Bristol, North Somerset and South Gloucestershire Clinical Commissioning Group

This Patient Group Direction (PGD) must only be used by registered nurses allied health care professionals who have been named and authorised by Brisdoc to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction

for the supply and/or administration of

CLARITHROMYCIN TABLETS and SUSPENSION

by registered Nurses and Emergency Care Practitioners for

Severe tonsillitis

Version number: 1.0

CHANGE HISTORY

Version number	Change details	Date
1.0	Written by Michelle Jones based on the BrisDoc penicillin PGD	October 2018

PGD DEVELOPMENT

Name	Job title and organisation	Date
Michelle Jones GPhC number: 2054641	Senior Medicines Optimisation Pharmacist BNSSGCCG	October 2018

PGD AUTHORISATION

Name	Job title and organisation	Signature	Date
Dr Peter Brindle	**Medical Director (Clinical Effectiveness)** **BNSSG CCG**		
Helen Wilkinson	**Principal Medicines Optimisation Pharmacist** **BNSSG CCG**		
Debbie Campbell	**Deputy Director (Medicines Optimisation)** **BNSSG CCG**		

TRAINING AND COMPETENCY OF REGISTERED NURSES AND HEALTHCARE PRACTITIONERS

Requirements of registered nurses and emergency healthcare practitioners working under the PGD	
Qualifications and professional registration	Registered nurse with a current NMC registration Registered Emergency Care Practitioner with a current HCPC registration
Initial training and competency assessment	• Has undertaken appropriate training and been assessed competent to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this PGD • Has undertaken appropriate training and been assessed competent for working under PGDs for the supply and administration of medicines • Has undertaken any specified updates relevant to supply under this PGD • Must be competent in the recognition and management of anaphylaxis.
Ongoing training and competency	The practitioner should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development. Regular updates in anaphylaxis and cardiopulmonary resuscitation to reinforce and update knowledge and skills in this area of practice, including basic resuscitation and anaphylaxis training, with particular reference to changes and national directives.

CLINICAL CONDITION

Clinical condition or situation to which this PGD applies	• **Severe tonsillitis** • Second-line agent when the recommended first-line drug, a penicillin, is contraindicated, as penicillin hypersensitivity is known or suspected
Inclusion criteria	• Adults and children over 2 years of age with symptoms of severe tonsillitis. • Children under 16 should demonstrate competence under Lord Fraser rules, or consent for treatment must be given by an adult with parental responsibility.

Inclusion criteria continued	Making the decision to prescribe antibiotics in tonsillitis requires a balanced clinical judgement. There is no reliable set of rules to accurately distinguish bacterial and non-bacterial causes. The following guidelines are intended to help practitioners select the group of patients most likely to benefit from antibiotic treatment where the benefit of treatment would appear to outweigh the risk of antibiotic resistance resulting from unnecessary antibiotic use.
	
	Note that antbiotics should be avoided as most throat infections are caused by viruses.
	82% of infections will resolve within 7 days without antibiotics and pain is only reduced by 16 hours
	
	Supply of clarithromycin for tonsillitis may be considered if:
	• Patient has a feverPAIN score of 4 (62-65% streptococci) or more use immediate antibiotic if severe
	FeverPAIN is a five item score used in the assessment of sore throats. The score consists of:
	  • Fever in the last 24 hours
	  • Purulence
	  • Attending rapidly (under 3 days)
	  • Severely inflamed tonsils
	  • No cough or coryza
	
	• Patients with features of marked systemic upset
	
	• Patients at risk of serious complications
	
	• Patients with valvular heart disease
	
	In addition the following clinical features suggestive of a **bacterial cause** may be used to add weight to the clinical decision favouring antibiotic treatment:
	
	• A history of recurrent tonsillitis and previous response to treatment
	
	• Tender lymph nodes
	
	• Patients who are at increased risk of severe infection (e.g. diabetes)

