capsules at a dose of TWO capsules THREE times a day. **Oral suspension**: **3 x 100 mL** (250 mg / 5 mL) at a dose of 10 mL THREE times a day. **OR** **2 x 100 mL** (500 mg / 5 mL) at a dose of 5 mL THREE times a day.
Storage	Medicines must be stored securely and in accordance with product SmPC.
Disposal	Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.
Drug interactions	The following list of interactions is not exhaustive. A detailed list of drug interactions can be found in the SmPC and the BNF. **Contraindicated** ➢ Methotrexate – use of amoxicillin while taking methotrexate can cause reduced excretion of methotrexate thereby increasing the risk of toxicity. ➢ Typhoid vaccine (oral) – antibacterial agents may inactivate oral typhoid vaccine if ingested concomitantly. The Green Book advises that the vaccine should not be commenced within three days of completing any antibacterial agent and similarly antibacterial therapy should not commence within 3 days after the last dose of vaccine. ➢ Bacteriostatic antibiotics – certain bacteriostatic antibiotics such as chloramphenicol, erythromycin, tetracyclines and sulphonamides have been reported to antagonize the bactericidal activity of penicillins and concomitant use is not recommended. ➢ Uricosuric drugs like probenecid and sulfinpyrazone can reduce the excretion of penicillins resulting in increased plasma levels and prolonged action. **Cautions** Amoxicillin should be used in caution in patients also prescribed:

(continued over page)	➢ allopurinol – concurrent administration with amoxicillin can increase the likelihood of allergic skin reactions.
Drug interactions (continued)	➢ coumarin anticoagulants – penicillins may interfere with anticoagulant control (see cautions). ➢ phenindione – penicillins may interfere with anticoagulant control (see cautions). ➢ oral contraceptives – amoxicillin does not reduce their efficacy but if it makes the individual sick or have severe diarrhoea for more than 24 hours, they may not be protected from pregnancy. Advise the individual to follow the instructions in their pill packet. More advice is available from What if I'm on the pill and I'm sick or have diarrhoea? - NHS (www.nhs.uk).
Identification & management of adverse reactions	Advise the patient that if any of the following side effects occur, discontinue treatment immediately and contact the emergency department or dial 999: ➢ allergic reactions such as sudden difficulty with breathing, speaking and swallowing. ➢ extreme dizziness or fainting. ➢ severe itchy skin rash especially if blistering, soreness of the eyes, mouth or genital organs. The following side effects have been reported by patients taking amoxicillin: **Very common to common** (affecting between 1 in 10 and 1 in 100 patients): ➢ nausea, diarrhoea, skin rash. **Concurrent Infection** Individuals, particularly adolescents with concurrent infection with Glandular fever/Epstein-Barr virus (EBV) have an increased frequency of amoxicillin associated skin rashes. This may lead to confusion and the individual labelled as penicillin allergic. The rash is similar to a penicillin allergy. Advise the individual that if a rash develops to seek medical attention. **Uncommon** (affecting between 1 in 100 and 1 in 1000 patients): ➢ vomiting, urticaria, pruritis. **Rare or very rare adverse effects** (affecting between 1 in 1000 and 1 in 10000 patients): ➢ mucocutaneous candidiasis. ➢ reversible leucopenia (including severe neutropenia or agranulocytosis), reversible thrombocytopenia and haemolytic anaemia. ➢ prolongation of bleeding time and prothrombin time. ➢ severe allergic reactions, including angioneurotic oedema, anaphylaxis,

(continued over page)	serum sickness and hypersensitivity vasculitis. ➢ hyperkinesia, dizziness, convulsions.
Identification & management of adverse reactions (continued)	➢ antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis), black hairy tongue. ➢ hepatitis and cholestatic jaundice. A moderate rise in AST and/or ALT. ➢ skin reactions such as erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous and exfoliative dermatitis, acute generalised exanthematous pustulosis (AGEP) and drug reaction with eosinophilia and systemic symptoms (DRESS). ➢ interstitial nephritis; crystalluria (including acute renal injury). **Frequency not known**: ➢ Jarish-Herxheimer reaction (reaction seen following treatment with amoxicillin for Lyme disease). ➢ aseptic meningitis. ➢ Kounis syndrome. ➢ drug-induced enterocolitis syndrome (DIES). ➢ linear IgA disease. DIES has been reported mainly in children receiving amoxicillin. It is an allergic reaction with the leading symptom of protracted vomiting (1-4 hours after drug intake) in the absence of allergic skin or respiratory symptoms. Further symptoms could comprise abdominal pain, diarrhoea and hypotension and in severe cases progressing to shock. See patient advice section. N.B. detailed lists of adverse reactions are available in the SmPC, and the BNF. Prior to issuing medication, please refer to these resources to check that there has been no change to the potential adverse reactions listed above.
Patient or carer advice/follow up	Supply the marketing authorisation holder's patient information leaflet (PIL). Supply an appropriate information leaflet from the TARGET: Respiratory tract infection resource suite: Patient facing materials (rcgp.org.uk) as a discussion tool and provide a copy if possible. Supply the information for parents and carers leaflet if they cannot swallow tablets and the liquid is unavailable or unsuitable. A patient information leaflet is available (PIL) to support an individual in their decision to use antibiotics during pregnancy. bumps - best use of medicine in pregnancy (medicinesinpregnancy.org). Inform the individual or their carer: ➢ the capsule should be swallowed whole with water. ➢ the capsule can be taken with or after food. ➢ the oral suspension should be shaken well before each dose.

(continued over page)	➢ the suspension can be taken with or after food. ➢ if the individual can't swallow capsules and the liquid is unavailable or unsuitable, the capsule can be opened and the contents tipped out and
Patient or carer advice/follow up (continued)	mixed with liquid or soft food if the oral suspension is not available; off-label use – see Welsh Medicines Advice Service guidance to support provision of antibiotic solid dosage forms when liquid preparations are not available. ➢ taking simple analgesics like paracetamol or ibuprofen at regular intervals will help temperature and discomfort. ➢ adults and older children may find sucking ice cubes, flavoured frozen desserts (e.g. ice lollies) or hard sweets provides symptomatic relief. ➢ they may wish to try medicated lozenges (containing a local anaesthetic, a nonsteroidal anti-inflammatory drug [NSAID] or an antiseptic) which may provide temporary relief from throat pain, but their benefit is likely to be small; it is unclear if throat sprays containing an antiseptic plus local anaesthetic or benzydamine gargles help symptoms. ➢ to avoid smoking and smoky environments. ➢ to drink plenty of cool or warm fluid and avoid very hot drinks that could irritate the throat; eat cool and soft foods. ➢ adults can try a warm saline mouthwash or gargle (half a teaspoon of salt in a glassful of warm water at frequent intervals), but do not swallow the mouthwash – this is not suitable for young children. ➢ the condition is self-limiting and is likely to get better within 7 days, with or without antibiotic treatment and to seek further medical advice from a GP if symptoms worsen or do not improve within 3-4 days of antibiotic treatment, for example: o pain does not improve. o it becomes difficult to swallow saliva or liquids. o if any difficulty in breathing develops. o one sided neck or throat swelling develops. ➢ if they take oral contraceptives – amoxicillin does not reduce their efficacy but if it makes the individual sick or have severe diarrhoea for more than 24 hours, they may not be protected from pregnancy. Advise the individual to follow the instructions in their pill packet. More advice is available from What if I'm on the pill and I'm sick or have diarrhoea? - NHS (www.nhs.uk). ➢ if they are breastfeeding, they can continue; penicillins can cause some babies to have mild stomach upsets. If their baby is not feeding as well as usual or they are unsettled after feeding, if they have diarrhoea and or vomiting, if they develop a rash or are unusually sleepy, if they have oral thrush, or any concerns, they should contact their health visitor, midwife or general practitioner. ➢ if they have diabetes, their blood sugars may be higher or lower than usual whilst they are unwell. They should follow their diabetes sick day

