NHS
Bath and North East Somerset, Swindon and Wiltshire
Clinical Commissioning Group

PATIENT GROUP DIRECTION (PGD)

Supply/Administration of Clarithromycin For the treatment of acute sore throat

Documentation details

Reference no:	CommPharm Clarithromycin Sore throat PGD
Version no:	V1.2
Valid from:	December 2021
Review date:	October 2023
Expiry date:	December 2023

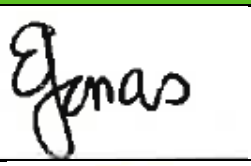
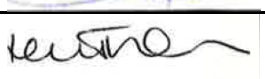
Change history

Version number	Change details	Date
1.0	Written by Elizabeth Jonas and checked by Helen Wilkinson	November 2021
1.1	Written by BNSSG CCG, adapted for BSW CCG and checked by Marco Yeung and Paul Clarke	December 2021
1.2	Fixed TARGET RTI leaflet link	January 2022

Glossary

Abbreviation	Definition

1. PGD template development

Developed by:	Name	Signature	Date
Pharmacist	Elizabeth Jonas, Senior Medicines Optimisation Pharmacist, BNSSG CCG		11.02.2020
Doctor	Dr Shaba Nabi, GP Prescribing lead, BNSSG CCG		13.02.2020
Registered Professional representing users of the PGD	Helen Wilkinson, Principal Medicines Optimisation Pharmacist, BNSSG CCG		12.02.2020

PGD Working Group Membership

Name	Designation
Helen Wilkinson	Principal Medicines Optimisation Pharmacist, BNSSG CCG
Elizabeth Jonas	Senior Medicines Optimisation Pharmacist, BNSSG CCG
Michelle Jones	Senior Medicines Optimisation Pharmacist , BNSSG CCG
Judith Poulton	Pharmacist, Avon Local Pharmaceutical Committee
Dr Shaba Nabi	GP Prescribing Lead, BNSSG CCG
Richard Brown	Pharmacist, Avon Local Pharmaceutical Committee

2. Organisational authorisations *(may require amendment depending on how the service using the PGD is being commissioned/the organisation who is responsible for authorising the PGD – not all fields may be applicable)*

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

Bath and North East Somerset, Swindon and Wiltshire CCG authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
All community pharmacies who are signed up to the BSW CCG Community Pharmacy PGD Service for Minor Ailments
Limitations to authorisation
None

Senior Doctor			
Role	**Name**	**Sign**	**Date**
Medical Director BSW CCG	Dr Ruth Grabham		**08.12.21**

Senior Pharmacist			
Role	**Name**	**Sign**	**Date**
Associate Director (Medicines Optimisation), BSW CCG	Paul Clarke		**02.12.21**

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Director (Medicines Optimisation), BSW CCG	Nadine Fox		**02.12.21**

Local enquiries regarding the use of this PGD may be directed to bswccg.prescribing@nhs.net

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD. Alternative authorisation sheets/templates may be used where appropriate in accordance with local policy.

3. Characteristics of staff

Qualifications and professional registration	• Pharmacists registered with the General Pharmaceutical Council (GPhC)
Initial training	• must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it • Has undertaken appropriate training and declared themselves assessed competent to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this PGD • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using patient group directions) • must have access to the Patient Group Direction and associated online resource • should fulfil any additional requirements defined by local policy ***The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate training and successfully completed the declaration of competence to undertake clinical assessment of patient leading to diagnosis of the conditions listed.***
Competency assessment	*Complete the self-declaration for this PGD on PharmOutcomes* *Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions* ***Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.***
Ongoing training and competency	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to this PGD and should be aware of any change to the recommendations for the medicines listed. It is the responsibility of the individual to keep up-to-date with Continued Professional Development (CPD).
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	**Treatment of acute sore throat** • Second-line agent when the recommended first-line drug, a penicillin, is contraindicated, as penicillin hypersensitivity is known or suspected
Criteria for inclusion	• Valid informed consent Children under 16 should demonstrate competence under Lord Fraser rules, or consent for treatment must be given by an adult with parental responsibility • Patients 5 years or over with an acute sore throat with a **Fever PAIN** score of 4 or 5 FEVERPAIN: • **F**ever in the last 24 hours • **P**urulence • **A**ttending rapidly (under 3 days) • Severely **i**nflamed tonsils • **N**o cough or coryza (catarrhal inflammation of the mucus membrane in the nose) Give a score of 1 to each of the criteria. Higher scores suggest more severe symptoms and the likely bacterial (streptococcal) cause. A score of 0 or 1 is associated with 13-18% likelihood of streptococcus A score of 2 or 3 is associated with at 34-40% likelihood of streptococcus A score of 4 or 5 is associated with a 62-65% likelihood of streptococcus Antibiotics should be avoided where possible as most throat infections are caused by viruses. Symptoms can last for around 1 week, but most people will get better within this time without antibiotics, regardless of cause. • Patients who are systemically unwell, have symptoms and signs of a more serious illness or condition • Patients at high-risk of complications • Patients with valvular heart disease and a risk of rheumatic fever

