This Patient Group Direction (PGD) must only be used by registered healthcare professionals 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)

Supply of Flucloxacillin for the treatment of Cellulitis from Infected Eczema (Widespread)in NHS England Midlands Region
Version Number 4.0 / 2022

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

This Patient Group Direction (PGD) must only be used by registered professionals 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:	1st June 2022
Review date	1st February 2023
Expiry date:	31st March 2023

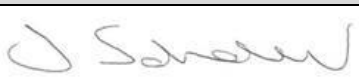
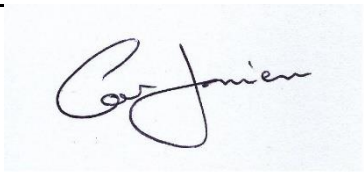
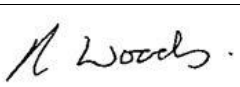
The template for this PGD has been peer reviewed by the Antimicrobial PGDs Short Life Working Group in accordance with their Terms of Reference and approved by the NHSE AMR Programme Board.

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.

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Dr Jessica Sokolov	Medical Director, NHSEI Midlands		23/05/22
Richard Seal	Regional Chief Pharmacist, NHSEI Midlands		23/05/22
Andrew Pickard	Regional Pharmacy Advisor		23/05/22
Dr Conor Jamieson	Regional Antimicrobial Stewardship Lead, NHSEI Midlands		23/05/22
Rebecca Woods	Head of Primary Care Commissioning, NHSEI Midlands		23/05/22

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 and Improvement Midlands to provide the Pharmacy Extended Care (Tier 2) Service.
Initial training	• 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. • 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 addressed and further training provided as required.
The decision to administer/supply any medication rests with the individual registered health professional 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 eczema that has become infected and is widespread.
First Line Treatment	Flucloxacillin is considered as first-line treatment for widespread areas of infected eczema.
Second Line Treatment	Clarithromycin is considered as second-line treatment for widespread areas of infected eczema for patients with 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 eczema with associated bacterial infection. • 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
Criteria for exclusion	• Patients must be excluded if informed consent is not given • Patients aged under one year • Severe eczema • Systemic illness including fever and malaise • Significant inflammation around lesions – consider cellulitis and refer • 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.) • Moderate to severe renal and/or hepatic impairment

	• History of hypersensitivity to β-lactam antibiotics (e.g. penicillins, cephalosporins) or excipients, consider clarithromycin if oral antibiotic required • Previous history of flucloxacillin-associated jaundice/hepatic dysfunction • Concomitant use of medication that has a clinically significant interaction with flucloxacillin. • The following list is not exhaustive; - Anticoagulants - Methotrexate - Probenecid THINK SEPSIS – check for signs/ symptoms using local / national tool e.g NICE - Please refer to SPC Home - electronic medicines compendium (emc) or BNF British National Formulary - NICE for full details
Cautions including any relevant action to be taken	• Pseudomembranous colitis has been reported with nearly all antibacterial agents, including flucloxacillin, 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 flucloxacillin 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. • Caution is advised when flucloxacillin is administered concomitantly with paracetamol due to the increased risk of high anion gap metabolic acidosis (HAGMA). Patients at high risk for HAGMA are in particular those with severe renal impairment, sepsis or malnutrition especially if the maximum daily doses of paracetamol are used. 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	• Hygiene measures are important to aid healing and stop infection. It is recommended that; antiseptic shampoos and products that combine an antiseptic with an emollient, or with a bath emollient, are available. These may reduce the bacterial population colonising the lesional and non-lesional skin. 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. • Seek medical attention if there is little improvement after 5 days of treatment.
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	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 clinician - Details of any referral made - The intended actions of the patient (including parent or guardian)

3. Description of treatment

Name, strength & formulation of drug	Flucloxacillin 250mg and 500mg capsules Flucloxacillin 125mg/5ml and 250mg/5ml oral solution (Sugar and Sugar Free formulations)
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, weight and severity of infection. Refer to cBNF and BNF. • • Usual children's dosage; • Aged 12-23 months; 62.5mg–125mg four times a day* • Aged 2-9 years; 125mg-250mg four times a day* • Aged 10-17 years; 250mg-500mg four times a day*

	**Use the higher dosage in each age range unless judged necessary to use lower cBNF dose* • Usual adult dosage; 500mg four times a day. Oral suspension in multiples of 100ml to provide 5 days of treatment • Flucloxacillin should be taken at least 1 hour before, or 2 hours after meals * • Note: In children, sugar-free versions of Flucloxacillin suspension may have a poor taste leading to reduced compliance. • In discussion with parent/guardian consider sugar-containing preparation. • Wherever possible, patients aged 12years and over should be treated with solid dosage forms and suspension only reserved for those who are genuinely unable to swallow tablets / capsules •
Duration of treatment	Duration of treatment is for 5 days
Storage	Capsules – Store in a dry place below 25°C Un-constituted powder: Store in a dry place below 25°C. Reconstituted oral suspension: Store between 2-8°C in a refrigerator and discard any remaining suspension after 7 days.
Drug interactions	• Probenecid and sulfinpyrazone slow down the excretion of flucloxacillin by decreasing tubular secretion. • Other drugs, such as piperacillin, which are excreted via renal tubular secretion, may interfere with flucloxacillin elimination • Oral typhoid vaccine may be inactivated by flucloxacillin. Flucloxacillin reduces the excretion of methotrexate which can cause methotrexate toxicity. • There are rare cases of altered international normalised ratio (INR) in patients taking warfarin and prescribed a course of flucloxacillin. • Bacteriostatic drugs may interfere with the bactericidal action of flucloxacillin • Concomitant use with paracetamol has been associated with high anion gap metabolic acidosis, especially in patients with risk factors. 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; - Diarrhoea - Nausea - Vomiting - Skin reactions

	Severe adverse reactions are rare, but anaphylaxis (delayed or immediate) has been reported. 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.
Further advice to be supplied to individuals	• Provide the patient with the manufacturer's Patient Information Leaflet and discuss as necessary. • Take doses at regular six hourly intervals, if possible, at least 1 hour before food or 2 hours after food and complete the course. • Flucloxacillin capsules should be taken with a full glass of water (250ml) to reduce the risk of oesophageal pain. • 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 • Patients should not lie down immediately after taking flucloxacillin. • Hygiene measures are important to aid healing and stop infection. It is recommended that; antiseptic shampoos and products that combine an antiseptic with an emollient, or with a bath emollient, are available. These may reduce the bacterial population colonising the lesional and non-lesional skin. 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. • Make sure they understand 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 flucloxacillin 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 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 health professional operating under the PGD • name of medication administered/supplied • batch number and expiry date • date of administration/supply • dose, form and route of administration • quantity administered/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 flucloxacillin 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 flucloxacillin 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 and BNFC https://bnf.nice.org.uk/ Clinical knowledge summaries – Eczema – atopic/infected 2021 https://cks.nice.org.uk/eczema-atopic#!scenario:4 Electronic Medicines Compendium - SPC Flucloxacillin – 2021 https://www.medicines.org.uk/emc/product/545/smpc https://www.medicines.org.uk/emc/product/527/smpc

Appendix A - Registered health professional authorisation sheet

Supply of Flucloxacillin for the treatment of Infected Eczema (widespread)

Version: 4.0/2022 Valid from: 1st June 2022 Expiry: 31st March 2023

Before signing this PGD, check that the document has had the necessary authorisations. 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

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.

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