(continued over page)	rules; see Diabetes and being ill | Managing when you're sick | Diabetes UK. ➢ if they get any side effects, to talk to their doctor, or pharmacist or nurse and report any suspected adverse reactions to the Medicines and
Patient or carer advice/follow up (continued)	Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme. This includes any possible side effects not listed in the PIL. ➢ in the event of a severe adverse reaction to discontinue treatment immediately and to seek medical advice if their condition deteriorates and/or they become systemically unwell. ➢ if they develop protracted vomiting within 1-4 hours of drug intake with or without the presence of diarrhoea, abdominal pain and feeling faint, they should seek medical attention immediately. ➢ if they develop severe diarrhoea, which may contain blood and mucus, stomach pain and fever, they should seek medical attention immediately. ➢ amoxicillin can cause dizziness as an adverse effect which may influence the individual's ability to drive or operate machinery. ➢ if they develop a rash they should seek medical attention immediately. ➢ to return any unused medicines to a pharmacy for disposal: do not dispose of medicines in the bin, down the sink or toilet. ➢ to read the PIL before taking the medication. ➢ to visit the NHS website on amoxicillin for more information. ➢ to visit the NHS 111 Wales site for further information on sore throat. ➢ reinforce messages around preventing infections e.g. wash hands frequently, avoid sharing glasses or utensils with people who are ill, cough or sneeze into a tissue and dispose of it in the bin.
Records	The consultation details including any medication supplied under the PGD must be recorded in Choose Pharmacy at the time of the consultation. Where the Choose Pharmacy platform is not available, temporary records must be made using the paper-based consultation record. Paper based records must be transferred onto the Choose Pharmacy Sore Throat module as soon as practically possible following the consultation. If the patient is excluded, and any specific advice that has been given, a record of the reason for exclusion must be documented within the consultation notes. If amoxicillin is being supplied because the first line recommended antibiotic is unavailable, document consent to receive the alternative treatment option in the consultation notes. For pregnant women record the antibiotic supplied in the hand-held maternity record (if available).

PGD for the supply of clarithromycin 250 mg or 500 mg tablets, clarithromycin 125 mg / 5 mL or 250 mg / 5 mL oral suspension

1. Clinical Condition

Clinical condition or situation to which this PGD applies	For the treatment of painful, inflamed throat, which makes swallowing difficult, where the use of phenoxymethylpenicillin and amoxicillin is contraindicated OR unavailable†, in accordance with the community pharmacy Sore Throat component of the Common Ailments Service.
Inclusion criteria	Clarithromycin can be given to: Adults and children aged 5 years and over presenting with symptoms of acute uncomplicated sore throat **AND** ➢ a FeverPAIN score of 2 or above **OR** ➢ a Centor Score of 3 or above **AND** ➢ a positive result from a throat swab Rapid Antigen Diagnostic Test (RADT) for Streptococcus A infection **AND** ➢ the use of phenoxymethylpenicillin and amoxicillin is contraindicated **OR unavailable**†. ➢ they have no contraindications to clarithromycin and macrolide type antibiotics. ➢ informed consent has been given. in accordance with the All Wales Common Ailments Service Formulary 2025. † **clarithromycin should only be issued when phenoxymethylpenicillin is contraindicated OR when the preferred antibiotic (phenoxymethylpenicillin) cannot be obtained within a reasonable time frame. Advise the individual that clarithromycin is not the recommended first line treatment and document in the record.**
Exclusion criteria[4]	Clarithromycin should not be given to individuals **in the presence of the following red flag symptoms – advise the individual to phone 999 or attend A&E immediately:** ➢ life-threatening symptoms such as stridor, breathing difficulty, drooling, inability to swallow or open the mouth. ➢ severe symptoms getting worse quickly. ➢ signs of marked systemic illness or sepsis including signs of changes in cognitive function, behaviour or mental state e.g. confusion, drowsiness, slurred speech. ➢ systemically unwell and at risk of immunosuppression.

[4] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required.

(continued over page)	➢ coughing up blood (**more** than just a few spots or streaks of blood present in the phlegm).
Exclusion criteria (continued)	➢ skin changes e.g. very cold or a strange colour or a rash. ➢ crushing central chest pain. ➢ severe headache and vomiting. ➢ suspected peri-tonsillar abscess or cellulitis, parapharyngeal abscess, retropharyngeal abscess or Lemierre's syndrome (risk of airway compromise or rupture of the abscess). ➢ if they are dehydrated, unable to take fluids or passing little or no urine, and/or have dry mucous membranes). ➢ Kawasaki disease. Presents with a high temperature lasting 5 days or more and with one or more of the following symptoms: rash, swollen neck glands, dry, red, cracked lips, swollen bumpy red tongue (strawberry tongue), red inside the mouth and back of the throat, swollen and red hands and feet, red eyes. **Advise the individual to see a GP, call NHS 111 or see a community PIP as appropriate for same day assessment if any of the following are present:** ➢ known immunosuppression (accompanied by other clinical symptoms of blood disorders), including for example: o a patient who is on chemotherapy, radiotherapy, has known or suspected leukaemia, asplenia, aplastic anaemia or HIV/AIDS, or is taking an immunosuppressive drug following a transplant. o a patient who is taking a disease-modifying anti-rheumatic drug (DMARD), e.g. sulfasalazine, azathioprine, methotrexate. o a patient who is taking a medicine that can cause blood disorders (e.g. neutropenia, agranulocytosis, thrombocytopenia) leading to infection and acute sore throat including cytotoxic drugs, carbimazole, clozapine and sulfasalazine. ➢ abnormal breathing pattern (but not struggling for breath). ➢ a rash, flushed cheeks and swollen tongue (scarlet fever). ➢ a persistent high temperature over 38°C uncontrolled by paracetamol or ibuprofen. ➢ oral mucositis. ➢ coughing up small amounts of blood (**no more** than a few spots or streaks of blood present in the phlegm). ➢ a suspected bacterial infection despite negative antigen test. ➢ moderate, severe or end stage renal failure (eGFR less than 60 mL / min) or patients with renal disease where renal function cannot be confirmed. ➢ high risk of serious complications because: o of significant heart, lung, kidney, liver, or neuromuscular disease (including patients with a history of valvular heart disease, rheumatic fever, post-streptococcal glomerular nephritis and cystic fibrosis).

(continued over page)	○ they are immunocompromised.
Exclusion criteria (continued)	➢ diabetes, if, in the opinion of the pharmacist: ○ there are concerns regarding their individual diabetic control. ○ the individual is at increased risk of detrimental symptoms associated with poorly controlled diabetes; symptoms can include thirst, blurred vision, fatigue, increased frequency of urination. ○ the individual is unsure how to manage their diabetes. ➢ if they are children under 5 years. ➢ if they are frail and or elderly over 75 years old. ➢ if they are systemically very unwell and there are no features indicating urgent referral to A&E. ➢ persistent alteration in voice, hoarseness, lasting longer than 3 weeks or is present with no other symptoms. ➢ if they present with additional symptoms atypical of acute sore throat that could indicate another infectious cause of sore throat including: ○ ulceration in the mouth, sloughing or bleeding of the mucous membranes of the pharynx. ○ presence of a mass or unilateral swelling. ○ skin, genital or eye lesions or a rash. ○ abdominal symptoms. ○ hand or foot symptoms. ○ grey/green oropharyngeal membranes ○ severe pain. **Advise the individual to see a GP for routine appointment an individual:** ➢ with a history of repeated episodes (more than 2 previous episodes) of Streptococcus A infection in the previous 6 months or a lower threshold if other concerns. ➢ with persistent symptoms that haven't improved after 7 days. A sore throat after 7 days with lethargy may indicate glandular fever, especially if they are aged 15-24 years old. **Clarithromycin is not suitable for individuals**: ➢ with a known hypersensitivity to clarithromycin or macrolide type antibiotics e.g. erythromycin and azithromycin– see SmPC. ➢ with a known hypersensitivity to any of the excipients – see SmPC. ➢ with known or suspected hepatic impairment or people concomitantly receiving potentially hepatotoxic drugs. – see drug interactions. ➢ with known or suspected pregnancy. ➢ who have myasthenia gravis — macrolides may aggravate weakness symptoms.