Criteria for exclusion	• COVID-19 Risk Triage, If a known recent contact or positive themselves or a family member – do not examine & refer for testing. Patients with suspected or confirmed COVID-19 should be managed by following the COVID-19 rapid guideline NG191. Pharmacists must follow the latest government infection prevention and control guidance issued to community pharmacies**.**
	• No valid informed consent
	• Age under 5 years
	• Fever pain score 0-3
	• Red Flags
	  ○ Severe suppurative complications (e.g. peri-tonsillar abscess or cellulitis (Quinsy) parapharyngeal abscess, retropharyngeal abscess, or Lemierre syndrome) as there is a risk of airway compromise or rupture of the abscess- refer to secondary care immediately
	  ○ Adult epiglottitis – suggested by severe and acute onset of sore throat and fever, muffled voice, drooling and stridor (do not examine the throat of anyone with possible epiglottitis)
	  ○ Child epiglottitis – high fever, sore throat, noisy breathing and dribbling (do not examine the throat of anyone with possible epiglottitis)
	  ○ Stridor or respiratory difficulty or severe airway obstruction
	  ○ Signs of sepsis or meningitis
	  ○ Dehydration or reluctance to take fluids – fluid intake less than 50% of normal
	  ○ Infection with Herpes virus – risk of airway compromise or rupture of the abscess
	  ○ Profoundly and systemically unwell and/ or risk of immunosuppression.
	• Pregnancy
	• Breastfeeding
	• Patients who are <u>not</u> allergic to penicillin – refer to Penicillin V PGD as first line option
	• Patients taking warfarin
	• Hypersensitivity to macrolide antibiotics including clarithromycin or any ingredients contained within the medication
	• Patients who are immuno-compromised
	• Previous course of antibiotics for the same episode
	• Patients with atypical symptoms e.g. other rashes/lesions
	• Patients with a history of QT prolongation or cardiac arrhythmia or conditions which predispose them to QT interval prolongation e.g. electrolyte disturbances.
	• Patients with hypokalaemia (risk of prolongation of QT time)
	• Patient with myasthenia gravis (macrolides may aggravate the condition)
	• Patients with severe (eGFR <30ml/min) renal or hepatic impairment
	• Patients taking colchicine (for gout) as may increase patient exposure to colchicine
	• Patients taking; efavirenz, nevirapine, rifapentine, itraconazole,

	digoxin, tolterodine, theophylline, triazolam, omeprazole, sildenafil, tadalafil, vardenafil, cilostazol, methylprednisolone, oral anticoagulants, quinine, sildenafil, alprazolam, midazolam, disopyramide, rifabutin, phenytoin, ciclosporin, valproate, vinblastine, sirolimus or tacrolimus. These drugs may have their metabolism inhibited by the clarithromycin and their plasma levels may increase. • Patients taking rifampicin, carbamazepine, phenobarbital, St John's wort, ritonavir. These drugs may increase the metabolism of clarithromycin leading to reduced efficacy. • Patients currently taking ticagrelor or ranolazine • Patients prescribed medication that can affect the QT interval including; cisapride, pimozide, astemizole, amiodarone, sotalol and terfenadine • Patients currently taking ergotamine or dihydroergotamine
Cautions including any relevant action to be taken	• Diphtheria: characteristic tonsillar or pharyngeal membrane. • Hepatic dysfunction, including increased liver enzymes, and hepatocellular and/or cholestatic hepatitis, with or without jaundice, has been reported with clarithromycin. This hepatic dysfunction may be severe and is usually reversible. 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. • Each 5ml constituted suspension contains: 2928.50mg of sucrose and 20mg of aspartame
Action to be taken if the patient is excluded	• Record reasons for exclusion and any action(s) taken in patient notes • Document advice given and the decision reached • Advise patient on alternative treatment. • Refer to a GP if appropriate
Action to be taken if the patient or carer declines treatment	• Record reasons for decline and any action(s) taken in patient notes • Advise patient on alternative treatment. • Document advice given and the decision reached • Refer to a GP if appropriate
Arrangements for referral for medical advice	• Clinical information should be sent to the patient's GP in accordance with local protocols

