Patient Group Direction (PGD)

This PGD authorises community pharmacists to supply flucloxacillin capsules or oral solution to patients aged 18 years and over presenting with symptoms of bacterial skin infection under NHS Pharmacy First Scotland.

Publication date: 20th February 2024

Version 2.0

NHS SCOTLAND

Most Recent Changes

Version	Date	Summary of changes
2.0	February 2024	Original PGD transferred into new NHS PFS template. 1.2 Inclusion criteria: ○ Amendment of wording of inclusion criterion for cellulitis 1.3 Exclusion criteria: ○ Addition of exclusion regarding recent antibiotic treatment for same infection ○ Amendment of definition of recurrent cellulitis ○ Clarification on definition of known severe renal impairment ○ Clarification on treatment of injecting drug users under this PGD ○ Removal of breastfeeding exclusion ○ Addition of lactational mastitis exclusion ○ Removal of examples of drugs which may interact with flucloxacillin ○ Standardisation across all NHS PFS PGDs of wording on interactions ○ Clarification of immunosuppression exclusion to bring in line with other NHS PFS PGDs ○ Addition of exclusion relating to acute diarrhoea and vomiting where antibiotic absorption would be impaired. 1.4 Cautions/need for further advice section: ○ Title – changed “doctor” to “prescriber” Updated to reflect range of professionals who are able to independently prescribe ○ Guidance on cholestatic jaundice moved to patient counselling section ○ Addition of further guidance on renal impairment 1.5 Action if excluded: ○ Addition of referral to Emergency Department if showing signs of sepsis 2.6 Maximum or minimum treatment period: clarification provided on number of days 3.3 Advice section: ○ Addition of advice about accessing analgesia ○ Guidance on cholestatic jaundice moved from caution section

Version	Date	Summary of changes
		3.5 Follow up section: ○ Clarification on action required if deterioration or no improvement of symptoms

Contents

Authorisation

This PGD is not legally valid until it has had the relevant organisational authorisation.

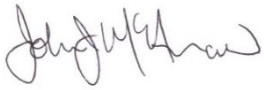
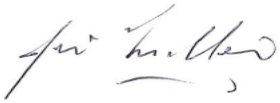
PGD flucloxacillin capsules or oral solution

This specimen PGD template has been produced in collaboration with the Primary Care Community Pharmacy Group to assist NHS Boards in the uniform provision of services under 'NHS Pharmacy First Scotland' banner across NHS Scotland. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The community pharmacist who may supply flucloxacillin capsules or oral solution under this PGD can do so only as a named individual. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with the General Pharmaceutical Council Standards for Pharmacy Professionals and to ensure familiarity with the manufacturer's product information/summary of product characteristics (SPC) for all medicines supplied in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Supply of the medicine must be by the same practitioner who has assessed the patient under the PGD.

This PGD has been approved on behalf of NHS Scotland by NHS 24 by:

Doctor	Dr Ronald Cook	Signature	
Pharmacist	Dr John McAnaw	Signature	
NHS Scotland Representative	Mr Jim Miller	Signature	

Approved on behalf of NHS Dumfries and Galloway by:

Medical Director: Ken Donaldson 

Director of Pharmacy: Graeme Bryson 

Nurse Director: Mark Kelly 

Date approved: 22/02/2024

Effective from: 22/02/2024

It is the responsibility of the person using the PGD to ensure they are using the most recent issue.

Expiry date: 19 February 2027

1. Clinical situation

1.1. Indication

Treatment of bacterial skin infection in patients aged 18 years and over.

1.2. Inclusion criteria

Infected insect bite.

Cellulitis (patient afebrile and no signs of systemic infection).

Acute paronychia with signs of cellulitis.

Valid consent to receiving treatment under this PGD has been obtained.

1.3. Exclusion criteria

Patient under 18 years of age.

Known hypersensitivity to beta-lactam antibiotics (penicillins or cephalosporins) or to any of the excipients within the capsules.

Cellulitis where patient is febrile and/or unwell (i.e., features suggestive of systemic infection).

Cellulitis related to a human or animal bite.

Cellulitis related to a surgical wound or chronic wound / leg ulcer or burns.

Peri-orbital (preseptal) / facial cellulitis present.

Cellulitis on arms or torso NOT linked to an insect bite.

Recent prescription of antibiotic (regardless of source) for same episode of cellulitis.

Recurrent cellulitis at the same site i.e., Two or more episodes within 6 months.

Acute paronychia with signs of cellulitis AND a collection of pus requiring drainage AND / OR patient in severe pain.

Diabetic foot infection.

Known hepatic impairment or previous flucloxacillin associated jaundice.

Known severe renal impairment - patients with eGFR <10mL/minute/1.73m^2 should be referred to GP/OOH for consideration of reduced dose due to the risk of nephrotoxicity.

History of MRSA infection or colonisation.

History of injecting drug use (e.g., illicit drugs, anabolic steroids) and infection is likely to be related to injecting practices

Known pregnancy.

Lactational mastitis.

Concomitant use of interacting medicines - See current BNF and SPC for full risk of possible interactions. If clinically significant interactions are identified, then patients should be referred to GP/OOH for consideration of an alternative treatment.

History of porphyria.

Current immunosuppression e.g., chemotherapy, long term corticosteroids or other immunosuppressant therapies.

Acute diarrhoea and vomiting where antibiotic absorption would be impaired.

Individuals for whom no valid consent has been received.

1.4. Cautions/need for further advice/ circumstances when further advice should be sought from a prescriber

Pharmacists are reminded that:

- Careful enquiry should be made about hypersensitivity reactions to beta-lactam antibacterials.
- Patients with no known renal impairment can be treated without the requirement to independently check levels of impairment. Determination of "no known renal impairment" can be made by asking patient if GP has advised that they have some degree of renal/kidney function impairment, or if they have ongoing reviews with a renal doctor.
- If there are any patient factors which could indicate an increased risk of renal impairment (e.g., current medication, relevant co-morbidities or age), treatment can be considered in community pharmacy if relevant patient records/blood results can be independently checked e.g., using Clinical Portal. If this is not possible, the patient should be referred to GP/OOH).
- See current BNF and SPC for full risk of possible interactions.
- Patients who are breastfeeding – make patient aware that trace amounts can be found in milk, but flucloxacillin is appropriate to use where necessary.

1.5. Action if excluded

Refer to GP Practice / Out-of-hours (OOH) service, or Emergency Department if showing signs of sepsis and document reason for exclusion and any action taken in Patient Medication Record (PMR).

1.6. Action if patient declines

If patient declines treatment: advise on self-care to relieve symptoms and advise to see their GP practice if symptoms fail to resolve within three days or if symptoms worsen.

Ensure patient is aware of risks and consequences of declining treatment.

Document the reason for declining treatment and advice given in PMR.

2. Description of treatment

2.1. Name of medicine/form/strength

Flucloxacillin 500mg capsules

OR
Flucloxacillin 250mg capsules

OR

Flucloxacillin 250mg/5ml oral solution (NB: This form is strictly limited to use in patients who are intolerant of gelatine or have severe dysphagia in relation to capsules)

2.2. Route of administration

Oral

2.3. Dosage

Adults aged 18 years and over:

Health Board Specific:

Ayrshire & Arran	500mg	Highland	500mg
Borders	1g	Lanarkshire	500mg
Dumfries & Galloway	500mg	Lothian	1g
Fife	1g	Orkney	500mg
Forth Valley	500mg	Shetland	500mg
Grampian	500mg	Tayside	1g
Gr Glasgow & Clyde	500mg	Western Isles	500mg

2.4. Frequency

FOUR times a day (during waking hours)

2.5. Duration of treatment

5 days

2.6. Maximum or minimum treatment period

500mg dose – 2g daily for 5 days (10g in total)

1g dose – 4g daily for 5 days (20g in total)

2.7. Quantity to supply

500mg dose – 20 x 500mg capsules or 40 x 250mg capsules or 2 x 100ml

1g dose – 40 x 500mg capsules or 80 x 250mg capsules or 4 x 100ml

2.8. ▼ black triangle medicines

No

2.9. Legal category

Prescription Only Medicine (POM).

In accordance with the MHRA all medicines **supplied** under a PGD **must** either be from over-labelled stock or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply.

2.10. Is the use out with the SPC?

No.

2.11. Storage requirements

Capsules - As per manufacturer's instructions. Store below 25ºC in a cool, dry place.

Oral solution – As per manufacturer's instructions. Unopened bottle – Store below 25ºC in a cool, dry place. Reconstituted solution – store between 2ºC and 8ºC, after reconstitution or when container is opened for the first time discard after 7 days.

2.12. Additional information

None

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these.

Please refer to current BNF or SPC for full details.

If a patient experiences any side effects that are intolerable or hypersensitivity reactions occur, the medication should be discontinued.

Common side effects include minor gastrointestinal disturbances (nausea, vomiting, diarrhoea and abdominal pain).

For a full list of side effects, refer to the marketing authorisation holder's Summary of Product Characteristics (SPC). A copy of the SPC must be available to the health professional supplying the medication under this PGD. This can be accessed on **www.medicines.org.uk.**

In the event of severe adverse reaction e.g., swelling of eyes, face, lips or throat, shortness of breath or wheezing, developing of rash, or feeling faint, individuals should be advised to seek medical advice immediately.

3.2. Reporting procedure for adverse reactions

Pharmacists should document and report all adverse incidents through their own internal governance systems.

All adverse reactions (actual and suspected) should be reported to the appropriate medical practitioner and recorded in the patient's medical record. Pharmacists should record in their PMR and inform the patient's GP as appropriate.

Where appropriate, healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme. Yellow cards and guidance on their use are available at the back of the BNF or online at **www.mhra.gov.uk/yellowcard.**

3.3. Advice to patient or carer including written information

Written information to be given to individuals:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL)

Verbal advice to be given to individuals/parent/carer:

- Advise the individual on mode of action, benefits of the medicine, possible side effects and their management.
- This medicine should be taken when the stomach is empty, which means one hour before food or two hours after food.
- This medicine should be taken regularly until the course is completed.

- Ensure the patient has access to appropriate analgesia for symptom relief if required.
- If symptoms worsen, the patient becomes systemically unwell, or develops a temperature then they should seek further medical advice that day from their GP practice or Out of hours (OOH).
- If symptoms have not improved after 2-3 days of treatment, the patient should seek further medical advice from their GP practice.
- Cholestatic jaundice and hepatitis may occur very rarely, up to two months after treatment with flucloxacillin has been stopped – seek further medical advice if showing symptoms of jaundice or have itchy skin, darker urine or paler stools than usual.
- The latest recommendations are than no additional contraceptive precautions are required when combined oral contraceptives are used with antibacterials that do not induce liver enzymes, unless diarrhoea and vomiting occur.
- Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: **www.mhra.gov.uk/yellowcard.**

3.4. Monitoring

Not applicable

3.5. Follow up

Advise patient to seek further medical advice if symptoms worsen, or do not begin to improve within 2 -3 days of treatment, or if area of inflammation spreads, or patient is becoming unwell or concerned.

3.6. Additional facilities

The following should be available when the medication is supplied:

- An acceptable level of privacy to respect patient's rights to confidentiality and safety
- Access to a working telephone
- Access to medical support (this may be via telephone)
- Approved equipment for the disposal of used materials
- Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel
- Access to current BNF (online version preferred)
    - BNF British National Formulary - NICE
    - BNF for Children British National Formulary - NICE
- Access to SmPC/PIL/Risk Minimisation Material:
    - Home - electronic medicines compendium (emc)
    - MHRA Products | Home
    - RMM Directory - (emc)
- Access to copy of current version of this PGD

4. Characteristics of staff authorised under the PGD

4.1. Professional qualifications

Pharmacist with current General Pharmaceutical Council (GPhC) registration.

Under PGD legislation there can be no delegation. Supply of the medication must be completed by the same practitioner who has assessed the patient under this PGD.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so.

All persons operating this PGD must:

- Be familiar with flucloxacillin medicine and alert to changes in the manufacturer's product information/summary of product information.
- Have read the most up to date guidance on the management of cellulitis e.g., PHE, NICE, SIGN, SAPG.
- Have successfully complete the NES Pharmacy e-learning module:

  Skin infections for NHS Pharmacy First Scotland | Turas | Learn

  https://learn.nes.nhs.scot/43886/pharmacy/cpd-resources/skin-infections-for-nhs-pharmacy-first-scotland
- Be able to assess the person's/ parent's/ carer's capacity to understand the nature of the purpose of the medication in order to give or refuse consent.

4.3. Continuing education and training

All practitioners operating under this PGD are responsible for:

- Maintaining their skills, knowledge, and their own professional level of competence in this area according to the General Pharmaceutical Council Standards for Pharmacy Professionals
- Ensuring they remain up to date with the use of medications included and be aware of local treatment recommendations.
- Attending approved training and training updates as appropriate.
- Undertake relevant continuing professional development when PGD or NES Pharmacy modules are updated.

5. Audit trail

5.1. Authorisation of supply

Pharmacists can be authorised to supply the medicine specified in this PGD when they have completed local Board requirements for service registration.

