Torbay and South Devon NHS
NHS Foundation Trust

Patient Group Direction 2230 version 1.0
Administration / Supply of Clarithromycin by Registered Practitioners employed by Torbay and South Devon NHS Foundation Trust

Date of Introduction: December 2017
Review Date: November 2019

Developed By	Name	Signature	Date
Physician	Emergency Department Consultant		
Pharmacist			
Lead Professional	Senior Manager MIU services / Nurse Consultant Emergency Care Unit		

Note: The Lead Professional is responsible for ensuring the co-ordination, composition, consultation, revision and distribution of the PGD to practitioners who will be using the PGD as well as ensuring that the PGD is no longer used if becomes out of date and once it has expired.

The Clinical Effectiveness Department will write to the Lead Professional approximately 4 months before the review date as a reminder that a review is required.

Ratified on behalf of: TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST	
Medicines Management Committee Chair	
Signed:	
Name:	**Clinical Director – Pharmacy and Prescribing**
Date:	
Lead Officer	
Signed:	
Name:	**Medical Director**
Date:	

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Administration / Supply of Clarithromycin by Registered Practitioners employed by Torbay and South Devon NHS Foundation Trust

Objective	To treat patients with known allergies to penicillin who otherwise would have been given flucloxacillin, amoxicillin or phenoxymethylpenicillin for minor injury and illness

1. Clinical Condition

Definition of condition/situation	To treat patients presenting with the conditions listed in the 'Criteria for Inclusion' section of the PGD and have a known allergy to penicillin.
Facilities required	▪ TTA packs of 14 x clarithromycin 250mg tablets ▪ TTA packs of 14 x clarithromycin 500mg tablets ▪ TTA packs of 70ml clarithromycin 125mg / 5ml suspension
Criteria for inclusion	Where the need for an antibiotic is justified, patients aged one year and over with known hypersensitivity to penicillin antibiotics presenting with: ▪ Acute otitis media ▪ Soft tissue infections / cellulitis ▪ Acute tonsillitis or possible scarlet fever ▪ Impetigo ▪ Ear canal furuncle ▪ Infected insect bite ▪ Paronychia ▪ Wounds including traumatic wounds ▪ Infective bursitis
Criteria for exclusion	▪ Children aged under one year ▪ Pregnancy ▪ Breast feeding ▪ Myasthenia gravis ▪ Clarithromycin is contraindicated in patients with known hypersensitivity to the active substance clarithromycin, to other macrolides or to any of the excipients. ▪ Concomitant administration of clarithromycin and any of the following active substances is contraindicated: astemizole, cisapride, pimozide and terfenadine as this may result in QT prolongation (congenital or documented acquired QT prolongation) and cardiac arrhythmias, including ventricular tachycardia, ventricular fibrillation and Torsade de Pointes. ▪ Concomitant administration with ticagrelor or renolazine is contraindicated. ▪ Concomitant administration of clarithromycin and ergotamine or dihydroergotamine is contraindicated, as this may result in ergot toxicity. ▪ Clarithromycin should not be given to patients with history of QT prolongation or ventricular cardiac arrhythmia, including torsades de pointe. ▪ Clarithromycin should not be used concomitantly with HMG-CoA reductase inhibitors (statins) that are extensively metabolosed by CYP3A4 (lovastatin or simvastatin), due to the increased risk of myopathy, including rhabdomyolysis. ▪ Clarithromycin should not be given to patients with hypokalaemia (risk of prolongation of QT-time). ▪ Clarithromycin should not be used in patients who suffer from severe hepatic failure in combination with renal impairment.

	▪ As with other strong CYP3A4 inhibitors, Clarithromycin should not be used in patients taking colchicine. ▪ If the patient is on **any** other medication interactions **must** be checked.
Action if excluded	▪ Refer to medical practitioner **(or non-medical prescriber if appropriate)** or alternative action as indicated by related protocol and document in patient's records
Action if patient refuses medication	▪ Document informed refusal in patient's records and action taken: a) Referral to protocol b) Referral to appropriate medical practitioner

