Patient Group Direction (PGD)
Supply of Clarithromycin for Impetigo in patients aged one year and over who are allergic to Penicillin
(Stoke on Trent and Staffordshire Pharmacies Only)

Version Control

This document is only valid on the day it was printed

The current version of this document will be found within the PharmOutcomes module – Pharmacy First PGD Service 2018 Impetigo

Revision History

Date of this revision: 1st July 2018

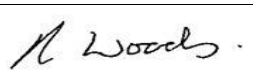
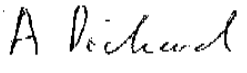
Date of next revision: Before 31st March 2020 (or in response to new local/national guidelines)

Version	Date	Author	Change description
6.0 / 2018	June 2018	Andrew Pickard	Review of date expired PGD (V5)

Authorisation

This document requires authorisation by the following individuals:

Management	
PGD Author	Andrew Pickard, Pharmacy Advisor - NHS England North Midlands Staffordshire and Shropshire

Authorisation			
Name and Designation	**Organisation**	**Signature**	**Date**
Dr Ken Deacon – Medical Director	NHS England North Midlands		30/07/2018
Rebecca Woods – Head of Primary Care	NHS England North Midlands		30/07/2018
Andrew Pickard - Pharmacy Advisor	NHS England North Midlands		30/07/2018

CLINICAL CONTENT OF PATIENT GROUP DIRECTION
Supply of Clarithromycin for Impetigo in patients aged one year and over who are allergic to Penicillin
(Stoke on Trent and Staffordshire Pharmacies Only)

Staff Characteristics	
1. Professional qualifications to be held by staff undertaking PGD	• Community pharmacists accredited by NHS England North Midlands to provide the Pharmacy First PGD Service
2. Competencies required to be held by staff undertaking this PGD	• Has a clear understanding of the legal requirements to operate a PGD. • Competent to follow and administer PGD showing clear understanding of indications for treatment (and subsequent actions to be taken), and the treatment itself. • Has a clear understanding of the drug to be administered including side effects and contraindications. • All clinicians operating within the PGD have a personal responsibility to ensure their on-going competency by continually updating their knowledge and skills.
3. Specialist qualifications, training, experience and competence considered relevant to the clinical condition treated under this PGD	• The community pharmacist must be registered with the General Pharmaceutical Council. • The community pharmacist must provide the service in accordance with the requirements of the associated Service Specification – Pharmacy First PGD Service 2018

Clinical Details	
Indication	Impetigo (non-bullous infection) for patients with hypersensitivity to penicillin. The use of oral antibiotics is considered as second-line therapy for localised lesions associated with impetigo.
Inclusion Criteria	Treat patients presenting with superficial infection of the skin with the following symptoms that are indicative of impetigo and who are hypersensitive to penicillin; • Lesions that begin as vesicles or pustules, that rapidly evolve into gold-crusted plaques (typically up to 2cm in diameter) • Generally painless, but sometimes itchy • Affecting areas of the face, typically around the mouth and nose
Exclusion Criteria	• Bullous impetigo • Patients aged under one year • Systemic illness • Significant inflammation around lesions – consider cellulitis and refer • Lesions that are painful • Recurrent impetigo infection treated within previous 4 weeks • More than two episodes of impetigo treated under this PGD within previous 12 months • Pregnancy and breastfeeding • Known or suspected allergy to clarithromycin or other macrolide antibiotics • Moderate to severe renal and/or hepatic impairment • History of QT prolongation or ventricular cardiac arrhythmia • Hypokalaemia and other electrolyte disturbances such as hypomagnesemia • Patients with symptoms of diarrhoea who have received an antibiotic within the previous 3 months • Clarithromycin is specifically contraindicated for use with the following medicines; astemizole, cisapride, pimozide, terfenadine, ticagrelor, ranolazine, ergotamine or dihydroergotamine, and colchicine. • Concomitant use of medication that has a clinically significant interaction with clarithromycin. The following list is not exhaustive; -Drugs metabolised by the cytochrome P450 system including oral anticoagulants, phenytoin, ciclosporin, and valproate. -HMG-CoA reductase inhibitors (such as simvastatin)

	For a comprehensive list of interactions, please refer to SPC or BNF
Management of excluded clients	• If patient meets 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. • If cellulitis suspected, or if patient presents with severe infection (including systemic symptoms) urgent referral to seek medical advice is required • Record the reason for exclusion and any action taken on PharmOutcomes.
Management of patients requiring referral	If patient declines treatment or advice, ensure the following details are recorded on PharmOutcomes; • The advice given by the clinician • Details of any referral made • The intended actions of the patient (including parent or guardian).

