



Dear Colleague

ADDITIONAL PHARMACEUTICAL SERVICES NHS PHARMACY FIRST SCOTLAND – ADDITION OF COMMON CLINICAL CONDITIONS

Purpose

1. This Circular advises that Patient Group Directions (PGDs) supporting two further common clinical conditions will be added to the NHS Pharmacy First Scotland service.

Background

2. NHS Circular [PCA \(P\)\(2020\) 13](#), issued on 1 July 2020, enclosed Directions for the Health Board Additional Pharmaceutical Services (NHS Pharmacy First Scotland) Directions 2020 which came into force as of 29 July 2020.

3. Two common clinical conditions, supported by PGDs, are currently included in the NHS Pharmacy First Scotland service: uncomplicated UTIs and impetigo.

Detail

4. From 15 June 2021, PGDs supporting two further common clinical conditions will be added as part of the national service to facilitate consultations for advice and treatment of shingles and skin infections.

5. Some Health Boards already have those conditions included in local pharmacy services, however, the expectation is that the national NHS Pharmacy First Scotland arrangements will replace those local services.

6. Community pharmacy contractors and pharmacy teams should ensure they are familiar with the new arrangements as detailed below.

24 May 2021

Addresses

For action

Chief Executives, NHS Boards
Directors of Pharmacy
Director of Practitioner Service,
NHS NSS

For information

Chief Executive, NHS NSS

Enquiries to:

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EDINBURGH
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Email:

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Patient Group Directions (PGDs)

7. Two PGDs have been developed nationally for NHS Pharmacy First Scotland to replace existing PGDs for aciclovir (for treatment of shingles) and flucloxacillin (for the treatment of skin infections).

8. **Annex A** of this circular provides copies of the **draft** PGDs which have been approved by NHS24 to allow pharmacists as much time as possible to familiarise themselves with the relevant details before launch on the 15th June. In the meantime, as local governance procedures must be followed even when a PGD is agreed nationally, Health Boards will each approve, sign and publish these PGDs through the appropriate channels. Individual authorisation forms will be published alongside these and should be completed by Pharmacists delivering NHS Pharmacy First Scotland and submitted to each Health Board area that they work in.

9. Where a Pharmacist Independent Prescriber is delivering an NHS service which would include consultations for shingles and/or skin infections (e.g. Pharmacy First Plus), they should not utilise the PGDs, instead using their qualification to prescribe as they ordinarily would under the agreed service specification.

Training

10. Community pharmacy contractors should ensure that their pharmacists complete e-learning modules for both shingles and skin infections. The e-learning modules are now available on the NES TURAS Learn website at <https://learn.nes.nhs.scot/43887/pharmacy/cpd-resources/shingles-for-pharmacy-first-scotland> and <https://learn.nes.nhs.scot/43886/pharmacy/cpd-resources/skin-infections-for-nhs-pharmacy-first-scotland>.

IT roll-out

11. All Patient Medication Record (PMR) suppliers have confirmed that pharmacy IT software will support pharmacy teams to deliver the two further common clinical conditions from the launch date of 15 June 2021.

12. Community Pharmacy Scotland has been consulted on the contents of this Circular and the Scottish Drug Tariff is being amended.

Action

Health Boards are asked to note the contents of this Circular and to bring it to the attention of community pharmacy contractors on their Pharmaceutical Lists, GPs, Health and Social Care Partnerships and Area Pharmaceutical Committees.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Alison Strath', with a long horizontal flourish extending to the right.

