Chief Medical Officer Directorate

Pharmacy and Medicines Division



Dear Colleague

ADDITIONAL PHARMACEUTICAL SERVICES NHS PHARMACY FIRST SCOTLAND – UPDATED PGDs

Summary

1. This Circular advises Health Boards and community pharmacy contractors of updated Patient Group Directions (PGDs) that are to be implemented for the treatment of shingles and skin infections under NHS Pharmacy First Scotland.

Background

2. The original national PGDs for the treatment of shingles and skin infections that have been in place since May 2021 have been reviewed and updated and are now ready for release.

Detail

- 3. Changes to the existing PGDs have been reviewed by the Scottish Antimicrobial Prescribing Group (SAPG) and signed off by NHS 24 for use in all Health Boards. The changes are listed in a summary table at the start of each PGD.
- 4. Health Boards are responsible for local governance processes to approve, sign and publish these PGDs and have been asked to complete this as soon as they are able to do so.

Patient Group Directions

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

21 March 2024

Addresses

For action

Chief Executives. NHS Boards

For information

NHS Directors of Pharmacy

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- 6. The **Annex** to this circular provides copies of the updated draft PGDs which have been approved by NHS 24 to allow pharmacists as much time as possible to familiarise themselves with the relevant details. 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.
- 7. Individual authorisation forms should be completed by pharmacists delivering NHS Pharmacy First Scotland and submitted to each Health Board area that they work in according to the usual process.

Training

8. The eLearning modules supporting the PGDs have been updated to reflect the changes made. Pharmacists who have previously completed the modules, should review these changes (details can be found at the start of each revised PGD), and then access the updated eLearning module to complete a short self-assessment. The modules are available on the NES TURAS Learn website at:

Shingles:

https://learn.nes.nhs.scot/43887/pharmacy/cpd-resources/shingles-for-pharmacy-first-scotland

Skin infections:

https://learn.nes.nhs.scot/43886/pharmacy/cpd-resources/skin-infections-for-nhs-pharmacy-first-scotland

9. The content of this Circular has been agreed with Community Pharmacy Scotland.

Action

10. 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

Alison Strath

Chief Pharmaceutical Officer Pharmacy & Medicines Division



Patient Group Direction (PGD)

This PGD authorises community pharmacists to supply aciclovir tablets / dispersible tablets to patients aged 18 years and over presenting with symptoms of shingles under NHS Pharmacy First Scotland.

Publication date: 20th February 2024



Most Recent Changes

		Summary of changes
2.0 Fe	ebruary 2024	Original PGD transferred into new NHS PFS template. 1.2 Inclusion criteria: amended to remove "torso" 1.3 Exclusion criteria: Removal of following to prevent duplication with inclusion criteria: Patients under 18 years of age Rash involving more than one dermatome Rash appeared more than 72 hours ago Clarification on which areas of body are excluded from treatment under PGD Addition of exclusion if patient already taking oral antiviral medication Removal of new vesicles forming after 7 days exclusion Addition of examples of impaired gastrointestinal absorption Clarification on immunosuppression definition and removal of reference to HIV Removal of breastfeeding exclusion Removal of fever and headache examples from systemically unwell exclusion Clarification on moderate to severe renal impairment Clarification on definition of recurrent shingles Removal of severe pain not responding to over-the-counter analgesics exclusion Standardisation across all NHS PFS PGDs of wording on interactions 1.4 "Cautions/need for further advice": Title – changed "doctor" to "prescriber" Updated to reflect range of professionals who are able to independently prescribe

Version	Date	Summary of changes
		 Addition of further guidance on renal impairment Addition of guidance to patients taking aciclovir whilst breastfeeding. Removal of paragraph regarding patient's physical presence in pharmacy to obtain treatment. 2.3 Dosage section: amendment to guidance on timing of dosage 2.4 Frequency section: amendment to guidance on frequency of dosage 2.6 Maximum or minimum treatment period section: amendment to clarify duration of treatment. 3.1 "Warnings including possible adverse reactions and management of those" section: removal of specific drugs which may interact with aciclovir and addition of generic statement about checking for clinically significant interactions. 3.3. "Advice to patient and carer": Clarification on avoiding contact with others Clarification on symptoms not improving after 7 days 3.5 "Follow up": clarification on advice to be given.

