



## **National Patient Group Direction (PGD)**

### **Supply of flucloxacillin capsules/oral solution Version – 1.0**

The purpose of this PGD is to allow management of skin infection in patients over 18 years of age by registered pharmacists within Community Pharmacies.

This PGD authorises pharmacists delivering the NHS Pharmacy First Scotland Service Level Agreement to supply flucloxacillin to patients aged 18 years and over presenting with symptoms of skin infection who meet the criteria for inclusion under the terms of the document.

**Change History - None**

## PGD Flucloxacillin Capsules / Oral solution

### Authorisation

This specimen PGD has been produced in collaboration with the Scottish Antimicrobial Prescribing Group, the Area Drug and Therapeutics collaborative and the Primary Care Community Pharmacy Group to assist NHS Boards provide uniform services under the '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 qualified health professionals who may supply flucloxacillin capsules or oral solution under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct, and to ensure familiarity with the marketing authorisation holder's 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 has to be by the same practitioner who has assessed the patient under the PGD.

### **This specimen PGD has been approved for use within NHS Lanarkshire :**

Chair of Antibiotic Management Team	Dr Stephanie Dundas	Signature	<u>By email 28 May 2021</u>
Chief Pharmacist Primary Care	George Lindsay	Signature	<u>George Lindsay 14 June 2021</u>
Chair of Area Drugs and Therapeutics Committee	Dr Mehrdad Malekian	Signature	<u>Agreed at ADTC Planning meeting 7<sup>th</sup> June 2021</u>

Date Approved 14<sup>th</sup> June 2021

Effective from 15<sup>th</sup> June 2021 Review Date 31<sup>st</sup> May 2023

## Clinical Situation

Indication	Treatment of bacterial skin infection in patients over 18 years of age.
Inclusion Criteria	<ul style="list-style-type: none"> <li>• Infected insect bite</li> <li>• Cellulitis (patient afebrile and healthy other than cellulitis)</li> <li>• Acute paronychia with signs of cellulitis</li> </ul>
Exclusion Criteria	<ul style="list-style-type: none"> <li>• Patient under 18 years old</li> <li>• Known hypersensitivity to beta-lactam antibiotic (penicillins or cephalosporins) or any excipients</li> <li>• Cellulitis where patient febrile and/or unwell (i.e. features suggestive of systemic infection)</li> <li>• Cellulitis related to a human or animal bite</li> <li>• Cellulitis related to surgical wound or chronic wound/ leg ulcer or burns</li> <li>• Peri-orbital (preseptal)/facial cellulitis present</li> <li>• Cellulitis on arms or torso <b>not</b> linked to an insect bite</li> <li>• Recurrent cellulitis i.e. more than once within a year</li> <li>• Acute paronychia with signs of cellulitis AND a collection of pus requiring drainage AND/OR in severe pain</li> <li>• Diabetic foot infection</li> <li>• Known hepatic impairment or flucloxacillin associated jaundice</li> <li>• Known severe renal impairment</li> <li>• History of MRSA infection or colonisation</li> <li>• History of injecting drug use (e.g. illicit drugs, anabolic steroids)</li> <li>• Concomitant use of interacting medication e.g. probenecid, methotrexate, oral typhoid capsule, warfarin</li> <li>• History of porphyria</li> <li>• Known immunosuppression or taking immunosuppressants</li> <li>• Pregnant or breastfeeding</li> <li>• Informed consent not obtained</li> </ul>
Cautions /Need for further advice/ Circumstances when further advice should be sought from a doctor	<p>Healthcare professionals are reminded that:</p> <ul style="list-style-type: none"> <li>• Careful enquiry should be made about hypersensitivity reactions to beta-lactam antibacterials</li> <li>• Cholestatic jaundice and hepatitis may occur very rarely, up to two months after treatment with flucloxacillin has been stopped.</li> </ul> <p>Cautions - see BNF and Summary of Product Characteristics</p>
Action if Excluded	Refer to GP Practice/Out-of-hours (OOH) service and document in Patient Medication Record (PMR) or Pharmacy Care Record (PCR).
Action if Patient Declines	<ul style="list-style-type: none"> <li>• If patient declines treatment, advise on self-care to relieve symptoms and advise to see their GP if symptoms fail to resolve within 3 days or if symptoms worsen.</li> <li>• The reason for declining treatment and advice given must be documented.</li> <li>• Ensure patient is aware of risks and consequences of declining treatment.</li> <li>• Record outcome in PMR or PCR if appropriate</li> </ul>

## Description of Treatment

Name of Medicine	Flucloxacillin			
Form/Strength	500 mg (or 2 x 250 mg) capsules			
Route of administration	Oral			
Dosage	<b>Health Board Specific</b>			
	Ayrshire & Arran	500mg	Highland	500mg
	Borders	500mg	Lanarkshire	500mg
	Dumfries & Galloway	500mg	Lothian	500mg
	Fife	1g	Orkney	500mg
	Forth Valley	500mg	Shetland	500mg
	Grampian	500mg	Tayside	1g
	GG&C	500mg	Western Isles	500mg
Frequency	Four times a day (during waking hours)			
Duration of treatment	5 days			
Maximum or minimum treatment period	500 mg dose - 2 g daily (10g in total) 1g dose – 4 g daily (20g in total)			
Quantity to supply/administer	500 mg dose - 20 x 500 mg capsules or 40 x 250 mg capsules 1g dose – 40 x 500 mg capsules or 80 x 250 mg capsules			
▼ additional monitoring	No			
Legal Category	POM (Prescription Only Medicine)			
Is the use outwith the SPC	No			
Storage requirements	As per manufacturer's instructions Ensure capsules are within expiry date			
Additional information	None			

## Description of treatment continued

Name of Medicine	Flucloxacillin			
Form/Strength	250 mg/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			
Route of administration	Oral			
Dosage	<b>Health Board specific</b>			
	Ayrshire & Arran	500mg	Highland	500mg
	Borders	500mg	Lanarkshire	500mg
	Dumfries & Galloway	500mg	Lothian	500mg
	Fife	1g	Orkney	500mg
	Forth Valley	500mg	Shetland	500mg
	Grampian	500mg	Tayside	1g
	GG&C	500mg	Western Isles	500mg
Frequency	Four times a day (during waking hours)			
Duration of treatment	5 days			
Maximum or minimum treatment period	500 mg dose - 2 g daily (10g in total) 1g dose – 4 g daily (20g in total)			
Quantity to supply/administer	500 mg dose - 2 x 100ml 1g dose – 4 x 100ml			
▼ additional monitoring	No			
Legal Category	POM			
Is the use out with the SPC	No			
Storage requirements	As per manufacturer's instructions Unopened bottle – store at or below 25°C in a dry place Reconstituted solution – store between 2°C and 8°C After reconstitution or when container is opened for the first time – discard after 7 days Ensure solution is within expiry date			

Warnings including possible adverse reactions and management of these	<p>Minor gastro-intestinal disturbances e.g. nausea, vomiting, diarrhoea</p> <p>Hypersensitivity</p> <p>For a full list of side effects – refer to the marketing authorisation holder’s SPC. A copy of the SPC must be available to the health professional administering medication under this Patient Group Direction. This can be accessed on <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>
Reporting procedure for adverse reactions	<p>Pharmacists should document and report all adverse incidents through their own internal governance systems.</p> <p>Pharmacists should record all adverse reactions (actual and suspected) in their PMR and send an SBAR (situation, background, assessment, recommendation) communication to the appropriate medical practitioner for documenting in the patient’s medical record as appropriate.</p> <p>Where appropriate, use the Yellow Card System to report adverse drug reactions. Yellow Cards and guidance on its use are available at the back of the BNF or online at <a href="http://yellowcard.mhra.gov.uk/">http://yellowcard.mhra.gov.uk/</a></p>
Advice to Patient/carer including written information	<ul style="list-style-type: none"> <li>• Take this medicine when your stomach is empty. This means an hour before food or 2 hours after food</li> <li>• Advise patient of the importance of taking flucloxacillin regularly and completing the course</li> <li>• Inform patient of possible side effects and their management and who to contact should they be troublesome</li> <li>• If rash or other signs of hypersensitivity occur, stop taking the medicine and contact your doctor for advice</li> <li>• Ensure patient is aware that if symptoms worsen, the patient becomes systemically unwell e.g. develops a temperature, racing heartbeat, rapid shallow breathing or confusion then they should seek medical advice that day</li> <li>• If symptoms have not improved after 2-3 days treatment, then patients should be advised to seek further medical advice</li> <li>• Latest recommendations are that 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</li> <li>• The Drug Manufacturer Patient Information Leaflet should be given. Patients should be informed who to contact should they experience an adverse drug reaction</li> </ul>
Monitoring	Not applicable
Follow-up	Advise patient to seek medical advice should symptoms worsen or not improve.
Additional Facilities	<p>The following should be available where the medication is supplied:</p> <ul style="list-style-type: none"> <li>• An acceptable level of privacy to respect patient’s right to confidentiality and safety</li> <li>• Access to medical support (this may be via the telephone)</li> <li>• Approved equipment for the disposal of used materials</li> <li>• Clean and tidy work areas, including access to hand washing facilities</li> <li>• Access to current BNF (online version preferred)</li> </ul>