Alison Strath
Interim Chief Pharmaceutical Officer

ANNEX A



National Patient Group Direction (PGD)

Supply of aciclovir tablets / dispersible tablets

Version – 1.0

The purpose of the PGD is to allow management of Herpes Zoster (Shingles) 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 aciclovir to patients aged 18 years and over presenting with symptoms of shingles who meet the criteria for inclusion under the terms of the document

Change History - None

PGD Aciclovir Tablets / Dispersible Tablets

Authorisation

This specimen PGD has been produced in collaboration with by 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 aciclovir tablets or dispersible tablets 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	<u>Click or tap here to enter text.</u>	Signature	<u>Click or tap here to enter text.</u>
Pharmacist	<u>Click or tap here to enter text.</u>	Signature	<u>Click or tap here to enter text.</u>
NHS Scotland Representative	<u>Click or tap here to enter text.</u>	Signature	<u>Click or tap here to enter text.</u>

Authorised for use on behalf of NHS [insert details] by

Medical Director	<u>Click or tap here to enter text.</u>	Signature	<u>Click or tap here to enter text.</u>
Director of Pharmacy/Senior Pharmacist	<u>Click or tap here to enter text.</u>	Signature	<u>Click or tap here to enter text.</u>
Clinical Governance Lead	<u>Click or tap here to enter text.</u>	Signature	<u>Click or tap here to enter text.</u>
Date Approved	<u>Click or tap to enter a date.</u>		
Effective from	<u>Click or tap to enter a date.</u>	Review Date	<u>Click or tap to enter a date.</u>

Clinical Situation

Indication	Treatment of herpes zoster (Shingles) infection.
Inclusion Criteria	<ul style="list-style-type: none"> • Patients 18 years of age and over • Untreated acute shingles rash on torso involving a single dermatome and present for less than 72 hours • Immunocompetent patients
Exclusion Criteria	<ul style="list-style-type: none"> • Patient under 18 years of age • Rash affecting areas other than the torso e.g. eyes • Rash involving more than one dermatome • Rash appeared > 72 hours ago • New vesicles formed after 7 days of treatment • Known hypersensitivity to aciclovir or any excipients • Patients with impaired gastro-intestinal absorption • Known immunocompromised patients including those with HIV and patients taking immunosuppressants • Known pregnancy • Breastfeeding • Patients who are systemically unwell, including symptoms of fever and headache • Known moderate to severe renal impairment • Recurrent shingles – immunocompetent patient with 2 or more episodes over the person's lifetime • Severe pain not responding to OTC analgesics • Informed consent not obtained • Concomitant use of interacting medication as listed in current BNF
Cautions /Need for further advice/ Circumstances when further advice should be sought from a doctor	<p>Caution should be used in:</p> <ul style="list-style-type: none"> • Elderly patients • Patients with mild renal impairment • Patients with liver impairment • Patients taking other drugs with an increased risk of renal impairment <p>See current BNF and SPC for full risk of possible interactions</p> <p>It would be preferable that the patient is present at the consultation. However, professional judgement should be used to decide if this is essential e.g. NHS Near Me could be used in circumstances where NHS or public health guidance supports virtual consultations</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"> • Note that self-care may be considered as an option depending on symptom severity. • 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

Name of Medicine	Aciclovir
Form/Strength	800 mg (or 2 x 400 mg) tablets
Route of administration	Oral
Dosage	800 mg
Frequency	Five times daily at 4 hourly intervals (during waking hours)
Duration of treatment	7 days
Maximum or minimum treatment period	28,000mg
Quantity to supply/administer	35 x 800 mg tablets or 70 x 400 mg tablets
▼ additional monitoring	No
Legal Category	POM (Prescription Only Medicine)
Is the use out with the SPC	No
Storage requirements	As per manufacturer's instructions Ensure tablets are within expiry date
Additional information	None

Name of Medicine	Aciclovir
Form/Strength	800 mg (or 2 x 400 mg) dispersible tablets NB This form is strictly limited to use in patients who are unable to swallow standard tablets
Route of administration	Oral
Dosage	800 mg
Frequency	Five times daily at 4 hourly intervals (during waking hours)
Duration of treatment	7 days
Maximum or minimum treatment period	28,000mg
Quantity to supply/administer	35 x 800 mg tablets or 70 x 400 mg tablets
▼ additional monitoring	No
Legal Category	POM (Prescription Only Medicine)
Is the use out with the SPC	No
Storage requirements	As per manufacturer's instructions Ensure tablets are within expiry date
Additional information	None

Warnings including possible adverse reactions and management of these	<p>Common side effects include gastrointestinal disorders (nausea, vomiting, diarrhoea and abdominal pain), taste disturbance, photosensitivity, pruritus, urticaria, fever, tiredness and occasionally headaches or dizziness.</p> <p>For a full list of side effects – refer to the British National Formulary (BNF) and/or 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</p> <p>Significant interactions with aciclovir may include the following medicines:</p> <p>Probenecid, Cimetidine, Theophylline, Mycophenolate</p> <p>Consult BNF and/or SPC for full list of interactions</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 http://yellowcard.mhra.gov.uk/</p>
Advice to Patient/carer including written information	<ul style="list-style-type: none"> • This medication should be taken with water and patient should drink plenty of water whilst taking this medication • Advise patient that medication should be taken regularly and must complete the course • Ensure patient is aware that if symptoms worsen, the patient becomes systemically unwell, or develops a temperature then they should seek medical advice that day either from their own GP or OOH service • If symptoms have not improved after 7 days treatment, then patients should be advised to seek further medical advice from GP practice • Manufacturers Patient Information Leaflet should be offered. • Common side effects of medication e.g. nausea, vomiting, diarrhoea and abdominal pain, taste disturbance, photo sensitivity, pruritus, urticarial, fever, tiredness and occasionally headaches or dizziness • Pharmacists should check that the patient has access to appropriate analgesia for symptomatic relief • Self –care - avoid sharing of towels and clothes, maintain good hand hygiene, wear loose fitting clothes to minimise irritation • Avoid use of topical creams and adhesive dressings as they can cause irritation and delay rash healing

	<ul style="list-style-type: none"> Shingles is infectious until all the vesicles have crusted over (usually 5-7 days after rash onset). Avoid attending work if the rash is weeping and can't be covered. A person who has not had chicken pox or the varicella vaccine can catch chicken pox from a person with shingles (if possible, avoid pregnant women, immunocompromised people and babies younger than 1 month old)
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"> 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	<p>Registered pharmacist with current General Pharmaceutical Council (GPhC) registration.</p> <p><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></p>
Specialist competencies or qualifications	<p>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 "Shingles for NHS Pharmacy First Scotland"</p> <p>https://learn.nes.nhs.scot/43887/pharmacy/cpd-resources/shingles-for-pharmacy-first-scotland</p> <p>Able to assess the person's capacity to understand the nature and purpose of the medication in order to give or refuse consent.</p> <p>Must be familiar with the aciclovir SPC.</p> <p>Authorised to use PGD on completion and submission of an approved practitioner form</p>
Continuing education and training	<p>It is the responsibility of the individual to keep up-to-date with continued professional development.</p> <p>Has read the most up to date guidance on the management of Shingles e.g. NICE CKS: https://cks.nice.org.uk/topics/shingles/</p> <p>Attends approved training and training updates as appropriate.</p> <p>Undertakes CPD when PGD or NES Pharmacy modules are updated.</p>

Audit Trail

Record/Audit Trail	<p>All records must be clear, legible and in an easily retrievable format. Pharmacists must record activities in PMR or PCR.</p> <p>The following records should be kept (paper or computer based) and are included in the patient assessment form:</p> <ul style="list-style-type: none"> • 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 patient group direction 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) <p><i>The patient's GP, where known, should be provided with a copy of the GP notification form for the supply of aciclovir on the same, or next available working day.</i></p> <p>These records should be retained in accordance with national guidance¹ (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><small>1. Scottish Government. <i>Scottish Government Records Management</i>. Edinburgh 2020. Available at SG-HSC-Scotland-Records-Management-Code-of-Practice-2020-v20200602.pdf (Accessed on 21/05/2021)</small></p>
Additional references	British National Formulary (BNF) current edition and aciclovir SPC

**PATIENT GROUP DIRECTION FOR THE SUPPLY OF ACICLOVIR TABLETS OR
DISPERSIBLE TABLETS BY COMMUNITY PHARMACISTS UNDER THE 'NHS PHARMACY
FIRST SCOTLAND' SERVICE**

Individual Authorisation

Forms to follow from individual Health Boards once PGD is signed off locally.

Patient Group Direction for treatment of Herpes Zoster (Shingles) in patients over 18 years

Patient assessment form

Patient Name:	<i>Click or tap here to enter text.</i>	Date of Birth /CHI:	<i>Click or tap here to enter text.</i>
		Sex	M <input type="checkbox"/> F <input type="checkbox"/>
Date of assessment:	<i>Click or tap to enter a date.</i>	Patient consents to GP being informed:	YES <input type="checkbox"/> NO <input type="checkbox"/> (exclude if no consent)

Patient clinical picture and related appropriate actions

Clinical features/symptom assessment	Yes	No	Actions
Is patient over 18 years of age?	<input type="checkbox"/>	<input type="checkbox"/>	If NO, do not treat and refer
Does the rash affect a single dermatome?	<input type="checkbox"/>	<input type="checkbox"/>	If NO, do not treat and refer
Is shingles rash affecting areas other than torso e.g. eyes?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Rash appeared \geq 72 hours ago?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
New vesicles formed after 7 days of treatment?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Known hypersensitivity to aciclovir or any excipients?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Does the patient have impaired gastrointestinal absorption?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Is the patient immunocompromised? E.g. auto-immune disease, chemotherapy, immunosuppressant medication?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Is the patient pregnant?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Is the patient breast feeding?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Is patient systemically unwell, including symptoms of fever and headache?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Known moderate to severe renal impairment?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Is this recurrent shingles? (Two or more episodes over the lifetime of a patient thought to be immunocompetent)	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Is patient in severe pain which hasn't responded to OTC analgesics?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Concomitant use of interacting medication e.g. probenecid, theophylline, cimetidine, mycophenolate?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Has informed consent to treatment been obtained?	<input type="checkbox"/>	<input type="checkbox"/>	If NO, do not treat and refer

Preparation options and supply method

Medicine and strength (Dispersible tablets strictly limited to those unable to swallow standard tablets)	Regimen	Supply method
Aciclovir 800 mg tablets	One tablet five times daily (at 4 hourly intervals during waking hours) x 35	PGD via NHS Pharmacy First Scotland
Aciclovir 400 mg tablets	Two tablets five times daily (at 4 hourly intervals during waking hours) x 70	
Symptomatic management	Appropriate analgesia – paracetamol or NSAID e.g. ibuprofen	NHS Pharmacy First Scotland or OTC or existing supply

Patient advice checklist

Advice	Provided (tick as appropriate)
How to take medication – with water, regularly and complete the course	<input type="checkbox"/>
Ensure adequate fluid intake whilst taking aciclovir tablets	<input type="checkbox"/>
Expected duration of symptoms - to seek medical assistance if symptoms worsen or are not resolving within 7 days	<input type="checkbox"/>
Patient information leaflet relating to the medication is given to the patient	<input type="checkbox"/>
Common side effects of medication e.g. nausea, vomiting, diarrhoea and abdominal pain, taste disturbance, photo sensitivity, pruritus, urticaria, fever, tiredness and occasionally headaches or dizziness.	<input type="checkbox"/>
Check patient has access to symptomatic relief (use of analgesia – paracetamol or NSAID e.g. ibuprofen)	<input type="checkbox"/>
Avoid sharing of towels and clothes	<input type="checkbox"/>
Maintain good hand hygiene	<input type="checkbox"/>
Wear loose fitting clothes to minimise irritation	<input type="checkbox"/>
Avoid use of topical creams and adhesive dressings as they can cause irritation and delay rash healing	<input type="checkbox"/>
Person with shingles is infectious until all the vesicles have crusted over (usually 5-7 days after rash onset)	<input type="checkbox"/>
Avoid attending work if the rash is weeping and can't be covered. If the lesions have dried or can be covered, this is not necessary	<input type="checkbox"/>
Person who has not had chicken pox or the varicella vaccine can catch chicken pox from person with shingles (if possible, avoid pregnant women, immunocompromised people and babies younger than 1 month old)	<input type="checkbox"/>

Communication

Contact made with	Details (include time and method of communication)
Patient's regular General Practice (details)	Click or tap here to enter text.