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Authorisation

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

PGD aciclovir tablets / dispersible tablets

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 aciclovir tablets / dispersible tablets 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	KILLE		
Pharmacist	Dr John McAnaw	Signature	John My Man		
NHS Scotland Representative	Mr Jim Miller	Signature	for holler		
Approved on behalf of NHS					

Effective from: insert date

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 herpes zoster (shingles) infection.

1.2. Inclusion criteria

Patients aged 18 years and older with untreated acute shingles rash involving a single dermatome and present for less than 72 hours.

Immunocompetent patient.

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

1.3. Exclusion criteria

Rash affecting areas other than those relating to dermatomes T1 - L2 e.g., rash extending to eye and any eye symptoms (including change in vision, redness, irritation, discomfort, gritty etc).

Patients already taking oral antiviral treatment.

Hypersensitivity to aciclovir or to any of the excipients within the tablets.

Patients with impaired gastro-intestinal absorption e.g., Crohn's disease, ulcerative colitis.

Acute diarrhoea and vomiting where aciclovir absorption could be impaired.

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

Known pregnancy.

Patients who are systemically unwell.

Known moderate to severe renal impairment – patients with eGFR <25mL/minute/1.73m² should be referred to GP/OOH for consideration of reduced dose due to increased risk of neurological reactions.

Recurrent shingles – immunocompetent patient with a history of 2 or more episodes in 12 months.

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.

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

Caution should be used in:

- Elderly patients
- Patients with mild renal impairment:
 - 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.
 - o 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).
- Patients taking other drugs with an increased risk of renal impairment (See current BNF and SPC for full risk of possible interactions)
- Patients with liver impairment

 Patients who are breastfeeding – make patient aware that manufacturer advises caution, but not known to be harmful.

1.5. Action if excluded

Refer to GP Practice / Out-of-hours (OOH) service 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

Aciclovir 800mg (or 2 x 400mg) tablet

OR

Aciclovir 800mg (or 2 x 400mg) dispersible tablet

NB: The dispersible form of tablet is strictly limited to use in patients who are unable to swallow standard tablets.

2.2. Route of administration

Oral

2.3. Dosage

Adults aged 18 years and over:

• 800mg to be taken FIVE times daily spread evenly throughout the day during waking hours, usually at 4 hourly intervals.

2.4. Frequency

FIVE times daily spread evenly throughout the day during waking hours, usually at 4 hourly intervals.

2.5. Duration of treatment

7 days

2.6. Maximum or minimum treatment period

One treatment cycle of 7 days

2.7. Quantity to supply

35 x 800mg tablets or 70 x 400mg tablets

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

As per manufacturer's instructions.

Store below 25°C in a cool, dry place

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 gastrointestinal disorders (nausea, vomiting, diarrhoea and abdominal pain), taste disturbance, photosensitivity, pruritis, urticaria, fever, tiredness and occasionally headaches or dizziness.

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.

Aciclovir is eliminated primarily unchanged in the urine via active renal tubular secretion. Any drugs administered concurrently that compete with this mechanism may increase aciclovir plasma concentrations.

Pharmacists should check patient medication history for clinically significant interactions using appropriate reference sources e.g., BNF, Stockley.

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) and information on shingles e.g. British Association of Dermatologists: Shingles-Update-May-2020-lay-reviewed-March-2020.pdf (bad.org.uk) (Accessed 19th December 2023)

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 with water and the patient should drink plenty of water whilst taking this course of treatment.
- This medicine should be taken regularly until the course is completed.
- Ensure the patient has access to appropriate analgesia for symptomatic relief.
- Advise on 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 these can cause irritation and delay rash healing.

- Shingles is infectious until all the vesicles have crusted over (usually 5-7 days after rash onset). Avoid contact with others wherever possible 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.)
- Ensure the patient is aware that 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 7 days of treatment, or if there is formation of new vesicles despite 7 days of antiviral treatment, or the eyes/hearing are affected, or other evidence of infection/discharge is present the patient should seek further medical advice from their GP practice.
- 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 there is ongoing concern following the completion of treatment course.

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
 - o BNF for Children British National Formulary NICE
- Access to SmPC/PIL/Risk Minimisation Material:
 - o Home electronic medicines compendium (emc)
 - o MHRA Products | Home
 - o 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 aciclovir medicine and alert to changes in the manufacturer's product information/summary of product information.
- Have successfully complete the NES Pharmacy e-learning module:

Shingles for NHS Pharmacy First Scotland | Turas | Learn

https://learn.nes.nhs.scot/43887/pharmacy/cpd-resources/shingles-for-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 aciclovir tablets or dispersible tablets, or appropriate referral on the same, or next available working day.

