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 on behalf of NHS Scotland by NHS 24 by:

Doctor	_____	Signature	_____
Pharmacist	_____	Signature	_____
NHS Scotland Representative	_____	Signature	_____

Approved on behalf of NHS [insert details] by

Medical Director	_____	Signature	_____
Director of Pharmacy/Senior Pharmacist	_____	Signature	_____
Clinical Governance Lead	_____	Signature	_____

Date Approved _____

Effective from	May 2021	Review Date	May 2023

Clinical Situation

Indication	Treatment of bacterial skin infection in patients over 18 years of age.
Inclusion Criteria	• Infected insect bite • Cellulitis (patient afebrile and healthy other than cellulitis) • Acute paronychia with signs of cellulitis
Exclusion Criteria	• Patient under 18 years old • Known hypersensitivity to beta-lactam antibiotic (penicillins or cephalosporins) or any excipients • Cellulitis where patient febrile and/or unwell (i.e. features suggestive of systemic infection) • Cellulitis related to a human or animal bite • Cellulitis related to 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 • Recurrent cellulitis i.e. more than once within a year • Acute paronychia with signs of cellulitis AND a collection of pus requiring drainage AND/OR in severe pain • Diabetic foot infection • Known hepatic impairment or flucloxacillin associated jaundice • Known severe renal impairment • History of MRSA infection or colonisation • History of injecting drug use (e.g. illicit drugs, anabolic steroids) • Concomitant use of interacting medication e.g. probenecid, methotrexate, oral typhoid capsule, warfarin • History of porphyria • Known immunosuppression or taking immunosuppressants • Pregnant or breastfeeding • Informed consent not obtained
Cautions /Need for further advice/ Circumstances when further advice should be sought from a doctor	Healthcare professionals are reminded that: • Careful enquiry should be made about hypersensitivity reactions to beta-lactam antibacterials • Cholestatic jaundice and hepatitis may occur very rarely, up to two months after treatment with flucloxacillin has been stopped. Cautions - see BNF and Summary of Product Characteristics
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	• 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. • The reason for declining treatment and advice given must be documented. • Ensure patient is aware of risks and consequences of declining treatment. • Record outcome in PMR or PCR if appropriate

Description of Treatment

<table>
<tr><td>Name of Medicine</td><td colspan="4">Flucloxacillin</td></tr>
<tr><td>Form/Strength</td><td colspan="4">500 mg (or 2 x 250 mg) capsules</td></tr>
<tr><td>Route of administration</td><td colspan="4">Oral</td></tr>
<tr><td rowspan="9">Dosage</td><td colspan="4">Health Board Specific</td></tr>
<tr><td>Ayrshire & Arran</td><td>500mg</td><td>Highland</td><td>500mg</td></tr>
<tr><td>Borders</td><td>500mg</td><td>Lanarkshire</td><td>500mg</td></tr>
<tr><td>Dumfries & Galloway</td><td>500mg</td><td>Lothian</td><td>500mg</td></tr>
<tr><td>Fife</td><td>1g</td><td>Orkney</td><td>500mg</td></tr>
<tr><td>Forth Valley</td><td>500mg</td><td>Shetland</td><td>500mg</td></tr>
<tr><td>Grampian</td><td>500mg</td><td>Tayside</td><td>1g</td></tr>
<tr><td>GG&C</td><td>500mg</td><td>Western Isles</td><td>500mg</td></tr>
<tr><td colspan="4"></td></tr>
<tr><td>Frequency</td><td colspan="4">Four times a day (during waking hours)</td></tr>
<tr><td>Duration of treatment</td><td colspan="4">5 days</td></tr>
<tr><td>Maximum or minimum treatment period</td><td colspan="4">500 mg dose - 2 g daily (10g in total)
1g dose – 4 g daily (20g in total)</td></tr>
<tr><td>Quantity to supply/administer</td><td colspan="4">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</td></tr>
<tr><td>▼ additional monitoring</td><td colspan="4">No</td></tr>
<tr><td>Legal Category</td><td colspan="4">POM (Prescription Only Medicine)</td></tr>
<tr><td>Is the use outwith the SPC</td><td colspan="4">No</td></tr>
<tr><td>Storage requirements</td><td colspan="4">As per manufacturer’s instructions
Ensure capsules are within expiry date</td></tr>
<tr><td>Additional information</td><td colspan="4">None</td></tr>
</table>