Details of medication supplied and pharmacist supplying under the PGD

Medication supplied	Click or tap here to enter text.	
Batch number	Click or tap here to enter text.	Expiry date Click or tap to enter a date.
Print name of pharmacist	Click or tap here to enter text.	
GPhC registration details	Click or tap here to enter text.	
Signature of pharmacist		

Patient Group Direction for treatment of Herpes Zoster (Shingles) in patients over 18 years

Notification of supply from community pharmacy

CONFIDENTIAL WHEN COMPLETED

Data protection confidentiality note: this message is intended only for the use of the individual or entity to whom it is addressed and may contain information that is privileged, confidential and exempt from disclosure under law. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited.

GP name	Click or tap here to enter text.	Pharmacy Stamp
GP practice address	Click or tap here to enter text.	
	Click or tap here to enter text.	
The following patient has attended this pharmacy for assessment and potential treatment of Herpes Zoster (Shingles)		
Patient name	Click or tap here to enter text.	Pharmacist name Click or tap here to enter text.
Date of birth/CHI	Click or tap here to enter text.	
Patient address	Click or tap here to enter text.	GPhC number Click or tap here to enter text.
	Click or tap here to enter text.	
Postcode	Click or tap here to enter text.	Date Click or tap to enter a date.

Following assessment (Tick as appropriate)

Your patient has been given a 7 day course of aciclovir 800 mg five times daily	<input type="checkbox"/>
Your patient has been given self-care advice only	<input type="checkbox"/>
Your patient is unsuitable for treatment via PGD for the following reasons and has been referred: Click or tap here to enter text.	<input type="checkbox"/>

Your patient has been advised to contact the practice if symptoms fail to resolve following treatment.

You may wish to include this information in your patient records.

Patient consent: I can confirm that the information is a true reflection of my individual circumstances and I give my consent to allow a pharmacist working under the terms of NHS Pharmacy First Scotland to provide the most appropriate advice and/or treatment for me. I also give my permission to allow the pharmacist to pass, to my own GP, details of this consultation and any advice given or treatment provided. I have been advised that some of the information may be used to assess the uptake of the service but this will be totally anonymous and not be attributable to any individual patient.

Patient signature	Date
Click or tap here to enter text.	Click or tap to enter a date.

This form should now be sent to the patient's GP and a copy retained in the pharmacy



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	_____	Review Date	_____

Clinical Situation

Indication	Treatment of bacterial skin infection in patients over 18 years of age.
Inclusion Criteria	<ul style="list-style-type: none"> • Infected insect bite • Cellulitis (patient afebrile and healthy other than cellulitis) • Acute paronychia with signs of cellulitis
Exclusion Criteria	<ul style="list-style-type: none"> • 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	<p>Healthcare professionals are reminded that:</p> <ul style="list-style-type: none"> • 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. <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"> • 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

Name of Medicine	Flucloxacillin			
Form/Strength	500 mg (or 2 x 250 mg) capsules			
Route of administration	Oral			
Dosage	Health Board Specific			
	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	Health Board specific			
	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 www.medicines.org.uk</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 http://yellowcard.mhra.gov.uk/</p>
Advice to Patient/carer including written information	<ul style="list-style-type: none"> • 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	<p>The following should be available where the medication is supplied:</p> <ul style="list-style-type: none"> • 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. <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>
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	<p>All records must be clear, legible and in an easily retrieval format. Pharmacists must record in PMR or PCR.</p> <p>The following records should be kept (paper or computer based) and are included in the patient assessment form:</p> <ul style="list-style-type: none"> • 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)
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	<p><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></p> <p><i>If the patient suffers an adverse drug reaction to flucloxacillin, the GP should also be informed.</i></p> <p>These records should be retained in accordance with national guidance¹ (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 SG-HSC-Scotland-Records-Management-Code-of-Practice-2020-v20200602.pdf (Accessed on 21/05/2021)</p>
Additional references	<p>British National Formulary (BNF) current edition flucloxacillin SPC.</p>

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

Individual Authorisation

Forms to follow from individual Health Boards once PGD is signed off locally.