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.

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 19th December 2023)

6. Additional references

Practitioners operating the PGD must be familiar with:

- National Institute for Clinical Excellence / Public Health England. Available at: Shingles | Health topics A to Z | CKS | NICE (Accessed 19th December 2023)
- Current edition of British National Formulary (BNF) <u>BNF British National</u> <u>Formulary - NICE</u>, and BNF for children <u>BNF for Children British National</u> <u>Formulary - NICE</u>
- Marketing authorisation holder's Summary of Product Characteristics.
 Electronic Medicines Compendium. Aciclovir 800mg tablets. SPC. Available
 Aciclovir 800mg Tablets Summary of Product Characteristics (SmPC) (emc) (medicines.org.uk) (Accessed 19th December 2023)

7. Individual authorisation (Appendix 1)

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



8. Version history

Version	Date	Summary of changes		
1.0	March 2021	New National Specimen PGD produced.		
		 Removal of breastfeeding exclusion Removal of fever and headache examples from systemically unwell exclusion Clarification on moderate to severe renal impairment 		
		 Clarification on definition of recurrent shingles Removal of severe pain not responding to over-the-counter analgesics exclusion Standardisation across all NHS PFS PGDs of wording on interactions 1.4 "Cautions/need for further advice": Title – changed "doctor" to "prescriber" 		

Version	Date	Summary of changes
		Updated to reflect range of professionals who are able to independently prescribe Insertion of further guidance on renal impairment Insertion of guidance to patients taking aciclovir whilst breastfeeding. Removal of paragraph regarding patient's physical presence in pharmacy to obtain treatment. 3 Dosage section – amendment to guidance on timing of dosage 4 Frequency section – amendment to guidance on frequency of dosage Maximum or minimum treatment period section – amendment to clarify duration of treatment. 1 "Warnings including possible adverse reactions and management of those" section – removal of specific drugs which may interact with aciclovir and addition of generic statement about checking for clinically significant interactions. 3.3 "Advice to patient and carer" Clarification on avoiding contact with others Clarification on symptoms not improving after 7 days 3.5 "Follow up" – clarification on advice to be given.



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



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		

Version	Date	Summary of changes		
		 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 		



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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	Kille		
Pharmacist	Dr John McAnaw	Signature	John My Man		
NHS Scotland Representative	Mr Jim Miller	Signature	for holler		
Approved on behalf of NHS <u>insert Board</u> by:					
Medical Director (Name / Signature)					
Director of Pharmacy/Senior Pharmacist (Name / Signature)					
Clinical Governan	ice Lead (Name / Signatur	e)			

Effective from: insert date

Date approved:

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/1.73m² 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:

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- Careful enquiry should be made about hypersensitivity reactions to betalactam 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 25°C in a cool, dry place.

Oral solution – As per manufacturer's instructions. Unopened bottle – Store below 25°C in a cool, 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.

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
 - o BNF for Children British National Formulary NICE
- Access to SmPC/PIL/Risk Minimisation Material:
 - o Home electronic medicines compendium (emc)
 - o MHRA Products | Home
 - o 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 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.

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:

- National Institute for Clinical Excellence / Public Health England. Available at: Cellulitis - acute | Health topics A to Z | CKS | NICE (Accessed 14th May 2023)
- Current edition of British National Formulary (BNF) <u>BNF British National</u> <u>Formulary - NICE</u>, and BNF for children <u>BNF for Children British National</u> <u>Formulary - NICE</u>
- 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)

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



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			

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

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

Patient assessment form

Patient name and address (including	Click or tap here to enter text.	Date of Birth /CHI:	Click or tap here to enter text.		
postcode):		Sex	М		F 🗆
Date of assessment:	Click or tap to enter a date.	Patient is aware that GP will be informed:	YES		NO 🗆