(continued over page)	➢ with a history of or current QT prolongation.
Exclusion criteria (continued)	➢ with a history of or current ventricular cardiac arrhythmia including torsade de pointes. ➢ with known or suspected electrolyte disturbances (hypokalaemia or hypomagnesaemia). ➢ with coronary artery disease, severe cardiac insufficiency, conduction disturbances or clinically relevant bradycardia. ➢ with porphyria. ➢ who have suffered severe diarrhoea following previous treatment with clarithromycin. ➢ with symptoms of diarrhoea and they have received an antibiotic within the previous 3 months. ➢ who are taking concurrent antibiotic treatment. ➢ with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency and the oral suspension is required. ➢ who are taking a contraindicated medicine (see drug interactions section for further detail) including: o recent typhoid vaccination (oral). o drugs that prolong the QT interval (see BNF for all drugs that can prolong the QT interval) e.g. • astemizole. • cisapride. • domperidone. • ivabradine. • pimozide. • terfenadine. o or who are taking the following: • ergotamine or dihydroergotamine. • hydroxychloroquine or chloroquine. • midazolam, ranolazine, ticagrelor, colchicine, lomitapide. • simvastatin (unless withheld – see cautions section for more information). o if there is current or recent treatment (within the last two weeks) with drugs that are inducers of CYP3A4, e.g. • rifampicin. • rifabutin. • phenytoin. • carbamazepine. • phenobarbital.

(continued over page)	• St John's Wort.
Exclusion criteria (continued)	○ who take medicines that are known or suspected to affect circulating concentrations of clarithromycin; for drugs that are metabolised by the cytochrome P450 system which could be affected by clarithromycin, see cautions and drug interactions sections. ➢ if informed consent has not been given by the individual, parent, guardian or carer; where individuals or their parent, guardian or carer do not agree to share relevant clinical information or there is no valid consent. ➢ if the pharmacist is unable to undertake an appropriate assessment, to determine the need for the medicine and that it would be appropriate for the patient to use it. ➢ to individuals who are unable to administer or use the product effectively themselves or who do not have a parent, guardian or carer to administer or apply the medication for them.
Cautions (including relevant actions to be taken)	Please refer to the SmPC for clarithromycin for full details of special warnings and precautions for use. **Hypersensitivity reactions** In the event of severe acute hypersensitivity reactions, such as anaphylaxis, severe cutaneous adverse reactions (SCAR) (e.g. acute generalised exanthematous pustulosis (AGEP), Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug rash with eosinophilia and systemic symptoms (DRESS), clarithromycin therapy should be discontinued immediately, and appropriate treatment should be urgently initiated. **Colitis** Caution should be used when treating patients with a history of antibiotic-associated colitis and other risk factors for *Clostridioides difficile* infection (CDI) (see Risk factors | Background information | Diarrhoea - antibiotic associated | CKS | NICE). Sustained severe diarrhoea should prompt suspicion of pseudomembranous colitis during or after treatment with an antibiotic. As this condition may be life threatening, clarithromycin should be withdrawn immediately. Pseudomembranous colitis has been reported with nearly all antibacterial agents and may range in severity from mild to life-threatening. *Clostridioides difficile*-associated diarrhoea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhoea to fatal colitis. Drugs inhibiting peristalsis should be avoided. **Cardiovascular events**

(continued over page)	Prolonged cardiac repolarisation and QT interval, imparting a risk of developing cardiac arrhythmia and torsade de pointes, have been seen in treatment with macrolides. Macrolides should be used with caution in the following patients:
Cautions (including relevant actions to be taken) (continued)	➢ Patients concomitantly taking other medicinal products that can cause hypokalaemia (e.g. corticosteroids, diuretics and short acting beta-2 agonists). **Diabetes** Individuals with diabetes can be supplied with treatment if, in the opinion of the pharmacist, there are no concerns or symptoms suggestive of poor control, for example, thirst, blurred vision, fatigue etc. Provided there are no features, signs or symptoms, treatment can be supplied. Individuals should be reminded of the diabetes sick day rules (see patient or carer advice). **Oral hypoglycaemic agents/insulin** – The concomitant use of macrolides and oral hypoglycaemic agents (such as sulphonylureas) and/or insulin can result in significant hypoglycaemia. **Careful monitoring of glucose is recommended.** **HMG-CoA reductase inhibitors (statins)** Caution should be exercised when prescribing macrolides with other statins. Rhabdomyolysis has been reported in patients taking macrolides and statins. Patients should be monitored for signs and symptoms of myopathy. **Patients that are currently taking an HMG-CoA reductase inhibitor (statin) must be given appropriate advice regarding the need to stop taking the statin until the course of treatment with clarithromycin has been completed in accordance with manufacturer's advice (see drug interactions section).** **Oral anticoagulants** There is a risk of serious haemorrhage and significant elevations in International Normalized Ratio (INR) and prothrombin time when clarithromycin is co-administered with warfarin. INR and prothrombin times should be frequently monitored while patients are receiving clarithromycin and oral anticoagulants concurrently. **Advise the individual to contact their clinic responsible for INR monitoring within 3 days of starting clarithromycin treatment.** Caution should be exercised when clarithromycin is co-administered with direct acting oral anticoagulants such as dabigatran, rivaroxaban, apixaban, and edoxaban particularly to patients at high risk of bleeding. **Calcium channel blockers (CCBs)** Due to an increased risk of hypotension, caution is advised with the concurrent use of macrolides and CCBs metabolised by CYP3A4 (such as verapamil, amlodipine, and diltiazem).

(continued over page)	**Breastfeeding** Macrolides pass into breast milk in very small amounts and are unlikely to be harmful. It can cause some babies to have mild stomach upsets. Individuals
Cautions (including relevant actions to be taken) (continued)	should contact their health visitor, midwife or general practitioner if their baby: ➢ is not feeding as well as usual. ➢ is unsettled after feeding. ➢ develops diarrhoea and or vomiting. ➢ develops a rash. ➢ is unusually sleepy. ➢ is sweaty. ➢ has oral thrush. **Phenylketonuria** Clarithromycin oral suspensions may contain aspartame (E951), a source of phenylalanine. This medicine should be used with caution in patients with phenylketonuria. **Sucrose** ➢ Clarithromycin oral suspension may contain sucrose. This should be taken into consideration in patients with diabetes mellitus. ➢ May be harmful to the teeth. **Crushing and dispersing** Only to be considered if liquid not available or suitable and would be off-label. There is a risk of sensitisation. Advise the individual to always wear gloves and mask and use a closed system where possible e.g. disperse tablet in the barrel of a syringe. See off-label section and Welsh Medicines Advice Service guidance to support provision of antibiotic solid dosage forms when liquid preparations are not available for further advice.
Action to be taken if the individual is excluded or declines treatment	➢ If the individual meets the exclusion criteria, refer to a medical practitioner or PIP appropriate. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination. ➢ Explain the reasons for exclusion to the individual and document in the consultation record. ➢ If the individual declines, advise of the consequences of not receiving treatment and document the advice given and details of any referral made and their (patient, parent/carer or guardian) intended actions. ➢ If appropriate, individuals may be offered a suitable alternative antibiotic or provided with advice and symptomatic treatment from the All Wales

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	Common Ailments Service Formulary. Alternatively, refer the individual to a GP or PIP if appropriate.
Further advice	If there is any doubt about the administration of the medication or the individual's fitness or suitability to receive the medication, a doctor or appropriate PIP should be consulted. ➢ Refer to SmPC, BNF and the All Wales Common Ailments Service.

2. Description of Treatment

Name, strength & formulation of drug	Clarithromycin 250 mg and 500 mg tablets. Clarithromycin 125 mg / 5 mL and 250 mg / 5 mL oral suspension.
Legal category	POM – Prescription Only Medicine.
Black triangle▼	No.
Off-label use	Yes. If the individual is unable to swallow tablets AND the oral suspension is unavailable or unsuitable, the tablets may be dispersed in water OR crushed and mixed with liquid or soft food. Please follow the guidance to support provision of antibiotic solid dosage forms when liquid preparations are not available. It is important to note the following: ➢ Administration in this way is off-label (used outside of the product licence). ➢ When crushing tablets, caution should be exercised on handling the antibiotic powder produced to avoid contact sensitisation or inhalation; safety measures that should be used include: o use a closed system e.g. dispersing a tablet in the barrel of a syringe. o wear gloves to reduce contact with the skin, and a mask to prevent dust inhalation. o sensitisation is a risk with all the antibiotics but may be of particular concern with penicillins. ➢ Parents/carers with clarithromycin allergy should avoid involvement in preparing and administering the tablets this way.
Route / method of administration	Oral. **Tablets**: For adults and children aged 12 years and over. Each tablet should be swallowed whole with water. If supplied because the liquid formulation is not available or unsuitable, see Welsh Medicines Advice Service guidance to support provision of antibiotic solid dosage forms when liquid preparations are not available for advice on dispersing or crushing and mixing with liquid or soft food. **Oral suspension**: For children under 12 years or when tablets are not suitable. Follow the instructions for reconstitution.