### Characteristics of staff authorised under the PGD

Professional qualifications	Registered pharmacist with current General Pharmaceutical Council (GPhC) registration. <b><i>Under PGD legislation there can be no delegation. Supply of the medication has to be by the same practitioner who has assessed the patient under this PGD.</i></b>
Specialist competencies or qualifications	Has undertaken appropriate training to carry out clinical assessment of patient which may lead to diagnosis that requires treatment according to the indications listed in this PGD, by successfully completing NES Pharmacy e-learning module on “Skin infections for NHS Pharmacy First Scotland” <a href="https://learn.nes.nhs.scot/43886/pharmacy/cpd-resources/skin-infections-for-nhs-pharmacy-first-scotland">https://learn.nes.nhs.scot/43886/pharmacy/cpd-resources/skin-infections-for-nhs-pharmacy-first-scotland</a>  Able to assess the person’s capacity to understand the nature and purpose of the medication in order to give or refuse consent.  Must be familiar with the flucloxacillin SPC.  Authorised to use PGD on completion and submission of an approved practitioner form.
Continuing education and training	It is the responsibility of the individual to keep up-to-date with continued professional development  Has read the most up to date guidance on the management of cellulitis e.g. PHE, NICE, SIGN, SAPG. Attends approved training and training updates as appropriate. Undertakes CPD when PGD or NES Pharmacy module are updated.

### Audit Trail

Record/Audit Trail	All records must be clear, legible and in an easily retrieval format. Pharmacists must record in PMR or PCR.  The following records should be kept (paper or computer based) and are included in the patient assessment form: <ul style="list-style-type: none"> <li>• Patient’s name/parent/guardian/person with parental responsibility, address, date of birth and consent given</li> <li>• Patient’s CHI number</li> <li>• Contact details of GP (if registered)</li> <li>• Presenting complaint and diagnosis</li> <li>• Details of medicine supplied</li> <li>• The signature and printed name of the healthcare professional who supplied the medicine.</li> <li>• Advice given to patient (including side effects)</li> <li>• The PGD title and/or number</li> <li>• Whether the patient met the inclusion criteria and whether the exclusion criteria were assessed</li> <li>• Details of any adverse drug reaction and actions taken including documentation in the patient’s medical record</li> <li>• Referral arrangements (including self-care)</li> </ul>
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	<p><b><i>The patient's GP, where known, should be provided with a copy of the client assessment form for the supply of flucloxacillin on the same, or next available working day.</i></b></p> <p><b><i>If the patient suffers an adverse drug reaction to flucloxacillin, the GP should also be informed.</i></b></p> <p>These records should be retained in accordance with national guidance<sup>1</sup> (see page 56 for standard retention periods summary table). Where local arrangements differ, clarification should be obtained through your Health Board Information Governance Lead.</p> <p>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.</p> <p>1. Scottish Government. <i>Scottish Government Records Management</i>. Edinburgh 2020. Available at <a href="https://www.gov.scot/Information/SG-HSC-Scotland-Records-Management-Code-of-Practice-2020-v20200602.pdf">SG-HSC-Scotland-Records-Management-Code-of-Practice-2020-v20200602.pdf</a> (Accessed on 21/05/2021)</p>
Additional references	British National Formulary (BNF) current edition flucloxacillin SPC.



**PATIENT GROUP DIRECTION FOR THE SUPPLY OF FLUCLOXACILLIN CAPSULES OR ORAL SOLUTION BY COMMUNITY PHARMACISTS UNDER THE 'NHS PHARMACY FIRST SCOTLAND' SERVICE**

**Individual Authorisation**

***PGD does not remove inherent professional obligations or accountability***

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

**Note to Authorising Authority:** authorised staff should be provided with access to the clinical content of the PGD and a copy of the document showing their authorisation.

I have read and understood the Patient Group Direction authorised by each of the individual NHS Boards that I wish to operate in and agree to provide flucloxacillin capsules/oral solution.

Name of Pharmacist \_\_\_\_\_

GPhC Registration Number \_\_\_\_\_

Normal Pharmacy Location

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

Name & Contractor code HB (1) \_\_\_\_\_

Name & Contractor code HB (2) \_\_\_\_\_

Name & Contractor code HB (3) \_\_\_\_\_

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

Locum  Employee  Manager  Owner

Signature \_\_\_\_\_ Date \_\_\_\_\_

Please tick and send to each Health Board you work in. Fax numbers, email and postal addresses are given overleaf.

