Patient Group Direction (PGD)
Supply of Clarithromycin for sore throat via the Pharmacy First Service

Version v01.01

Valid from November 2023 to end November 2025*

Review date November 2025

*(*or earlier in event of changes to any related guidance or withdrawal of Pharmacy First Service)*

This patient group direction must be agreed to and signed by all pharmacists involved in its use. The PGD must be easily accessible in the community pharmacy.

Purpose of this Patient Group Direction

This PGD covers the supply of Clarithromycin via the SPPG Pharmacy First Service for the management of sore throats.

The Pharmacy First Service is available from community pharmacies in Northern Ireland contracted to provide the service.

Change History

Version number	Change details	Date
V01.01	➢ New SPPG PGD template for the supply of Clarithromycin via the Pharmacy First Service	14/09/2023

Patient Group Direction (PGD) for supply/administration of

Clarithromycin	POM

Staff Characteristics

Qualifications	Pharmacists currently registered with the Pharmaceutical Society of Northern Ireland
Specialist competencies or qualifications	Pharmacists must: 1. Be working as a community pharmacist in a pharmacy contracted to provide the Pharmacy First Service. 2. Be familiar with the relevant Summary of Product Characteristics for the medicines that may be supplied via this Patient Group Direction (PGD). 3. Be familiar with and adhere to relevant Pharmaceutical Society of Northern Ireland standards and guidance 4. Have completed all the required training modules/courses outlined in the service specification and guidance. The pharmacists must be able to assess the person's capacity to understand the nature and purpose of the medication in order to provide informed consent. All pharmacists are personally accountable for their practice and must be competent to work under PGD. In the exercise of professional accountability there is a requirement to maintain and improve professional knowledge and competence. Under PGD legislation there can be no delegation. Supply of the medication has to be by the same practitioner who has assessed the patient under this PGD.
Continuing training & education	The pharmacist should be aware of any change to the recommendations for the medicines that may be supplied via this PGD. **The community pharmacist must provide the service in accordance with the requirements of the associated Service Specification and Guidance** available at https://hscbusiness.hscni.net/services/2800.htm It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice.

Patient Group Direction (PGD) for supply/administration of

Clarithromycin	POM

Clinical Condition or situation to which this PGD applies

Clinical Condition or situation to which this PGD applies	For the treatment of patients with painful, inflamed throat, which makes swallowing difficult, where the use of phenoxymethylpenicillin and amoxycillin is contraindicated OR unavailable, in accordance with the Pharmacy First Sore Throat service.
Criteria for inclusion	Clarithromycin can be given to: Adults and children aged 5 years and over presenting with symptoms of acute uncomplicated sore throat and: ➢ They have a FeverPain score of 2 or above **AND** ➢ A positive result from a Rapid Antigen Point of Care Test (POCT) for Streptococcus A infection ➢ The use of phenoxymethylpenicillin and amoxicillin is contraindicated OR ➢ Phenoxymethylpenicillin and amoxicillin are unavailable ➢ They have no contraindications to clarithromycin and macrolide type antibiotics ➢ Informed consent has been given
Criteria for exclusion[1]	Clarithromycin 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 patients 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 ➢ To children aged 4 years and under ➢ To patients with a known hypersensitivity to clarithromycin or any excipients – see SmPC ➢ Clarithromycin oral suspension should not be given to 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: ○ significant heart, lung, kidney, liver, or neuromuscular

[1] 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

disease (including patients with a history of valvular heart disease, rheumatic fever, post-streptococcal glomerular nephritis)
    - uncontrolled diabetes
    - patients who are immunocompromised.
- To patients with known or suspected pregnancy
- To patients who are breastfeeding
- To patients known to be immunosuppressed (accompanied by other clinical symptoms of blood disorders) including for example:
    - A patient who is on chemotherapy, radiotherapy, has known or suspected leukaemia, asplenia, aplastic anaemia or HIV/AIDS, or is taking an immunosuppressive drug following a transplant.
    - A patient who is taking a disease-modifying anti-rheumatic drug (DMARD) e.g. sulfasalazine, methotrexate
    - A patient who is taking a medicine that can cause blood disorders (e.g. neutropenia, agranulocytosis, thrombocytopenia) leading to infection and acute sore throat including cytotoxic drugs, carbimazole, clozapine etc.
- To patients with a history of repeated episodes (> 2 previous episodes) of Streptococcus A infection in 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). ➢ 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 taking concurrent antibiotic treatment. ➢ 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. ○ astemizole ○ cisapride ○ pimozide ○ terfenadine ○ domperidone • Clarithromycin should not be given if the patient takes: ○ ergotamine or dihydroergotamine ○ 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. ○ rifampicin ○ phenytoin ○ carbamazepine ○ phenobarbital ○ 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 Drug Interactions section. ➢ 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 any relevant action to be taken)	Please refer to the SmPC for clarithromycin for full details of special warnings and precautions for use. **Hypersensitivity Reactions** ➢ In the event of severe acute hypersensitivity reactions, such as