5. Description of treatment

Name, strength & formulation of drug	CLARITHROMYCIN oral suspension paediatric 125mg/5ml CLARITHROMYCIN oral suspension paediatric 250mg/5ml CLARITHROMYCIN tablets 250mg

Legal category	Prescription-only medicine (POM)
Route / method of administration	ORAL
Dose and frequency of administration	**Children aged 5 – 12 years** Bodyweight 12 – 19kg = 125mg every 12 hours (5ml of 125mg/5ml) Bodyweight 20 – 29kg = 187.5mg every 12 hours (7.5ml of 125mg/5ml) Bodyweight 30 – 40kg = 250mg twice daily (5ml of 250mg/5ml) If unable to weigh refer to SPC for the brand supplying for age based dosing. **Children aged 12 – 17 years** 250mg twice daily (1 x 250mg tablet or 5ml of 250mg/5ml suspension, only if patient is unable to swallow) **Adults** 250mg twice daily (1 x 250mg tablet or 5ml of 250mg/5ml suspension, only if patient is unable to swallow)
Duration of treatment	5 days
Quantity to be supplied	70ml x clarithromycin paediatric oral suspension (if body weight 20-29kg dose 2x70ml) 10 x clarithromycin tablets Supply the minimum number of full packs sufficient to complete the course. Note the expiry of oral suspension once reconstituted. The suspension must be prepared by tapping the bottle to loosen the powder then adding the required volume of tap water (as stated on the pack). Agitate rapidly for a few seconds to ensure all powder is wetted and uniformly suspended Containers should be marked with the length of course, and expiry date of reconstituted oral suspension where appropriate. Ensure appropriately labelled with the patient's name, date and Pharmacy contact details.
Storage	Stock must be stored in conditions in line with SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk Do not store above 25°C
Drug interactions	• Concomitant use of clarithromycin with lovastatin or simvastatin is contraindicated as these statins are extensively metabolized by CYP3A4 and concomitant treatment with clarithromycin increases their plasma concentration, which increases the risk of myopathy, including rhabdomyolysis. Reports of rhabdomyolysis have been received for patients taking clarithromycin concomitantly with these statins. Advise patients to discontinue their statin whilst taking clarithromycin • The following drugs or drug classes are known or suspected to be metabolized by the same CYP3A isozyme: alprazolam, astemizole, carbamazepine, cilostazol, cisapride, cyclosporine, disopyramide, ergot alkaloids, lovastatin, methylprednisolone,

	midazolam, omeprazole, oral anticoagulants (e.g. warfarin) atypical antipsychotics (e.g. quetiapine), pimozide, quinidine, rifabutin, sildenafil, simvastatin, sirolimus, tacrolimus, terfenadine, triazolam and vinblastine, but this list is not comprehensive. Drugs interacting by similar mechanisms through other isozymes within the cytochrome P450 system include phenytoin, theophylline and valproate. • Caution is advised regarding the concomitant administration of clarithromycin and calcium channel blockers metabolized by CYP3A4 (e.g., verapamil, amlodipine, diltiazem) due to the risk of hypotension. ***A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk***
Identification & management of adverse reactions	Side effects are usually mild and transient • Common ○ Insomnia, dysgeusia, headache, taste perversion, vasodilation, diarrhoea, vomiting, dyspepsia, nausea, abdominal pain, abnormal liver function test, rash, hyperhidrosis, • Uncommon ○ Cellulitis, candidiasis, gastroenteritis infection, vaginal infection, leukopenia, neutropenia, thrombocythemia, eosinophilia, anaphylactoid reaction, hypersensitivity, anorexia, decreased appetite, anxiety, nervousness, loss of consciousness, dyskinesia, dizziness, somnolence, tremor, vertigo, hearing impaired, tinnitus, cardiac arrest, atrial fibrillation, electrocardiogram QT prolonged, extrasystoles, palpitations, asthma[1], epistaxis, pulmonary embolism, oesophagitis, gastrooesophageal reflux disease, gastritis, proctalgia, stomatitis, glossitis, abdominal distension, constipation, dry mouth, eructation, flatulence, cholestasis[4], hepatitis[4], alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyltransferase increased, dermatitis bullous, pruritus, urticaria, rash maculo-papular, muscle spasms, musculoskeletal stiffness, myalgia, blood creatinine increased, blood urea increased, malaise, pyrexia, asthenia, chest pain, chills, fatigue, albumin globulin ratio abnormal, blood alkaline phosphatase increased, blood lactate dehydrogenase increased • Unknown ○ Pseudomembranous colitis, erysipelas, agranulocytosis, thrombocytopenia**,** anaphylactic reaction, angioedema, psychotic disorder, confusional state, depersonalisation, depression, disorientation, hallucination, abnormal, dreams, mania, convulsion, ageusia, parosmia, anosmia, paraesthesia, deafness, haemorrhage, *Torsade de pointes,* ventricular tachycardia, ventricular fibrillation, pancreatitis acute, tongue discolouration, tooth discolouration, hepatic failure, jaundice hepatocellular, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug rash with eosinophilia and systemic symptoms (DRESS), acne, acute generalised