Patient clinical picture and related appropriate actions

Clinical features/symptom assessment	Yes	No	Actions
Is patient over 18 years of age?			If NO, do not treat with this PGD. Refer to GP/OOH/ED as appropriate.
Does the rash affect a single dermatome?			If NO, do not treat with this PGD. Refer to GP/OOH/ED as appropriate.
Has rash been present for less than 72 hours?			If NO, do not treat with this PGD. Refer to GP/OOH/ED as appropriate.
Is shingles rash affecting areas other than those relating to dermatomes T1 – L2 e.g. extending to around eyes?			
Is patient already taking antiviral medication?			
Known hypersensitivity to aciclovir or any excipients?			
Does the patient have impaired gastrointestinal absorption e.g. Crohn's disease, ulcerative colitis?			
Does patient have acute diarrhoea and vomiting where aciclovir absorption could be impaired?			If YES to any of the exclusion
Is the patient immunocompromised? E.g. auto-immune disease, current chemotherapy or immunosuppressant medication?			criteria , do not treat with this PGD.
Is the patient pregnant?			Refer to GP/OOH/ED as appropriate.
Is patient systemically unwell?			
Known moderate to severe renal impairment? (eGFR <25mL/minute/1.73m²)?			
Is this recurrent shingles? (Immunocompetent patient with a history of 2 or more episodes in last 12 months)			
Concomitant use of interacting medication?			
Has informed consent to treatment been obtained?			If NO, patient is unable to receive treatment.

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 spread evenly throughout the day during waking hours (usually at 4 hourly intervals) x 35		PGD via NHS Pharmacy First Scotland
Aciclovir 400 mg tablets	TWO tablets FIVE times daily spread evenly throughout the day during waking hours (usually at 4 hourly intervals) x 70	
Symptomatic management	Appropriate analgesia – paracetamol	NHS Pharmacy First Scotland, OTC or existing supply

Patient advice checklist

Advice	Provided (tick as appropriate)
How to take medication – with water, regularly and complete the course	
Ensure adequate fluid intake whilst taking aciclovir tablets	
Expected duration of symptoms - to seek medical assistance if symptoms worsen or are not resolving within 7 days	
Patient information leaflet relating to the medication is given to the patient	
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.	
Check patient has access to symptomatic relief (use of analgesia – paracetamol)	
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	
Person with shingles is infectious until all the vesicles have crusted over (usually 5-7 days after rash onset)	
Avoid contact with others wherever possible, if the rash is weeping and can't be covered. If the lesions have dried or can be covered, this is not necessary	
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)	

Communication

Contact made with	Details (include time and method of communication)
Patient's 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 aged 18 years and over

Notification of supply from community pharmacy

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GP name	Click or tap here to enter text.		Pharmacy Stamp	/ Address details
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 poter	itial treatment of Herpes Zoster (Shing	les)		
Patient name	Click or tap here to enter text			
Date of birth/CHI	Click or tap here to enter		Pharmacist name	
Patient address	Click or tap here to enter text.		Click or tap here to	enter text.
	Click or tap here to enter text.		GPhC number click enter text.	k or tap here to
Postcode	Click or tap here to enter text		DateClick or tap to	enter a date.
times daily			L	
Following assessment (The patient has been a	given a 7 day course of aciclovir 800 m	g five	Г	 1
The patient has been	given self-care advice only			1
			L	
•	ole for treatment via PGD for the follow	ving		
reasons and has been]
Click or tap here to ente	r text.			
our patient has been a	advised to contact the practice if symp	toms fai	l to resolve followin	g treatment.
ra e e e e e e e e e e e e e e e e e e e				
ou may wish to includ	e this information in your patient reco	ras.		
Patient consent: I can con	ifirm that the information is a true reflection o	f my indi	vidual circumstances	Consent
and I give my consent to a	llow a pharmacist working under the terms of	NHS Phar	macy First Scotland	received
	priate advice and/or treatment for me. I also			
-	my own GP, details of this consultation and ar ised that some of the information may be use	-	_	

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

service, but this will be totally anonymous and not be attributable to any individual patient.