Drug Details	
Name, form & strength of medicine	Clarithromycin tablets 250mg Clarithromycin oral suspension 125mg/5ml or 250mg/5ml
Legal classification	Prescription Only Medicine (POM)
Route/Method	Oral
Dosage/Frequency/ Duration of Treatment	By weight for children aged 1 year to 12 years Under 8kg = 7.5mg/kg twice daily 8kg to 11kg = 62.5mg twice daily (2.5ml of 125mg/5ml) 12kg to 19kg = 125mg twice daily 20kg to 29kg = 187.5mg twice daily (7.5ml of 125mg/5ml) 30kg to 40kg= 250mg twice daily Age 12 to adult = 250mg twice daily Duration of treatment is for 5 days
Quantity to supply/administer	10 x 250mg tablets Oral suspension in multiples of 70ml to provide 5 days of treatment

Storage	Tablets – Store in a dry place below 25°C Unconstituted powder: Store in a dry place below 25°C. Protect from light Reconstituted oral suspension: Store for 7 days in a refrigerator.
Cautions	• Pseudomembranous colitis has been reported with nearly all antibacterial agents, including macrolides, and may range in severity from mild to life-threatening. • *Clostridium difficile*-associated diarrhoea (CDAD) has been reported with use of nearly all antibacterial agents including clarithromycin, and may range in severity from mild diarrhoea to fatal colitis. CDAD must be considered in all patients who present with diarrhoea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents • Patients with coronary artery disease, severe cardiac insufficiency, conduction disturbances or clinically relevant bradycardia. **Please refer to current BNF http://bnf.org/bnf/ and SPC for full details http://www.medicines.org.uk/emc/**
Side Effects	Common side effects; • Oral thrush • Insomnia • Dysgeusia, headache, taste perversion, • Diarrhoea, vomiting, dyspepsia, nausea, abdominal pain • Rash, hyperhidrosis Please refer to SPC for uncommon and rare side effects Use the Yellow Card System to report adverse drug reactions directly to the MHRA. http://yellowcard.mhra.gov.uk/
Drug interactions	• Clarithromycin is specifically contraindicated for use with the following medicines; astemizole, cisapride, pimozide, terfenadine, ticagrelor, ranolazine, ergotamine or dihydroergotamine, and colchicine • Patients that are currently taking a HMG-CoA reductase inhibitor (statin) must be advised to stop taking the statin until the course of treatment with clarithromycin has been completed (ie. for 5 days) • The concomitant use of clarithromycin and oral

	hypoglycaemic agents (such as sulphonylureas) and/or insulin can result in significant hypoglycaemia. Careful monitoring of glucose is recommended. • Caution is advised regarding concomitant administration of clarithromycin with other ototoxic drugs, especially with aminoglycosides. **Please refer to current BNF http://bnf.org/bnf and SPC www.medicines.org.uk/emc for full details**
Advice to patients	Provide the patient with the manufacturer's Patient Information Leaflet and discuss as necessary. • Take doses at regular 12 hourly intervals if possible, and complete the course • Reassure the patient that impetigo usually heals completely without scarring, and that serious complications are rare • If symptoms have not improved after 5 days, advise patient to contact their GP • Hygiene measures are important to aid healing and stop infection spreading to other parts of the body and to other people. It is recommended that the patient; - washes the affected areas with soapy water - washes hands after touching a patch of impetigo - avoids scratching affected areas, and keeps fingernails clean and cut short - avoids sharing towels, flannels, clothing and bathwater until infection has cleared • Children and adults should stay away from school or work until the lesions are dry and scabbed over, or, if the lesions are still crusted or weeping, for 48 hours after antibiotic treatment has started. • May be taken without regard to meals as food does not affect the bioavailability of clarithromycin; • It is no longer necessary to use an extra method of contraception with the pill, patch or vaginal ring when taking clarithromycin unless the patient experiences diarrhoea and vomiting. This change in advice comes because to date there is no evidence to prove that antibiotics (other than rifampicin or rifabutin) affect these contraceptives. This is the latest guidance from the Faculty of Sexual &Reproductive Healthcare. **Please refer to current BNF http://bnf.org/bnf/ or SPC for full details http://www.medicines.org.uk/emc/**