Ayrshire & Arran  Grampian  Orkney

Borders  Gr Glasgow & Clyde  Shetland

Dumfries & Galloway  Highland  Tayside

Fife  Lanarkshire  Western Isles

Forth Valley  Lothian

NHS Board	Address	Fax Number
Ayrshire & Arran	Allan Thomas, NHS Ayrshire & Arran, Eglinton House, Ailsa Hospital, Dalmellington Road, Ayr, KA6 6AB <a href="mailto:Angela.oumoussa@aapct.scot.nhs.uk">Angela.oumoussa@aapct.scot.nhs.uk</a>	Please e-mail or post
Borders	Adrian Mackenzie, Lead Pharmacist Pharmacy Department, Borders General Hospital, Melrose, TD6 9BS <a href="mailto:communitypharmacy.team@borders.scot.nhs.uk">communitypharmacy.team@borders.scot.nhs.uk</a>	Please e-mail or post
Dumfries & Galloway	NHS Dumfries & Galloway, Primary Care Development, Ground Floor North, Mountainhall Treatment Centre, Bankend Rd, Dumfries, DG1 4TG <a href="mailto:Dg.pcd@nhs.scot">Dg.pcd@nhs.scot</a>	Please e-mail or post
Fife	PGD Administrator, Pharmacy Services, NHS Fife, Pentland House, Lynebank Hospital, Halbeath Road, Dunfermline, KY11 4UW <a href="mailto:Fife.pgd@nhs.scot">Fife.pgd@nhs.scot</a>	Please e-mail or post
Forth Valley	Community Pharmacy Development Team, Forth Valley Royal Hospital, Stirling Road, Larbert, FK5 4WR <a href="mailto:fv.communitypharmacysupport@nhs.scot">fv.communitypharmacysupport@nhs.scot</a>	Please e-mail or post
Grampian	Pharmaceutical Care Services Team NHS Grampian, Pharmacy & Medicines Directorate, Westholme, Woodend, Queens Road, Aberdeen, AB15 6LS <a href="mailto:gram.pharmaceuticalcareservices@nhs.scot">gram.pharmaceuticalcareservices@nhs.scot</a>	Please e-mail or post
Greater Glasgow & Clyde	Janine Glen, Contracts Manager, Community Pharmacy, NHS Greater Glasgow & Clyde, Clarkston Court, 56 Busby Road, Glasgow G76 7AT <a href="mailto:ggc.cpdevteam@nhs.scot">ggc.cpdevteam@nhs.scot</a>	0141 201 6044 Or e-mail
Highland	Community Pharmaceutical Services, NHS Highland, Assynt House, Beechwood Park, Inverness. IV2 3BW <a href="mailto:nhsh.cpsoffice@nhs.scot">nhsh.cpsoffice@nhs.scot</a>	Please e-mail or post
Lanarkshire	Pharmacy/Prescribing Admin Team, NHS Lanarkshire Headquarters, Kirklands, Fallside Road, Bothwell, G71 8BB <a href="mailto:PharmacyAdminTeam@lanarkshire.scot.nhs.uk">PharmacyAdminTeam@lanarkshire.scot.nhs.uk</a>	Please e-mail or post
Lothian	Primary Care Contractor Organisation, 2ND Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG <a href="mailto:CommunityPharmacy.Contract@nhslothian.scot.nhs.uk">CommunityPharmacy.Contract@nhslothian.scot.nhs.uk</a>	Please e-mail or post
Orkney	Lyndsay Steel, Lead General Practice Pharmacist. The Balfour, Foreland Road, Kirkwall, KW15 1NZ Phone: 01856 888 911 <a href="mailto:ork.primarycarepharmacy@nhs.scot">ork.primarycarepharmacy@nhs.scot</a>	Please e-mail or post
Shetland	Mary McFarlane, , Principle Pharmacist, NHS Shetland, Gilbert Bain Hospital, Lerwick, Shetland, ZE1 0TB	01595 743356
Tayside	Diane Robertson, Pharmacy Department, East Day Home, Kings Cross Hospital, Clepington Road, Dundee, DD3 8AE <a href="mailto:Diane.Robertson9@nhs.scot">Diane.Robertson9@nhs.scot</a>	Please e-mail or post
Western Isles	Stephan Smit, Primary Care Department, The Health Centre, Springfield Road, Stornoway, Isle of Lewis, HS1 2PS	No fax, please post