Patient Group Direction for the treatment of bacterial skin infections in patients over 18 years, including infected insect bite, cellulitis (patient afebrile and healthy other than cellulitis), and acute paronychia (with signs of cellulitis)

Patient assessment form

Patient Name:	Click or tap here to enter text.	Date of Birth /CHI:	Click or tap here to enter text.
		Sex	M <input type="checkbox"/> F <input type="checkbox"/>
Date of assessment:	Click or tap to enter a date.	Patient consents to GP being informed:	Yes <input type="checkbox"/> No <input type="checkbox"/> (Exclude if no consent)

Patient clinical picture and related appropriate actions

Clinical features/symptom assessment	Yes	No	Actions
Is patient over 18 years of age?	<input type="checkbox"/>	<input type="checkbox"/>	If NO, do not treat and refer
Is presenting condition any one of the following three?			
Infected insect bite	<input type="checkbox"/>	<input type="checkbox"/>	If NO, do not treat and refer
Cellulitis (patient afebrile and otherwise healthy)	<input type="checkbox"/>	<input type="checkbox"/>	
Acute paronychia (nail infection) with signs of cellulitis	<input type="checkbox"/>	<input type="checkbox"/>	
Other exclusion criteria			
Known hypersensitivity to beta-lactam antibiotic (penicillins or cephalosporins) or any excipients?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Is patient febrile and/or unwell (i.e. features suggestive of systemic infection)?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Is cellulitis related to a human or animal bite, a surgical wound, chronic wound/ leg ulcer or burns?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Is peri-orbital (preseptal)/facial cellulitis present?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Is cellulitis present on arms or torso but NOT linked to an insect bite?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Does the patient have recurrent cellulitis i.e. more than once within a year?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Does the patient have paronychia which requires drainage of pus and/or severe pain?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Does the patient have a diabetic foot infection?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Known hepatic impairment or flucloxacillin associated jaundice?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Known severe renal impairment?	<input type="checkbox"/>	<input type="checkbox"/>	If YES do not treat and refer
Is there any history of MRSA infection or colonisation?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Does the patient have history of injecting drug use (e.g. illicit drugs, anabolic steroids)?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer

Concomitant use of interacting medication? e.g. probenecid, methotrexate, oral typhoid capsule, warfarin	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
History of porphyria?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Does the patient have known immunosuppression or taking immunosuppressants?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Is the patient pregnant or breastfeeding?	<input type="checkbox"/>	<input type="checkbox"/>	If YES, do not treat and refer
Has informed consent to treatment been obtained?	<input type="checkbox"/>	<input type="checkbox"/>	If NO, do not treat and refer

Preparation options and supply method

Medicine and strength	Regimen - Health Board specific (during waking hours)	Supply method
Flucloxacillin 500 mg capsules	500 mg - One capsule FOUR times daily x 20 1g – Two capsules FOUR times daily x 40	PGD via NHS Pharmacy First Scotland
Flucloxacillin 250 mg capsules	500 mg - Two capsules FOUR times daily x 40 1g – Four capsules FOUR times daily x 80	
Flucloxacillin 250mg/5ml oral solution	500 mg - Two 5ml spoonful (10ml) FOUR times daily x 200ml 1g - Four 5ml spoonful (20ml) FOUR times daily x 400ml	