Inclusion criteria continued	• Absence of other viral symptoms e.g. coryza and cough • Patients with a history of rheumatic fever
Exclusion criteria	• No valid consent • Under 2 years of age • Patients who are not allergic to penicillin - refer to phenoxymethylpenicillin PGD as first line option. • Known hypersensitivity to macrolide antibiotics or their excipients • Patients who are immunocompromised or at risk of immunosuppression (e.g. as a result of medication such as DMARDs or carbimazole or clinical condition) • 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) • Pregnancy and breastfeeding • Patients with **severe** renal or hepatic impairment (may require dose reduction) as clarithromycin is principally excreted by the liver and kidney • Patients taking colchicine (for gout) as may increase patient exposure to colchicine • Patients taking: itraconazole, digoxin, tolterodine, theophylline, triazolam, omeprazole, sildenafil, tadalafil, vardenafil, cilostazol, methylprednisolone, oral anticoagulants, quinine, sildenafil, alprazolam, midazolam, disopyramide, rifabutin, phenytoin, ciclosporin, valproate, vinblastine, sirolimus, atazanavir, zidovudine calcium channel blockers or tacrolimus, saquinavir. These drugs may have their metabolism inhibited by the clarithromycin and their plasma levels may increase.

Exclusion criteria continued	• Patients taking rifampicin, carbamazepine, phenobarbital, St John's wort. These drugs may increase the metabolism of clarithromycin leading to reduced efficacy.
	• Patients currently taking ticagrelor or ranolazine
	• Patients taking lovastatin or simvastatin is contraindicated (see 4.3) 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
	• Patients prescribed medication that can affect the QT interval including; cisapride, pimozide, astemizole, amiodarone, sotalol and terfenadine
	• Patients currently taking ergotamine or dihydroergotamine
	• Previous course of antibiotics for the same episode
	• Patients with atypical symptoms e.g. other rashes/lesions
	• Refer patients with peritonsillar abscess or peritonsillar cellulitis to secondary care immediately
	• Do not use antibiotics if the FeverPAIN score is 0 or 1 (13-18% likelihood of streptococci)
	• Patients with features suggestive of a **viral cause** and favouring conservative, non-antibiotic treatment:
	  ○ Low grade (<38°C) fever
	  ○ Exudate in the absence of obvious inflammation

Cautions and considerations	• A child with a high fever, sore throat, noisy breathing on inspiration and dribbling may have epiglottitis. Epiglottitis may also be seen in adults. Patients with suspected epiglottitis must be referred to a prescriber
	Cautions and considerations relating to admission
	• Admit immediately anyone who has:
	  ○ Stridor or respiratory difficulty.
	  ▪ Respiratory distress, drooling, systemically very unwell, painful swallowing, muffled voice: suspect acute epiglottitis. Do not examine the throat of anyone who has suspected epiglottitis.
	  ▪ Upper airway obstruction.

Caution and considerations continued	○ Dehydration or reluctance to take any fluids. ○ 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 rare cause such as 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: high fever, arthralgia, myalgia, extensive bullae in the mouth followed by erosion and a grey–white membrane. ▪ Yersinial pharyngitis : fever, prominent cervical lymphadenopathy, abdominal pain with or without diarrhoea. • Arrange appropriate specialist referral for anyone with a suspected serious (but not immediately life-threatening) cause for sore throat (such as cancer or HIV), with urgency determined by clinical judgement. **Other cautions:** • FeverPAIN score 2-3 (34-40% likelihood of streptococci) consider referring to prescriber for 3 day back-up antibiotic prescription • . • The oral suspension contains sucrose. This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. • Consider potential drug interactions – refer to current edition of the BNF or Summary of Product Characteristics for a full list of interactions. These include: • Oral hypoglycaemic dugs such as nateglinide and repaglinide - inhibition of CYP3A enzyme by clarithromycin may be involved and could cause

Caution and considerations continued	hypolgycemia when used concomitantly. Careful monitoring of glucose is recommended • Oral contracetives - Patients should be warned that if diarrhoea, vomiting or breakthrough bleeding occur there is a possibility of contraceptive failure.
Referral arrangements	Clinical information must be forwarded in accordance with local protocols to patient's GP or non-medical prescriber.
Action if patient declines treatment or is excluded	• Consider alternative treatment. • Where appropriate reassure the person that antibiotics are not needed immediately as they will make little difference to symptoms, and may have adverse effects. • Where a delayed prescription is considered more appropriate refer to a prescriber and advise the patient to use the antibiotic prescription only if their condition has deteriorated. • Document clearly in patient records the reason for refusal or exclusion, any action taken and any advice given • Refer to a prescriber or patient's own GP or consider hospital admission as necessary.