anaphylaxis, severe cutaneous adverse reactions (SCAR) (e.g. Acute generalised exanthematous pustulosis (AGEP), Stevens-Johnson Syndrome, toxic epidermal necrolysis, and drug rash with eosinophilia and systemic symptoms (DRESS) clarithromycin therapy should be discontinued immediately and appropriate treatment should be urgently initiated.

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.

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.

HMG-CoA reductase inhibitors (statins)

- Caution should be exercised when prescribing macrolides with statins. Rhabdomyolysis has been reported in patients taking macrolides and statins. Patients should be monitored for signs and symptoms of myopathy.
- **Patients that are currently taking a 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.**

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.

Pseudomembranous colitis

- Pseudomembranous colitis has been reported with nearly all antibacterial agents and may range in severity from mild to life-threatening.
- Clostridioides difficile-associated diarrhoea (CDAD) has been reported with use of nearly all antibacterial agents, and may range in severity from mild diarrhoea to fatal colitis.
- Drugs inhibiting peristalsis should be avoided.

Phenylketonuria and clarithromycin oral suspension

- Clarithromycin oral suspension may contain aspartame (E951), a source of phenylalanine. This medicine should be used with caution in patients with phenylketonuria.

Sucrose and clarithromycin oral suspension

- Clarithromycin oral suspension may contain sucrose

	➢ To be taken into consideration in patients with diabetes ➢ May be harmful to teeth
Action to be taken if 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 the 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 patient and document in the consultation record. ➢ If the patient declines treatment; 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 from the analgesic section of the 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 and BNF.

Description of treatment

Name, form & strength of medicine	• Clarithromycin 500mg tablets • Clarithromycin 125mg / 5ml oral suspension • Clarithromycin 250mg / 5ml oral suspension
Legal category	POM - Prescription only medicine

Patient Group Direction (PGD) for supply/administration of

Clarithromycin	POM

Indicate any off-label use **(if relevant)**	• Clarithromycin oral suspension – **No off-label use** • Clarithromycin tablets – **Yes** If the patient is unable to swallow tablets AND clarithromycin oral suspension is unavailable the tablets may be dispersed in water OR crushed and mixed with liquid or soft food. See Specialist Pharmacy Service (SPS) guidance for patients with swallowing difficulties for further advice. It is important to note the following: ○ administration in this way is off-label (used outside of the product licence). ○ when crushing tablets or opening capsules, caution should be exercised on handling the antibiotic powder produced to avoid contact sensitisation or inhalation. Safety measures that should be used include: ○ use a closed system e.g. dispersing a tablet in the barrel of a syringe. ○ wear gloves to reduce contact with the skin, and a mask to prevent dust inhalation. ○ sensitisation is a risk with all of the antibiotics but may be of particular concern with penicillins. Parents/carers with clarithromycin allergy should avoid involvement in preparing and administering the tablets this way.
Route / Method of administration	**Oral** ➢ Clarithromycin tablets should be swallowed whole with water. If being supplied in cases where the liquid formulation is not available, see Specialist Pharmacy Service (SPS) guidance for patients with swallowing difficulties for guidance on dispersing or crushing and mixing with liquid or soft food. ➢ Clarithromycin oral suspension: follow the instructions for reconstitution
Dose and frequency of administration	**Adults and children aged 12 years and over:** One (500mg) tablet to be taken TWICE daily for FIVE days **OR** 500mg (10ml of 250mg/5ml oral suspension) TWICE daily for FIVE days **For children aged 5 -11 years the dose is calculated by weight**

Weight in Kg / approximate age	Dose in mg	Volume/ strength of oral suspension

	12kg-19kg (3-6 years)	125mg	5ml (125mg/5ml)
	20kg-29kg (7-9 years)	187.5mg	7.5ml (125mg/5ml)
	30kg-40kg (10-11 years)	250mg	5ml (250mg/5ml)
	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	Appropriately labelled packs to provide treatment for FIVE days: **10 x 500MG tablets OR oral suspension as per table below**

Strength to supply	Dose	Quantity to supply
125mg/5ml	5ml twice a day	1 x 70ml
125mg/5ml	7.5ml twice a day	2 x 70ml
250mg/5ml	5ml twice a day	1 x 70ml
250mg/5ml	10ml twice a day	2 x 70ml