2. Characteristics of Staff

Qualifications required	▪ Minor Injury Practitioner (nurse or paramedic) working in community MIU. ▪ Emergency Nurse Practitioners (or paramedic) working in ED
Additional requirements	▪ Working knowledge of relevant Organisation Policies, including Medicines Policy and associated Standard Operating Procedures, Anaphylaxis Policy, Consent Policy and Injectable Medicines Policy and associated risk assessments where appropriate. ▪ Working knowledge of relevant Organisation protocols ▪ Evidence of continuing professional development in immunisation and vaccination ▪ Working knowledge of the NMC Standards for Medicines Management 2007, (updated 2010) www.nmc-uk.org and other relevant codes of professional practice. ▪ Knowledge of "Immunisation against Infectious Disease" (Green book) and relevant updates. www.dh.gov.uk ▪ Knowledge of NPSA/2010/RRR008 Vaccine Cold Storage www.nrls.npsa.nhs.uk/alerts ▪ Working knowledge of the NMC Standards of Proficiency for Paramedics (September 2014), http://www.hpc-uk.org/assets/documents/1000051C Standards of Proficiency paramedics.pdf and other relevant codes of professional practice.

3. Description of Treatment

Name of Medicine	Clarithromycin 250mg tablets Clarithromycin 500mg tablets Clarithromycin 125mg/5ml suspension (powder for reconstitution with water)
Legal Class	POM (Prescription Only Medicine)
Storage	**Tablets:** Do not store above 25°C, in a dry place in original packaging **Suspension:** Do not store above 25°C. Reconstituted suspension has a shelf life of 14 days; do not store above 25°C
Dose to be used (including criteria for use of differing doses)	Adults and Children over 12 years of age: 250mg – 500mg (500mg for severe infections) Children between 8 - 12 years of age (30-40 kg): 250mg (10ml of 125mg/5ml) Children between 4 - 8 years of age (20-29 kg): 187.5mg (7.5ml of 125mg/5ml) Children between 2 - 4 years of age (12-19 kg): 125mg (5ml of 125mg/5ml) Children between 1 - 2 years of age (8-11 kg): 62.5mg (2.5ml of 125mg/5ml)

Method or route of administration	Oral Suspension only to be used for patients unable to swallow tablets or when dose less than 250mg.
Total dose and number of times drug to be given. Details of supply (if supply made)	Adults and Children over 12 years of age: 250mg twice daily for 5 days (500mg for severe infections) Children between 8 - 12 years of age (30-40 kg):250mg twice daily for 5 days (10ml of 125mg/5ml) Children between 4 - 8 years of age (20-29 kg): 187.5mg twice daily for 5 days (7.5ml of 125mg/5ml) Children between 2 - 4 years of age (12-19 kg): 125mg twice daily for 5 days (5ml of 125mg/5ml) Children between 1 - 2 years of age (8-11 kg): 62.5mg twice daily for 5 days (2.5ml of 125mg/5ml) **Liquid dose forms must include expiry date of reconstituted suspension and must be supplied with an oral syringe.**
Contra-indications	See exclusion criteria If the patient is on **any** other medication interactions **must** be checked.
Cautions	▪ If the patient is on **any** other medication interactions **must** be checked in BNF Appendix 1. ▪ Caution is advised in patients with moderate to severe renal insufficiency. ▪ Caution should be exercised in patients with impaired hepatic function ▪ **Patients taking oral anticoagulants** – owing to high risk of altered international normalised ratio (INR), the risk/benefit of the use of this antibiotic in patients taking anticoagulation therapy should be carefully considered and advice sought as necessary. Where a decision to treat is made, the patient should be warned of the possibility that the anticoagulant effect may be altered – also see patient advice. ▪ **Patients taking statins** – stop statin until course of antibiotics is finished e.g. **Atorvastatin, Pravastatin, Simvastatin** ▪ Caution is advised regarding concomitant administration of clarithromycin and triazolobenzodiazepines, such as triazolam, and midazolam. ▪ Caution is advised regarding concomitant administration of clarithromycin with other ototoxic drugs, especially with aminoglycosides. ▪ Patients with coronary artery disease, severe cardiac insufficiency, conduction disturbances or clinically relevant bradycardia due to prolongation of the QT interval. ▪ Patients concomitantly taking other medicinal products associated with QT prolongation. ▪ In the event of severe acute hypersensitivity reactions, such as anaphylaxis, Stevens-Johnson Syndrome, and toxic epidermal necrolysis, clarithromycin therapy should be discontinued immediately and appropriate treatment should be urgently initiated. ▪ Clarithromycin should be used with caution when administered concurrently with medications that induce the cytochrome CYP3A4 enzyme. ▪ Oral hypoglycaemic agents/Insulin: The concomitant use of clarithromycin and oral hypoglycaemic agents (such as sulfonylureas) and/or insulin can result in significant hypoglycaemia. Careful monitoring of glucose is recommended.