Description of treatment continued

<table>
<tr><td>Name of Medicine</td><td colspan="4">Flucloxacillin</td></tr>
<tr><td>Form/Strength</td><td colspan="4">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</td></tr>
<tr><td>Route of administration</td><td colspan="4">Oral</td></tr>
<tr><td>Dosage</td><td colspan="4">Health Board specific</td></tr>
<tr><td></td><td>Ayrshire & Arran</td><td>500mg</td><td>Highland</td><td>500mg</td></tr>
<tr><td></td><td>Borders</td><td>500mg</td><td>Lanarkshire</td><td>500mg</td></tr>
<tr><td></td><td>Dumfries & Galloway</td><td>500mg</td><td>Lothian</td><td>500mg</td></tr>
<tr><td></td><td>Fife</td><td>1g</td><td>Orkney</td><td>500mg</td></tr>
<tr><td></td><td>Forth Valley</td><td>500mg</td><td>Shetland</td><td>500mg</td></tr>
<tr><td></td><td>Grampian</td><td>500mg</td><td>Tayside</td><td>1g</td></tr>
<tr><td></td><td>GG&C</td><td>500mg</td><td>Western Isles</td><td>500mg</td></tr>
<tr><td>Frequency</td><td colspan="4">Four times a day (during waking hours)</td></tr>
<tr><td>Duration of treatment</td><td colspan="4">5 days</td></tr>
<tr><td>Maximum or minimum treatment period</td><td colspan="4">500 mg dose - 2 g daily (10g in total)
1g dose – 4 g daily (20g in total)</td></tr>
<tr><td>Quantity to supply/administer</td><td colspan="4">500 mg dose - 2 x 100ml
1g dose – 4 x 100ml</td></tr>
<tr><td>▼ additional monitoring</td><td colspan="4">No</td></tr>
<tr><td>Legal Category</td><td colspan="4">POM</td></tr>
<tr><td>Is the use out with the SPC</td><td colspan="4">No</td></tr>
<tr><td>Storage requirements</td><td colspan="4">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</td></tr>
</table>

Warnings including possible adverse reactions and management of these	Minor gastro-intestinal disturbances e.g. nausea, vomiting, diarrhoea Hypersensitivity 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 www.medicines.org.uk
Reporting procedure for adverse reactions	Pharmacists should document and report all adverse incidents through their own internal governance systems. 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. 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 http://yellowcard.mhra.gov.uk/
Advice to Patient/carer including written information	• Take this medicine when your stomach is empty. This means an hour before food or 2 hours after food • Advise patient of the importance of taking flucloxacillin regularly and completing the course • Inform patient of possible side effects and their management and who to contact should they be troublesome • If rash or other signs of hypersensitivity occur, stop taking the medicine and contact your doctor for advice • 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 • If symptoms have not improved after 2-3 days treatment, then patients should be advised to seek further medical advice • 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 • The Drug Manufacturer Patient Information Leaflet should be given. Patients should be informed who to contact should they experience an adverse drug reaction
Monitoring	Not applicable
Follow-up	Advise patient to seek medical advice should symptoms worsen or not improve.
Additional Facilities	The following should be available where the medication is supplied: • An acceptable level of privacy to respect patient's right to confidentiality and safety • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities • Access to current BNF (online version preferred)

Characteristics of staff authorised under the PGD

Professional qualifications	Registered pharmacist with current General Pharmaceutical Council (GPhC) registration. ***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.***
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" https://learn.nes.nhs.scot/43886/pharmacy/cpd-resources/skin-infections-for-nhs-pharmacy-first-scotland 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: • Patient's name/parent/guardian/person with parental responsibility, address, date of birth and consent given • Patient's CHI number • Contact details of GP (if registered) • Presenting complaint and diagnosis • Details of medicine supplied • The signature and printed name of the healthcare professional who supplied the medicine. • Advice given to patient (including side effects) • The PGD title and/or number • Whether the patient met the inclusion criteria and whether the exclusion criteria were assessed • Details of any adverse drug reaction and actions taken including documentation in the patient's medical record • Referral arrangements (including self-care)

	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. ***If the patient suffers an adverse drug reaction to flucloxacillin, the GP should also be informed.*** 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 21/05/2021)
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, Eglington House, Ailsa Hospital, Dalmellington Road, Ayr, KA6 6AB Angela.oumoussa@aapct.scot.nhs.uk	Please e-mail or post
Borders	Adrian Mackenzie, Lead Pharmacist Pharmacy Department, Borders General Hospital, Melrose, TD6 9BS communitypharmacy.team@borders.scot.nhs.uk	Please e-mail 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 e-mail or post
Fife	PGD Administrator, Pharmacy Services, NHS Fife, Pentland House, Lynebank Hospital, Halbeath Road, Dunfermline, KY11 4UW Fife.pgd@nhs.scot	Please e-mail or post
Forth Valley	Community Pharmacy Development Team, Forth Valley Royal Hospital, Stirling Road, Larbert, FK5 4WR fv.communitypharmacysupport@nhs.scot	Please e-mail or post
Grampian	Pharmaceutical Care Services Team NHS Grampian, Pharmacy & Medicines Directorate, Westholme, Woodend, Queens Road, Aberdeen, AB15 6LS gram.pharmaceuticalcareservices@nhs.scot	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 ggc.cpdevteam@nhs.scot	0141 201 6044 Or e-mail
Highland	Community Pharmaceutical Services, NHS Highland, Assynt House, Beechwood Park, Inverness. IV2 3BW nhsh.cpsoffice@nhs.scot	Please e-mail or post
Lanarkshire	Pharmacy/Prescribing Admin Team, NHS Lanarkshire Headquarters, Kirklands, Fallside Road, Bothwell, G71 8BB PharmacyAdminTeam@lanarkshire.scot.nhs.uk	Please e-mail 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 e-mail 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 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 Diane.Robertson9@nhs.scot	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