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<table>
<tr><td>Dose and frequency of administration</td><td>

Children aged 5-11 years:

The dose is calculated by weight:

<table>
<tr><th>Weight (kg)</th><th>Dose (mg)</th><th>Volume and strength of oral suspension</th><th>Frequency and duration</th></tr>
<tr><td>12 kg – 19 kg</td><td>125 mg</td><td>5 mL
(125 mg / 5 mL)</td><td rowspan="3">TWICE a day for FIVE days</td></tr>
<tr><td>20 kg – 29 kg</td><td>187.5 mg</td><td>7.5 mL
(125 mg / 5 mL)</td></tr>
<tr><td>30 kg – 40 kg</td><td>250 mg</td><td>5 mL
(250 mg / 5 mL)</td></tr>
</table>

Adults and children aged 12 years and over:

500 mg to be taken TWICE a day for FIVE days.

</td></tr>
<tr><td>Duration of treatment</td><td>

FIVE days.

This PGD only allows for the duration stated in the dosage schedule above.

</td></tr>
<tr><td>Quantity to be supplied</td><td>

The best value product available at the time to meet clinical need should be appropriately labelled and supplied to provide treatment for FIVE days:

Tablets:

10 x 500 mg tablets at a dose of ONE tablet TWICE a day.

If 500 mg tablets unavailable:

20 x 250 mg tablets at a dose of TWO tablets TWICE a day.

Oral suspension:

Quantity to supply to provide TWICE a day dosing for FIVE days treatment:

<table>
<tr><th>Weight (kg)</th><th>Dose (mg)</th><th>Volume and strength of oral suspension</th><th>Quantity to supply</th></tr>
<tr><td>12 kg – 19 kg</td><td>125 mg</td><td>5 mL
(125 mg / 5 mL)</td><td>1 x 70 mL</td></tr>
<tr><td>20 kg – 29 kg</td><td>187.5 mg</td><td>7.5 mL
(125 mg / 5 mL)</td><td>2 x 70 mL</td></tr>
<tr><td>30 kg – 40 kg</td><td>250 mg</td><td>5 mL
(250 mg / 5 mL)</td><td>1 x 70mL</td></tr>
<tr><td>>40 kg</td><td>500 mg</td><td>10 mL
(250 mg / 5 mL)</td><td>2 x 70 mL</td></tr>
</table>

</td></tr>
</table>

Storage	Medicines must be stored securely and in accordance with product SmPC.
Disposal	Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.
Drug interactions	The following list is not exhaustive. A detailed list of drug interactions can be found in the SmPC and the BNF. **Contraindicated** ➢ Typhoid vaccine (oral): antibacterial agents may inactivate oral typhoid vaccine if ingested concomitantly. The Green Book advises that the vaccine should not be commenced within three days of completing any antibacterial agent and similarly antibacterial therapy should not commence within 3 days after the last dose of vaccine. ➢ Drugs that prolong the QT interval (see BNF or Stockley's Drug Interactions for all drugs that can prolong the QT interval) including: o astemizole. o cisapride. o domperidone. o fluconazole, ketoconazole, itraconazole. o haloperidol. o hydroxychloroquine, chloroquine. o ivabradine. o pimozide. o quinidine, disopyramide. o ranolazine. o sotalol. o terfenadine. ➢ Drugs that are inducers of CYP3A4 (e.g. rifampicin, rifabutin, phenytoin, carbamazepine, phenobarbital, St John's wort) currently taking or in the last 2 weeks. ➢ Drugs that are known or suspected to affect or be affected by circulating concentrations of clarithromycin: o bromocriptine. o colchicine. o digoxin. o efavirenz, etravirine, nevirapine, rifapentine. o ergotamine or dihydroergotamine. o cilostazol, ciclosporin, ibrutinib, methadone, methylprednisolone, atypical antipsychotics (e.g. quetiapine), saquinavir, sirolimus, (continued over page)

Drug interactions (continued)	tacrolimus, theophylline, tolterodine, valproate, vinblastine, zidovudine. o lomitapide. o opioids – buprenorphine, fentanyl, methadone, oxycodone. o sildenafil, tadalafil and vardenafil. o ticagrelor. o triazolobenzodiazepines (e.g., alprazolam, midazolam, triazolam). **Cautions** Clarithromycin should be used with caution in patients also prescribed: ➢ HMG-CoA reductase inhibitors (statins) – patients that are currently taking an HMG-CoA reductase inhibitor (statin) must be advised to stop taking the statin until the course of treatment with clarithromycin has been completed (i.e. for 5 days) (see cautions). ➢ oral hypoglycaemic agents/insulin – careful monitoring of glucose is recommended (see cautions). ➢ oral anticoagulants – macrolides may interfere with anticoagulant control (see cautions). ➢ calcium channel blockers (CCBs) – due to an increased risk of hypotension, caution is advised with the concurrent use of macrolides and CCBs metabolised by CYP3A4, such as verapamil, amlodipine, and diltiazem (see cautions). ➢ medicinal products that can cause hypokalaemia (e.g. corticosteroids, diuretics, short acting beta-2 agonists). ➢ oral contraceptives – clarithromycin does not reduce their efficacy but if it makes the individual sick or have severe diarrhoea for more than 24 hours, they may not be protected from pregnancy. Advise the individual to follow the instructions in their pill packet. More advice is available from What if I'm on the pill and I'm sick or have diarrhoea? - NHS (www.nhs.uk).
Identification & management of adverse reactions (continued over page)	Advise the patient that if any of the following side effects occur, discontinue treatment immediately and contact the emergency department or dial 999: ➢ allergic reactions such as sudden difficulty with breathing, speaking and swallowing. ➢ extreme dizziness or fainting. ➢ severe itchy skin rash especially if blistering, soreness of the eyes, mouth or genital organs. Advise the patient to contact a doctor if any of the following occur: ➢ diarrhoea that is serious, prolonged or has blood and mucus in it. ➢ severe stomach pain. ➢ fever.

Identification & management of adverse reactions (continued)	➢ yellowing of the skin and eyes. ➢ pale stools, dark urine. ➢ itchy skin. ➢ abdominal pain. ➢ palpitations or irregular heartbeat. The following side effects have been reported by patients taking clarithromycin: **Very Common to common** (affecting between 1 in 10 and 1 in 100 patients): ➢ diarrhoea, appetite decreased, dyspepsia, abdominal pain, gastrointestinal discomfort or disorders, nausea, vomiting, taste altered, abnormal liver function test, pancreatitis. ➢ dizziness, headache, hearing impairment, insomnia, paraesthesia, vision disorders. ➢ vasodilation, skin reactions, sweating. **Uncommon** (affecting between 1 in 100 and 1 in 1000 patients): ➢ eosinophilia, leucopenia, neutropenia, thrombocythemia, hypersensitivity. ➢ anxiety, nervousness, drowsiness, vertigo, tinnitus, tremor. ➢ arrhythmias, palpitations, QT interval prolongation, chest pain. ➢ *Candida* infection, vaginal infection, infection. ➢ gastritis, stomatitis, glossitis, abdominal distension, constipation, dry mouth, burping, flatulence. ➢ hepatic disorders. ➢ muscle spasm, weakness, chills, fatigue, pyrexia. ➢ urticaria, pruritis, maculopapular rash, angioedema, severe cutaneous adverse reactions (SCARs). N.B. detailed lists of adverse reactions are available in the SmPC, and the BNF. Prior to issuing medication, please refer to these resources to check that there has been no change to the potential adverse reactions listed above.
Patient or carer advice/follow up (continued over page)	Supply the marketing authorisation holder's patient information leaflet (PIL). Supply an appropriate information leaflet from the TARGET: Respiratory tract infection resource suite: Patient facing materials (rcgp.org.uk) as a discussion tool and provide a copy if possible. Supply the information for parents and carers leaflet if they cannot swallow tablets and the liquid is unavailable or unsuitable.