Interactions	If the patient is on **any** other medication interactions **must** be checked in BNF Appendix 1. Many medicines interact with clarithromycin and can lead to serious problems. Do not give clarithromycin to patients taking ANY of the following **drugs in BOLD TYPE** - Anti-arrhythmics – **digoxin, disopyramide, dronedarone, propafenone** - Antibacterials – **delamanid, rifabutin, rifampicin** - Anticancer drugs – **abiraterone, axitinib, bosutinib, brentuximab, cabazitaxel, ceritinib, cobimetinib, crizotinib, dabrafenib, dasatinib, docetaxel, everolimus, irinotecan, lapatinib, nilotinib, paclitaxel, palbociclib, pazopanib, temsirolimus, topotecan, trabectedin, trastuzumab, vemurafenib, venetoclax, vinca alkaloids** - Anticoagulants – **apixaban, edoxaban** - Antidepressants – **reboxetine, trazodone** - Antiepileptics – **carbamazepine, phenytoin** - Antihistamines – **mizolastine** - Antimalarials – **artemether / lumefantrine, piperaquine** - Antivirals – **elbasvir, etravirine, grazoprevir, maraviroc, paritaprevir, saquinavir , simepravir** - Antipsychotics – **clozapine, lurasidone, pimozide, quetiapine, sertindole** - Calcium channel blockers – **diltiazem, lercanidipine, verapamil** - **Colchicine** - **Domperidone** - Ergot alkaloids – **ergometrine, ergotamine, methysergide** - **Eplerenone** - **Fidaxomicin** - $5HT_1$Agonists – **eletriptan** - Immunosuppressants – **ciclosporin, everolimus, tacrolimus, sirolimus** - **Ivabradine** - **Lomitapide** - **Midazolam** - **Naloxegol** - Opioids – **alfentanil, buprenorphine, fentanyl, oxycodone, sufentanil** - Phosphodiesterase type-5 inhibitors – **avanafil, sildenafil, tadalafil, vardenafil** - **Ranolazine** - Respiratory medicines – **aminophylline, ivacaftor, salmeterol, theophylline** - Statins – **atorvastatin, lovastatin, pravastatin, simvastatin** - Steroids – **budesonide, ciclesonide, fluticasone, triamcinolone** - **Ticagrelor** - **Tolvaptan** - Urological medicines – **fesoterodine, solifenacin, tolterodine** - **Ulipristal**

Potential side-effects and adverse reactions	Infections and infestations: Cellulitis, candidiasis, gastroenteritis, infection, vaginal infection, Pseudomembranous colitis, erysipelas. Blood and lymphatic system: Leukopenia, neutropenia, thrombocythemia, eosinophilia, agranulocytosis, thrombocytopenia. Immune system disorders: Anaphylactoid reaction, hypersensitivity, anaphylactic reaction, angioedema. Metabolism and nutrition disorders: Anorexia, decreased appetite. Psychiatric disorders: Insomnia, anxiety, nervousness, psychotic disorder, confusional state, depersonalisation, depression, disorientation, hallucination, abnormal dreams, mania. Nervous system disorders: Dysgeusia, headache, taste perversion, loss of consciousness, dyskinesia, dizziness, somnolence, tremor, convulsion, ageusia, parosmia, anosmia, paraesthesia. Ear and labyrinth disorders: Vertigo, hearing, impaired, tinnitus, deafness. Cardiac disorders: Cardiac arrest, atrial fibrillation, electrocardiogram QT prolonged, extra systoles, palpitations, Torsade de pointes, ventricular tachycardia, ventricular fibrillation. Vascular disorders: Vasodilation, haemorrhage. Respiratory, thoracic and mediastinal disorder: Asthma, epistaxis, pulmonary embolism. Gastrointestinal disorders: Diarrhoea, vomiting, dyspepsia, nausea, abdominal pain, esophagitis, gastrooesophageal reflux disease, gastritis, proctalgia, stomatitis, glossitis, abdominal distension, constipation, dry mouth, eructation, flatulence, pancreatitis acute, tongue discolouration, tooth discoloration. Hepatobiliary disorders: Liver function test abnormal, cholestasis, hepatitis, alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyltransferase increased, hepatic failure, jaundice hepatocellular. Skin and subcutaneous tissue disorders: Rash, hyperhidrosis, dermatitis bullous, pruritus, urticaria, rash maculo-papular, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug rash with eosinophilia and systemic symptoms (DRESS), acne. Musculoskeletal and connective tissue disorders: Muscle spasms, musculoskeletal stiffness, myalgia, rhabdomyolysis, myopathy. Renal and urinary disorders: Blood creatinine increased, blood urea increased, renal failure, nephritis interstitial. General disorders and administration site conditions: Injection site phlebitis, injection site pain, injection site inflammation, malaise, pyrexia, asthenia, chest pain, chills, fatigue. Investigations: Albumin globulin ratio abnormal, blood alkaline phosphatase increased, blood lactate dehydrogenase increased, international normalised ratio increased, prothrombin time prolonged, urine colour abnormal.