Pharmacists should complete the individual authorisation form contained in the PGD (Appendix 1) and submit to the relevant NHS Health Board prior to using the PGD.

5.2. Record of supply

All records must be clear, legible, contemporaneous and in an easily retrievable format to allow audit of practice.

A Universal Claim Framework (UCF) record of the screening and subsequent supply, or not, of the medicine specified in this PGD should be made in accordance with the NHS Pharmacy First Scotland service specification.

Pharmacists must record the following information, included in the assessment form, in the PMR (either paper or computer based):

- name of individual, address, date of birth / CHI number
- name of GP with whom the individual is registered (if known)
- confirmation that valid consent to be treated under this PGD was obtained (include details of parent/guardian/person with parental responsibility where applicable)
- details of presenting complaint and diagnosis
- details of medicine supplied - name of medicine, batch number and expiry date, with date of supply.
- details of exclusion criteria – why the medicine was not supplied (if applicable)

- advice given, including advice given if excluded or declines treatment under this PGD
- details of any adverse drug reactions and actions taken
- referral arrangements (including self-care)
- signature and printed name of the pharmacist who undertook assessment of clinical suitability and, where appropriate, subsequently supplied the medicine

The patient's GP (where known) should be provided with a copy of the GP notification form for the supply of flucloxacillin, or appropriate referral on the same, or next available working day.

These records should be retained in accordance with national guidance[1] (see page 56 for standard retention periods summary table). Where local arrangements differ, clarification should be obtained through your Health Board Information Governance Lead.

All records of the drug(s) specified in this PGD will be filed with the normal records of medicines in each service. A designated person within each service will be responsible for auditing completion of drug forms and collation of data.

1. Scottish Government. *Scottish Government Records Management.* Edinburgh 2020. Available at **SG-HSC-Scotland-Records-Management-Code-of-Practice-2020-v20200602.pdf** (Accessed on 19th December 2023)

6. Additional references

Practitioners operating the PGD must be familiar with:

1. National Institute for Clinical Excellence / Public Health England. Available at: **Cellulitis - acute | Health topics A to Z | CKS | NICE** (Accessed 14th May 2023)

2. Current edition of British National Formulary (BNF) BNF British National Formulary - NICE, and BNF for children BNF for Children British National Formulary - NICE

3. Marketing authorisation holder's Summary of Product Characteristics. Electronic Medicines Compendium. *Flucloxacillin 500mg capsules. SPC.* Available **Flucloxacillin 500mg Capsules - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)** (Accessed 19th December 2023)

7. Individual authorisation (Appendix 1)

PGD FOR THE SUPPLY OF FLUCLOXACILLIN CAPSULES OR ORAL SOLUTION BY COMMUNITY PHARMACISTS UNDER THE "NHS PHARMACY FIRST SCOTLAND" SERVICE

This PGD does not remove professional obligations and accountability.

It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with the General Pharmaceutical Council Standards for Pharmacy Professionals.

Authorised staff should be provided with an individual copy of the clinical content of the PGD and a copy of the document showing their authorisation.

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

I have read and understood the PGD authorised by each of the NHS Boards I wish to operate in and agree to provide flucloxacillin capsules or oral solution only in accordance with the specific PGD.

Name of Pharmacist _____ GPhC Registration Number _____

Normal Pharmacy Location

(Only one Pharmacy name and contractor code is required for each Health Board area where appropriate. If you work in more than 3 Health Board areas, please use additional forms.)

Name of Pharmacy	Contractor Code	Health Board
Click or tap here to enter text.	Click or tap here to enter text.	Choose an item.
Click or tap here to enter text.	Click or tap here to enter text.	Choose an item.
Click or tap here to enter text.	Click or tap here to enter text.	Choose an item.

Please indicate your position within the pharmacy by ticking one of the following:

Locum ☐ Employee ☐ Manager ☐ Owner ☐

Signature _____ Date _____

Please complete form, sign and send to each Health Board you work in.
Email and postal addresses are given overleaf.