	exanthematous pustulosis (AGEP), rhabdomyolysis, myopathy, renal failure, nephritis interstitial, international normalised ratio increased, prothrombin time prolonged, urine colour abnormal Use the Yellow Card System to report unexpected adverse drug reactions directly to the CSM. Guidance on the use of the Yellow Card System and Yellow Cards are available in the current BNF or via www.yellowcard.gov.uk **A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk**
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: ***https://yellowcard.mhra.gov.uk*** • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report via organisation incident policy. • If anaphylaxis management may be required include this information here (e.g. adrenaline to be held/resuscitation team details)
Written information to be given to patient or carer	• Give marketing authorisation holder's patient information leaflet (PIL) provided with the product. • Provide copy of TARGET RTI leaflet Leaflets to discuss with patients: RTI Leaflet (rcgp.org.uk)
Patient advice / follow up treatment	• Reassure the individual that a sore throat is generally self-limiting, with most people recovering after 7-8 days with or without antibiotic treatment. • Take at regular intervals and complete the course supplied, even if feeling better • 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. • Discuss side effects and advise to see GP if side effects occur • All patient/carers must be given appropriate safety-netting advice – to consider the exclusion criteria. See GP if symptoms do not improve after 3-4 days or at any time if symptoms are worsening rapidly or significantly. Explain that they should seek urgent medical attention if they develop any difficulty breathing, stridor, drooling, a muffled voice, severe pain, dysphagia or if they are not able to swallow adequate fluids or become systemically unwell. • Advise on symptom relief including appropriate 'over the counter' analgesia. • Encourage adequate fluid intake to avoid dehydration (especially when a fever is present) • Provide advice regarding food and drink to avoid exacerbating pain (e.g. avoid hot drinks). ○ Adults or older children may find sucking throat lozenges, hard boiled sweets, ice, or flavoured frozen desserts (such as ice lollies) to provide additional symptomatic

	relief. • Suggest the use of simple mouthwashes (e.g. warm salty water) at frequent intervals until the discomfort and swelling subside.
Records	Record: • that valid informed consent was given • name/signature of individual, address, date of birth and GP with whom the individual is registered (if relevant) • History, examination, investigations, diagnosis • Drug history including any allergies • name of registered health professional • name and brand of medication supplied/administered • date and time of supply/administration • dose, form and route of supply/administration • quantity supplied/administered • batch number and expiry date (if applicable) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • supplied via Patient Group Direction (PGD) • Referral arrangements (including self-care) • Add patient name and date of supply to the pack before issuing. Liquid dose forms must include the expiry date of reconstituted suspension. ***Records should be signed and dated (or a password controlled e-records).*** ***All records should be clear, legible and contemporaneous.*** ***A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.***

6. Key references

Key references	• Summary of Product Characteristics for clarithromycin (available at www.emc.medicines.org.uk • British National Formulary (available online at www.medicinescomplete.com) • BSW Antimicrobial Prescribing Guidelines available https://prescribing.bswccg.nhs.uk/wpdm-package/wiltshire-swindon-banes-primary-care-antibiotic-guidance-jan-2019-nice-update • NICE Clinical Knowledge Summaries (available at https://cks.nice.org.uk/sore-throat-acute) • NICE NG84 Sore throat(acute): antimicrobial prescribing(available at Overview | Sore throat (acute): antimicrobial prescribing | Guidance | NICE) • NICG NG191 COVID-19 rapid guideline: managing COVID-19(available at Overview | COVID-19 rapid guideline: managing COVID-19 | Guidance | NICE)

7. Registered health professional authorisation sheet

CommPharm Clarithromycin Sore throat Vs 1 Valid from: December 2021 **Expiry:** December 2023

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

Registered health professional

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager (if applicable)

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of INSERT NAME OF ORGANISATION for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.