Storage	Medicines must be stored securely and in accordance with product SmPC Tablets: no special storage instructions Reconstituted oral suspension: Store below 25ºC, do not refrigerate and use within 14 days
Disposal	Advise return of any unused medication to community pharmacy for safe disposal
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** ➢ Typhoid vaccine (oral): Antibacterial agents may inactivate oral typhoid vaccine if ingested concomitantly. Avoid where recent vaccination or vaccination due. ➢ 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 for use

Clarithromycin should be used with caution in patients also prescribed:

- HMG-CoA reductase inhibitors (statins) - Patients that are currently taking a 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: 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. ➢ Advise the patient to contact a doctor if any of the following occur: o Diarrhoea that is serious, prolonged or has blood in it o Severe stomach pain o Fever o Loss of appetite o Yellowing of the skin and eyes o Pale stools, dark urine o Itchy rash o Abdominal pain o Palpitations or irregular heart beat ➢ Very common to common adverse effects (affecting between 1 in 10 and 1 in 100 patients): o Appetite decreased; diarrhoea; dizziness; gastrointestinal discomfort; gastrointestinal disorders; headache; hearing impairment; insomnia; nausea; pancreatitis; paraesthesia; skin reactions; taste altered; vasodilation; vision disorders; vomiting. ➢ Uncommon adverse effects (affecting between 1 in 100 and 1 in 1000 patients): o 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 or very rare adverse effects (affecting between 1 in 1000 and 1 in 10,000 patients) ○ Antibiotic associated colitis; myasthenia gravis; nephritis tubulointerstitial ○ Superficial tooth discolouration has been reported in children taking clarithromycin oral suspension. Good oral hygiene may help to prevent tooth discolouration as it can usually be removed by brushing. ➢ Adverse effects with unknown frequency: ○ Hallucination; hypotension; seizure; smell altered; thrombocytopenia; tongue discolouration; abnormal dreams; agranulocytosis; depersonalisation; depression; mania; myopathy; psychotic disorder; renal failure; tooth discolouration; urine discolouration.
Management of and reporting procedure for adverse reactions	Any adverse reaction to the product should be documented in the patient's medical record (PMR). 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 other information to be given to individual or carer	➢ Supply the marketing authorisation holder's patient information leaflet (PIL). ➢ Supply the PIL for parents and carers on using solid dosage forms of antibiotics for children ➢ Provide all patients/carers with a copy of the TARGET PIL
Individual advice / follow up	Inform the patient or their carer: ➢ The tablets should be swallowed whole with a full glass of water ➢ Clarithromycin can be taken irrespective of food intake ➢ If the patient can't swallow tablets and the liquid is unavailable the tablets can be dispersed in liquid or crushed and mixed with liquid or soft food. ➢ The oral suspension should be shaken well before each dose ➢ The importance of good oral hygiene to prevent tooth discolouration when taking the oral suspension ➢ If they get any side effects, to talk to their doctor, 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 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 patient 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 medical advice if symptoms do not improve within 7 days or worsen. ➢ That taking simple analgesics, at regular intervals, will help temperature and discomfort. ➢ 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 and Audit Trail

Records	Appropriate records must include the following: ➢ That valid informed consent has been given. ➢ Patient's name, address and date of birth. ➢ Name of GP patient is registered with.

	➢ Specify how the patient has/has not met the criteria of the PGD. ➢ Name/dose/form/quantity of medicine supplied. ➢ Date and time of supply. ➢ Relevant past and present medical history. ➢ Documentation of cautions as appropriate. ➢ Advice given if patient excluded or declines treatment. ➢ Details of any ADRs/allergy status and actions taken. ➢ The supply must be entered in the Patient Medication Record (PMR). ➢ That supply was made under a PGD. ➢ Any safety incidents, such as medication errors, near misses and suspected adverse events. ➢ Any additional requirements in accordance with the service specification. ➢ GP to be notified within 24 hours (where possible) of the supply. ➢ All records must be kept for the time periods in line with the DOH Good Management, Good records guidelines. This includes individual data, master copies of the PGD and lists of authorised practitioners. **Records should be signed and dated.** **All records should be clear, legible and contemporaneous.** **A record of all patients receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.**
Additional Facilities / Requirements	➢ The pharmacy must have a Standard Operating Procedure (SOP) for providing the service, with the appropriate procedures and policies in place, including consent, record keeping, competency and training requirements. ➢ Medication supplied using this PGD must be labelled with the same labelling and other information which patients would otherwise have received if the medicine had been supplied against a prescription. If a PMR system is used it should be documented that the medicine was supplied via PGD. ➢ Access to medical support (this may be via telephone). ➢ Safe storage areas for medicines and equipment. ➢ Clean and tidy clinical rooms that allow confidentiality and patient privacy and access to hand washing facilities. ➢ Access to the latest information on clarithromycin contraindications, cautions, side effects and interactions. ➢ Access to PPE and suitable RAD tests. ➢ Pharmacists must possess appropriate professional indemnity

Patient Group Direction (PGD) for supply/administration of

Clarithromycin	POM

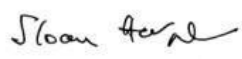
Key references

- Electronic BNF https://bnf.nice.org.uk/
- Summary Product Characteristics SmPC. Available from: Home - electronic medicines compendium (emc) https://www.medicines.org.uk
- Patient Group Directions. Medicines practice guideline [MPG2] http://www.nice.org.uk/guidance/mpg2/resources
- 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
- 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
- Clinical Knowledge Summaries Sore Throat – acute. Available from https://cks.nice.org.uk
- BMJ Best Practice. Acute pharyngitis. Available from https://bestpractice.bmj.com
- Management of Sore Throat and Indications for tonsillectomy – SIGN guidance 117 April 2010 Available from https://www.sign.ac.uk
- AWMSG All Wales Common Ailments Formulary Common ailments formulary - All Wales Therapeutics and Toxicology Centre (nhs.wales) https://awttc.nhs.wales
- NICE Guideline NG84 Sore throat (acute): antimicrobial prescribing, https://www.nice.org.uk/guidance/ng84/chapter/Recommendations#managing-acute-sore-throat
- Patient UK. Sore Throat Cause, Symptoms and Treatment. Available from https://patient.info
- BMJ Best Practice. Tonsillitis. Available from https://bestpractice.bmj.com
- Specialist Pharmacy Service (SPS) guidance for patients with swallowing difficulties
- Yellow Card Reporting site. http://yellowcard.mhra.gov.uk
- Leaflets A to Z. Best Use of Medicines in Pregnancy BUMPS provided by the UK Teratology Information Service (UKTIS) Available from bumps - best use of medicine in pregnancy (medicinesinpregnancy.org)

Patient Group Direction (PGD) for supply/administration of

Clarithromycin	**POM**

PGD Template Development

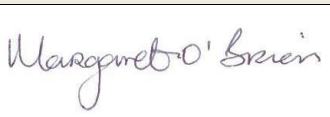
	Name	Signature	Date
Clinician	Dr Sloan Harper SPPG Medical Adviser		11/10/23
Pharmacist	Siobhan O'Hare-Smith SPPG Pharmacy Adviser		18/10/23

This PGD has been reviewed and updated by the Regional PGD Review Group:

Name	Designation
Sinead McElroy	SPPG Pharmacy Adviser

SPPG Authorisation for use in Community Pharmacies in Northern Ireland

This Patient Group Direction has been approved for use by the DoH Strategic Planning and performance Group by:

Primary Care approval			
Role	**Name**	**Sign**	**Date**
SPPG Head of General Medical Services	Dr Margaret O'Brien		25/10/2023
SPPG Head of Pharmacy & Medicines Management	Joe Brogan FPSNI		19/10/2023
SPPG Clinical Governance Lead	Sharon Gallagher Deputy Secretary Department of Health		30/10/2023

Patient Group Direction (PGD) for supply/administration of

Clarithromycin	**POM**

Authorisation Page – Community Pharmacies

Organisations using PGDs must designate an appropriate person within the organisation to ensure that only fully competent, qualified and trained healthcare professionals operate within a PGD.
This page must be completed by pharmacists who will operate under the PGD i.e. pharmacists working in the community pharmacy

Name of Community Pharmacy: .....……

The Pharmacy Manager / Contractor on behalf of the independent pharmacy contractor has accepted the responsibility to ensure that:

1. The named pharmacists (listed on the signature sheet) have received the appropriate training as detailed in the service specification and guidance.
2. Only fully competent, qualified and trained pharmacists operate within these directions on behalf of the community pharmacy.
3. The content of the Patient Group Direction is agreed on behalf of the independent pharmacy contractor.
4. Authorised staff should have access to a copy of the PGD indicating their authorisation to work within the scope of the PGD.

Signature ……..…… **Date**……

Name (please print) .....

Patient Group Direction (PGD) for supply/administration of

Clarithromycin	**POM**

Authorisation Page - Individual Signature Sheet

The following registered pharmacists are allowed to operate under this PGD

I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD. I understand that PGDs do not remove inherent professional obligations or accountability and it is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with the "Code for pharmacists in Northern Ireland".

Name of Professional (PRINT)	Signature	Date

Print extra copies of this page as need be. Page __ of __