NHS Board	Address	
Ayrshire & Arran	Iain Fulton, NHS Ayrshire & Arran, Eglington House, Ailsa Hospital, Dalmellington Road, Ayr, KA6 6AB **margaret.scott3@aapct.scot.nhs.uk**	Please email or post
Borders	Malcolm Clubb, Lead Pharmacist Pharmacy Department, Borders General Hospital, Melrose, TD6 9BS **communitypharmacy.team@borders.scot.nhs.uk**	Please email or post
Dumfries & Galloway	NHS Dumfries & Galloway, Primary Care Development, Ground Floor North, Mountainhall Treatment Centre, Bankend Rd, Dumfries, DG1 4TG **Dg.pcd@nhs.scot**	Please email or post
Fife	PGD Administrator, Pharmacy Services, NHS Fife, Pentland House, Lynebank Hospital, Halbeath Road, Dunfermline, KY11 4UW **Fife.pgd@nhs.scot**	Please email or post
Forth Valley	Community Pharmacy Development Team, Forth Valley Royal Hospital, Stirling Road, Larbert, FK5 4WR **fv.communitypharmacysupport@nhs.scot**	Please email or post
Grampian	Pharmaceutical Care Services Team NHS Grampian, Pharmacy & Medicines Directorate, Westholme, Woodend, Queens Road, Aberdeen, AB15 6LS **gram.pharmaceuticalcareservices@nhs.scot**	Please email or post
Greater Glasgow & Clyde	Janine Glen, Contracts Manager, Community Pharmacy, NHS Greater Glasgow & Clyde, Clarkston Court, 56 Busby Road, Glasgow G76 7AT **ggc.cpdevteam@nhs.scot**	0141 201 6044 Or email
Highland	Community Pharmaceutical Services, NHS Highland, Assynt House, Beechwood Park, Inverness. IV2 3BW **nhsh.cpsoffice@nhs.scot**	Please email or post
Lanarkshire	Pharmacy/Prescribing Admin Team, NHS Lanarkshire Headquarters, Kirklands, Fallside Road, Bothwell, G71 8BB **Pharmacy.AdminTeam@lanarkshire.scot.nhs.uk**	Please email or post
Lothian	Primary Care Contractor Organisation, 2ND Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG **CommunityPharmacy.Contract@nhslothian.scot.nhs.uk**	Please email or post
Orkney	Lyndsay Steel, Lead General Practice Pharmacist. The Balfour, Foreland Road, Kirkwall, KW15 1NZ Phone: 01856 888 911 **ork.primarycarepharmacy@nhs.scot**	Please email or post
Shetland	Mary McFarlane, Principle Pharmacist, NHS Shetland, Gilbert Bain Hospital, Lerwick, Shetland, ZE1 0TB	01595 743370
Tayside	Diane Robertson Pharmacy Department, East Day Home, Kings Cross Hospital, Clepington Road, Dundee, DD3 8AE **Diane.Robertson9@nhs.scot**	Please email or post
Western Isles	Michelle Taylor, Primary Care Dept, The Health Centre, Springfield Road, Stornoway, Isle of Lewis, HS1 2PS	Please post

8. Version history

Version	Date	Summary of changes
1.0	March 2021	New National Specimen PGD produced.
1.1	December 2021	Change to dose in individual Health Boards • NHS Borders and NHS Lothian changed from 500mg – NOW 1g FOUR times daily. • All other Health Boards remain unchanged Updated contact details for Individual Authorisation forms
2.0	February 2024	Original PGD transferred into new NHS PFS template. 1.2 Inclusion criteria: ○ Amendment of wording of inclusion criterion for cellulitis 1.3 Exclusion criteria: ○ Addition of exclusion regarding recent antibiotic treatment for same infection ○ Amendment of definition of recurrent cellulitis ○ Clarification on definition of known severe renal impairment ○ Clarification on treatment of injecting drug users under this PGD ○ Removal of breastfeeding exclusion ○ Addition of lactational mastitis exclusion ○ Removal of examples of drugs which may interact with flucloxacillin ○ Clarification on assessment of potential drug interactions ○ Clarification of immunosuppression exclusion to bring in line with other NHS PFS PGDs ○ Addition of exclusion relating to acute diarrhoea and vomiting where antibiotic absorption would be impaired. 1.4 Cautions/need for further advice section: ○ Title – changed “doctor” to “prescriber” Updated to reflect range of professionals who are able to independently prescribe ○ Guidance on cholestatic jaundice moved to patient counselling section ○ Addition of further guidance on renal impairment 1.5 Action if excluded: ○ Addition of referral to Emergency Department if

Version	Date	Summary of changes
		showing signs of sepsis 2.6 Maximum or minimum treatment period: clarification provided on number of days 3.3 Advice section: ○ Addition of advice about accessing analgesia ○ Guidance on cholestatic jaundice moved from caution section 3.5 Follow up section: ○ Clarification on action required if deterioration or no improvement of symptoms