DETAILS OF THE MEDICINE

Name, form and strength of medicine	Clarithromycin 125mg/5ml oral suspension* Clarithromycin 250mg/5ml oral suspension Clarithromycin 500mg tablets *supplied as granules for reconstitution
Legal category	**POM**
Route/method of administration	ORAL
Dosage	**Children 2 to 11 years (body-weight 8-11Kg)*** 62.5mg (2.5ml of 125mg/5ml suspension) **Children 2 to 11 years(body-weight 12-19Kg)*** 125mg (2.5ml of 250mg/5ml suspension or 5ml 125mg/5ml suspension)

Dosage continued	**Children 2 to 11 years (body-weight 20-29 Kg)*** 187.5mg (7.5mls of 125mg/5ml suspension) **Children 2 to 11 years (body weight 30-40Kg)*** 250mg (5ml of 250mg/5ml suspension or 10ml of 125mg/5ml suspension) **Adults** and children* over 12** 500mg (one tablet or 10ml of 250mg/5ml suspension) **dosing based on BNF for Children online* ***dosing based on BNSSG antimicrobial guidelines 2018*
Frequency	Every 12 hours (TWICE daily)
Quantity to be supplied	Supply the minimum number of full packs sufficient to complete the course. Supply: 1 x14 x clarithromycin 500mg tablets 1 x 100ml x clarithromycin oral suspension 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. Note that a reconstituted bottle of clarithromycin oral suspension must be discarded 14 days after reconstitution. Provide a measuring spoon or oral syringe where appropriate. Containers should be marked with the patient's name, BrisDoc Walk-in Centre contact details, length of course, and expiry date of reconstituted oral suspension where appropriate.
Duration of treatment	FIVE days (as per BNSSG Antimicrobial Guidelines 2018)

Adverse reaction / side effects	Side effects are usually mild and transient, but may include: **Common** Insomnia, dysgeusia, headache, taste perversion, vasodilation, diarrhoea, vomiting, dyspepsia, nausea, abdominal pain, Liver function test abnormal **Uncommon** Cellulitis, candidiasis, gastroenteritis, infection, vaginal infection, leukopenia, neutropenia, thrombocythaemia, eosinophilia, anaphylactoid reaction, hypersensitivity, anorexia, decreased appetite, anxiety, nervousness albumin globulin ratio abnormal, blood alkaline phosphatase increased, blood lactate dehydrogenase increased, malaise, pyrexia, asthenia, chest pain, chills, fatigue, blood creatinine increased[1], blood urea increased, blood creatinine increased, blood urea increased, muscle spasms, musculoskeletal stiffness, myalgia cholestasis, hepatitis, alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyltransferase increased dermatitis bullous, pruritus, urticaria, rash maculo-papular oesphagitis, gastrooesophageal reflux disease, gastritis, proctalgia, stomatitis, glossitis, abdominal distension, constipation, dry mouth, eructation, flatulence, asthma, epistaxis, pulmonary embolism, asthma, epistaxis, pulmonary embolism loss of consciousness, dyskinesia, dizziness, somnolence, tremor. **Not Known** Pseudomembranous colitis, erysipelas, agranulocytosis, thrombocytopenia, anaphylactic reaction, angioedema, psychotic disorder, confusional state, depersonalisation, depression, disorientation, hallucination, abnormal dreams, mania, convulsion, ageusia, parosmia, anosmia, paraesthesia, torsade de pointes, ventricular tachycardia, ventricular fibrillation, deafness, haemorrhage, pancreatitis acute, tongue discolouration, tooth discolouration, hepatic failure, jaundice hepatocellular, severe cutaneous adverse reactions (SCAR) (e.g. Acute generalised exanthematous pustulosis (AGEP), Stevens-Johnson syndrome, toxic epidermal necrolysis, drug rash with eosinophilia and systemic symptoms (DRESS), acne, rhabdomyolysis, myopathy, renal failure, nephritis interstitial, international normalised ratio increased, prothrombin time prolonged, urine color abnormal.

