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

PATIENT GROUP DIRECTION (PGD)

Supply/Administration of clarithromycin
For the treatment of extensive and/or severe impetigo

Documentation details

Reference no:	CommPharm Clarithromycin Impetigo PGD
Version no:	V1.0
Valid from:	December 2021
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Expiry date:	December 2023

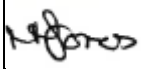
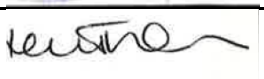
Change history

Version number	Change details	Date
1.0	Written by Michelle Jones and checked by Helen Wilkinson & Elizabeth Jonas	November 2019
1.1	Written by BNSSG CCG, adapted for BSW CCG and checked by Marco Yeung and Paul Clarke	December 2021

Glossary

Abbreviation	Definition

1. PGD template development

Developed by:	Name	Signature	Date
Pharmacist	Michelle Jones, Senior Medicines Optimisation Pharmacist, BNSSG CCG		10.02.2020
Doctor	Dr Shaba Nabi, GP Prescribing lead, BNSSG CCG		12.02.2020
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 contracted to provide 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	**Widespread impetigo in children aged 2 years and over and adults** • Second-line agent when the recommended first-line drug, a penicillin, is contraindicated, as penicillin hypersensitivity is known or suspected
Criteria for inclusion	• Adults and children over 2 year of age with widespread impetigo • 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

Criteria for exclusion	• No valid informed consent
	• Under 2 years old
	• **Red flags**
	  ○ Signs of Sepsis- refer urgently
	  ○ Has significant lymphoedema (gross swelling of the limb)
	  ○ Acute glomerulonephritis (following streptococcal impetigo).
	  ○ Cellulitis.
	  ○ Staphylococcal scalded skin syndrome.
	  ○ Lymphangitis.
	  ○ Osteomyelitis and septic arthritis
	  ○ Scarlet fever, urticaria and erythema multiforme
	  ○ Patients who are immuno-compromised
	
	• Previous course of antibiotics for the same episode
	• Bullous impetigo – refer for differential diagnosis
	• Pregnancy
	• Breast-feeding
	• Patients who are <u>not</u> allergic to penicillin - refer to flucloxacillin PGD as first line option.
	• Not to be used for localised lesions (see Fucidin® PGD)
	• Patients currently taking warfarin - clarithromycin may affect INR level.
	• Known colonisation with MRSA
	• Hypersensitivity to macrolide antibiotics including clarithromycin or any ingredients contained within the medication
	• 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	• 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 CLARITHROMYCIN tablets 500mg
Legal category	Prescription-only medicine (POM)
Route / method of administration	ORAL

Dose and frequency of administration	**Children aged 2 – 12 years** Bodyweight 8 -11kg = 62.5mg every 12 hours (2.5ml of 125mg/5ml) 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 every 12 hours (5ml of 250mg/5ml) **Children aged 12 – 17 years** 250mg (1 x 250mg tablet or 5ml of 250mg/5ml suspension, only if patient is not able to swallow) every 12 hours **Adults** 250mg every 12 hours
Duration of treatment	FIVE days
Quantity to be supplied	70ml x clarithromycin paediatric oral suspension (if body weight 20Kg or above dose 2x70ml) 10 x clarithromycin 250mg 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 25ºC.
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 PIL on impetigo, which can be downloaded from the British of Dermatologists website http://www.bad.org.uk/shared/get-file.ashx?id=211&itemtype=document • Information on impetigo can be downloaded from the NHS choices website http://www.nhs.uk/conditions for patients
Patient advice / follow up treatment	• Explain that impetigo is not usually serious but can spread if not treated. • Reassure the patient that impetigo usually heals completely without scarring and that serious complications are rare • Take the antibiotics 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 come back if side effects occur • Give safety netting advice/see GP if lesions are not improving 5 days after initiation of clarithromycin or are becoming more widespread and consider red flags. • Advice on management of impetigo including hygiene measures to aid healing, including recommending that the person washes the affected area with soapy water. Advise patient to try not to touch patches of impetigo and if they do to wash hands afterwards. • Avoid scratching affected areas and keep fingernails clean and cut short. • Don't share towels, clothing, bathwater or flannels etc. until the infection has cleared. • Children and adults should be advised to stay away from school and other childcare facilities or work until the lesions are healed dry and crusted over or 48 hours after clarithromycin treatment has started. • Food handlers are required by law to inform employers immediately if they have impetigo

	• Advise on symptom relief including appropriate 'over the counter' analgesia. • Advise the patient or their carer to return any tablets or suspension remaining at completion of course to their community pharmacist for disposal
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) • British National Formulary for Children (available online at www.medicinescomplete.com) • BSW Antimicrobial Prescribing Guidelines available (available online at 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/impetigo) • NICE NG 153 Impetigo: antimicrobial prescribing (available online at https://www.nice.org.uk/guidance/ng153/resources/visual-summary-pdf-7084853533)

7. Registered health professional authorisation sheet

CommPharm Clarithromycin v1 Valid from: Dec 2021 Expiry: Dec 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.