Records and Follow Up	
Follow up	• Seek medical attention immediately if condition deteriorates and/or patient becomes systemically unwell • Advise patient that if rash or other signs of hypersensitivity occur, stop taking the medicine and contact their medical practitioner immediately • Seek medical attention if there is little improvement after 5 days of treatment
Records/audit trail	• In discussion with the client enter consultation details onto the relevant module within PharmOutcomes or complete the paper proforma if unable to access PharmOutcomes at the time of the consultation. All consultations must be entered onto PharmOutcomes on the day that the consultation takes place. • Details of the supply must also be made in the patients (PMR) record. • All supplies of clarithromycin must be labelled in accordance with the labelling requirements for a dispensed medicine as stated within Schedule 5 of The Medicines (Marketing Authorisations etc) Regulations 1994. No 3144 as amended. In addition to the above, the label must also state the words “Supplied under a PGD” to help with audit purposes. • Informed verbal consent should be obtained (for clients aged under 16 years, Fraser guidelines should be followed) • Electronic patient records and/or the completed paper proforma should be retained for adults for a period of 10 years after attendance and for children until the child is 25 years old. Computerised patient medication records are recommended to be kept. • If the client is excluded, a record of the reason for exclusion must be documented within PharmOutcomes, and any specific advice that has been given. • In every case when a supply of clarithromycin is made in accordance with this PGD, the pharmacist must inform the patients GP of the supply within two working days. This will be done through secure nhs.net email accounts via PharmOutcomes once the consultation data has been recorded within the specified module. Where no nhs.net account is available to PharmOutcomes, the pharmacist will be informed by the system and must make alternative arrangements to send the information (within two working days).

Adverse drug reactions	All serious adverse reactions must be reported to MHRA via the yellow card system **www.yellowcard.gov.uk**. A client presenting with a suspected serious ADR should be referred to their medical practitioner.
Date last reviewed: June 2018	**Date for next review: January 2020**
Expiry date: 31st March 2020	**Version No: 6.0 / August 2018**

References	BNF – Current Version Clinical knowledge summaries – Impetigo – July 2015 Antimicrobial prescribing guidelines in general practice (Staffordshire) – 2016 Antibiotic guidance for Shropshire and Powys Primary Care – 2017 Electronic Medicines Compendium - SPC Clarithromycin - 2018
Glossary	BNF – British National Formulary CKS – Clinical Knowledge Summaries SPC – Summary of Product Characteristics PIL – Patient Information Leaflet PGD – Patient Group Direction PMR – Patient Medication Record POM – Prescription Only Medicine MHRA – Medicines and Healthcare Products Regulatory Agency ADR – Adverse Drug Reaction LPC – Local Pharmaceutical Committee

PGD Workgroup

The following individuals have been involved with the production and review of this PGD;

Andrew Pickard MRPharmS	Pharmacy Advisor – NHS England North Midlands
Tania Cork MRPharmS	Chief Operating Officer – North Staffs and Stoke LPC
Hitesh Patel MRPharmS	Senior Pharmaceutical Advisor – Telford and Wrekin CCG

Register of practitioners qualified to supply Clarithromycin for the treatment of Impetigo via PGD (Stoke on Trent and Staffordshire Pharmacies Only)

Operation of this PGD is the responsibility of the commissioner and service providers.

The practitioner must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Contractors who are commissioned to provide the service will be notified of any amendments, and provided with updated documentation for use by individual practitioners.

NHS England authorise this PGD for use by accredited community pharmacists delivering the service from community pharmacies that meet the requirements as outlined in the service specification and that have been commissioned by NHS England.

This page must be completed and retained by each individual pharmacist who intends to work in accordance with this PGD.

Professional Responsibility and Declaration

- I have successfully completed the relevant training as outlined in the Service Specification and this Patient Group Direction
- I agree to maintain my clinical knowledge appropriate to my practice in order to maintain competence to deliver this service
- I am a registered pharmacist with the General Pharmaceutical Council
- I confirm that indemnity insurance is in place to cover my scope of practice
- I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD

Name of professional (please print)	Signature	Date of signing

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY