This Patient Group Direction (PGD) must only be used by registered pharmacists who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

PATIENT GROUP DIRECTION (PGD)

For use in the community pharmacy extended care service

Supply of Clarithromycin for the treatment of Infected Eczema (Widespread) in NHS England Midlands Region

Version Number 6.0 / 2023

Change History	
Version and Date	**Change details**
2.0 / 2022	Existing PGD incorporated into national template
3.0 / 2022	FINAL Draft following NHSEI clinical review
4.0 / 2022	FINAL following system review
5.0 / 2023	Annual review
6.0 / 2023	FINAL PGD following system review

This Patient Group Direction (PGD) must only be used by registered pharmacists who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

PGD DEVELOPMENT GROUP

Date PGD comes into effect:	31st March 2023
Review date	January 2024
Expiry date:	31st March 2024

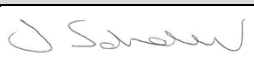
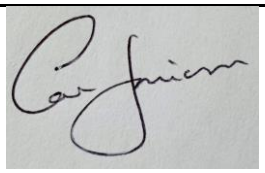
The template for this PGD has been peer reviewed by the Antimicrobial PGDs Short Life Working Group in accordance with their Terms of Reference and approved by the NHSE AMR Programme Board.

This section MUST REMAIN when a PGD is adopted by an organisation.

Name	Designation

The PGD is not legally valid until it has had the relevant organisational approval - see below.

CLINICAL AUTHORISATION OF PGD

Name	Job title and organisation	Signature	Date
Dr Jessica Sokolov	Medical Director, NHSE Midlands		14/03/2023
Richard Seal	Regional Chief Pharmacist, NHSE Midlands		10/03/2023
Andrew Pickard ***(Lead author)***	Regional Pharmacy Advisor, NHSE Midlands		09/03/2023
Dr Conor Jamieson	Regional Antimicrobial Stewardship Lead, NHSE Midlands		10/03/2023

ORGANISATIONAL AUTHORISATION OF PGD

Name	Job title and organisation	Signature	Date
Rebecca Woods	Head of Primary Care Commissioning, NHSE Midlands		**14.03.23**

1. Characteristics of staff

Qualifications and professional registration	• The community pharmacist must be registered with the General Pharmaceutical Council. • The community pharmacist must be accredited by NHS England Midlands to provide the Pharmacy Extended Care (Tier 2) Service.
Training requirements	• The community pharmacist authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patient leading to diagnosis of the conditions listed in this PGD in accordance with local policy. • Undertaken appropriate training and successfully completed the competencies for the identification of sepsis • Undertaken appropriate training and successfully completed the competencies for safeguarding vulnerable adults and children. • Individuals operating under this PGD should follow the national guidance for diagnosis and management of infected eczema in the UK • Individuals operating under this PGD must be familiar with the product and alert to changes in the Summary of Product Characteristics (SPC) • The community pharmacist must provide the service in accordance with the requirements of the associated Service Specification – Pharmacy Extended Care (Tier 2) Service.
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for the recognition and management of infected eczema. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring that they remain up to date with the use of all medicines and guidance 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 (eg. superintendent pharmacist or line manager), and further training provided as required.
The decision to supply any medication rests with the individual registered pharmacist who must abide by the PGD and any associated organisational policies.	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Mild to moderate infected eczema with Eron Class1 cellulitis (no signs of systemic toxicity and no uncontrolled comorbidities) which is widespread, and has not responded to topical corticosteroids and emollients.
First Line Treatment	Flucloxacillin is considered as first-line treatment for widespread areas of infected eczema which has not responded to topical corticosteroids and emollients.
Second Line Treatment	Clarithromycin is considered as second-line treatment for widespread areas of infected eczema which has not responded to topical corticosteroids and emollients, and the patient has a hypersensitivity to penicillin.
Criteria for inclusion	• Informed consent must be obtained prior to continuing with the consultation • Patients aged 1 year and over • Mild to moderate infected eczema with Eron Class1 cellulitis (no signs of systemic toxicity and no uncontrolled comorbidities) which is widespread, and has not responded to topical corticosteroids and emollients. • Treat patients presenting with superficial infection of the skin with the following symptoms that are indicative of infected mild to moderate eczema; not all eczema flares are caused by infection even if crusts and weeping are present. - Infection should be suspected if there is crusting, weeping, erythema, cracks, frank pus or multiple excoriations and increased soreness and itching which may suggest bacterial infection. A common causative organism is *Staphylococcus aureus*. - Infection is widespread rather than localized • Patient has a hypersensitivity to penicillin
Criteria for exclusion	• Patients must be excluded if informed consent is not given • Patients aged under one year • Where topical corticosteroids and emollients have not been applied to the infected area. • Severe eczema • Systemic illness including fever and malaise • Significant inflammation around lesions – cellulitis that has progressed beyond Eron Class1 • Lesions that are painful • More than two episodes of infected eczema treated under this PGD within previous 12 months • Pregnancy and breastfeeding • Immunocompromised patients • Patients already taking oral antibiotics • Herpes simplex infected eczema (herpes simplex complicating atopic eczema (eczema herpeticum) may be misdiagnosed as a *S. aureus* infection. Secondary