Adverse reaction / side effects continued	In addition always refer to current edition of the British National Formulary (BNF) and the Summary of Product Characteristics (via www.medicines.org.uk - search under medicine name) 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 and online https://yellowcard.mhra.gov.uk/
Records to be kept /audit trail	The following record should be kept in the clinical notes • Patient's name, address, date of birth and consent given • Date and time of supply • History, examination, investigations, diagnosis including feverPAIN score • Drug history including allergy status • Dose and form supplied • Route of administration • 'Supplied under PGD' • Advice given to the patient (including side effects) • Signature and name of staff who administered or supplied the medication • Details of any adverse drug reaction and actions taken including documentation in the patient's medical record • Referral arrangements (including self-care) • Record supply in drug record file including batch number and expiry date • Add patient name and date of supply to pre-labelled pack before issuing and ensure the medication is labelled appropriately with BrisDoc Walk in Centre's contact details. **All records must be clear, legible and contemporaneous**

PATIENT INFORMATION

Advice to patient	• Reassure the individual that a sore throat is generally self-limiting, with most people recovering after 7 days with or without antibiotic treatment. • Take at regular intervals and complete the course supplied, even if feeling better • Clarithromycin oral suspension can cause a bitter after-taste. This can be avoided by drinking juice or water soon after intake of the suspension. Advise patients/carers to shake well before use. • Discuss side effects and advise to see GP if side effects occur • See GP if symptoms do not improve after 3 or 4 days or if symptoms are worsening. Explain that they should seek urgent medical attention if they develop any difficulty breathing, stridor, drooling, a muffled voice, sever pain, dysphagia if one sided neck or throat swelling occur 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) provide additional symptomatic relief. • Children may return to school or daycare after fever has resolved and they are no longer feeling unwell, and/or after taking antibiotics for at least 24 hours. • Suggest the use of simple mouthwashes (e.g. warm salty water) at frequent intervals until the discomfort and swelling subside. • Advise to return any tablets or suspension remaining at completion of course to their community pharmacist for destruction

Written information to be given to patient or carer	• Provide copy of Patient Information Leaflet and discuss as required • Offer TARGET sore throat leaflet if not providing antibiotics
Follow-up advice to be given to patient or carer	Routine follow up is not required, but advise patient to refer to their GP / prescriber / return to OOH or WIC if symptoms have not improved after 3 or 4 days of antibiotic therapy. If decision is made not to supply antibiotics, reassure the patient or their parent/carer that the antibiotic is not needed as a sore throat is generally self-limiting, with most people recovering after 7 days with or without antibiotics. Advise patient to seek medical advice if pain does not improve after 3 days and/or there is a fever over 38.3^{o}C.

REFERENCES

- British National Formulary online (available at www.medicinescomplete.com) [accessed 08/05/2017, 17/10/2018]
- BNF for children (available at www.medicinescomplete.com) [accessed 08/05/2017, 17/10/2018]
- Antimicrobial Guidelines for the BNSSG Health Community 2018 available at www.bnssgformulary.nhs.uk [accessed 08/05/2017, 17/10/2018]
- Summary of Product Characteristics for clarithromycin(available at www.emc.medicines.org.uk) [accessed 08/05/2017, 17/10/2018]
- NICE Clinical Knowledge Summaries (available at http://cks.nice.org.uk/) [accessed 17/10/2018]

Individual Authorisation for the supply of clarithromycin tablets/suspension
Patient Group Directions do not remove inherent professional obligations or accountability. This patient group direction is to be read, agreed to and signed by all health professionals to whom it applies. The attached PGD is agreed for use in at BRISDOC HEALTHCARE SERVICES. Agreed on behalf of the organisation by Kathy Ryan (Medical Director). Registered Health Care Professional: By signing below I confirm that I understand the legal framework for the use of PGDs. I confirm I have read and understood the PGD above. I am competent to undertake supply/administration of clarithromycin accordance with the PGD listed above within my professional code of conduct. It is the responsibility of each professional to practice only within the bounds of their own competence. I have read and understood the Patient Group Direction and agree to supply/administer this medicine only in accordance with this PGD.

Name of Professional	Signature	Authorising Manager	Authorising Manager signature	Date