Patient Group Direction for the treatment of bacterial skin infections in patients aged 18 years and over, including infected insect bite, cellulitis (patient afebrile and no sign of systemic infection), and acute paronychia (with signs of cellulitis)

Patient assessment form

Patient name and address (including postcode):	Click or tap here to enter text.	Date of Birth /CHI: Sex	Click or tap here to enter text. M
Date of assessment:	Click or tap to enter a date.	Patient is aware that GP will be informed:	Yes No No

Patient clinical picture and related appropriate actions

Patient clinical picture and related appropriate actions			
Clinical features/symptom assessment	Yes	No	Actions
Is patient over 18 years of age?			If NO, do not treat with this PGD. Refer if appropriate.
Is presenting condition any one of the following three?			
Infected insect bite			If NO, do not treat with this
Cellulitis (patient afebrile and no signs of systemic infection)			PGD. Consider alternative diagnosis and refer if
Acute paronychia (nail infection) with signs of cellulitis			appropriate.
Other exclusion criteria			
Known hypersensitivity to beta-lactam antibiotic (penicillins or cephalosporins) or any excipients?			
Is patient febrile and/or unwell (i.e. features suggestive of systemic infection)?			
Is cellulitis related to a human or animal bite, a surgical wound, chronic wound/ leg ulcer or burns?			
Is peri-orbital (preseptal)/facial cellulitis present?			If YES to any of the exclusion
Has patient had recent antibiotics (regardless of source) for same episode of cellulitis?			criteria, do not treat with this PGD.
Does the patient have recurrent cellulitis i.e. 2 or more episodes in 6 months at the SAME SITE? ?			Refer to GP/OOH/ED as appropriate.
Is cellulitis present on arms or torso but NOT linked to an insect bite?			
Does the patient have paronychia with signs of cellulitis which requires drainage of pus and/or severe pain?			
Does the patient have a diabetic foot infection?			
Known hepatic impairment or previous flucloxacillin associated jaundice?			

Known severe renal impairment (eGFR <10mL/min/1.73m²)?		
Is there any history of MRSA infection or colonisation?		
Does the patient have history of injecting drug use (e.g. illicit drugs, anabolic steroids) and infection is likely to be related to injecting practices?		
Is the patient pregnant?		
Is the patient breastfeeding AND have symptoms of lactational mastitis?		
Concomitant use of interacting medication?		
History of porphyria?		
Current immunosuppression e.g. taking chemotherapy, long term corticosteroids or other immunosuppressant therapies?		
Does the patient have acute diarrhoea or vomiting which would impair the absorption of antibiotics?		
Has informed consent to treatment been obtained?		If NO, patient is unable to receive treatment.

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	
Flucloxacillin 250 mg capsules	500 mg - Two capsules FOUR times daily x 40 1g – Four capsules FOUR times daily x 80	Pharmacy First	
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	Scotland	

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	
Take regularly and complete the course	
Common side effects of medication e.g. nausea, vomiting and diarrhoea – speak to pharmacist or GP if troublesome	
Appropriate analgesia may be taken if required for pain relief	

If a rash or other signs of hypersensitivity occur, STOP taking medication and contact GP or NHS 24 for advice		
Expected duration of symptoms - Seek medical advice from GP if symptoms do not resolve after 2 - 3 days treatment.		
Seek medical assistance that day if symptoms worsen – becomes systemically unwell, or develops a raised temperature, racing heartbeat, rapid shallow breathing or confusion		
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.		
If taking oral contraceptives, no additional precautions are required unless diarrhoea and vomiting occur (absorption of contraception may be affected)		
Patient information leaflet relating to medication is given to patient		

Communication

Contact made with	Details (include time and method of communication)
Patient's 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 aged 18 years and over, including infected insect bite, cellulitis (patient afebrile and no sign of systemic infection), and acute paronychia (with signs of cellulitis)

Notification of supply from community pharmacy

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GP name	Click or tap here to enter text.	Pharmacy Stamp	/ Address details
GP practice address	Click or tap here to enter text.		
	Click or tap here to enter text.		
	as attended this pharmacy for cial treatment of a skin infection:		
Patient name	Click or tap here to enter text.		
Date of birth/CHI	Click or tap here to enter text.	Pharmacist name	
Patient address	Click or tap here to enter text.	Click or tap here to	
	Click or tap here to enter text.	GPhC number Clic	k or tap here to
Postcode	Click or tap here to enter text.	DateClick or tap to enter a date.	
Presenting condition Infected insect bite □ Cellulitis □ The patient has been given a 5-day course of flucloxacillin		Paronychia	
The patient has been given a 5-day course of flucloxacillin 500 mg / 1g four times daily (delete as appropriate)			
	iven self-care advice only		
The patient is unsuitab reasons and has been r Click or tap here to enter			
•	dvised to contact the practice if symptoms fa	il to resolve followin	ig treatment.
Patient consent: I can confirm that the information is a true reflection of my individual circumstances			Consent
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			received
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.			

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