Management of potential side-effects and adverse reactions	Unusual or life threatening reactions require immediate medical attention. ▪ Document adverse reaction in the patients notes. ▪ Notify the doctor responsible for assessing the patient immediately. ▪ Nurse to seek medical advice. Advise patient to seek medical advice.
Advice and information to patient/carer including follow-up	Unusual or life threatening reactions require immediate medical attention. ▪ Inform patient of possible side effects and appropriate management, including advice on completing the course and taking regularly. ▪ Supply manufacturer's patient information leaflet ▪ Reconstituted oral suspension to be taken to a community pharmacy for safe disposal on completion of course. ▪ **Patients taking anticoagulants:** Warn patient that antibiotics are likely to alter the anticoagulant effect. Advise them to tell the clinic responsible for monitoring their anticoagulant dose that they are taking antibiotics and to arrange for an INR test within 4 – 7 days of starting the antibiotic. ▪ Remind patients taking statins to restart their cholesterol lowering medication once the course of Clarithromycin is finished. ▪ 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. Patient should be advised to seek further medical advice if symptoms do not improve or if symptoms worsen.
Specify method of recording supply /administration including audit trail	The following will be recorded in the patient's records: ▪ The diagnosis and treatment ▪ The dose administered and/or the quantity supplied ▪ The route of administration ▪ The frequency of administration ▪ The time and date of supply/administration ▪ The signature and name of the person supplying/administering the medication and phrase 'PGD' or if documenting in Symphony, an electronic signature recorded by the system is acceptable & endorse 'PGD'. Document allergies and other adverse drug reactions clearly in patient records and inform the GP and other relevant practitioners/patient/carer for further reporting and action if required. Report any adverse drug reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) through the yellow card reporting system (www.mhra.gov.uk).

4. Other Information

Follow up treatment:	N/A

Arrangements for medicine supply:	Stock is available in MIUs and ED
Arrangements for medical referral:	Medical referral should be made as detailed in the protocol
Lines of accountability:	▪ Individual nurses are accountable for their own practice under the code of professional conduct laid down by the NMC (Nursing and Midwifery Council 2002 – section 1) ▪ Individual paramedics are accountable for their own practice under the HCPC Standards of Proficiency for Paramedics (September 2014) ▪ Minor Injury Practitioners are accountable to the senior practitioner on duty and their line manager ▪ Registered nurses are accountable to their line manager and senior nurse

5. Appendices

References used in the development of this PGD:	▪ Health Protection Agency ▪ Clinical Knowledge Summaries http://www.cks.nhs.uk/clinical_topics/by_clinical_specialty/infections_and_infestations ▪ British National formulary 74 ▪ British National formulary for children 17/18 ▪ Stockley for Drug Interactions 10th Edition ▪ Summary of Product characteristics Accessed 12.12.17 https://www.medicines.org.uk/emc/product/7085 https://www.medicines.org.uk/emc/product/7072 https://www.medicines.org.uk/emc/product/515 ▪ NHS Devon protocol for the management of patients with sore throat (over 1 year of age)
Audit details	▪ Periodic audit of compliance. ▪ Case note review of identified patients. We will ask nurses to identify patients they have given medication against the PGD and review the appropriateness and documentation against the criteria.
Training	▪ **Medical treatment:** As per clinical protocol ▪ **Competency assessment:** Ongoing CPD – benchmarked competency assessment in clinical protocol. ▪ **Frequency of training / review process:** Ongoing review / supervision.

Please refer to the summary of product characteristics for full information

This Patient Group Direction is operational from the start of December 2017 and expires end of November 2019

Version History

Version	Date	Brief Summary of Change	Owner's Name
v 1.0	November 2017	Developed for MIUs and ED minors to provide alternative antibiotic for penicillin allergic patients	Torbay and South Devon NHS Foundation Trust

For more information on the status of this document, contact:	Medicines Governance Team Administrator Pharmacy Department Torbay Hospital tsdft.medicinesgovernance@nhs.net
Date of Issue	**December 2017**
Reference	PGD 2230 v 1.0 Clarithromycin
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Objective	To treat patients with known allergies to penicillin who otherwise would have been given Flucloxacillin, Amoxycillin or Penicillin V for minor injury and illness

The individual practitioners named below are authorised to operate within the above PGD, being employees of Torbay and South Devon NHS Foundation Trust

CLINICAL AREA	LOCATION / DEPARTMENT

The following list must be kept with a copy of the PGD in each clinical area using that PGD. Each practitioner will receive and sign for an individual copy of the PGD. Only fully competent, qualified and trained professionals may operate within PGDs.

I agree to administer/supply the above preparation in accordance with this Patient Group Direction and I have received an up to date copy of the ratified PGD:

NAME *(please print)*	PROFESSIONAL TITLE	SIGNATURE	AUTHORISING MANAGER *(please print)*	MANAGER'S SIGNATURE	DATE

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Document title:	Clarithromycin, Administration / Supply of		
Purpose of document:	Patient Group Direction		
Date of issue:	12 January 2018	**Next review date:**	30 November 2019
Version:	1	**Last review date:**	
Author:	Emergency Department Consultant Pharmacist Senior Manager MIU Services / Nurse Consultant Emergency Care Unit		
Directorate:	Medical Services		
Equality Impact:	The guidance contained in this document is intended to be inclusive for all patients within the clinical group specified, regardless of age, disability, gender, gender identity, sexual orientation, race and ethnicity & religion or belief		
Committee(s) approving the document:	Medical Director Chair, Trust Medicines Management Committee		
Date approved:	21 December 2017		
Links or overlaps with other policies:	All TSDFT Trust Strategies, policies and procedure documents		

	Please select	
	Yes	*No*
Does this document have training implications? *If yes please state:*	☐	☐
Does this document have financial implications? *If yes please state:*	☐	☐
Is this document a direct replacement for another? *If yes please state which documents are being replaced:*	☐	☐

Document Amendment History

Date	Version no.	Amendment summary	Ratified by:
12 January 2018	1	New	Medical Director Chair, Trust Medicines Management Committee

Clinical and Non-Clinical Policies - General Data Protection Regulation (GDPR)

Torbay and South Devon NHS Foundation Trust (TSDFT) has a commitment to ensure that all policies and procedures developed act in accordance with all relevant data protection regulations and guidance. This policy has been designed with the EU General Data Protection Regulation (GDPR) in mind and therefore provides the reader with assurance of effective information governance practice.

GDPR intends to strengthen and unify data protection for all persons; consequently, the rights of individuals have changed. It is assured that these rights have been considered throughout the development of this policy.

Furthermore, GDPR requires that the Trust is open and transparent with its personal identifiable processing activities and this has a considerable effect on the way TSDFT holds, uses, and shares personal identifiable data. The most effective way of being open is through data mapping. Data mapping for GDPR was initially undertaken in November 2017 and must be completed on a triannual (every 3 years) basis to maintain compliance. This policy supports the data mapping requirement of the GDPR.

For more information:

- Contact the Data Access and Disclosure Office on dataprotection.tsdft@nhs.net,
- See TSDFT's Data Protection & Access Policy,
- Visit our GDPR page on ICON.