Patient or carer advice/follow up (continued)	Inform the individual or their carer: ➢ the tablets should be swallowed whole with at least half a glass of water. ➢ the tablets or the oral suspension can be taken with or after food. ➢ the suspension should be shaken well before each use. ➢ if the individual can't swallow tablets and the liquid is unavailable or unsuitable, the tablets can be dispersed in liquid or crushed and mixed with liquid or soft food; see Welsh Medicines Advice Service guidance to support provision of antibiotic solid dosage forms when liquid preparations are not available. ➢ taking simple analgesics like paracetamol or ibuprofen at regular intervals will help temperature and discomfort. ➢ adults and older children may find sucking ice cubes, flavoured frozen desserts (e.g. ice lollies) or hard sweets provides symptomatic relief. ➢ they may wish to try medicated lozenges (containing a local anaesthetic, a nonsteroidal anti-inflammatory drug [NSAID] or an antiseptic) which may provide temporary relief from throat pain, but their benefit is likely to be small; it is unclear if throat sprays containing an antiseptic plus local anaesthetic or benzydamine gargles help symptoms. ➢ to avoid smoking and smoky environments. ➢ to drink plenty of cool or warm fluid and avoid very hot drinks that could irritate the throat; eat cool and soft foods. ➢ adults can try a warm saline mouthwash or gargle (half a teaspoon of salt in a glassful of warm water at frequent intervals), but do not swallow the mouthwash – this is not suitable for young children. ➢ the condition is self-limiting and is likely to get better within 7 days, with or without antibiotic treatment and to seek further medical advice from a GP if symptoms worsen or do not improve within 3-4 days of antibiotic treatment, for example: o pain does not improve. o it becomes difficult to swallow saliva or liquids. o if any difficulty in breathing develops. o one sided neck or throat swelling develops. ➢ if they take oral contraceptives – clarithromycin does not reduce their efficacy but if it makes the individual sick or have severe diarrhoea for more than 24 hours, they may not be protected from pregnancy. Advise the individual to follow the instructions in their pill packet. More advice is available from What if I'm on the pill and I'm sick or have diarrhoea? - NHS (www.nhs.uk). ➢ if they are breastfeeding, they can continue; macrolides can cause some babies to have mild stomach upsets. If their baby is not feeding as well as usual or they are unsettled after feeding, if they have diarrhoea and or vomiting, if they develop a rash or are unusually sleepy, if they are

(continued over page)	sweaty, if they have oral thrush, or any concerns, they should contact their health visitor, midwife or general practitioner.
Patient or carer advice/follow up (continued)	➢ if they have diabetes, their blood sugars may be higher or lower than usual whilst they are unwell. They should follow their diabetes sick day rules; see Diabetes and being ill | Managing when you're sick | Diabetes UK. ➢ if they get any side effects, to talk to their doctor, or pharmacist or nurse and report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme. This includes any possible side effects not listed in the PIL. ➢ in the event of a severe adverse reaction to discontinue treatment immediately and to seek medical advice if their condition deteriorates and/or they become systemically unwell. ➢ clarithromycin can cause dizziness, vertigo and confusion as an adverse effect which may influence the individual's ability to drive or operate machinery. ➢ to seek medical attention if the individual develops: o signs of liver problems, e.g. yellowing of the skin, dark urine, itchiness, stomach pain. o diarrhoea that is serious, prolonged or has blood and mucus in it. o palpitations or irregular heartbeat. ➢ to return any unused medicines to a pharmacy for disposal: do not dispose of medicines in the bin, down the sink or toilet. ➢ to read the PIL before taking the medication. ➢ to visit the NHS website on clarithromycin for more information. ➢ to visit the NHS 111 Wales site for further information on sore throat. ➢ reinforce messages around preventing infections, e.g. wash hands frequently, avoid sharing glasses or utensils with people who are ill, cough or sneeze into a tissue and dispose of it in the bin.
Records	The consultation details including any medication supplied under the PGD must be recorded in Choose Pharmacy at the time of the consultation. Where the Choose Pharmacy platform is not available, temporary records must be made using the paper-based consultation record. Paper based records must be transferred onto the Choose Pharmacy Sore Throat module as soon as practically possible following the consultation. If the patient is excluded, and any specific advice that has been given, a record of the reason for exclusion must be documented within the consultation notes. If clarithromycin is being supplied because the first line recommended antibiotic is unavailable, document consent to receive the alternative treatment option in the consultation notes.

PGD for the supply of erythromycin 250 mg tablets, erythromycin ethyl succinate 250 mg / 5 mL and 500 mg / 5 mL oral suspension and erythromycin ethyl succinate 250 mg / 5 mL and 500 mg / 5 mL oral suspension sugar free

1. Clinical condition

Clinical condition or situation to which this PGD applies	For the treatment of painful, inflamed throat, which makes swallowing difficult, where the use of phenoxymethylpenicillin and amoxicillin is contraindicated **AND** they are pregnant. **OR** For the treatment of painful, inflamed throat, which makes swallowing difficult **AND** phenoxymethylpenicillin, amoxicillin and clarithromycin is unavailable[§]. In accordance with the community pharmacy sore throat component of the Common Ailments Service.
Inclusion criteria (continued over page)	Erythromycin can be given to: Adults and children aged 13 years and over presenting with symptoms of acute uncomplicated sore throat and they have an established pregnancy or risk of pregnancy and the use of phenoxymethylpenicillin, and amoxicillin is contraindicated **AND** ➢ a FeverPAIN score of 2 or above **OR** ➢ a Centor Score of 3 or above **AND** ➢ a positive result from a throat swab Rapid Antigen Diagnostic Test (RADT) for Streptococcus A infection **AND** ➢ they have no contraindications to erythromycin and macrolide type antibiotics. ➢ informed consent has been given. in accordance with the All Wales Common Ailments Service Formulary 2025. **OR** **If phenoxymethylpenicillin, amoxicillin and clarithromycin are unavailable[§], erythromycin can be given to**: Adults and children aged 5 years and over presenting with symptoms of acute uncomplicated sore throat **AND** ➢ a FeverPAIN score of 2 or above **OR** ➢ a Centor Score of 3 or above **AND** ➢ a positive result from a throat swab Rapid Antigen Diagnostic Test (RADT) for Streptococcus A infection **AND** ➢ they have no contraindications to erythromycin and macrolide type antibiotics.

Inclusion criteria (continued)	➢ informed consent has been given. in accordance with the All Wales Common Ailments Service Formulary 2025. § **erythromycin should only be issued when phenoxymethylpenicillin is contraindicated AND they are pregnant or there is a risk of pregnancy OR when the preferred antibiotic (phenoxymethylpenicillin) cannot be obtained within a reasonable time frame. Advise the individual that erythromycin is not the recommended first line treatment and document in the record.**
Exclusion criteria[5] (continued over page)	Erythromycin should not be given to individuals **in the presence of the following red flag symptoms – advise the individual to phone 999 or attend A&E immediately:** ➢ life-threatening symptoms such as stridor, breathing difficulty, drooling, inability to swallow or open the mouth. ➢ severe symptoms getting worse quickly. ➢ signs of marked systemic illness or sepsis including signs of changes in cognitive function, behaviour or mental state e.g. confusion, drowsiness, slurred speech. ➢ systemically unwell and at risk of immunosuppression. ➢ coughing up blood (**more** than just a few spots or streaks of blood present in the phlegm). ➢ skin changes e.g. very cold or a strange colour or a rash. ➢ crushing central chest pain. ➢ severe headache and vomiting. ➢ suspected peri-tonsillar abscess or cellulitis, parapharyngeal abscess, retropharyngeal abscess or Lemierre's syndrome (risk of airway compromise or rupture of the abscess). ➢ if they are dehydrated, unable to take fluids or passing little or no urine, and or have dry mucous membranes). ➢ Kawasaki disease. Presents with a high temperature lasting 5 days or more and with one or more of the following symptoms: rash, swollen neck glands, dry, red, cracked lips, swollen bumpy red tongue (strawberry tongue), red inside the mouth and back of the throat, swollen and red hands and feet, red eyes. **Advise the individual to see a GP, call NHS 111 or see a community PIP as appropriate for same day assessment if any of the following are present:** ➢ known immunosuppression (accompanied by other clinical symptoms of blood disorders), including for example:

[5] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required.

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Exclusion criteria (continued)	○ a patient who is on chemotherapy, radiotherapy, has known or suspected leukaemia, asplenia, aplastic anaemia or HIV/AIDS, or is taking an immunosuppressive drug following a transplant. ○ a patient who is taking a disease-modifying anti-rheumatic drug (DMARD) e.g. sulfasalazine, azathioprine, methotrexate. ○ a patient who is taking a medicine that can cause blood disorders (e.g. neutropenia, agranulocytosis, thrombocytopenia) leading to infection and acute sore throat including cytotoxic drugs, carbimazole, clozapine and sulfasalazine. ➢ abnormal breathing pattern (but not struggling for breath). ➢ a rash, flushed cheeks and swollen tongue (scarlet fever). ➢ a persistent high temperature over 38°C uncontrolled by paracetamol or ibuprofen. ➢ oral mucositis. ➢ coughing up small amounts of blood (**no more** than a few spots or streaks of blood). ➢ a suspected bacterial infection despite negative antigen test. ➢ moderate, severe or end stage renal failure (eGFR less than 60 mL / min) or patients with renal disease where renal function cannot be confirmed. ➢ high risk of serious complications because: ○ of significant heart, lung, kidney, liver, or neuromuscular disease (including patients with a history of valvular heart disease, rheumatic fever, post-streptococcal glomerular nephritis and cystic fibrosis). ○ they are immunocompromised. ➢ diabetes, if, in the opinion of the pharmacist: ○ there are concerns regarding their individual diabetic control. ○ the individual is at increased risk of detrimental symptoms associated with poorly controlled diabetes; symptoms can include thirst, blurred vision, fatigue, increased frequency of urination. ○ the individual is unsure how to manage their diabetes. ➢ if they are children under 5 years. ➢ if they are frail and or elderly over 75 years old. ➢ if they are systemically very unwell and there are no features indicating urgent referral to A&E. ➢ persistent alteration in voice, hoarseness, lasting longer than 3 weeks or is present with no other symptoms. ➢ if they present with additional symptoms atypical of acute sore throat that could indicate another infectious cause of sore throat including: ○ ulceration in the mouth, sloughing or bleeding of the mucous membranes of the pharynx. ○ presence of a mass or unilateral swelling. ○ skin, genital or eye lesions or a rash.
(continued over page)	

Exclusion criteria (continued)	○ abdominal symptoms. ○ hand or foot symptoms. ○ grey/green oropharyngeal membranes. ○ severe pain. **Advise the individual to see a GP for routine appointment an individual:** ➢ with a history of repeated episodes (more than 2 previous episodes) of Streptococcus A infection in the previous 6 months or a lower threshold if other concerns. ➢ with persistent symptoms that haven't improved after 7 days. A sore throat after 7 days with lethargy may indicate glandular fever, especially if they are aged 15-24 years old. **Erythromycin is not suitable for individuals:** ➢ with a known or suspected hypersensitivity to erythromycin or other macrolide antibiotics e.g. clarithromycin and azithromycin– see SmPC. ➢ with a known hypersensitivity to any of the excipients – see SmPC. ➢ with known or suspected hepatic impairment or people concomitantly receiving potentially hepatotoxic drugs see drug interactions. ➢ who has myasthenia gravis – macrolides may aggravate weakness symptoms. ➢ with a history of or current QT prolongation. ➢ with a history of or current ventricular cardiac arrhythmia including torsade de pointes. ➢ with known or suspected electrolyte disturbances (hypokalaemia or hypomagnesaemia). ➢ with coronary artery disease, severe cardiac insufficiency, conduction disturbances or clinically relevant bradycardia. ➢ with porphyria. ➢ who have suffered severe diarrhoea following previous treatment with erythromycin. ➢ with symptoms of diarrhoea and they have received an antibiotic within the previous 3 months. ➢ who are taking concurrent antibiotic treatment. ➢ with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency and the oral suspension is required. ➢ who are taking a contraindicated medicine (see drug interactions section for further detail) including: ○ recent typhoid vaccine (oral). (continued over page)

Exclusion criteria (continued)	○ drugs that prolong the QT interval (see BNF for all drugs that can prolong the QT interval) e.g. • astemizole. • cisapride. • domperidone. • ivabradine. • pimozide. • terfenadine. ○ who are taking the following: • amisulpride, colchicine. • ergotamine or dihydroergotamine. • hydroxychloroquine or chloroquine. • lomitapide, mizolastine, simvastatin (unless withheld – see cautions section for more information), tolterodine. ○ if there is current or recent treatment (within the last two weeks) with drugs that are inducers of CYP3A4, e.g. • rifampicin. • rifabutin. • phenytoin. • carbamazepine. • phenobarbital. • St John's Wort. ○ who take medicines that are known or suspected to affect circulating concentrations of erythromycin; for drugs that are metabolised by the cytochrome P450 system which could be affected by erythromycin, see cautions and drug interactions sections. ➢ if informed consent has not been given by the individual, parent, guardian or carer; where individuals or their parent, guardian or carer do not agree to share relevant clinical information or there is no valid consent. ➢ if the pharmacist is unable to undertake an appropriate assessment, to determine the need for the medicine and that it would be appropriate for the patient to use it. ➢ to individuals who are unable to administer or use the product effectively themselves or who do not have a parent, guardian or carer to administer or apply the medication for them.

Cautions (including relevant actions to be taken)	Please refer to the SmPC for erythromycin for full details of special warnings and precautions for use. **Hypersensitivity reactions** In the event of severe acute hypersensitivity reactions, such as anaphylaxis, severe cutaneous adverse reactions (SCAR) (e.g. acute generalised exanthematous pustulosis (AGEP), Stevens-Johnson syndrome, and toxic epidermal necrolysis, erythromycin therapy should be discontinued immediately, and appropriate treatment should be urgently initiated. **Colitis** Caution should be used when treating patients with a history of antibiotic-associated colitis and other risk factors for *Clostridioides difficile* infection (CDI) (see Risk factors | Background information | Diarrhoea - antibiotic associated | CKS | NICE). Sustained severe diarrhoea should prompt suspicion of pseudomembranous colitis during or after treatment with an antibiotic. As this condition may be life threatening, erythromycin should be withdrawn immediately. Pseudomembranous colitis has been reported with nearly all antibacterial agents and may range in severity from mild to life-threatening. *Clostridioides difficile*-associated diarrhoea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhoea to fatal colitis. Drugs inhibiting peristalsis should be avoided. **Cardiovascular events** Prolonged cardiac repolarisation and QT interval, imparting a risk of developing cardiac arrhythmia and torsade de pointes, have been seen in treatment with macrolides. Macrolides should be used with caution in the following patients: ➢ patients concomitantly taking other medicinal products that can cause hypokalaemia (e.g. corticosteroids, diuretics and short acting beta-2 agonists). **Diabetes** Individuals with diabetes can be supplied with treatment if, in the opinion of the pharmacist, there are no concerns or symptoms suggestive of poor control, for example, thirst, blurred vision, fatigue etc. Provided there are no features, signs or symptoms, treatment can be supplied. Individuals should be reminded of the diabetes sick day rules (see patient or carer advice). **Oral hypoglycaemic agents/insulin** – The concomitant use of macrolides and oral hypoglycaemic agents (such as sulphonylureas) and/or insulin can result in significant hypoglycaemia. **Careful monitoring of glucose is recommended.**
(continued over page)	

Cautions (including relevant actions to be taken) (continued)	**Effects on laboratory tests** Erythromycin interferes with the fluorometric determination of urinary catecholamines. **HMG-CoA reductase inhibitors (statins)** Caution should be exercised when issuing macrolides with statins. Rhabdomyolysis has been reported in patients taking macrolides and statins. Patients should be monitored for signs and symptoms of myopathy. **Patients that are currently taking an HMG-CoA reductase inhibitor (statin) must be given appropriate advice regarding the need to stop taking the statin until the course of treatment with erythromycin has been completed in accordance with manufacturer's advice (see drug interactions section).** **Oral anticoagulants** There is a risk of serious haemorrhage and significant elevations in International Normalized Ratio (INR) and prothrombin time when erythromycin is co-administered with warfarin. INR and prothrombin times should be frequently monitored while patients are receiving erythromycin and oral anticoagulants concurrently. **Advise the individual to contact their clinic responsible for INR monitoring within 3 days of starting erythromycin treatment**. Caution should be exercised when erythromycin is co-administered with direct acting oral anticoagulants such as dabigatran, rivaroxaban, apixaban and edoxaban particularly to patients at high risk of bleeding. **Calcium channel blockers (CCBs)** Due to an increased risk of hypotension, caution is advised with the concurrent use of macrolides and CCBs metabolised by CYP3A4 (such as verapamil, amlodipine, and diltiazem). **Sucrose** ➢ Erythromycin oral suspension may contain sucrose. This should be taken into consideration in patients with diabetes mellitus. ➢ May be harmful to the teeth. **Pregnancy** A patient information leaflet is available (PIL) to support an individual in their decision to use antibiotics during pregnancy bumps - best use of medicine in pregnancy (medicinesinpregnancy.org). **Breastfeeding** Macrolides pass into breast milk in very small amounts and is unlikely to be harmful. It can cause some babies to have mild stomach upsets. They

(continued over page)

Cautions (including relevant actions to be taken) (continued)	should contact their health visitor, midwife or general practitioner if their baby: ➢ is not feeding as well as usual. ➢ is unsettled after feeding. ➢ develops diarrhoea and or vomiting. ➢ develops a rash. ➢ is unusually sleepy. ➢ is sweaty. ➢ has oral thrush. **Crushing and dispersing:** Only to be considered if liquid not available or suitable and would be off-label. There is a risk of sensitisation. Advise the individual to always wear gloves and mask, and use a closed system where possible, e.g. disperse tablet in the barrel of a syringe. See off-label section and Welsh Medicines Advice Service guidance to support provision of antibiotic solid dosage forms when liquid preparations are not available for further advice.
Action to be taken if the individual is excluded or declines treatment	➢ If the individual meets the exclusion criteria, refer to a medical practitioner or PIP as appropriate. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination. ➢ Explain the reasons for exclusion to the individual and document in the consultation record. ➢ If the individual declines, advise of the consequences of not receiving treatment and document the advice given and details of any referral made and their (patient, parent, carer or guardian) intended actions. ➢ If appropriate, individuals may be offered a suitable alternative antibiotic or provided with advice and symptomatic treatment from the All Wales Common Ailments Service Formulary. Alternatively, refer the individual to a GP or PIP if appropriate.
Further advice	If there is any doubt about the administration of the medication or individual's fitness or suitability to receive the medication, a doctor or appropriate PIP should be consulted. ➢ Refer to SmPC, BNF and the All Wales Common Ailments Service.

2. Description of Treatment

Name, strength & formulation of drug	Erythromycin 250 mg tablets. Erythromycin ethyl succinate 250 mg / 5 mL and 500 mg / 5 mL oral suspension. Erythromycin ethyl succinate 250 mg / 5 mL and 500 mg / 5 mL oral suspension sugar free.
Legal category	POM – Prescription Only Medicine.
Black triangle▼	No.
Off-label use	Yes. If the individual is unable to swallow tablets AND erythromycin oral suspension is unavailable or unsuitable, the tablets may be dispersed in water OR crushed and mixed with liquid or soft food. Please follow the guidance to support provision of antibiotic solid dosage forms when liquid preparations are not available. It is important to note the following: ➢ Administration in this way is off-label (used outside of the product licence). ➢ When crushing tablets, caution should be exercised on handling the antibiotic powder produced to avoid contact sensitisation or inhalation; safety measures that should be used include: o use a closed system e.g. dispersing a tablet in the barrel of a syringe. o wear gloves to reduce contact with the skin, and a mask to prevent dust inhalation. o sensitisation is a risk with all the antibiotics but may be of particular concern with penicillins. ➢ Parents or carers with erythromycin allergy should avoid involvement in preparing and administering the tablets this way.
Route / method of administration	Oral. **Tablets**: For adults and children aged 8 years and over. Each tablet should be swallowed whole with water. If supplied because the liquid formulation is not available or unsuitable, see Welsh Medicines Advice Service guidance to support provision of antibiotic solid dosage forms when liquid preparations are not available for advice on dispersing or crushing and mixing with liquid or soft food. **Oral suspension**: For children under 8 years. For adults and children aged 8 years and over and the tablets are not suitable. Follow the instructions for reconstitution.

Dose and frequency of administration	**Adults and children aged 8 years and over**: 500 mg to be taken FOUR times a day for FIVE days. **Children aged 5 to 7 years**: 250 mg to be taken FOUR times a day for FIVE days
Duration of treatment	FIVE days. This PGD only allows for the duration stated in the dosage schedule above.
Quantity to be supplied	The best value product available at the time to meet clinical need should be appropriately labelled and supplied to provide FIVE days treatment: **Adults and children aged 8 years and over**: **40 x 250 mg** tablets at a dose of TWO tablets FOUR times a day. **OR** **2 x 100mL** erythromycin ethyl succinate **250 mg / 5 mL** oral suspension or sugar-free oral suspension at a dose of: 10 mL FOUR times a day. **If 250 mg / 5 mL unavailable**: **1 x 100mL** erythromycin ethyl succinate **500 mg / 5 mL** oral suspension or sugar-free oral suspension at a dose of: 5 mL FOUR times a day. **Children aged 5-7 years**: **1 x 100 mL** erythromycin ethyl succinate **250 mg / 5 mL** oral suspension or sugar free oral suspension at a dose of: 5 mL FOUR times a day. **If 250 mg / 5 mL unavailable**: **1 x 100 mL** erythromycin ethyl succinate **500 mg / 5 mL** oral suspension or sugar free oral suspension at a dose of: 2.5 mL FOUR times a day.
Storage	Medicines must be stored securely and in accordance with product SmPC.
Disposal	Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.
Drug interactions (continued over page)	The following list is not exhaustive. A detailed list of drug interactions can be found in the SmPC and the BNF.

Drug interactions (continued)	**Contraindicated** ➢ Typhoid vaccine (oral) – antibacterial agents may inactivate oral typhoid vaccine if ingested concomitantly. The Green Book advises that the vaccine should not be commenced within three days of completing any antibacterial agent and similarly antibacterial therapy should not commence within 3 days after the last dose of vaccine. ➢ Drugs that prolong the QT interval (see BNF or Stockley's Drug Interactions for all drugs that can prolong QT interval) including: o amisulpride, astemizole. o cisapride. o domperidone. o fluconazole, ketoconazole, itraconazole. o haloperidol. o hydroxychloroquine, chloroquine. o ivabradine. o pimozide. o quinidine, disopyramide. o ranolazine. o sotalol. o terfenadine. ➢ Drugs that are inducers of CYP3A4 (e.g. rifampicin, rifabutin, phenytoin, carbamazepine, phenobarbital, St John's Wort) currently taking or in the last 2 weeks. ➢ Drugs that are known or suspected to affect or be affected by circulating concentrations of erythromycin: o bromocriptine. o colchicine. o digoxin. o ergotamine and dihydroergotamine. o cilostazol, ciclosporin, cimetidine, hexobarbitone, methylprednisolone, mizolastine, sirolimus, tacrolimus, theophylline, tolterodine, valproate, vinblastine. o lomitapide. o opioids – alfentanil, buprenorphine, fentanyl, oxycodone. o sildenafil, tadalafil and vardenafil. o triazolobenzodiazepines such as triazolam, alprazolam and midazolam. o zopiclone.

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Drug interactions (continued)	**Cautions** Erythromycin should be used with caution in patients also prescribed: ➢ HMG-CoA reductase inhibitors (statins) – patients that are currently taking an HMG-CoA reductase inhibitor (statin) must be advised to stop taking the statin until the course of treatment with erythromycin has been completed (i.e. for 5 days). (see cautions). ➢ oral hypoglycaemic agents/insulin – careful monitoring of glucose is recommended. (see cautions). ➢ oral anticoagulants – macrolides may interfere with anticoagulant control (see cautions). ➢ calcium channel blockers (CCBs) – due to an increased risk of hypotension, caution is advised with the concurrent use of macrolides and CCBs metabolised by CYP3A4, such as verapamil, amlodipine, and diltiazem (see cautions). ➢ medicinal products that can cause hypokalaemia (e.g. corticosteroids, diuretics, short-acting beta-2 agonists). ➢ oral contraceptives – erythromycin does not reduce their efficacy but if it makes the individual sick or have severe diarrhoea for more than 24 hours, they may not be protected from pregnancy. Advise the individual to follow the instructions in their pill packet. More advice is available from What if I'm on the pill and I'm sick or have diarrhoea? - NHS (www.nhs.uk). ➢ cimetidine may inhibit the metabolism of erythromycin which may lead to an increased plasma concentration.
Identification & management of adverse reactions	Advise the patient that if any of the following side effects occur, discontinue treatment immediately and contact the emergency department or dial 999: ➢ a red scaly rash with bumps under the skin and blisters (exanthematous pustulosis). ➢ difficulty breathing. ➢ fainting. ➢ swelling of the face, lips or throat. ➢ skin rashes. ➢ severe skin reactions including large fluid filled blisters, sores and ulcers. ➢ ulcers in the mouth or throat. The following side effects have been reported by patients taking erythromycin: **Very common to common** (affecting between 1 in 10 and 1 in 100 patients): ➢ upper abdominal pain/discomfort. ➢ nausea, vomiting, loss of appetite. ➢ diarrhoea.

(continued over page)	➢ pancreatitis.
Identification & management of adverse reactions (continued)	Other side effects reported include: ➢ cholestatic hepatitis, jaundice, hepatic dysfunction, hepatomegaly, hepatic failure, hepatocellular hepatitis, increased liver enzymes. ➢ chest pain, fever, malaise (feeling generally unwell). ➢ allergic reactions, ranging from urticaria and mild skin eruptions to anaphylaxis. ➢ low blood pressure. ➢ vertigo (problems with balance that can cause dizziness or sickness). ➢ visual impairment or blurred vision. ➢ confusion, hallucinations. ➢ antibiotic-associated colitis. ➢ QT interval prolongation, torsade de pointes, palpitations, ventricular tachyarrhythmias. N.B. detailed lists of adverse reactions are available in the SmPC, and the BNF. Prior to issuing medication, please refer to these resources to check that there has been no change to the potential adverse reactions listed above.
Patient or carer advice/follow up (continued over page)	Supply the marketing authorisation holder's patient information leaflet (PIL). Supply an appropriate information leaflet from the TARGET: Respiratory tract infection resource suite: Patient facing materials (rcgp.org.uk) as a discussion tool and provide a copy if possible. Supply the information for parents and carers leaflet if they cannot swallow tablets and the liquid is unavailable or unsuitable. A patient information leaflet is available (PIL) to support an individual in their decision to use antibiotics during pregnancy bumps - best use of medicine in pregnancy (medicinesinpregnancy.org). Inform the individual or their carer: ➢ the tablets should be swallowed whole with a glass of water. ➢ the tablets are better taken with food, so they do not upset your stomach. ➢ the suspension should be shaken well before each use. ➢ the suspension is better taken with food, so it does not upset your stomach. ➢ not to eat grapefruit or drink grapefruit juice while taking erythromycin. It can increase the amount of erythromycin in the body and increase the chance of side effects. ➢ if they have been given erythromycin gastro-resistant tablets, not to take indigestion remedies 2 hours before or after taking erythromycin.

Patient or carer advice/follow up (continued)	➢ the tablets should not be crushed or chewed. However, if the individual can't swallow tablets and the liquid is unavailable or unsuitable, the tablets can be dispersed in liquid or crushed and mixed with liquid or soft food; see Welsh Medicines Advice Service guidance to support provision of antibiotic solid dosage forms when liquid preparations are not available. ➢ taking simple analgesics like paracetamol or ibuprofen at regular intervals will help temperature and discomfort. ➢ adults and older children may find sucking ice cubes, flavoured frozen desserts (e.g. ice lollies) or hard sweets provides symptomatic relief. ➢ they may wish to try medicated lozenges (containing a local anaesthetic, a nonsteroidal anti-inflammatory drug [NSAID] or an antiseptic) which may provide temporary relief from throat pain, but their benefit is likely to be small; it is unclear if throat sprays containing an antiseptic plus local anaesthetic or benzydamine gargles help symptoms. ➢ to avoid smoking and smoky environments. ➢ to drink plenty of cool or warm fluid and avoid very hot drinks that could irritate the throat; eat cool and soft foods. ➢ adults can try a warm saline mouthwash or gargle (half a teaspoon of salt in a glassful of warm water at frequent intervals), but do not swallow the mouthwash – this is not suitable for young children. ➢ the condition is self-limiting and is likely to get better within 7 days, with or without antibiotic treatment and to seek further medical advice from a GP if symptoms worsen or do not improve within 3-4 days of antibiotic treatment, for example: o pain does not improve. o it becomes difficult to swallow saliva or liquids. o if any difficulty in breathing develops o one sided neck or throat swelling develops. ➢ oral contraceptives – erythromycin does not reduce their efficacy but if it makes the individual sick or have severe diarrhoea for more than 24 hours, they may not be protected from pregnancy. Advise the individual to follow the instructions in their pill packet. More advice is available from What if I'm on the pill and I'm sick or have diarrhoea? - NHS (www.nhs.uk). ➢ if they are breastfeeding, they can continue; macrolides can cause some babies to have mild stomach upsets. If their baby is not feeding as well as usual or they are unsettled after feeding, if they have diarrhoea and or vomiting, if they develop a rash or are unusually sleepy, if they are sweaty, if they have oral thrush, or any concerns, they should contact their health visitor, midwife or general practitioner. ➢ if they have diabetes, their blood sugars may be higher or lower than usual whilst they are unwell. They should follow their diabetes sick day rules; see Diabetes and being ill | Managing when you're sick | Diabetes UK.

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Patient or carer advice/follow up (continued)	➢ if they get any side effects, to talk to their doctor, or pharmacist or nurse and report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme. This includes any possible side effects not listed in the PIL. ➢ in the event of a severe adverse reaction to discontinue treatment immediately and to seek medical advice if their condition deteriorates and/or they become systemically unwell. ➢ to seek medical attention if the individual develops: o signs of liver problems, e.g. loss of appetite, yellowing of the skin, dark urine, itchiness, stomach pain. o diarrhoea that is serious, prolonged or has blood and mucus in it. o palpitations or irregular heartbeat. ➢ to return any unused medicines to a pharmacy for disposal: do not dispose of medicines in the bin, down the sink or toilet. ➢ to read the PIL before taking the medication. ➢ to visit the NHS website on erythromycin for more information. ➢ to visit the NHS 111 Wales site for further information on sore throat. ➢ reinforce messages around preventing infections e.g. wash hands frequently, avoid sharing glasses or utensils with people who are ill, cough or sneeze into a tissue and dispose of it in the bin.
Records	The consultation details including any medication supplied under the PGD must be recorded in Choose Pharmacy at the time of the consultation. Where the Choose Pharmacy platform is not available, temporary records must be made using the paper-based consultation record. Paper based records must be transferred onto the Choose Pharmacy Sore Throat module as soon as practically possible following the consultation. If the patient is excluded, and any specific advice that has been given, a record of the reason for exclusion must be documented within the consultation notes. If erythromycin is being supplied because the first line recommended antibiotic is unavailable, document consent to receive the alternative treatment option in the consultation notes. For pregnant women record the antibiotic supplied in the hand-held maternity record (if available).

Appendices

Appendix A: *Key references*

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- Yellow Card Reporting. Available from: https://yellowcard.mhra.gov.uk/ [accessed 18 December 2024].

Appendix B: *Healthcare Professionals Agreement to Practice*

Authorisation for the use of the Patient Group Direction for the supply of: phenoxymethylpenicillin, amoxicillin, clarithromycin and erythromycin by community pharmacists under the Clinical Community Pharmacy Service, Common Ailment Service (sore throat) commissioned by

Powys Teaching Health Board]

Patient Group Directions do not remove inherent professional obligations or accountability.

Once completed and approved, health professionals wishing to use the PGD must sign up to the PGD for the local health board in which they will be providing services. Only pharmacists who are accredited in line with the National Service Specification can operate under the PGD.

This Patient Group Direction is to be read, agreed and signed by all registered healthcare professionals authorised to operate the PGD. By signing this document, the professional operating the PGD **confirms that they have read and understood the content of this PGD and are willing and competent to work under it within their professional code of conduct**. One copy should be given to each named pharmacist and a signed copy must be kept within the pharmacy by the nominated member of staff with responsibility for PGDs. This will usually be the Superintendent Pharmacist or Responsible Pharmacist.

Name and address of pharmacy:

For registered professional

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work under it within my professional code of conduct.

Name of registered pharmacist	Signature	GPhC number	Date

This authorisation sheet should be kept serving as a record of those practitioners authorised to work under this PGD in accordance with the retention statement in the organisational authorisation section.