Community Pharmacy Sore Throat Test & Treat Service

Patient Group Directions for the Supply of Antibiotics

Valid From: 1st November 2022
Review: 1st October 2025
Expires: 31st October 2025

Managerial Content of Patient Group Direction			
Name of Clinical Programme Group	Pharmacy and Medicines Management		
Name of local health board			
Stage of Development.	**Version No**	**Change Details**	**Date**
	1		1st Nov. 2022

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. PGD development

This PGD has been developed and peer reviewed by an expert panel and approved by the Community Pharmacy Clinical Reference Group in accordance with the PGD Policy.

This section MUST REMAIN when a PGD is adopted by an organisation

Expert panel

Name	Designation
Expert Reviewer – Dr Charlotte Jones	General Practitioner Uplands and Mumbles Surgery, Sketty Road, Uplands, Swansea
Main author – Dianne Burnett	National Lead Pharmacist Medicines Advice. Welsh Medicines Information Centre Cardiff and Vale UHB
Professional group reviewer – Adam Mackridge	Chair of Community Pharmacy Clinical Reference Group and Strategic Lead Pharmacist for Community Pharmacy Betsi Cadwallader UHB

Date CPCRG approval of PGD: 27th September 2025

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

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3. Organisational authorisations

These PGDs are not legally valid until it has 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 the PGD.

authorises these PGDs for use by community pharmacies within its area that have been commissioned to provide the sore throat test and treat component of the Clinical Community Pharmacy 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**

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 this PGDs.

4. Characteristics of Staff

Qualifications and professional registration	**Practitioners must only work under this PGD where they are competent to do so.** 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 Sore Throat Test and Treat 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 Test and Treat service. ➢ have met the training requirements for the service as set out by HEIW (Health Education and Improvement Wales)
Initial training	Pharmacists must: ➢ have completed the HEIW Pharmacy Generic Skills and Competency assessment in line with the National Clinical Services Accreditation Process ➢ have completed the HEIW Pharmacy Clinical Knowledge Assessment for Sore Throat Test and Treat ➢ be familiar with the British National Formulary (BNF) and SmPC entries for phenoxymethylpenicillin ➢ have awareness of the adverse drug reactions associated with 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, 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 training and competence must be maintained in the individual's personal file

PGD For the Supply of Phenoxymethylpenicillin 250mg Tablets

1. Clinical condition

Clinical condition or situation to which this PGD applies	First line treatment for the treatment of painful, inflamed throat which makes swallowing difficult, in accordance with the community pharmacy Sore Throat Test and Treat component of the clinical community pharmacy service.
Criteria for inclusion	Phenoxymethylpenicillin 250mg tablets can be given to: Adults and children aged 6 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 Rapid Antigen Point of Care Test (POCT) for Streptococcus A infection ➢ No contraindications to penicillins and penicillin type antibiotics ➢ Informed consent has been given ➢ They can swallow tablets
Criteria for exclusion[2]	Phenoxymethylpenicillin 250mg tablets should not be given: ➢ **Red Flag Symptoms:** o To anyone attending who has life-threatening symptoms such as stridor, breathing difficulty or dehydration that is associated with sore throat. Phone 999 immediately o To individuals with persistent symptoms (lasting > 2 weeks) and/or severe symptoms which may be indicative of more serious disease, such as cancer. Smoking and alcohol are risk factors that should be considered as part of clinical assessment. ➢ If informed consent is not given. Patients do not agree to share relevant clinical information or there is no valid consent ➢ To children aged 6 years and under ➢ To patients who can't swallow tablets ➢ To patients with a known hypersensitivity to penicillin and penicillin type antibiotics – see SmPC

[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

Criteria for exclusion continued[2]	➢ To patients with known hypersensitivity to any of the excipients – see SmPC ➢ To patients with known or suspected hepatic failure. ➢ To patients with moderate, severe or end stage renal failure (creatinine clearance <60mL/min) or patient has renal disease where renal function cannot be confirmed. ➢ To patients at high risk of serious complications because of: o significant heart, lung, kidney, liver, or neuromuscular disease (including patients with a history of valvular heart disease, rheumatic fever, post-streptococcal glomerular nephritis) o uncontrolled diabetes o patients who are immunocompromised. ➢ To patients known to be immunosuppressed (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 medicine that can cause blood disorders (e.g. neutropenia, agranulocytosis, thrombocytopenia) leading to infection and acute sore throat including cytotoxic drugs, carbimazole, clozapine etc. o A patient who is taking a disease-modifying anti-rheumatic drug (DMARD) e.g. sulfasalazine, methotrexate ➢ To patients with a history of repeated episodes (> 2 previous episodes) of Streptococcus A infection in previous 6 months. ➢ If patients present with: o Signs of airway obstruction (inability to swallow, drooling, stridor, hoarse voice, muffled voice, holding a tripod position). o Signs of marked systemic illness or sepsis. o Breathing difficulty. o Dehydration. o Severe neck pain and or stiffness.

Criteria for exclusion continued[2]	○ Severe pain. ○ Persistent sore throat especially if unilateral. ○ Persistent change in voice. ○ Severe swallowing problems (dysphagia/ odynophagia). ○ Trismus or difficulty opening the jaw. ○ Persistent mouth ulcer / lesions. ○ Masses / unilateral swelling. ○ Severe oral mucositis. ○ Rash (e.g. scarlet fever). ○ Suspected rare cause e.g. Kawasaki disease. ○ Symptoms of suppurative complications (e.g. otitis media, sinusitis, mastoiditis, peri-tonsillar abscess (quinsy), scarlet fever). ➢ To patients who are taking contra-indicated medicines (see drug interactions section for further detail) including: ○ methotrexate ○ bacteriostatic antibiotics e.g. tetracyclines, erythromycin, chloramphenicol and sulphonamides ○ recent typhoid vaccination. ➢ To patients also receiving long-term phenoxymethylpenicillin treatment. ➢ To patients who the pharmacist has assessed as not having capacity to understand the nature and purpose of treatment. ➢ Where a request has been made by a third party on behalf of a patient.
Cautions (including relevant actions to be taken)	Please refer to the SmPC for phenoxymethylpenicillin for full details of special warnings and precautions for use. Oral penicillins are not indicated in patients with severe illness or with a gastrointestinal disease that causes persistent nausea, vomiting, gastric dilation, cardiospasm, intestinal hypermotility or diarrhoea because absorption may be reduced. Occasionally, patients do not absorb therapeutic amounts of orally administered penicillin. Caution should be used when treating patients with a history of antibiotic-associated colitis.

Cautions (including relevant actions to be taken) continued	In renal impairment the safe dosage may be lower than usually recommended. During treatment with phenoxymethylpenicillin non-enzymatic glucose tests may be false-positive. **History of Allergy** ➢ Phenoxymethylpenicillin should be given with caution to patients with a history of allergy, especially to other drugs. ➢ Phenoxymethylpenicillin should also be given cautiously to cephalosporin-sensitive patients, as there is some evidence of partial cross-allergenicity between the cephalosporins and penicillins. Patients have had severe reactions (including anaphylaxis) to both 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). ➢ Particular caution should be exercised in prescribing phenoxymethylpenicillin to patients with an allergic diathesis or with bronchial asthma **Diabetes** If a patient with diabetes is unsure of how to manage their condition when they are unwell or are not eating and drinking they should be advised to contact their GP or diabetic nurse Oral hypoglycaemic agents/Insulin - Careful monitoring of glucose is recommended. **Potassium** Each tablet of phenoxymethylpenicillin 250 mg contains 28 mg of 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. **Oral anticoagulants** There is a risk of serious haemorrhage and significant elevations in International Normalized Ratio (INR) and prothrombin time when antibiotics are co-administered with warfarin. INR and prothrombin times should be frequently monitored while patients are receiving antibiotics and oral anticoagulants concurrently. **Patients must be referred to the clinic responsible for INR monitoring within 3 days of starting antibiotic treatment.** Caution should be exercised when antibiotics are co-administered with direct acting oral anticoagulants such as dabigatran, rivaroxaban and apixaban, particularly to patients at high risk of bleeding

Cautions (including relevant actions to be taken) continued	**Pregnancy** ➢ Not known to be harmful. ➢ Phenoxymethylpenicillin potassium 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 prescribing to pregnant patients. **Lactation** ➢ Trace amounts in milk, but appropriate to use ➢ Breast feeding is not contraindicated with phenoxymethylpenicillin potassium. Trace quantities of phenoxymethylpenicillin potassium can be detected in breast milk. While adverse effects are apparently rare, two potential problems exist for nursing infant: o modification of bowel flora o direct effects on the infant such as allergy/sensitisation Caution should therefore be exercised when prescribing for the nursing mother. **Pseudomembranous colitis** Pseudomembranous colitis has been reported with nearly all antibacterial agents, including macrolides, 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 including penicillin, and may range in severity from mild diarrhoea to fatal colitis
Action to be taken if the individual is excluded or declines treatment	➢ Phone 999 immediately for anyone attending who has life-threatening symptoms such as stridor, breathing difficulty or dehydration that is associated with sore throat. ➢ If patient meets the exclusion criteria, refer to a medical practitioner. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination. Patients presenting with any of the following symptoms must be referred to an Emergency Department; - o Severe suppurative complications (e.g. peri-tonsillar abscess or cellulitis, parapharyngeal abscess, retropharyngeal abscess, or Lemierre syndrome) as there is a risk of airway compromise or rupture of the abscess. o Signs of being markedly systemically unwell and is at risk of immunosuppression. o Suspected Kawasaki disease. o Diphtheria: characteristic tonsillar or pharyngeal membrane. o Signs of being profoundly unwell and the cause is unknown or a rare cause is suspected, for example: Stevens–Johnson syndrome or Yersinial pharyngitis ➢ 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 or guardian) intended actions

	➢ Patients may be provided with advice and symptomatic treatment for the All Wales Common Ailments Service Formulary
Further advice	If there is any doubt about the administration of the medication or patient's fitness or suitability to receive the medication, a doctor should be consulted. ➢ Refer to SmPC, BNF and the All Wales Common Ailments Service

2. Description of treatment

Name, strength & formulation of drug	Phenoxymethylpenicillin 250mg tablets
Legal category	POM – Prescription Only Medicine
Black triangle▼	NO
Off-label use	NO
Route / method of administration	Oral Each tablet should be swallowed whole with water, at least 30 minutes before food, or 2 hours after food
Dose and frequency of administration	Children aged 6-11 years – 250mg (one tablet) four times a day for TEN days Where a patient is unable to comply with four times a day dosing regime, the dose can be given as: 500mg (two tablets) twice a day for TEN days. Over 12 years and adults – 500mg (two tablets) four times a day for TEN days Where patient is unable to comply with four times a day dosing regime, the dose can be given as: 1000mg (four tablets) 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/administered	Appropriately labelled packs to provide treatment for TEN days: 40 x 250mg tablets to provide TEN days treatment at a dose of 250mg every six hours (four times a day) **OR** 80 x 250mg tablets to provide TEN days treatment at a dose of 500mg every six hours (four times a day)
Storage	Store below 25ºC Medicines must be stored securely and in accordance with product SmPC
Disposal	No special requirements
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.

	Contraindications ➢ Methotrexate: Use of phenoxymethylpenicillin while taking methotrexate can cause reduced excretion of methotrexate thereby increasing the risk of toxicity. ➢ Typhoid vaccine (oral): Penicillins may inactivate oral typhoid vaccine if ingested concomitantly. Avoid where recent vaccination or vaccination due. ➢ 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. **Cautions for use** ➢ Guar gum: Reduced absorption of phenoxymethylpenicillin. ➢ Coumarin anticoagulants: Penicillins may interfere with anticoagulant control (see cautions). ➢ Phenindione - Penicillins may interfere with anticoagulant control. (see cautions). ➢ Aminoglycosides: Neomycin is reported to reduce the absorption of phenoxymethylpenicillin. ➢ Probenecid: Reduced excretion of phenoxymethylpenicillin by competing with it for renal tubular secretion. ➢ Sulfinpyrazone: Excretion of penicillins reduced by sulfinpyrazone. ➢ Patients receiving potassium-containing drugs or potassium sparing-diuretics. ➢ During treatment with phenoxymethylpenicillin non-enzymatic urinary glucose tests may be false-positive.
Identification & management of adverse reactions	The following are side effects reported for all penicillins. This list is not exhaustive. A detailed list of adverse reactions is available in the SmPC, and the BNF ➢ Advise the patient that if any of the following side effects occur, discontinue treatment immediately and contact the emergency department or dial 999: o Allergic reactions such as sudden difficulty with breathing, speaking and swallowing o Extreme dizziness or fainting o Severe itchy skin rash especially if blistering, soreness of the eyes mouth or genital organs. Very common to common (affecting between 1 in 10 and 1 in 100 patients) with phenoxymethylpenicillin (and does not reflect all reported side effects): Nausea, vomiting, diarrhoea, abdominal pain, allergic reactions, hypersensitivity; skin reactions, urticarial, erythematous or morbilliform rash, pruritis.

	Rare or very rare adverse effects (affecting between 1 in 1000 and 1 in 10000 patients): Sore mouth, black hairy tongue, hepatitis, cholestatic jaundice, Agranulocytosis; angioedema; laryngeal oedema, anaphylaxis, serum sickness like reactions characterised by fever, chills, arthralgia and oedema, pseudomembranous colitis, interstitial nephritis, thrombocytopenia, neutropenia, leucopenia, eosinophilia and haemolytic anaemia, exfoliative dermatitis, cerebral irritation, convulsions Frequency not known: Circulatory collapse; coagulation disorder, faeces soft; fever; increased risk of infection; neurotoxicity; oral disorders; paraesthesia
Reporting procedure of adverse reactions	Any adverse reaction to the product should be documented in the individual's medical records. Alert a doctor in the event of a serious adverse reaction. Report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme.
Written or verbal information to be given to individual or their carer	➢ Supply the marketing authorisation holder's patient information leaflet (PIL).
Patient or carer advice/follow up	Inform the individual or their carer: ➢ That the tablets should be swallowed whole with water, at least 30 minutes before food ➢ if they get any side effects, to talk to their doctor, or pharmacist or nurse. This includes any possible side effects not listed in the PIL ➢ that in the event of a severe adverse reaction to discontinue treatment immediately and seek to medical advice ➢ to read the PIL before taking the medication ➢ to visit the NHS website on phenoxymethylpenicillin for more information ➢ to visit the NHS 111 Wales site for further information on sore throat ➢ to seek medical advice if their condition deteriorates and/or they become systemically unwell ➢

Special considerations / additional information	Inform the individual or their carer: ➢ That the condition is self-limiting and is likely to get better within 7 days, with or without antibiotic treatment. ➢ To seek further healthcare advice if symptoms do not improve within 7 days or worsen. ➢ That taking simple analgesics will help temperature and discomfort. ➢ To take painkillers at regular intervals to relieve pain and fever. ➢ That adults and older children may find sucking throat lozenges, ice cubes or flavoured frozen desserts (e.g. ice lollies) provides symptomatic relief. ➢ That they may wish to try medicated lozenges to help reduce 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. ➢ That 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. 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 must be recorded in Choose Pharmacy as prompted at the time of the consultation. Where the Choose Pharmacy platform is not available records, must be made to document the consultation, using the paper-based consultation record. Paper based records must be transferred onto the Choose Pharmacy Sore Throat Test and Treat module as soon as practically possible and by the end of the next working day. ➢ All records, electronically or otherwise must be kept in accordance with NHS record keeping and Community Pharmacy Information Governance requirements see https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/information-governance-alliance-iga ➢ All records should be clear, legible and contemporaneous. ➢ If the patient is excluded, a record of the reason for exclusion must be documented within Choose pharmacy, and any specific advice that has been given. ➢ The consultation summary must be forwarded to the patient's GP within 72 hours of making the supply. Where practically possible summaries should be returned to local practices within 24 hours, particularly where an antibiotic has been supplied. ➢ All supplies of antibiotic must be labelled in accordance with the labelling requirements for a dispensed medicine as stated within Schedule 5 of The Medicines (Marketing Authorisations etc) Regulations 1994. No 3144 as amended.

	A record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes in accordance with local policy. For pregnant women record the antibiotic supplied in the hand-held maternity record (if available).

PGD for the Supply of Phenoxymethylpenicillin 250mg/5ml Oral Solution and Phenoxymethylpenicillin 250mg/5ml Sugar Free Oral Solution

1. Clinical condition

Clinical condition or situation to which this PGD applies	First line treatment for the treatment of painful, inflamed throat, which makes swallowing difficult, in accordance with the community pharmacy Sore Throat Test and Treat component of the clinical community pharmacy service.
Criteria for inclusion	Phenoxymethylpenicillin 250mg/5mL oral solution can be given to: Adults and children aged 6 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 Rapid Antigen Point of Care Test (POCT) for Streptococcus A infection ➢ No contraindications to penicillins and penicillin type antibiotics ➢ Informed consent has been given ➢ They are unable to swallow tablets
Criteria for exclusion[2]	Phenoxymethylpenicillin 250mg/5mL oral solution should not be given: ➢ **Red Flag Symptoms:** o To anyone attending who has life-threatening symptoms such as stridor, breathing difficulty or dehydration that is associated with sore throat. Phone 999 immediately o To individuals with persistent symptoms (lasting > 2 weeks) and/or severe symptoms which may be indicative of more serious disease, such as cancer. Smoking and alcohol are risk factors that should be considered as part of clinical assessment. ➢ If informed consent not given. Patients who do not agree to share relevant clinical information or there is no valid consent ➢ To children aged 6 years and under ➢ To patients who can swallow tablets ➢ To patients with a known hypersensitivity to penicillin and penicillin type antibiotics – see SmPC

[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

Criteria for exclusion continued[2]	➢ To patients with known hypersensitivity to any of the excipients – see SmPC ➢ Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency. ➢ To patients with known or suspected hepatic failure. ➢ To patients with moderate, severe or end stage renal failure (creatinine clearance <60mL/min) or patient has renal disease where renal function cannot be confirmed. ➢ To patients at high risk of serious complications because of: o significant heart, lung, kidney, liver, or neuromuscular disease (including patients with a history of valvular heart disease, rheumatic fever, post-streptococcal glomerular nephritis) o uncontrolled diabetes o patients who are immunocompromised. ➢ To patients known to be immunosuppressed (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 medicine that can cause blood disorders (e.g. neutropenia, agranulocytosis, thrombocytopenia) leading to infection and acute sore throat including cytotoxic drugs, carbimazole, clozapine etc o A patient who is taking a disease-modifying anti-rheumatic drug (DMARD) e.g. sulfasalazine, methotrexate ➢ To patients with a history of repeated episodes (> 2 previous episodes) of Streptococcus A infection in previous 6 months ➢ If patients present with: o Signs of airway obstruction (inability to swallow, drooling, stridor, hoarse voice, muffled voice, holding a tripod position). o Signs of marked systemic illness or sepsis. o Breathing difficulty.

Criteria for exclusion continued[2]	○ Dehydration. ○ Severe neck pain and or stiffness. ○ Severe pain. ○ Persistent sore throat especially if unilateral. ○ Persistent change in voice. ○ Severe swallowing problems (dysphagia/ odynophagia). ○ Trismus or difficulty opening the jaw ○ Persistent mouth ulcer / lesions. ○ Masses / unilateral swelling. ○ Severe oral mucositis. ○ Rash (e.g. scarlet fever). ○ Suspected rare cause e.g. Kawasaki disease. ○ Symptoms of suppurative complications (e.g. otitis media, sinusitis, mastoiditis, peri-tonsillar abscess (quinsy), scarlet fever). ➢ In patients taking contra-indicated medicines (see drug interactions section for further detail) including: ○ methotrexate ○ bacteriostatic antibiotics e.g. tetracyclines, erythromycin, chloramphenicol and sulphonamides ○ recent typhoid vaccination. ➢ In patients also receiving long-term phenoxymethylpenicillin treatment. ➢ To patients who the pharmacist has assessed as not having capacity to understand the nature and purpose of treatment. ➢ Where a request has been made by a third party on behalf of a patient.
Cautions (including relevant actions to be taken)	Please refer to the SmPC for phenoxymethylpenicillin for full details of special warnings and precautions for use. Oral penicillins are not indicated in patients with severe illness or with a gastrointestinal disease that causes persistent nausea, vomiting, gastric dilation, cardiospasm, intestinal hypermotility or diarrhoea because absorption may be reduced. Occasionally, patients do not absorb therapeutic amounts of orally administered penicillin.

	Caution should be used when treating patients with a history of antibiotic-associated colitis. In renal impairment the safe dosage may be lower than usually recommended. During treatment with phenoxymethylpenicillin non-enzymatic glucose tests may be false-positive. **History of Allergy** ➢ Phenoxymethylpenicillin should be given with caution to patients with a history of allergy, especially to other drugs. ➢ Phenoxymethylpenicillin should also be given cautiously to cephalosporin-sensitive patients, as there is some evidence of partial cross-allergenicity between the cephalosporins and penicillins. Patients have had severe reactions (including anaphylaxis) to both 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). ➢ Particular caution should be exercised in prescribing phenoxymethylpenicillin to patients with an allergic diathesis or with bronchial asthma **Diabetes** If a patient with diabetes is unsure of how to manage their condition when they are unwell or are not eating and drinking they should be advised to contact their GP or diabetic nurse Oral hypoglycaemic agents/Insulin - Careful monitoring of glucose is recommended. **Potassium** Phenoxymethylpenicillin 250 mg/5mL preparations can 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. **Oral anticoagulants** There is a risk of serious haemorrhage and significant elevations in International Normalized Ratio (INR) and prothrombin time when antibiotics are co-administered with warfarin. INR and prothrombin times should be frequently monitored while patients are receiving antibiotics and oral anticoagulants concurrently.

Cautions (including relevant actions to be taken) continued	**Patients must be referred to the clinic responsible for INR monitoring within 3 days of starting antibiotic treatment.** Caution should be exercised when antibiotics are co-administered with direct acting oral anticoagulants such as dabigatran, rivaroxaban and apixaban, particularly to patients at high risk of bleeding **Pregnancy** ➢ Not known to be harmful. ➢ Phenoxymethylpenicillin potassium 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 prescribing to pregnant patients. **Lactation** ➢ Trace amounts in milk, but appropriate to use ➢ Breast feeding is not contraindicated with phenoxymethylpenicillin potassium. Trace quantities of phenoxymethylpenicillin potassium can be detected in breast milk. While adverse effects are apparently rare, two potential problems exist for nursing infant: o modification of bowel flora o direct effects on the infant such as allergy/sensitisation Caution should therefore be exercised when prescribing for the nursing mother **Pseudomembranous colitis** Pseudomembranous colitis has been reported with nearly all antibacterial agents, including macrolides, 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 including penicillin, and may range in severity from mild diarrhoea to fatal colitis **Sucrose** ➢ Phenoxymethylpenicillin oral solution may contain sucrose. ➢ To be taken into consideration in patients with diabetes mellitus. ➢ May be harmful to the teeth.
Action to be taken if the individual is excluded or declines treatment	➢ Phone 999 immediately for anyone attending who has life-threatening symptoms such as stridor, breathing difficulty or dehydration that is associated with sore throat. ➢ If patient meets the exclusion criteria, refer to a medical practitioner. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination. Patients presenting with any of the following symptoms must be referred to an Emergency Department; - o Severe suppurative complications (e.g. peri-tonsillar abscess or cellulitis, parapharyngeal abscess,

Action to be taken if the individual is excluded or declines treatment continued	retropharyngeal abscess, or Lemierre syndrome) as there is a risk of airway compromise or rupture of the abscess. ○ Signs of being markedly systemically unwell and is at risk of immunosuppression. ○ Suspected Kawasaki disease. ○ Diphtheria: characteristic tonsillar or pharyngeal membrane. ○ Signs of being profoundly unwell and the cause is unknown or a rare cause is suspected, for example: Stevens–Johnson syndrome or Yersinial pharyngitis ➢ 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 or guardian) intended actions ➢ Patients may be provided with advice and symptomatic treatment for the All Wales Common Ailments Service Formulary
Further advice	If there is any doubt about the administration of the medication or patient's fitness or suitability to receive the medication, a doctor should be consulted. ➢ Refer to SmPC, BNF and the All Wales Common Ailments Service