	viral infection caused by herpes simplex virus (HSV) is characterized by a sudden onset of grouped, small white or clear fluid filled vesicles, satellite or "punch out" lesions, pustules, and erosions. It is often tender, painful and itchy. The presence of punched-out erosions, vesicles, or infected skin lesions that fail to respond to oral antibiotics should raise suspicion of a herpes simplex infection.) • 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, domperidone, 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) THINK SEPSIS – check for signs/ symptoms using local / national tool relevant to the patients age and risk factors - Assessment | Diagnosis | Sepsis | CKS | NICE Please refer to SPC Home - electronic medicines compendium (emc), BNF BNF (British National Formulary) | NICE or BNFC BNFC (British National Formulary for Children) | NICE for full details
Deferred treatment	If clinically appropriate, and the individual agrees to defer treatment, the pharmacist should determine that they could be treated under the service PGDs if they do return. If the individual then returns after waiting the appropriate amount of time, the pharmacist can then supply the medication once an appropriate follow-up assessment under the PGD is undertaken. The pharmacist making the assessment may refer to the original consultation notes, but must fully reassess the individual for suitability for treatment. The supply

	should be recorded in the Deferred Treatment Module within PharmOutcomes.
Cautions including any relevant action to be taken	• Pseudomembranous colitis has been reported with nearly all antibacterial agents, including macrolides, and may range in severity from mild to life-threatening. • *Clostridioides 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. Patients must be advised of the risk when commencing antibacterial agents. 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 suspected CDAD must be referred to their GP for further assessment, or Emergency Department if severely unwell. • Patients with coronary artery disease, severe cardiac insufficiency, conduction disturbances or clinically relevant bradycardia. • Patients with myasthenia gravis Please refer to SPC Home - electronic medicines compendium (emc) or BNF British National Formulary - NICE for full details.
Specific information for suspected infection to be provided	• Seek medical attention if there is little improvement after 5 days of treatment. • Provide Atopic Eczema leaflet from the British Association of Dermatologists -British Association of Dermatologists (bad.org.uk)
Management of excluded clients	• If patient meets exclusion criteria, refer to a Primary Care Clinician. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination. • If eczema herpeticum (herpes simplex eczema) 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). • Discuss potential consequences of not undertaking treatment and provide safety netting advice.

3. Description of treatment

Name, strength & formulation of drug	Clarithromycin tablets 250mg Clarithromycin oral suspension 125mg/5ml or 250mg/5ml
Legal category	Prescription Only Medicine (POM)
Route of administration	Oral
Off label use	Not applicable
Dose and frequency of administration	Dosage is dependent on age and weight. Refer to BNFC and BNF. 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 years to adult = 250mg twice daily 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 liquids only reserved for those who are genuinely unable to swallow tablets / capsule.
Duration of treatment	Duration of treatment is for 5 days
Quantity to be supplied	10 x 250mg tablets or oral suspension in multiples of 70ml to provide 5 days of treatment
Storage	Storage of tablets, and reconstituted oral suspensions as recommended by the manufacturer. Refer to the manufacturers Summary of Product Characteristics (SPC), which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF.
Drug interactions	• Clarithromycin is specifically contraindicated for use with the following medicines; astemizole, domperidone, 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 (i.e. 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 SPC Home - electronic medicines compendium (emc) or BNF British National Formulary - NICE for full details.
Identification & management of adverse reactions	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. In the event of a severe adverse reaction, the patient must be advised to stop treatment immediately and seek urgent medical advice
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse drug reactions (ADRs) to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk • Record all ADRs in the patient's medical record. • It is considered good practice to notify the individual's GP in the event of an adverse reaction.
Further advice to be supplied to individuals	• Provide the patient with the manufacturer's Patient Information Leaflet and discuss as necessary. • Provide Atopic Eczema leaflet from the British Association of Dermatologists -British Association of Dermatologists (bad.org.uk) • Take doses at regular 12 hourly intervals if possible, and complete the course • May be taken without regard to meals as food does not affect the bioavailability of clarithromycin • 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 there is little improvement after 5 days of treatment • Give guidance that daily baths are a treatment for eczema and help to clean and remove the bacterial load from the skin, add moisture and decrease inflammation and itch. • Continue treatment with topical corticosteroids and emollients if these have been prescribed. • Advise when to begin flaring treatment (as soon as the flare begins and cease flaring treatment when symptoms decrease). This is for all flare ups of eczema, not just those areas that may have become infected. • 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 • FOLLOW UP – Individuals must be contacted within 7 days of the initial consultation to ascertain success of treatment, and arrange referral to an appropriate clinician if symptoms have not resolved, and the individual has not already sought additional advice. Please refer to SPC Home - electronic medicines compendium (emc) or BNF British National Formulary - NICE for full details.
Records	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. The record itself must include the following: • that valid informed consent was given where applicable • name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • any known medication allergies • name of registered pharmacist operating under the PGD • name of medication supplied • batch number and expiry date • date of supply • dose, form and route of administration • quantity supplied • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • administered via Patient Group Direction (PGD) • 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 patient's 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).

4. Key references

Key references	Electronic BNF BNF (British National Formulary) | NICE and BNFC BNFC (British National Formulary for Children) | NICE Clinical knowledge summaries – Atopic Eczema Scenario Infected Eczema- Scenario: Infected eczema | Management | Eczema - atopic | CKS | NICE British Association of Dermatologists – Atopic Eczema - British Association of Dermatologists (bad.org.uk) Summary of product characteristics SPC Home - electronic medicines compendium (emc) NICE ANTIMICROBIAL SUMMARY GUIDANCE for infected eczema https://www.bnf.org/news/2021/07/29/bnf-hosts-antimicrobial-summary-guidance-on-behalf-of-nice-and-phe/ Principles of Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use https://www.nice.org.uk/guidance/ng15

Appendix A - Registered pharmacist authorisation sheet

Supply of Clarithromycin for the Treatment of Infected Eczema

Version: 6.0/2023 Valid from: 31st March 2023 Expiry: 31st March 2024

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered pharmacist

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

I confirm that the registered pharmacists 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 pharmacists 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 pharmacists to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered pharmacists authorised to work under this PGD.

Add details on how this information is to be retained according to organisation PGD policy.