CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR TREATMENT OF CELLULITIS FROM INFECTED INSECT BITES

CLARITHROMYCIN

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 – Community Pharmacy Extended Care (Tier 2) Service 2021

Revision History

Date of this revision: 01/06/2021

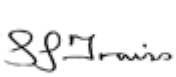
Date of next revision: Jan 2021 (or in response to new local/national guidelines)

Version	Date	Author	Change description
1.2/ 2021	June 2021	Andrew Pickard	New PGD

Authorisation

This document requires authorisation by the following individuals:

Management	
PGD Author	Andrew Pickard, Pharmacy Advisor - NHS England and Improvement Midlands

Authorisation			
Name and Designation	**Organisation**	**Signature**	**Date**
Dr Jessica Sokolov – Medical Director	NHS England and Improvement Midlands		1.7.2021
Rebecca Woods – Head of Primary Care	NHS England and Improvement Midlands		01/07/2021
Samantha Travis - Pharmacist	NHS England and Improvement Midlands		29.06.2021

CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR TREATMENT OF CELLULITIS FROM INFECTED INSECT BITES

CLARITHROMYCIN

Staff Characteristics	
1. Professional qualifications to be held by staff undertaking PGD	• Community pharmacists accredited by NHS England and Improvement Midlands to provide the Pharmacy Extended Care (Tier2) 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 Extended Care (Tier2) Service

Clinical Details	
Indication	Infected insect bites with Eron Class1 cellulitis for patients with hypersensitivity to penicillin.
First line treatment	Flucloxacillin is considered as first line treatment for infected insect bites.
Second line treatment	Clarithromycin is considered as second line treatment for infected insect bites.
Inclusion Criteria	• Patients aged 1 year and over • Treat patients presenting with superficial infection of the skin following an insect bite with the following symptoms that are indicative of Eron Class 1 Cellulitis. Symptoms may include; o Redness of skin, o Pain or tenderness to the area, o Swelling of skin, o Skin may feel hot in the area surrounding the bite o Blistering • Patient has no signs of systemic toxicity, • Patient has no uncontrolled co-morbidities and can be managed with oral antimicrobials. • Treatment via this PGD should only be initiated where there is clear evidence of infection, indicated by cellulitis that is present or worsening at least 24 hours after the initial bite(s).
Exclusion Criteria	• Patient aged under one year • No clear evidence of infection. Initial swelling/inflammation around the site of the bite should be managed in accordance with self-care guidance outlined in the 'Advice to patients' section of this PGD. • Cellulitis that has progressed beyond Eron Class1 • Signs of sepsis such as; o patches of **discoloured skin** indicative of haemorrhagic (purpuric) rash. o **fever** o decreased **urination**. o **changes** in **mental** ability. o **problems** breathing. o **abnormal** heart functions. o **chills** due to fall in body temperature. o **unconsciousness**. • Signs of systemic illness such as; o Fever o Headache o Chills

	o Weakness • A very large area of red, inflamed skin • rapidly spreading erythema and fulminant sepsis seen with necrotising fasciitis. • If the area affected is causing numbness, tingling, or other changes in a hand, arm, leg, or foot • If the skin appears black • Facial cellulitis • Animal (dogs, cats etc.) or human bites • More than two episodes of infected insect bites treated under this PGD within previous 12 months • Pregnancy and breastfeeding • Immunocompromised patients • Patients already taking oral antibiotics • 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, or if the patient is taking any medication that prolongs the QT interval • 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, oral midazolam, lomitapide, 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 Primary Care Clinician. The spectrum of severity may range from localised erythema in a systemically well patient to the rapidly spreading erythema and fulminant sepsis seen with necrotising fasciitis.The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination.

	• If sepsis suspected, or if patient presents with severe infection (including systemic symptoms) urgent referral to seek medical advice is required, or contact 999. • Record the reason for exclusion and any action taken on PharmOutcomes.
Management of patients requiring referral	For referred patients, ensure the following details are recorded on PharmOutcomes; • The advice given by the clinician • Details of any referral made If patients declines treatment or advice, ensure the following details are recorded on PharmOutcomes; • The advice given by the clinincian • 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 or 500mg 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 11 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 = 500mg twice daily Duration of treatment is for 7 days Children under 12 years of age should be treated using oral suspension only. Wherever possible, patients aged 12 years and over should be treated with solid dosage forms, and suspension only reserved for those who are genuinely unable to swallow tablets / capsules.

Quantity to supply/administer	14 x 500mg tablets (or 28 tablets if the 250mg tablet is supplied) Oral suspension in multiples of 70ml to provide 7 days of treatment
Storage	Tablets – Store in a dry place below 25ºC Unconstituted powder: Do not store above 30ºC Reconstituted oral suspension: Store at room temperature (15º to 30ºC) and use within 14 days. Do not refrigerate.
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; • 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, oral midazolam, lomitapide, 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 7 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. **This is not an exhaustive list, so please refer to current BNF http://bnf.org/bnf and SPC www.medicines.org.uk/emc for full details**
Advice to patients	• Initial pain and swelling as a result of an insect bite should be managed with appropriate OTC pain relief such as paracetamol or ibuprofen, and the use of a cold compress (flannel or cloth cooled with cold water) over the affected area. There is little good evidence to support the use of oral antihistamines or topical corticosteroids. • Hygiene measures are important to aid healing It is recommended that the patient; - washes the affected areas with soapy water keep hands clean before and after touching the skin - avoids scratching affected areas, and keeps fingernails clean and cut short, wear cotton gloves if necessary • If treatment via this PGD is required, 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 • If symptoms have not improved after 7 days of treatment, or if there has been a slow response to treatment, advise patient to contact a Primary Care Clinician • 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 a Primary Care Clinician immediately • Seek medical attention if symptoms have not improved, or if there has been a slow response after 7 days of treatment
Records/audit trail	• In discussion with the client enter consultation details onto the relevant module within 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 should be retained for adults for a period of 10 years after attendance and for children until the child is 25 years old. • 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 a Primary Care Clinician.

Date last reviewed: June 2021	**Date for next review: January 2022**
Expiry date: 31st May 2022	**Version No: 1.2 / June 2021**

References	• BNF – Current Version • Clinical knowledge summaries – Insect bites and stings (2020) and acute cellulitis (2021) https://cks.nice.org.uk/insect-bites-and-stings#!scenario:2 https://cks.nice.org.uk/cellulitis-acute#!scenario • Electronic Medicines Compendium - SPC Clarithromycin 2021 https://www.medicines.org.uk/emc/product/6094/smpc https://www.medicines.org.uk/emc/product/515
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

Membership of the NHS England and NHS Improvement (Midlands) Pharmacy Governance Group

Register of practitioners qualified to supply Clarithromycin for the treatment of cellulitis from infected insect bites via PGD

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 and Improvement 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 and Improvement.

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