2. Description of treatment

Name, strength & formulation of drug	Phenoxymethylpenicillin 250mg/5mL oral solution Phenoxymethylpenicillin 250mg/5mL sugar-free oral solution
Legal category	POM – Prescription Only Medicine
Black triangle▼	No
Off-label use	No
Route / method of administration	Oral Follow the instructions for reconstitution Phenoxymethylpencillin should be taken at least 30 minutes before food, or 2 hours after food
Dose and frequency of administration	Children aged 6-11 years – 250mg (ONE 5mL spoonful) four times a day for TEN days Where a patient is unable to comply with four times a day dosing regime, the dose can be given as: 500mg (TWO 5mL spoonful's) twice a day for TEN days. Over 12 years and adults – 500mg (TWO 5mL spoonful's) four times a day for TEN days Where patient is unable to comply with four times a day dosing regime, the dose can be given as: 1000mg (FOUR 5mL spoonful's) 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/administered	Appropriately labelled packs to provide treatment for TEN days: 2 x 100mL to provide TEN days treatment at a dose of 250mg every six hours (four times daily) **OR** 4 x 100mL to provide TEN days treatment at a dose of 500mg every six hours (four times daily)
Storage	Medicines must be stored securely and in accordance with the product SmPC

Disposal	No special requirements
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. **Contraindications** ➢ Methotrexate: Use of phenoxymethylpenicillin while taking methotrexate can cause reduced excretion of methotrexate thereby increasing the risk of toxicity. ➢ Typhoid vaccine (oral): Penicillins may inactivate oral typhoid vaccine if ingested concomitantly. Avoid where recent vaccination or vaccination due. ➢ 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. **Cautions for use** ➢ Guar gum: Reduced absorption of phenoxymethylpenicillin. ➢ Coumarin anticoagulants: Penicillins may interfere with anticoagulant control (see cautions). ➢ Phenindione - Penicillins may interfere with anticoagulant control. (see cautions). ➢ Aminoglycosides: Neomycin is reported to reduce the absorption of phenoxymethylpenicillin. ➢ Probenecid: Reduced excretion of phenoxymethylpenicillin by competing with it for renal tubular secretion. ➢ Sulfinpyrazone: Excretion of penicillins reduced by sulfinpyrazone. ➢ Patients receiving potassium-containing drugs or potassium sparing-diuretics. ➢ During treatment with phenoxymethylpenicillin non-enzymatic urinary glucose tests may be false-positive
Identification & management of adverse reactions	The following are side effects reported for all penicillins. This list is not exhaustive. A detailed list of adverse reactions is available in the SmPC, and the BNF ➢ Advise the patient that if any of the following side effects occur, discontinue treatment immediately and contact the emergency department or dial 999: o Allergic reactions such as sudden difficulty with breathing, speaking and swallowing o Extreme dizziness or fainting o Severe itchy skin rash especially if blistering, soreness of the eyes mouth or genital organs. Very common to common (affecting between 1 in 10 and 1 in 100 patients)

	with phenoxymethylpenicillin (and does not reflect all reported side effects): Nausea, vomiting, diarrhoea, abdominal pain, allergic reactions, hypersensitivity; skin reactions, urticarial, erythematous or morbilliform rash, pruritis. Rare or very rare adverse effects (affecting between 1 in 1000 and 1 in 10000 patients): Sore mouth, black hairy tongue, hepatitis, cholestatic jaundice, Agranulocytosis; angioedema; laryngeal oedema, anaphylaxis, serum sickness like reactions characterised by fever, chills, arthralgia and oedema, pseudomembranous colitis, interstitial nephritis, thrombocytopenia, neutropenia, leucopenia, eosinophilia and haemolytic anaemia, exfoliative dermatitis, cerebral irritation, convulsions Superficial tooth discolouration has been reported in children. Good oral hygiene may help to prevent tooth discolouration as it can usually be removed by brushing Frequency not known: Circulatory collapse; coagulation disorder, faeces soft; fever; increased risk of infection; neurotoxicity; oral disorders; paraesthesia
Reporting procedure of adverse reactions	Any adverse reaction to the product should be documented in the individual's medical records. Alert a doctor in the event of a serious adverse reaction. Report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme.
Written information to be given to individual or their carer	➢ Supply the marketing authorisation holder's patient information leaflet (PIL).
Patient or carer advice/follow up	Inform the individual or their carer: ➢ The oral solution should be shaken well before each dose ➢ Each dose should be taken 30 minutes before food ➢ The importance or good oral hygiene to prevent tooth discolouration in children ➢ if they get any side effects, to talk to their doctor, or pharmacist or nurse. This includes any possible side effects not listed in the PIL ➢ that in the event of a severe adverse reaction to discontinue treatment immediately and seek to medical advice

	➢ to read the PIL before taking the medication ➢ to visit the NHS website on phenoxymethylpenicillin for more information ➢ to visit the NHS 111 Wales site for further information on sore throat ➢ to seek medical advice if their condition deteriorates and/or they become systemically unwell or if their symptoms do not improve ➢
Special considerations / additional information	Inform the individual or their carer: ➢ That the condition is self-limiting and is likely to get better within 7 days, with or without antibiotic treatment. ➢ To seek further healthcare advice if symptoms do not improve within 7 days or worsen. ➢ That taking simple analgesics will help temperature and discomfort. ➢ To take painkillers at regular intervals to relieve pain and fever. ➢ That adults and older children may find sucking throat lozenges, ice cubes or flavoured frozen desserts (e.g. ice lollies) provides symptomatic relief. ➢ That they may wish to try medicated lozenges to help reduce 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. ➢ That 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 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 must be recorded in Choose Pharmacy as prompted at the time of the consultation. Where the Choose Pharmacy platform is not available records, must be made to document the consultation, using the paper-based consultation record. Paper based records must be transferred onto the Choose Pharmacy Sore Throat Test and Treat module as soon as practically possible and by the end of the next working day. ➢ All records, electronically or otherwise must be kept in accordance with NHS record keeping and Community Pharmacy Information Governance requirements see https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/information-governance-alliance-iga ➢ All records should be clear, legible and contemporaneous. ➢ If the patient is excluded, a record of the reason for exclusion must be documented within Choose pharmacy, and any specific advice that has been given. ➢ The consultation summary must be forwarded to the patient's GP within 72 hours of making the supply. Where practically possible summaries

	should be returned to local practices within 24 hours, particularly where an antibiotic has been supplied. ➢ All supplies of antibiotic must be labelled in accordance with the labelling requirements for a dispensed medicine as stated within Schedule 5 of The Medicines (Marketing Authorisations etc) Regulations 1994. No 3144 as amended. A record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes in accordance with local policy. For pregnant women record the antibiotic supplied in the hand-held maternity record (if available).

PGD for the supply of clarithromycin 500mg tablets

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 penicillin is contraindicated in accordance with the community pharmacy Sore Throat Test and Treat component of the clinical community pharmacy service.
Criteria for inclusion	Clarithromycin 500mg tablets can be given to: Adults and children over 12 years of age presenting with symptoms of acute uncomplicated sore throat and: ➢ They have 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 for Streprococcus A infection **AND** ➢ The use of phenoxymethylpenicillin is contraindicated ➢ They can swallow tablets ➢ They have no contraindications to clarithromycin ➢ Informed consent has been given
Criteria for exclusion[2]	Clarithromycin tablets should not be given: ➢ **Red Flag Symptoms:** ○ To anyone attending who has life-threatening symptoms such as stridor, breathing difficulty or dehydration that is associated with sore throat. Phone 999 immediately ○ To individuals with persistent symptoms (lasting > 2 weeks) and/or severe symptoms which may be indicative of more serious disease, such as cancer. Smoking and alcohol are risk factors that should be considered as part of clinical assessment. ➢ When informed consent has not been given. Where patients do not agree to share relevant clinical information or there is no valid consent ➢ If patients have a known hypersensitivity to clarithromycin or any excipients – see SmPC ➢ If children are under 12 years of age ➢ If they are unable to swallow tablets ➢ In patients with known hepatic failure

[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

Criteria for exclusion continued[2]	Clarithromycin should not be given: ➢ In patients with moderate, severe or end stage renal failure (creatinine clearance <60mL/min) or patients with renal disease where renal function cannot be confirmed. ➢ In patients who are at high risk of serious complications because of significant heart, lung, kidney, liver, or neuromuscular disease ➢ In patients with known or suspected pregnancy ➢ In patients who are breastfeeding ➢ To patients who are at high risk of serious complications because of: o significant heart, lung, kidney, liver, or neuromuscular disease (including patients with a history of valvular heart disease, rheumatic fever, post-streptococcal glomerular nephritis) o uncontrolled diabetes o patients who are immunocompromised. ➢ In patients known to be immunosuppressed (accompanied by other clinical symptoms of blood disorders) including for example: o A person 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 medicine that can cause blood disorders (e.g. neutropenia, agranulocytosis, thrombocytopenia) leading to infection and acute sore throat including cytotoxic drugs, carbimazole, clozapine etc o A patient who is taking a disease-modifying anti-rheumatic drug (DMARD) e.g. sulfasalazine, methotrexate ➢ To patients with a history of repeated episodes (>2 previous episodes) of Streptococcus A infection in the previous 6 months

Criteria for exclusion continued[2]	➢ If patients present with: ○ Signs of airway obstruction (inability to swallow, drooling, stridor, hoarse voice, muffled voice, holding a tripod position). ○ Signs of marked systemic illness or sepsis. ○ Breathing difficulty. ○ Dehydration. ○ Severe neck pain and or stiffness. ○ Severe pain. ○ Persistent sore throat especially if unilateral. ○ Persistent change in voice. ○ Severe swallowing problems (dysphagia/ odynophagia). ○ Trismus or difficulty opening the jaw ○ Persistent mouth ulcer / lesions. ○ Masses / unilateral swelling. ○ Severe oral mucositis. ○ Rash (e.g. scarlet fever). ○ Suspected rare cause e.g. Kawasaki disease. ○ Symptoms of suppurative complications (e.g. otitis media, sinusitis, mastoiditis, peri-tonsillar abscess (quinsy), scarlet fever). ➢ If the patient has Myasthenia gravis — macrolides may aggravate weakness symptoms. ➢ Where here is a history of or current Q-T prolongation ➢ Where there is a history of or current Ventricular cardiac arrhythmia including torsade de pointes ➢ If the patient has known or suspected electrolyte disturbances (hypokalaemia or hypomagnesaemia) ➢ If the patient has symptoms of diarrhoea and they have received an antibiotic within the previous 3 months ➢ If the patient is taking concurrent antibiotic treatment

Criteria for exclusion continued[2]	➢ If the patient is also taking a contraindicated medicine (see significant interactions section for further detail) including: ➢ Drugs that prolong the QT interval. See BNF for all drugs that can prolong the QT interval e.g. o astemizole, o cisapride, o pimozide, o terfenadine, o domperidone, ➢ Clarithromycin should not be given if the patient takes: o ergotamine or dihydroergotamine, o midazolam, ranolazine, ticagrelor, colchicine, lomitapide ➢ Clarithromycin should not be given if there is current or recent treatment (within the last two weeks) with drugs that are inducers of CYP3A4 e.g. o rifampicin o phenytoin o carbamazepine o phenobarbital o St. John's Wort ➢ Clarithromycin should not be given if the patient takes drugs 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 Caution and Drug Interactions section ➢ If the patient is taking concurrent antibiotic treatment ➢ To patients who the pharmacist has assessed as not having capacity to understand the nature and purpose of treatment. ➢ Where a request has been made by a third party on behalf of a patient.
Cautions (including relevant actions to be taken)	Please refer to the SmPC for clarithromycin for full details of special warnings and precautions for use.

Cautions (including relevant actions to be taken) continued	**Hepatic failure** Cases of fatal hepatic failure have been reported. Some patients may have had pre-existing hepatic disease or may have been taking other hepatotoxic medicinal products. Patients should be advised to stop treatment and contact their doctor if signs and symptoms of hepatic disease develop, such as anorexia, jaundice, dark urine, pruritus, or tender abdomen. **Pseudomembranous colitis** Pseudomembranous colitis has been reported with nearly all antibacterial agents, including macrolides, 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 including clarithromycin, 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) See BNF for further information **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. **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 a 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 manufacturers advice**

Cautions (including relevant actions to be taken) continued	**Diabetes** If a patient with diabetes is unsure of how to manage their condition when they are unwell or are not eating and drinking they should be advised to contact their GP or diabetic nurse. **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.** **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. **Patients must be referred to the 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 and apixaban, particularly to patients at high risk of bleeding **Calcium channel blockers (CCB's)** — due to an increased risk of hypotension, caution is advised with the concurrent use of macrolides and CCB's metabolised by CYP3A4 (such as verapamil, amlodipine, and diltiazem).
Action to be taken if the individual is excluded or declines treatment	➢ Phone 999 immediately for anyone attending who has life-threatening symptoms such as stridor, breathing difficulty or dehydration that is associated with sore throat. ➢ If patient meets the exclusion criteria, refer to a medical practitioner. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination. Patients presenting with any of the following symptoms must be referred to an Emergency Department; - o Severe suppurative complications (e.g. peri-tonsillar abscess or cellulitis, parapharyngeal abscess, retropharyngeal abscess, or Lemierre syndrome) as there is a risk of airway compromise or rupture of the abscess. o Signs of being markedly systemically unwell and is at risk of immunosuppression. o Suspected Kawasaki disease. o Diphtheria: characteristic tonsillar or pharyngeal membrane. o Signs of being profoundly unwell and the cause is unknown or a rare cause is suspected, for example: Stevens–Johnson syndrome or Yersinial pharyngitis

Action to be taken if the individual is excluded or declines treatment continued	➢ 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 or guardian) intended actions ➢ Patients may be provided with advice and symptomatic treatment for the All Wales Common Ailments Service Formulary
Further advice	➢ If there is any doubt about the administration of the medication or patient's fitness or suitability to receive the medication, a doctor should be consulted. ➢ Refer to SmPC, BNF and the All Wales Common Ailments Service

2. Description of treatment

Name, strength & formulation of drug	Clarithromycin 500mg tablets
Legal category	POM – Prescription Only Medicine
Black triangle▼	No
Off-label use	No
Route / method of administration	Oral
Dose and frequency of administration	ONE (500mg) tablet to be taken TWICE daily for FIVE days
Duration of treatment	This PGD only allows for the duration stated in the dosage schedule above.
Quantity to be supplied/administered	Appropriately labelled pack to provide FIVE days treatment ➢ 10 x 500mg tablets
Storage	Medicines must be stored securely and in accordance with product SmPC
Disposal	No special requirements

Drug interactions	The following list is not exhaustive. A detailed list of drug interactions can be found in the SmPC and the BNF.
	Contraindications:
	• Drugs that prolong the QT interval (see BNF for all drugs that can prolong the QT interval) including:
	  ○ astemizole,
	  ○ cisapride,
	  ○ pimozide,
	  ○ terfenadine
	  ○ hydroxychloroquine and chloroquine
	• ergotamine or dihydroergotamine,
	• ranolazine
	• ticagrelor,
	• colchicine
	• lomitapide
	• Drugs that are inducers of CYP3A4 (e.g. rifampicin, rifabutin, phenytoin, carbamazepine, phenobarbital, St John's wort
	• drugs that are known or suspected to affect circulating concentrations of clarithromycin
	  ○ Strong inducers of the cytochrome P450 metabolism system (e.g. Efavirenz, nevirapine, rifampicin, rifabutin and rifapentine)
	  ○ Etravirine

	• Drugs that are known or suspected to be affected by clarithromycin
	  ○ drug primarily metabolised by CYP3A4 (e.g. cilostazol, ciclosporin, ibrutinib, methylprednisolone, omeprazole, atypical antipsychotics (e.g. quetiapine), sirolimus, tacrolimus and vinblastine
	  ○ Antiarrhythmics – quinidine, disopyramide
	  ○ Sildenafil, tadalafil and vardenafil
	  ○ Theophylline,
	  ○ Tolterodine
	  ○ Triazolobenzodiazepines (e.g., alprazolam, midazolam, triazolam)
	  ○ Aminoglycosides
	  ○ Digoxin
	  ○ Zidovudine
	  ○ Valproate
	  ○ Saquinavir
	  ○ Trastuzumab emtansine
	  ○ Trabectedin
	  ○ Tolvaptan
	  ○ Tofacitinib
	  ○ Tipranavir
	
	Cautions:
	Clarithromycin should be used with caution in patients also prescribed:
	• HMG-CoA reductase inhibitors (statins) - Patients that are currently taking a 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).
	
	• Oral hypoglycaemic agents/Insulin - Careful monitoring of glucose is recommended.
	• Oral anticoagulants - Patients must be referred to the clinic responsible for INR monitoring within 3 days of starting clarithromycin treatment.
	• Calcium channel blockers (CCB's) - due to an increased risk of hypotension, caution is advised with the concurrent use of macrolides and CCB's metabolised by CYP3A4 (such as verapamil, amlodipine, and diltiazem).
	• medicinal products that can cause hypokalaemia (e.g. corticosteroids, diuretics)

Identification & management of adverse reactions	The following list of adverse reactions is not exhaustive. A detailed list is available in the SmPC, and the BNF
	
	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 in it • Severe stomach pain • Fever • Loss of appetite • Yellowing of the skin and eyes • Pale stools, dark urine • Itchy rash • Abdominal pain • Palpitations or irregular heart beat Very Common to common (affecting between 1 in 10 and 1 in 100 patients) appetite decreased; diarrhoea; dizziness; gastrointestinal discomfort; gastrointestinal disorders; headache; hearing impairment; insomnia; nausea; pancreatitis; paraesthesia; skin reactions; taste altered; vasodilation; vision disorders; vomiting Uncommon (affecting between 1 in 100 and 1 in 1000 patients) Angioedema; anxiety; arrhythmias; candida infection; chest pain; constipation drowsiness; eosinophilia; epistaxis; hepatic disorders; leukopenia; neutropeni palpitations; QT interval prolongation; severe cutaneous adverse reactions (SCARs); tinnitus; vertigo; burping; dry mouth; muscle complaints; oral disord thrombocytosis; tremor Rare of very rare (affecting between 1 in 1000 and 1 in 10000 patients) Antibiotic associated colitis; myasthenia gravis; nephritis tubulointerstitial Frequency unknown Hallucination; hypotension; seizure; smell altered; thrombocytopenia; tongue discolouration; abnormal dreams; agranulocytosis; depersonalisation; depression; mania; myopathy; psychotic disorder; renal failure; tooth discolouration; urine discolouration.
Reporting procedure of adverse reactions	Any adverse reaction to the product should be documented in the individual's medical records. Alert a doctor in the event of a serious adverse reaction. Report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme.
Written information to be given to individual or their carer	➢ Supply the marketing authorisation holder's patient information leaflet (PIL).

Patient or carer advice/follow up	Inform the individual or their carer: ➢ The tablets should be swallowed whole with a full glass of water ➢ The tablets can be taken with or after food ➢ if they get any side effects, to talk to their doctor, or pharmacist or nurse. This includes any possible side effects not listed in the PIL ➢ to discontinue treatment and seek medical advice in the event of a severe adverse reaction ➢ to seek medical attention immediately if their condition deteriorates and or the patient becomes systemically unwell ➢ 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 ➢ to seek medical advice if their condition deteriorates and/or they become systemically unwell or if their symptoms do not improve ➢
Special considerations / additional information	Inform the individual or their carer: ➢ That the condition is self-limiting and is likely to get better within 7 days, with or without antibiotic treatment. ➢ To seek further healthcare advice if symptoms do not improve within 7 days or worsen. ➢ That taking simple analgesics will help temperature and discomfort. ➢ To take painkillers at regular intervals to relieve pain and fever. ➢ That adults and older children may find sucking throat lozenges, ice cubes or flavoured frozen desserts (e.g. ice lollies) provides symptomatic relief. ➢ That they can try medicated lozenges to help reduce 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 avoiding 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. ➢ That 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. 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 must be recorded in Choose Pharmacy as prompted at the time of the consultation. Where the Choose Pharmacy platform is not available records, must be made to document the consultation, using the

	paper-based consultation record. Paper based records must be transferred onto the Choose Pharmacy Sore Throat Test and Treat module as soon as practically possible and by the end of the next working day. ➢ All records, electronically or otherwise must be kept in accordance with NHS record keeping and Community Pharmacy Information Governance requirements see https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/information-governance-alliance-iga ➢ All records should be clear, legible and contemporaneous. ➢ If the patient is excluded, a record of the reason for exclusion must be documented within Choose Pharmacy, and any specific advice that has been given ➢ The consultation summary must be forwarded to the patient's GP within 72 hours of making the supply. Where practically possible summaries should be returned to local practices within 24 hours, particularly where an antibiotic has been supplied. ➢ All supplies of antibiotic must be labelled in accordance with the labelling requirements for a dispensed medicine as stated within Schedule 5 of The Medicines (Marketing Authorisations etc) Regulations 1994. No 3144 as amended A record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes in accordance with local policy.

PGD for the supply of clarithromycin 125mg/5mL or 250mg/5mL 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 penicillin is contraindicated in accordance with the community pharmacy Sore Throat Test and Treat component of the clinical community pharmacy service.
Criteria for inclusion	Clarithromycin oral suspension can be given to: Children aged 6-12 years presenting with symptoms of acute uncomplicated sore throat and the use of phenoxymethylpenicillin is contraindicated **AND** they: ➢ Have a FeverPAIN score of 2 or above **OR** ➢ They have a Centor score of 3 or above **AND** ➢ A positive result from a Rapid Antigen Point of Care Test (POCT) for Streptococcus A infection Adults or children aged 12 years and above where the use of phenoxymethylpenicillin is contraindicated **AND** they: ➢ have a FeverPAIN score of 2 or above **OR** ➢ have a Centor score of 3 or above **AND** ➢ have a positive result from a Rapid Antigen Point of Care Test (POCT) for Streptococcus A infection **AND** ➢ Are unable to swallow tablets ➢ have no contraindications to clarithromycin and macrolide type antibiotics ➢ have given informed consent
Criteria for exclusion[2]	Clarithromycin oral suspension should not be given: ➢ **Red Flag Symptoms:** ○ To anyone attending who has life-threatening symptoms such as stridor, breathing difficulty or dehydration that is associated with sore throat. Phone 999 immediately ○ To individuals with persistent symptoms (lasting > 2 weeks) and/or severe symptoms which may be indicative of more serious disease, such as cancer. Smoking and alcohol are risk factors that should be considered as part of clinical assessment.

[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

Criteria for exclusion continued[2]	Clarithromycin should not be given: ➢ When informed consent has not been given. Where patients do not agree to share relevant clinical information or there is no valid consent ➢ If patients have a known hypersensitivity to clarithromycin or any excipients – see SmPC ➢ If children are under 6 years of age ➢ If adults and children aged 12 years and above can swallow tablets ➢ In patients with known hepatic failure ➢ In patients with moderate, severe or end stage renal failure (creatinine clearance <60mL/min) or patients with renal disease where renal function cannot be confirmed. ➢ In patients with known or suspected pregnancy ➢ In patients who are breastfeeding ➢ To patients who are at high risk of serious complications because of: o significant heart, lung, kidney, liver, or neuromuscular disease (including patients with a history of valvular heart disease, rheumatic fever, post-streptococcal glomerular nephritis) o uncontrolled diabetes o patients who are immunocompromised. ➢ In patients known to be immunosuppressed (accompanied by other clinical symptoms of blood disorders) including for example: o A person 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 medicine that can cause blood disorders (e.g. neutropenia, agranulocytosis, thrombocytopenia) leading to infection and acute sore throat including cytotoxic drugs, carbimazole, clozapine etc

Criteria for exclusion continued[2]	○ A patient who is taking a disease-modifying anti-rheumatic drug (DMARD) e.g. sulfasalazine, methotrexate ➢ To patients with a history of repeated episodes (>2 previous episodes) of Streptococcus A infection in the previous 6 months ➢ If patients present with: ○ Signs of airway obstruction (inability to swallow, drooling, stridor, hoarse voice, muffled voice, holding a tripod position). ○ Signs of marked systemic illness or sepsis. ○ Breathing difficulty. ○ Dehydration. ○ Severe neck pain and or stiffness. ○ Severe pain. ○ Persistent sore throat especially if unilateral. ○ Persistent change in voice. ○ Severe swallowing problems (dysphagia/ odynophagia). ○ Trismus or difficulty opening the jaw ○ Persistent mouth ulcer / lesions. ○ Masses / unilateral swelling. ○ Severe oral mucositis. ○ Rash (e.g. scarlet fever). ○ Suspected rare cause e.g. Kawasaki disease. ○ Symptoms of suppurative complications (e.g. otitis media, sinusitis, mastoiditis, peri-tonsillar abscess (quinsy), scarlet fever). ➢ If the patient has Myasthenia gravis — macrolides may aggravate weakness symptoms. ➢ Where there is a history of or current Q-T prolongation ➢ Where there is a history of or current ventricular cardiac arrhythmia including torsade de pointes ➢ If the patient has known or suspected electrolyte disturbances (hypokalaemia or hypomagnesaemia)

Criteria for exclusion continued[2]	➢ If the patient has symptoms of diarrhoea and they have received an antibiotic within the previous 3 months ➢ If the patient is also taking a contraindicated medicine (see drug interactions section for further detail) including: ➢ Drugs that prolong the QT interval. See BNF for all drugs that can prolong the QT interval e.g. o astemizole, o cisapride, o pimozide, o terfenadine, o domperidone, ➢ Clarithromycin should not be given if the patient takes: o ergotamine or dihydroergotamine, o midazolam, ranolazine, ticagrelor, colchicine, lomitapide ➢ Clarithromycin should not be given if there is current or recent treatment (within the last two weeks) with drugs that are inducers of CYP3A4 e.g. o rifampicin o phenytoin o carbamazepine o phenobarbital o St. John's Wort ➢ Clarithromycin should not be given if the patient takes drugs 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 Caution and Drug Interactions section ➢ Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency. ➢ If the patient is taking concurrent antibiotic treatment ➢ To patients who the pharmacist has assessed as not having capacity to understand the nature and purpose of treatment.

	➢ Where a request has been made by a third party on behalf of a patient.
Cautions (including relevant actions to be taken)	Please refer to the SmPC for clarithromycin for full details of special warnings and precautions for use. **Hepatic failure** Cases of fatal hepatic failure have been reported. Some patients may have had pre-existing hepatic disease or may have been taking other hepatotoxic medicinal products. Patients should be advised to stop treatment and contact their doctor if signs and symptoms of hepatic disease develop, such as anorexia, jaundice, dark urine, pruritus, or tender abdomen. **Pseudomembranous colitis** Pseudomembranous colitis has been reported with nearly all antibacterial agents, including macrolides, 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 including clarithromycin, 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) See BNF for further information **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. **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 a HMG-CoA reductase inhibitor (statin) must be given appropriate advice regarding the need to stop taking the**

Cautions (including relevant actions to be taken) continued	**statin until the course of treatment with clarithromycin has been completed in accordance with manufacturers advice** **Diabetes** If a patient with diabetes is unsure of how to manage their condition when they are unwell or are not eating and drinking they should be advised to contact their GP or diabetic nurse. **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.** **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. **Patients must be referred to the 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 and apixaban, particularly to patients at high risk of bleeding **Calcium channel blockers (CCB's)** — due to an increased risk of hypotension, caution is advised with the concurrent use of macrolides and CCB's metabolised by CYP3A4 (such as verapamil, amlodipine, and diltiazem). **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 ➢ To be taken into consideration in patients with diabetes mellitus. ➢ May be harmful to the teeth.
Action to be taken if the individual is excluded or declines treatment	➢ Phone 999 immediately for anyone attending who has life-threatening symptoms such as stridor, breathing difficulty or dehydration that is associated with sore throat. ➢ If patient meets the exclusion criteria, refer to a medical practitioner. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical

	examination. Patients presenting with any of the following symptoms must be referred to an Emergency Department; - ○ Severe suppurative complications (e.g. peri-tonsillar abscess or cellulitis, parapharyngeal abscess, retropharyngeal abscess, or Lemierre syndrome) as there is a risk of airway compromise or rupture of the abscess. ○ Signs of being markedly systemically unwell and is at risk of immunosuppression. ○ Suspected Kawasaki disease. ○ Diphtheria: characteristic tonsillar or pharyngeal membrane. ○ Signs of being profoundly unwell and the cause is unknown or a rare cause is suspected, for example: Stevens–Johnson syndrome or Yersinial pharyngitis ➢ 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 or guardian) intended actions ➢ Patients may be provided with advice and symptomatic treatment for the All Wales Common Ailments Service Formulary
Further advice	➢ If there is any doubt about the administration of the medication or patient's fitness or suitability to receive the medication, a doctor should be consulted. ➢ Refer to SmPC, BNF and the All Wales Common Ailments Service

2. Description of treatment

<table>
<tr><td>Name, strength & formulation of drug</td><td>Clarithromycin 125mg/5mL oral suspension
Clarithromycin 250mg/5mL oral suspension</td></tr>
<tr><td>Legal category</td><td>POM – Prescription Only Medicine</td></tr>
<tr><td>Black triangle▼</td><td>No</td></tr>
<tr><td>Off-label use</td><td>No</td></tr>
<tr><td>Route / method of administration</td><td>Oral
Follow the instructions for reconstitution</td></tr>
<tr><td>Dose and frequency of administration</td><td>➢ For children aged 6-11 years the dose is calculated by weight
<table>
<tr><td>Weight in kg</td><td>Dose in mg</td><td>Volume/strength of oral suspension</td></tr>
<tr><td>12kg-19 kg</td><td>125mg/5mL</td><td>5mL (125mg/5mL)</td></tr>
<tr><td>20kg – 29kg</td><td>187.5mg</td><td>7.5mL (125mg/5mL)</td></tr>
<tr><td>30kg – 40kg</td><td>250mg</td><td>5mL (250mg/5mL)</td></tr>
</table>
To be taken TWICE DAILY for FIVE DAYS
➢ Adults and children aged 12 years and above
○ 500mg (10mL of 250mg/5mL oral suspension) to be taken TWICE DAILY for FIVE DAYS</td></tr>
<tr><td>Duration of treatment</td><td>This PGD only allows for the duration stated in the dosage schedule above.</td></tr>
<tr><td>Quantity to be supplied/administered</td><td>Appropriately labelled pack to provide FIVE days treatment
<table>
<tr><td>Strength to supply</td><td>Dose</td><td>Quantity to supply</td></tr>
<tr><td>125mg/5mL</td><td>5mL twice daily</td><td>1 x 70mL</td></tr>
<tr><td>125mg/5mL</td><td>7.5mL twice daily</td><td>2 x 70mL</td></tr>
<tr><td>250mg/5mL</td><td>5mL twice daily</td><td>1 x 70mL</td></tr>
<tr><td>250mg/5mL</td><td>10mL twice daily</td><td>2 x 70mL</td></tr>
</table></td></tr>
</table>

Storage	Medicines must be stored securely and in accordance with product SmPC
Disposal	No special requirements

Drug interactions	The following list is not exhaustive. A detailed list of drug interactions can be found in the SmPC and the BNF.
	
	Contraindications:
	• Drugs that prolong the QT interval (see BNF for all drugs that can prolong the QT interval) including:
	  ○ astemizole,
	  ○ cisapride,
	  ○ pimozide,
	  ○ terfenadine
	  ○ hydroxychloroquine and chloroquine
	• ergotamine or dihydroergotamine,
	• midazolam, ranolazine, ticagrelor, colchicine, lomitapide
	• Drugs that are inducers of CYP3A4 (e.g. rifampicin, rifabutin, phenytoin, carbamazepine, phenobarbital, St John's wort
	• drugs that are known or suspected to affect circulating concentrations of clarithromycin
	  ○ Strong inducers of the cytochrome P450 metabolism system (e.g. Efavirenz, nevirapine, rifampicin, rifabutin and rifapentine)
	  ○ Etravirine
	• Drugs that are known or suspected to be affected by clarithromycin
	  ○ drug primarily metabolised by CYP3A4 (e.g. cilostazole, ciclosporin, ibrutinib, methylprednisolone, omeprazole, atypical antipsychotics (e.g. quetiapine), sirolimus, tacrolimus and vinblastine
	  ○ Antiarrhythmics – quinidine, disopyramide
	  ○ Sildenafil, tadalafil and vardenafil
	  ○ Theophylline,
	  ○ Tolterodine
	  ○ Triazolobenzodiazepines (e.g., alprazolam, midazolam, triazolam)
	  ○ Aminoglycosides
	  ○ Digoxin
	  ○ Zidovudine
	  ○ Valproate
	  ○ Saquinavir
	  ○ Trastuzumab emtansine
	  ○ Trabectedin
	  ○ Tolvaptan
	  ○ Tofacitinib
	  ○ Tipranavir
	
	Cautions:
	Clarithromycin should be used with caution in patients also prescribed:

	• HMG-CoA reductase inhibitors (statins) - Patients that are currently taking a 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). • Oral hypoglycaemic agents/Insulin - Careful monitoring of glucose is recommended. • Oral anticoagulants - Patients must be referred to the clinic responsible for INR monitoring within 3 days of starting clarithromycin treatment. • Calcium channel blockers (CCB's) - due to an increased risk of hypotension, caution is advised with the concurrent use of macrolides and CCB's metabolised by CYP3A4 (such as verapamil, amlodipine, and diltiazem). • medicinal products that can cause hypokalaemia (e.g. corticosteroids, diuretics)
Identification & management of adverse reactions	The following list of adverse effects is not exhaustive. A detailed list of adverse reactions is available in the SmPC, and the BNF ➢ 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 in it • Severe stomach pain • Fever • Loss of appetite • Yellowing of the skin and eyes • Pale stools, dark urine • Itchy rash • Abdominal pain • Palpitations or irregular heart beat Very Common to common (affecting between 1 in 10 and 1 in 100 patients) appetite decreased; diarrhoea; dizziness; gastrointestinal discomfort; gastrointestinal disorders; headache; hearing impairment; insomnia; nausea; pancreatitis; paraesthesia; skin reactions; taste altered; vasodilation; vision disorders; vomiting Uncommon (affecting between 1 in 100 and 1 in 1000 patients) Angioedema; anxiety; arrhythmias; candida infection; chest pain; constipation; drowsiness; eosinophilia; epistaxis; hepatic disorders;

	leukopenia; neutropenia; palpitations; QT interval prolongation; severe cutaneous adverse reactions (SCARs); tinnitus; vertigo; burping; dry mouth; muscle complaints; oral disorders; thrombocytosis; tremor Rare of very rare (affecting between 1 in 1000 and 1 in 10000 patients) Antibiotic associated colitis; myasthenia gravis; nephritis tubulointerstitial Superficial tooth discolouration has been reported in children. Good oral hygiene may help to prevent tooth discolouration as it can usually be removed by brushing Frequency unknown Hallucination; hypotension; seizure; smell altered; thrombocytopenia; tongue discolouration; abnormal dreams; agranulocytosis; depersonalisation; depression; mania; myopathy; psychotic disorder; renal failure; tooth discolouration; urine discolouration.
Reporting procedure of adverse reactions	Any adverse reaction to the product should be documented in the individual's medical records. Alert a doctor in the event of a serious adverse reaction. Report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme.
Written information to be given to individual or their carer	➢ Supply the marketing authorisation holder's patient information leaflet (PIL).
Patient or carer advice/follow up	Inform the individual or their carer: ➢ The suspension should be shaken well before each use ➢ It can be given with or after food ➢ The importance of good oral hygiene to prevent tooth discolouration in children ➢ if they get any side effects, to talk to their doctor, or pharmacist or nurse. This includes any possible side effects not listed in the PIL ➢ to discontinue treatment and seek medical advice in the event of a severe adverse reaction ➢ to seek medical attention immediately if their condition deteriorates and or the patient becomes systemically unwell ➢ 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 ➢ to seek medical advice if their condition deteriorates and/or they become systemically unwell or if their symptoms do not improve ➢
Special considerations / additional information	Inform the individual or their carer: ➢ That the condition is self-limiting and is likely to get better within 7 days, with or without antibiotic treatment. ➢ To seek further healthcare advice if symptoms do not improve within 7 days or worsen. ➢ That taking simple analgesics will help temperature and discomfort. ➢ To take painkillers at regular intervals to relieve pain and fever. ➢ That adults and older children may find sucking throat lozenges, ice cubes or flavoured frozen desserts (e.g. ice lollies) provides symptomatic relief. ➢ That they can try medicated lozenges to help reduce 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 avoiding 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. ➢ That 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. 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 must be recorded in Choose Pharmacy as prompted at the time of the consultation. Where the Choose Pharmacy platform is not available records, must be made to document the consultation, using the paper-based consultation record. Paper based records must be transferred onto the Choose Pharmacy Sore Throat Test and Treat module as soon as practically possible and by the end of the next working day. ➢ All records, electronically or otherwise must be kept in accordance with NHS record keeping and Community Pharmacy Information Governance requirements see https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/information-governance-alliance-iga ➢ All records should be clear, legible and contemporaneous. ➢ If the patient is excluded, a record of the reason for exclusion must be documented within Choose Pharmacy, and any specific advice that has been given ➢ The consultation summary must be forwarded to the patient's GP within 72 hours of making the supply. Where practically possible summaries should be returned to local practices within 24 hours, particularly where an antibiotic has been supplied.

	➢ All supplies of antibiotic must be labelled in accordance with the labelling requirements for a dispensed medicine as stated within Schedule 5 of The Medicines (Marketing Authorisations etc) Regulations 1994. No 3144 as amended A record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes in accordance with local policy.

PGD for the supply of erythromycin 250mg tablets

1. Clinical condition

Clinical condition or situation to which this PGD applies	For the treatment of individuals with painful, inflamed throat, which makes swallowing difficult, where the use of penicillin is contraindicated AND they are pregnant in accordance with the community pharmacy Sore Throat Test and Treat component of the clinical community pharmacy service
Criteria for inclusion	Erythromycin tablets 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 is contraindicated **AND they**: ➢ Have a FeverPAIN score of 2 or above **OR** ➢ They have a Centor Score of 3 or above **AND** ➢ Have a positive result from a Rapid Antigen Point of Care Test (POCT) for Streprococcus A infection **AND** ➢ They can swallow tablets ➢ They have no contraindications to erythromycin ➢ They have given informed consent
Criteria for exclusion[2]	Erythromycin tablets should not be given: ➢ **Red Flag Symptoms:** ○ To anyone attending who has life-threatening symptoms such as stridor, breathing difficulty or dehydration that is associated with sore throat. Phone 999 immediately ○ To individuals with persistent symptoms (lasting > 2 weeks) and/or severe symptoms which may be indicative of more serious disease, such as cancer. Smoking and alcohol are risk factors that should be considered as part of clinical assessment. ➢ Where informed consent has not been given. Where patients do not agree to share relevant clinical information or there is no valid consent ➢ In patients with a known or suspected hypersensitivity to erythromycin or other macrolide antibiotics – see SmPC ➢ In patients with a known or suspected hypersensitivity to any of the suspension excipients

[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

Criteria for exclusion continued[2]	Erythromycin tablets should not be given:
	• If patients cannot swallow tablets.
	• If children are under 13 years of age
	• In patients with known or suspected hepatic impairment or people concomitantly receiving potentially hepatotoxic drugs
	• In patients currently on phenoxymethylpenicillin treatment
	• In patients with moderate, severe or end stage renal failure (creatinine clearance <60mL/min) or patients with renal disease where renal function cannot be confirmed.
	• To patients who are at 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)
	  ○ uncontrolled diabetes
	  ○ patients who are immunocompromised.
	• In patients known to be immunosuppressed (accompanied by other clinical symptoms of blood disorders) including for example:
	  ○ A person 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 medicine that can cause blood disorders (e.g. neutropenia, agranulocytosis, thrombocytopenia) leading to infection and acute sore throat including cytotoxic drugs, carbimazole, clozapine etc
	  ○ A patient who is taking a disease-modifying anti-rheumatic drug (DMARD) e.g. sulfasalazine, methotrexate
	• To patients with a history of repeated episodes (>2 previous episodes) of Streptococcus A infection in the previous 6 months
	• If patients present with:

Criteria for exclusion continued[2]	○ Signs of airway obstruction (inability to swallow, drooling, stridor, hoarse voice, muffled voice, holding a tripod position). ○ Signs of marked systemic illness or sepsis. ○ Breathing difficulty. ○ Dehydration. ○ Severe neck pain and or stiffness. ○ Severe pain. ○ Persistent sore throat especially if unilateral. ○ Persistent change in voice. ○ Severe swallowing problems (dysphagia/ odynophagia). ○ Trismus or difficulty opening the jaw ○ Persistent mouth ulcer / lesions. ○ Masses / unilateral swelling. ○ Severe oral mucositis. ○ Rash (e.g. scarlet fever). ○ Suspected rare cause e.g. Kawasaki disease. ○ Symptoms of suppurative complications (e.g. otitis media, sinusitis, mastoiditis, peri-tonsillar abscess (quinsy), scarlet fever). • If the patient has Myasthenia Gravis – macrolides may aggravate weakness symptoms • If the patient has a history of or current Q-T prolongation • If the patient has a history of or current Ventricular cardiac arrhythmia including torsade de pointes. • If the patient has known or suspected electrolyte disturbances (hypokalaemia or hypomagnesaemia) • If the patient has Porphyria • If the patient has symptoms of diarrhoea and they have received an antibiotic within the previous 3 months • If the patient is also taking a contraindicated medicine (see drug interactions section for further detail) including:

Criteria for exclusion continued[2]	• Drugs that prolong the QT interval. See BNF for all drugs that can prolong the QT interval e.g.
	  ○ astemizole,
	  ○ cisapride,
	  ○ pimozide,
	  ○ terfenadine,
	  ○ domperidone
	• Erythromycin should not be given if the patient takes:
	  ○ ergotamine or dihydroergotamine,
	• Erythromycin should not be given if there is current or recent treatment (within last two weeks) with drugs that are inducers of CYP3A4 e.g.
	  ○ rifampicin
	  ○ phenytoin
	  ○ carbamazepine
	  ○ phenobarbital
	  ○ St. John's Wort
	• Erythromycin should not be given if the patient takes drugs that are known or suspected to affect circulating concentrations of erythromycin. Drugs that are metabolised by the Cytochrome P450 system which could be affected by erythromycin see Caution and Drug Interactions section
	• Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.
	• If the patient is taking concurrent antibiotic treatment
	• To patients who the pharmacist has assessed as not having capacity to understand the nature and purpose of treatment.
	• Where a request has been made by a third party on behalf of a patient.

Cautions (including relevant actions to be taken)	Please refer to the SmPC for erythromycin for full details of special warnings and precautions for use. **Hepatic failure** Hepatic dysfunction including increased liver enzymes and/or cholestatic hepatitis, with or without jaundice, has been infrequently reported with erythromycin. Some patients may have had pre-existing hepatic disease or

Cautions (including relevant actions to be taken) continued	may have been taking other hepatotoxic medicinal products. Patients should be advised to stop treatment and contact their doctor if signs and symptoms of hepatic disease develop, such as anorexia, jaundice, dark urine, pruritus, or tender abdomen. **Pseudomembranous colitis** Pseudomembranous colitis has been reported with nearly all antibacterial agents, including macrolides, 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 including erythromycin, 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) See BNF for further information **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. **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 a 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 manufacturers advice** **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 oral anticoagulants. Oral anticoagulants should not be used in pregnancy.

Cautions (including relevant actions to be taken) continued	**Diabetes** If a patient with diabetes is unsure of how to manage their condition when they are unwell or are not eating and drinking they should be advised to contact their GP or diabetic nurse. **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.** **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. **Patients must be referred to the 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 and apixaban, particularly to patients at high risk of bleeding **Calcium channel blockers (CCB's)** — due to an increased risk of hypotension, caution is advised with the concurrent use of macrolides and CCB's metabolised by CYP3A4 (such as verapamil, amlodipine, and diltiazem). **Breastfeeding** Erythromycin passes into breast milk in very small amounts and is unlikely to be harmful. It can cause some babies to have mild stomach upsets Long-term use may, as with other antibiotics, result in colonisation with increased numbers of non-susceptible bacteria and fungi. If superinfections occur, appropriate therapy should be instituted. Erythromycin interferes with the fluorometric determination of urinary catecholamines
Action to be taken if the individual is excluded or declines treatment	➢ Phone 999 immediately for anyone attending who has life-threatening symptoms such as stridor, breathing difficulty or dehydration that is associated with sore throat. ➢ If patient meets the exclusion criteria, refer to a medical practitioner. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination. Patients presenting with any of the following symptoms must be referred to an Emergency Department; - o Severe suppurative complications (e.g. peri-tonsillar abscess or cellulitis, parapharyngeal abscess,

Action to be taken if the individual is excluded or declines treatment continued	retropharyngeal abscess, or Lemierre syndrome) as there is a risk of airway compromise or rupture of the abscess. ○ Signs of being markedly systemically unwell and is at risk of immunosuppression. ○ Suspected Kawasaki disease. ○ Diphtheria: characteristic tonsillar or pharyngeal membrane. ○ Signs of being profoundly unwell and the cause is unknown or a rare cause is suspected, for example: Stevens–Johnson syndrome or Yersinial pharyngitis ➢ 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 or guardian) intended actions ➢ Patients may be provided with advice and symptomatic treatment for the All Wales Common Ailments Service Formulary
Further advice	➢ If there is any doubt about the administration of the medication or patient's fitness or suitability to receive the medication, a doctor should be consulted. ➢ Refer to SmPC, BNF and the All Wales Common Ailments Service

2. Description of treatment

Name, strength & formulation of drug	Erythromycin 250mg tablets
Legal category	POM – Prescription Only Medicine
Black triangle▼	No
Off-label use	No
Route / method of administration	Oral
Dose and frequency of administration	TWO tablets (500mg) to be taken FOUR times daily for FIVE days
Duration of treatment	This PGD only allows for the duration stated in the dosage schedule above.
Quantity to be supplied/administered	Appropriately labelled pack(s) to provide FIVE days treatment ➢ 40 x 250mg tablets
Storage	Medicines must be stored securely and in accordance with product SmPC
Disposal	No special requirements
Drug interactions	The following list is not exhaustive. A detailed list of drug interactions can be found in the SmPC and the BNF. **Contraindications** Please note many drugs listed are contraindicated in pregnancy but have been included for completeness. Concurrent treatment with: ➢ Drugs that prolong the QT interval (see BNF for all drugs that can prolong QT interval) including: ○ amisulpride, ○ astemizole, ○ cisapride, ○ dronedarone, ○ mizolastine, ○ pimozide, ○ terfenadine, ○ tolterodine, ○ domperidone ➢ ergotamine or dihydroergotamine ➢ Drugs that are inducers of CYP3A4 (e.g. rifampicin, phenytoin, carbamazepine, phenobarbital, St John's Wort may induce the

	metabolism of erythromycin. Erythromycin should not be used during and two weeks after treatment with CYP3A4 inducers. ➢ Anti-bacterial agents: an in vitro antagonism exists between erythromycin and the bactericidal beta-lactam antibiotics (e.g. penicillin, cephalosporin). Erythromycin antagonises the action of clindamycin, lincomycin and chloramphenicol. The same applies for streptomycin, tetracyclines and colistin. ➢ Theophylline ➢ Hydroxychloroquine and chloroquine ➢ drugs are known or suspected to affect or be affected by circulating concentrations of erythromycin, including: ○ Colchicine ○ Protease inhibitors ○ Zopiclone **Cautions** Erythromycin should be used with caution in patients also prescribed the following drugs. ➢ HMG-CoA reductase inhibitors (statins) - Patients that are currently taking a 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). ➢ Oral hypoglycaemic agents/Insulin - Careful monitoring of glucose is recommended. ➢ Oral anticoagulants - Patients must be referred to the clinic responsible for INR monitoring within 3 days of starting erythromycin treatment. ➢ Calcium channel blockers (CCB's) - due to an increased risk of hypotension, caution is advised with the concurrent use of macrolides and CCB's metabolised by CYP3A4 (such as verapamil, amlodipine, and diltiazem). ➢ medicinal products that can cause hypokalaemia (e.g. corticosteroids, diuretics) ➢ Contraceptives ➢ Cimetidine may inhibit the metabolism of erythromycin which may lead to an increased plasma concentration. ➢ Drugs that are metabolised by the cytochrome P450 system: including: acenocoumarol, alfentanil, bromocriptine, cilostazol, cyclosporin, digoxin, disopyramide, hexobarbitone, methylprednisolone, omeprazole, quinidine, rifabutin, sildenafil, tacrolimus, valproate, vinblastine and antifungals e.g. fluconazole, ketoconazole and itraconazole ➢ Triazolobenzodiazepines such as triazolam, alprazolam and midazolam
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SmPC, and the BNF 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 are very common to common (affecting between 1 in 10 and 1 in 100 patients) with erythromycin (and does not reflect all reported side effects): ○ Abdominal pain/discomfort ○ Nausea ○ Vomiting ○ Diarrhoea Other side effects reported: ○ Cholestatic hepatitis with or without jaundice ○ Hepatotoxicity ○ Rash ○ Low blood pressure ○ Visual impairment or blurred vision ○ Hallucinations ○ Confusion ○ Problems with balance or feeling dizzy ○ Antibiotic associated colitis ○ Arrythmias ○ Pancreatitis ○ QT interval prolongation ○ Steven Johnson syndrome ○ Toxic epidermal necrolysis ○ Hypersensitivity /allergic reactions ranging from urticaria to anaphylaxis have occurred Frequency not known ○ Reversible hearing loss (sometimes with tinnitus) can occur after large doses
Reporting procedure of adverse reactions	Any adverse reaction to the product should be documented in the individual's medical records. Alert a doctor in the event of a serious adverse reaction. Report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme.
Written information to be given to individual or their carer	➢ Supply the marketing authorisation holder's patient information leaflet (PIL).

Patient or carer advice/follow up	Inform the individual or their carer: ➢ The tablets should be swallowed whole with a glass of water ➢ The tablets should not be crushed or chewed ➢ if they get any side effects, to talk to their doctor, or pharmacist or nurse. This includes any possible side effects not listed in the PIL ➢ to discontinue treatment and seek medical advice in the event of a severe adverse reaction ➢ to seek medical attention immediately if their condition deteriorates and or the patient becomes systemically unwell ➢ 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 ➢ to seek medical advice if their condition deteriorates and/or they become systemically unwell or if their symptoms do not improve ➢
Special considerations / additional information	Inform the individual or their carer: ➢ That the condition is self-limiting and is likely to get better within 7 days, with or without antibiotic treatment. ➢ To seek further healthcare advice if symptoms do not improve within 7 days or worsen. ➢ That taking simple analgesics will help temperature and discomfort. ➢ To take painkillers at regular intervals to relieve pain and fever. ➢ That adults and older children may find sucking throat lozenges, ice cubes or flavoured frozen desserts (e.g. ice lollies) provides symptomatic relief. ➢ That they can try medicated lozenges to help reduce 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 avoiding 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. ➢ That 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. ➢ If they are breastfeeding they can continue. Erythromycin 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 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. 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 must be recorded in Choose Pharmacy as prompted at the time of the consultation. Where the Choose Pharmacy platform is not available records, must be made to document the consultation, using the paper-based consultation record. Paper based records must be transferred onto the Choose Pharmacy Sore Throat Test and Treat module as soon as practically possible and by the end of the next working day. ➢ All records, electronically or otherwise must be kept in accordance with NHS record keeping and Community Pharmacy Information Governance requirements see https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/information-governance-alliance-iga ➢ All records should be clear, legible and contemporaneous. ➢ If the patient is excluded, a record of the reason for exclusion must be documented within Choose Pharmacy, and any specific advice that has been given ➢ The consultation summary must be forwarded to the patient's GP within 72 hours of making the supply. Where practically possible summaries should be returned to local practices within 24 hours, particularly where an antibiotic has been supplied. ➢ All supplies of antibiotic must be labelled in accordance with the labelling requirements for a dispensed medicine as stated within Schedule 5 of The Medicines (Marketing Authorisations etc) Regulations 1994. No 3144 as amended A record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes in accordance with local policy. For pregnant women record the antibiotic supplied in the hand-held maternity record (if available)

PGD for the supply of erythromycin ethylsuccinate 250mg/5mL or 500mg/5mL oral suspension or erythromycin ethylsuccinate 250mg/5mL or 500mg/5mL sugar-free oral suspension.

1. Clinical condition

Clinical condition or situation to which this PGD applies	For the treatment of individuals with painful, inflamed throat, which makes swallowing difficult, where the use of penicillin is contraindicated AND they are pregnant in accordance with the community pharmacy Sore Throat Test and Treat component of the clinical community pharmacy service
Criteria for inclusion	Erythromycin oral suspension 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 is contraindicated **AND they**: ➢ Have a FeverPAIN score of 2 or above **OR** ➢ They have a Centor Score of 3 or above **AND** ➢ Have a positive result from a Rapid Antigen Point of Care Test (POCT) for Streprococcus A infection **AND** ➢ They are unable to swallow tablets ➢ They have no contraindications to erythromycin ➢ They have given informed consent
Criteria for exclusion[2]	Erythromycin oral suspension should not be given: ➢ **Red Flag Symptoms:** ○ To anyone attending who has life-threatening symptoms such as stridor, breathing difficulty or dehydration that is associated with sore throat. Phone 999 immediately ○ To individuals with persistent symptoms (lasting > 2 weeks) and/or severe symptoms which may be indicative of more serious disease, such as cancer. Smoking and alcohol are risk factors that should be considered as part of clinical assessment. ➢ Where informed consent has not been given. Where patients do not agree to share relevant clinical information or there is no valid consent ➢ In patients with a known or suspected hypersensitivity to erythromycin or other macrolide antibiotics – see SmPC ➢ In patients with a known or suspected hypersensitivity to any of the suspension excipients

[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

Criteria for exclusion continued[2]	Erythromycin oral suspension should not be given:
	• If patients can swallow tablets.
	• If children are under 13 years of age
	• In patients with known or suspected hepatic impairment or people concomitantly receiving potentially hepatotoxic drugs
	• In patients currently on phenoxymethylpenicillin treatment
	• In patients with moderate, severe or end stage renal failure (creatinine clearance <60mL/min) or patients with renal disease where renal function cannot be confirmed.
	• To patients who are at 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)
	  ○ uncontrolled diabetes
	  ○ patients who are immunocompromised.
	• In patients known to be immunosuppressed (accompanied by other clinical symptoms of blood disorders) including for example:
	  ○ A person 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 medicine that can cause blood disorders (e.g. neutropenia, agranulocytosis, thrombocytopenia) leading to infection and acute sore throat including cytotoxic drugs, carbimazole, clozapine etc
	  ○ A patient who is taking a disease-modifying anti-rheumatic drug (DMARD) e.g. sulfasalazine, methotrexate
	• To patients with a history of repeated episodes (>2 previous episodes) of Streptococcus A infection in the previous 6 months
	• If patients present with:

Criteria for exclusion continued[2]	○ Signs of airway obstruction (inability to swallow, drooling, stridor, hoarse voice, muffled voice, holding a tripod position). ○ Signs of marked systemic illness or sepsis. ○ Breathing difficulty. ○ Dehydration. ○ Severe neck pain and or stiffness. ○ Severe pain. ○ Persistent sore throat especially if unilateral. ○ Persistent change in voice. ○ Severe swallowing problems (dysphagia/ odynophagia). ○ Trismus or difficulty opening the jaw ○ Persistent mouth ulcer / lesions. ○ Masses / unilateral swelling. ○ Severe oral mucositis. ○ Rash (e.g. scarlet fever). ○ Suspected rare cause e.g. Kawasaki disease. ○ Symptoms of suppurative complications (e.g. otitis media, sinusitis, mastoiditis, peri-tonsillar abscess (quinsy), scarlet fever). • If the patient has Myasthenia Gravis – macrolides may aggravate weakness symptoms • If the patient has a history of or current Q-T prolongation • If the patient has a history of or current Ventricular cardiac arrhythmia including torsade de pointes. • If the patient has known or suspected electrolyte disturbances (hypokalaemia or hypomagnesaemia) • If the patient has Porphyria • If the patient has symptoms of diarrhoea and they have received an antibiotic within the previous 3 months • If the patient is also taking a contraindicated medicine (see drug interactions section for further detail) including:

Criteria for exclusion continued[2]	• Drugs that prolong the QT interval. See BNF for all drugs that can prolong the QT interval e.g.
	  ○ astemizole,
	  ○ cisapride,
	  ○ pimozide,
	  ○ terfenadine,
	  ○ domperidone
	• Erythromycin should not be given if the patient takes:
	  ○ ergotamine or dihydroergotamine,
	• Erythromycin should not be given if there is current or recent treatment (within last two weeks) with drugs that are inducers of CYP3A4 e.g.
	  ○ rifampicin
	  ○ phenytoin
	  ○ carbamazepine
	  ○ phenobarbital
	  ○ St. John's Wort
	• Erythromycin should not be given if the patient takes drugs that are known or suspected to affect circulating concentrations of erythromycin. Drugs that are metabolised by the Cytochrome P450 system which could be affected by erythromycin see Caution and Drug Interactions section
	• Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.
	• If the patient is taking concurrent antibiotic treatment
	• To patients who the pharmacist has assessed as not having capacity to understand the nature and purpose of treatment.
	• Where a request has been made by a third party on behalf of a patient.

Cautions (including relevant actions to be taken)	Please refer to the SmPC for erythromycin for full details of special warnings and precautions for use. **Hepatic failure** Hepatic dysfunction including increased liver enzymes and/or cholestatic hepatitis, with or without jaundice, has been infrequently reported with erythromycin. Some patients may have had pre-existing hepatic disease or

Cautions (including relevant actions to be taken) continued	may have been taking other hepatotoxic medicinal products. Patients should be advised to stop treatment and contact their doctor if signs and symptoms of hepatic disease develop, such as anorexia, jaundice, dark urine, pruritus, or tender abdomen. **Pseudomembranous colitis** Pseudomembranous colitis has been reported with nearly all antibacterial agents, including macrolides, 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 including erythromycin, 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) See BNF for further information **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. **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 a 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 manufacturers advice** **Diabetes** If a patient with diabetes is unsure of how to manage their condition when they are unwell or are not eating and drinking they should be advised to contact their GP or diabetic nurse.

Cautions (including relevant actions to be taken) continued	**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.** **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. **Patients must be referred to the 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 and apixaban, particularly to patients at high risk of bleeding **Calcium channel blockers (CCB's)** — due to an increased risk of hypotension, caution is advised with the concurrent use of macrolides and CCB's metabolised by CYP3A4 (such as verapamil, amlodipine, and diltiazem). **Breastfeeding** Erythromycin passes into breast milk in very small amounts and is unlikely to be harmful. It can cause some babies to have mild stomach upsets **Sucrose** ➢ Erythromycin oral suspension may contain sucrose ➢ To be taken into consideration by patients with diabetes mellitus. ➢ May be harmful to the teeth Long-term use may, as with other antibiotics, result in colonisation with increased numbers of non-susceptible bacteria and fungi. If superinfections occur, appropriate therapy should be instituted. Erythromycin interferes with the fluorometric determination of urinary catecholamines
Action to be taken if the individual is excluded or declines treatment	➢ Phone 999 immediately for anyone attending who has life-threatening symptoms such as stridor, breathing difficulty or dehydration that is associated with sore throat. ➢ If patient meets the exclusion criteria, refer to a medical practitioner. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical

Action to be taken if the individual is excluded or declines treatment continued	examination. Patients presenting with any of the following symptoms must be referred to an Emergency Department; - ○ Severe suppurative complications (e.g. peri-tonsillar abscess or cellulitis, parapharyngeal abscess, retropharyngeal abscess, or Lemierre syndrome) as there is a risk of airway compromise or rupture of the abscess. ○ Signs of being markedly systemically unwell and is at risk of immunosuppression. ○ Suspected Kawasaki disease. ○ Diphtheria: characteristic tonsillar or pharyngeal membrane. ○ Signs of being profoundly unwell and the cause is unknown or a rare cause is suspected, for example: Stevens–Johnson syndrome or Yersinial pharyngitis ➢ 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 or guardian) intended actions ➢ Patients may be provided with advice and symptomatic treatment for the All Wales Common Ailments Service Formulary
Further advice	➢ If there is any doubt about the administration of the medication or patient's fitness or suitability to receive the medication, a doctor should be consulted. ➢ Refer to SmPC, BNF and the All Wales Common Ailments Service

2. Description of treatment

Name, strength & formulation of drug	Erythromycin 250mg/5mL or 500mg/5mL oral suspension Erythromycin 250mg/5mL or 500mg/5mL sugar-free oral suspension
Legal category	POM – Prescription Only Medicine
Black triangle▼	No
Off-label use	No
Route / method of administration	Oral Follow the instructions for reconstitution
Dose and frequency of administration	When supplying the 250mg/5mL formulation: 500mg (TWO 5mL spoonful) to be taken every SIX hours (FOUR times daily) for FIVE days When supplying the 500mg/5mL formulation: 500mg (One 5mL spoonful) to be taken every SIX hours (FOUR times daily) for FIVE days
Duration of treatment	This PGD only allows for the duration stated in the dosage schedule above.
Quantity to be supplied/administered	Supplying the 250mg/5mL formulation: Supply appropriately labelled packs to provide FIVE days treatment: ➢ 2 original packs Erythromycin ethylsuccinate 250mg/5mL oral suspension **OR** ➢ 2 original packs Erythromycin ethylsuccinate 250mg/5mL sugar-free oral suspension Supplying the 500mg/5mL formulation: Supply an appropriately labelled pack to provide FIVE days treatment: ➢ 1x original pack Erythromycin ethylsuccinate 500mg/5mL oral suspension **OR** ➢ 1 original pack Erythromycin ethylsuccinate 500mg/5mL sugar-free oral suspension
Storage	Medicines must be stored securely and in accordance with product SmPC Following reconstitution: store as per manufacturer's instructions (SmPC)
Disposal	No special requirements
Drug interactions	The following list is not exhaustive. A detailed list of drug interactions can be found in the SmPC and the BNF.

	Contraindications Please note many drugs listed are contraindicated in pregnancy but have been included for completeness. Concurrent treatment with: ➢ Drugs that prolong the QT interval (see BNF for all drugs that can prolong QT interval) including: ○ amisulpride, ○ astemizole, ○ cisapride, ○ dronedarone, ○ mizolastine, ○ pimozide, ○ terfenadine, ○ tolterodine, ○ domperidone ➢ ergotamine or dihydroergotamine ➢ Drugs that are inducers of CYP3A4 (e.g. rifampicin, phenytoin, carbamazepine, phenobarbital, St John's Wort may induce the metabolism of erythromycin. Erythromycin should not be used during and two weeks after treatment with CYP3A4 inducers. ➢ Anti-bacterial agents: an in vitro antagonism exists between erythromycin and the bactericidal beta-lactam antibiotics (e.g. penicillin, cephalosporin). Erythromycin antagonises the action of clindamycin, lincomycin and chloramphenicol. The same applies for streptomycin, tetracyclines and colistin. ➢ Theophylline ➢ Hydroxychloroquine and chloroquine ➢ drugs are known or suspected to affect or be affected by circulating concentrations of erythromycin, including: ○ Colchicine ○ Protease inhibitors ○ Zopiclone **Cautions** Erythromycin should be used with caution in patients also prescribed the following drugs. ➢ HMG-CoA reductase inhibitors (statins) - Patients that are currently taking a 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). ➢ Oral hypoglycaemic agents/Insulin - Careful monitoring of glucose is recommended. ➢ Oral anticoagulants - Patients must be referred to the clinic responsible for INR monitoring within 3 days of starting erythromycin treatment. ➢ Calcium channel blockers (CCB's) - due to an increased risk of hypotension, caution is advised with the concurrent use of macrolides and CCB's metabolised by CYP3A4 (such as verapamil, amlodipine, and diltiazem).

	➢ medicinal products that can cause hypokalaemia (e.g. corticosteroids, diuretics) ➢ Contraceptives ➢ Cimetidine may inhibit the metabolism of erythromycin which may lead to an increased plasma concentration. ➢ Drugs that are metabolised by the cytochrome P450 system: including: acenocoumarol, alfentanil, bromocriptine, cilostazol, cyclosporin, digoxin, disopyramide, hexobarbitone, methylprednisolone, omeprazole, quinidine, rifabutin, sildenafil, tacrolimus, valproate, vinblastine and antifungals e.g. fluconazole, ketoconazole and itraconazole ➢ Triazolobenzodiazepines such as triazolam, alprazolam and midazolam
Identification & management of adverse reactions	The following list of adverse effects is not exhaustive. A detailed list of adverse reactions is available in the SmPC, and the BNF Advise the patient that if any of the following side effects occur, discontinue treatment immediately and contact the emergency department or dial 999: o A red scaly rash with bumps under the skin and blisters (exanthematous pustulosis) o Difficulty breathing o Fainting o Swelling of the face, lips or throat o Skin rashes o Severe skin reactions including large fluid filled blisters, sores and ulcers o Ulcers in the mouth or throat The following side effects are very common to common (affecting between 1 in 10 and 1 in 100 patients) with erythromycin (and does not reflect all reported side effects): o Abdominal pain/discomfort o Nausea o Vomiting o Diarrhoea Other side effects reported: o Cholestatic jaundice with or without jaundice o Hepatotoxicity o Rash o Low blood pressure o Visual impairment or blurred vision o Hallucinations o Confusion o Problems with balance or feeling dizzy o Antibiotic associated colitis o Arrythmias o Pancreatitis o QT interval prolongation o Steven Johnson syndrome o Toxic epidermal necrolysis

	○ Hypersensitivity /allergic reactions ranging from urticaria to anaphylaxis have occurred Frequency not known ○ Reversible hearing loss (sometimes with tinnitus) can occur after large doses
Reporting procedure of adverse reactions	Any adverse reaction to the product should be documented in the individual's medical records. Alert a doctor in the event of a serious adverse reaction. Report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme.
Written information to be given to individual or their carer	➢ Supply the marketing authorisation holder's patient information leaflet (PIL).
Patient or carer advice/follow up	Inform the individual or their carer: ➢ The suspension should be shaken well before each use ➢ It can be given with or after food ➢ if they get any side effects, to talk to their doctor, or pharmacist or nurse. This includes any possible side effects not listed in the PIL ➢ to discontinue treatment and seek medical advice in the event of a severe adverse reaction ➢ to seek medical attention immediately if their condition deteriorates and or the patient becomes systemically unwell ➢ 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 ➢ to seek medical advice if their condition deteriorates and/or they become systemically unwell or if their symptoms do not improve ➢
Special considerations / additional information	Inform the individual or their carer: ➢ That the condition is self-limiting and is likely to get better within 7 days, with or without antibiotic treatment. ➢ To seek further healthcare advice if symptoms do not improve within 7 days or worsen. ➢ That taking simple analgesics will help temperature and discomfort. ➢ To take painkillers at regular intervals to relieve pain and fever. ➢ That adults and older children may find sucking throat lozenges, ice cubes or flavoured frozen desserts (e.g. ice lollies) provides symptomatic relief. ➢ That they may wish to try medicated lozenges to help reduce 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. ➢ That 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 ➢ If they are breastfeeding they can continue. Erythromycin 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 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 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 must be recorded in Choose Pharmacy as prompted at the time of the consultation. Where the Choose Pharmacy platform is not available records, must be made to document the consultation, using the paper-based consultation record. Paper based records must be transferred onto the Choose Pharmacy Sore Throat Test and Treat module as soon as practically possible and by the end of the next working day. ➢ All records, electronically or otherwise must be kept in accordance with NHS record keeping and Community Pharmacy Information Governance requirements see https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/information-governance-alliance-iga ➢ All records should be clear, legible and contemporaneous. ➢ If the patient is excluded, a record of the reason for exclusion must be documented within Choose Pharmacy, and any specific advice that has been given ➢ The consultation summary must be forwarded to the patient's GP within 72 hours of making the supply. Where practically possible summaries should be returned to local practices within 24 hours, particularly where an antibiotic has been supplied. ➢ All supplies of antibiotic must be labelled in accordance with the labelling requirements for a dispensed medicine as stated within Schedule 5 of The Medicines (Marketing Authorisations etc) Regulations 1994. No 3144 as amended A record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes in accordance with local policy. For pregnant women record the antibiotic supplied in the hand-held maternity record (if available)

Appendices

Appendix A: *Key references*

- Summary Product Characteristics SmPC. Available from: Home - electronic medicines compendium (emc) (last accessed on 19th September 2022) (https://www.medicines.org.uk)
- Patient Group Directions. Medicines practice guideline [MPG2] Published August 2013 last updated March 2017. http://www.nice.org.uk/guidance/mpg2/resources (last accessed 19th September 2022)
- Current edition of BNF. Available at: BNF British National Formulary - NICE (last accessed on 19th September 2022) (https://bnf.org.uk)
- GPhC In Practice: Guidance on Consent 2018. Available at: https://www.pharmacyregulation.org/sites/default/files/document/in_practice_guidance_on_consent_june_2018.pdf (last accessed 19th September 2022)
- GPhC in Practice: Guidance on confidentiality 2018. Available at: https://www.pharmacyregulation.org/sites/default/files/document/in_practice_guidance_on_confidentiality_june_2018.pdf (last accessed 19th September 2022)
- Clinical Knowledge Summaries Sore Throat – acute. Last revised January 2021 Available from https://cks.nice.org.uk (last accessed 19th September 2022)
- BMJ Best Practice. Acute pharyngitis. Last reviewed 16th August 2022 last updated 29th June 2022 Available from https://bestpractice.bmj.com (last accessed 19th September 2022)
- Management of Sore Throat and Indications for tonsillectomy – SIGN guidance 117 April 2010 Available from https://www.sign.ac.uk (last accessed 19th September 2022)
- AWMSG All Wales Common Ailments Formulary. February 2018 Common ailments formulary - All Wales Therapeutics and Toxicology Centre (nhs.wales) https://awttc.nhs.wales (last accessed 19th September 2022)
- NICE Guideline NG84 Sore throat (acute): antimicrobial prescribing, January 2018 https://www.nice.org.uk/guidance/ng84/chapter/Recommendations#managing-acute-sore-throat (last accessed 14th September 2022)
- Patient UK. Sore Throat Cause, Symptoms and Treatment. 24th May 2022. Available from https://patient.info (last accessed 14th September 2022)
- BMJ Best Practice. Tonsillitis. Last reviewed 20 August 2022 last updated 12 October 2021 Available from https://bestpractice.bmj.com (last accessed 14th September 2022)
- Yellow Card Reporting site. http://yellowcard.mhra.gov.uk
- NHS 111 Wales Health A-Z Sore Throat Last updated 10th June 2022 Available from NHS 111 Wales (last accessed 19th September 2022) (https://111.wales.nhs.uk
- NHS Medicines A-Z. Last update 26th January 2022. (last accessed 19th September 2022). (https://www.nhs.uk)

Appendix B: *Healthcare Professionals Agreement to Practice*

Authorisation for the use of the Patient Group Direction for the Supply of:
Phenoxymethylpenicillin, clarithromycin and erythromycin by community pharmacists under the Clinical Community Pharmacy Service: Sore Throat Test and Treat service commissioned by

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

A signed copy of this form must also be returned to:
Primary Care Services, Floor 3, Matrix House, Northern Boulevard, Matrix Park,
Swansea Enterprise Park,
Swansea
SA6 8BX

E-mail: nwssp-primarycareservices@wales.nhs.uk
Fax: 01792 860481