Patient advice checklist

Advice	Provided (tick as appropriate)
How to take medication – when stomach is empty – either ONE hour before food, or TWO hours after food	<input type="checkbox"/>
Take regularly and complete the course	<input type="checkbox"/>
Common side effects of medication e.g. nausea, vomiting and diarrhoea – speak to pharmacist or GP if troublesome	<input type="checkbox"/>
If a rash or other signs of hypersensitivity occur, STOP taking medication and contact GP or NHS 24 for advice	<input type="checkbox"/>
Expected duration of symptoms Seek medical assistance that day if symptoms worsen – becomes systemically unwell, or develops a raised temperature, racing heartbeat, rapid shallow breathing or confusion	<input type="checkbox"/>
Seek medical advice from GP if symptoms do not resolve after 2 - 3 days treatment	<input type="checkbox"/>
If taking oral contraceptives, no additional precautions are required unless diarrhoea and vomiting occur (absorption of contraception may be affected)	<input type="checkbox"/>
Patient information leaflet relating to medication is given to patient	<input type="checkbox"/>

Communication

Contact made with	Details (include time and method of communication)
Patient's regular General Practice (details)	Click or tap here to enter text.

Details of medication supplied and pharmacist supplying under the PGD

Medication supplied	Click or tap here to enter text.
Batch number and expiry	Click or tap here to enter text.
Print name of pharmacist	Click or tap here to enter text.
Signature of pharmacist	Click or tap here to enter text.
GPhC registration number	Click or tap here to enter text.

Patient Group Direction for the treatment of bacterial skin infection in patients over 18 years, including infected insect bite, cellulitis (patient afebrile and healthy other than cellulitis), and acute paronychia (with signs of cellulitis)

Notification of supply from community pharmacy

CONFIDENTIAL WHEN COMPLETED

Data protection confidentiality note: this message is intended only for the use of the individual or entity to whom it is addressed and may contain information that is privileged, confidential and exempt from disclosure under law. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited.

GP name	Click or tap here to enter text.	<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;">Pharmacy Stamp</div> <div style="border: 1px solid black; height: 100px; margin-bottom: 5px;"></div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;">Pharmacist name</div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;">Click or tap here to enter text.</div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;">GPhC number</div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;">Click or tap here to enter text.</div> <div style="border: 1px solid black; padding: 5px;">Date</div> <div style="border: 1px solid black; padding: 5px;">Click or tap to enter a date.</div>
GP practice address	Click or tap here to enter text.	
	Click or tap here to enter text.	
The following patient has attended this pharmacy for assessment and potential treatment of skin infection:		
Patient name	Click or tap here to enter text.	
Date of birth/CHI	Click or tap here to enter text.	
Patient address	Click or tap here to enter text.	
	Click or tap here to enter text.	
Postcode	Click or tap here to enter text.	

Following assessment (Tick as appropriate)

Presenting condition		
Infected insect bite <input type="checkbox"/>	Cellulitis <input type="checkbox"/>	Paronychia <input type="checkbox"/>
Your patient has been given a 5 day course of flucloxacillin 500 mg / 1g four times daily (delete as appropriate)		<input type="checkbox"/>
Your patient has been given self-care advice only		<input type="checkbox"/>
Your patient is unsuitable for treatment via PGD for the following reasons and has been referred: Click or tap here to enter text.		<input type="checkbox"/>

Your patient has been advised to contact the practice if symptoms fail to resolve following treatment.

You may wish to include this information in your patient records.

Patient consent: I can confirm that the information is a true reflection of my individual circumstances and I give my consent to allow a pharmacist working under the terms of NHS Pharmacy First Scotland to provide the most appropriate advice and/or treatment for me. I also give my permission to allow the pharmacist to pass, to my own GP, details of this consultation and any advice given or treatment provided. I have been advised that some of the information may be used to assess the uptake of the service but this will be totally anonymous and not be attributable to any individual patient.

Patient signature	Date
Click or tap to enter a date.	Click or tap to enter a date.

This form should now be sent to the patient's GP and a copy retained in the pharmacy