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 urinary tract infections (UTI) and impetigo under NHS Pharmacy First Scotland.

Background

2. The original national PGDs for the treatment of UTI and Impetigo that have been in place since July 2020 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 to the UTI PGD in particular will allow many more people to be treated in community pharmacy.

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 and by the final deadline of 31 October 2022.

Patient Group Directions

5. Updated PGDs have been developed nationally for NHS Pharmacy First Scotland to replace the existing PGDs for trimethoprim and nitrofurantoin (for treatment of UTIs) and fusidic acid (for the treatment of impetigo).

18 August 2022

Addresses

For action

Chief Executives, NHS Boards

For information

NHS Directors of Pharmacy

Enquiries to:

Pharmacy & Medicines Division 1st Floor East Rear St Andrew's House EDINBURGH EH1 3DG Email: PharmacyTeam@gov.scot

www.gov.scot



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. Community pharmacy contractors should ensure that pharmacists complete the short updates to the e-learning modules for UTI and impetigo, now available on the NES TURAS Learn website at:

UTI:

https://learn.nes.nhs.scot/33556/pharmacy/cpd-resources/urinary-tract-infections-utis-for-nhs-pharmacy-first-scotland

Impetigo:

https://learn.nes.nhs.scot/34440/pharmacy/cpd-resources/impetigo-for-nhs-pharmacy-firstscotland

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



National Patient Group Direction (PGD)

Supply of Nitrofurantoin Capsules MR 100mg / Tablets 50mg

Version – 2.0

The purpose of the PGD is to allow management of acute uncomplicated urinary tract infection (UTI) in non-pregnant females aged 16 years and over, by registered pharmacists within Community Pharmacies.

This PGD authorises pharmacists delivering the NHS Pharmacy First Service Level Agreement to supply nitrofurantoin to non-pregnant females aged 16 years and over presenting with symptoms of an acute uncomplicated urinary tract infection (UTI) who meet the criteria for inclusion under the terms of the document.

Change History – see table at end of document for more details

Change to eligibility

- 1. Eligible age range extended to 16 years and over
- 2. Haematuria can now be considered for treatment in community pharmacy under certain circumstances (some exclusions still apply)
- 3. Diabetes patients with diabetes can now be considered for treatment in community pharmacy
- 4. Symptoms of UTI lasting longer than 7 days can now be considered for treatment in community pharmacy with guidance to report to GP practice
- 5. Breastfeeding patients who are breastfeeding can now be considered for treatment in community pharmacy
- 6. Presence of vaginal discharge or itch can now be considered for treatment in community pharmacy unless "presence of new, unexplained vaginal discharge or itch suggestive of other pathology"

Clarification for community pharmacy network

- 7. Renal impairment clarified as known "moderate to severe"
- 8. Folate deficiency clarified as known folate deficiency "which has not been corrected"
- 9. Hepatic insufficiency clarified as "severe known liver fibrosis/encephalopathy"
- 10. Immunosuppressed clarified as "current immunosuppression e.g. chemotherapy, long term oral corticosteroids, other immunosuppressant therapies"

If this PGD is past the review date, the content shall remain valid until such time that the review is complete and a new version has been published. <u>It is the responsibility of the person using the PGD to ensure they are using the most recent issue.</u>

PGD Nitrofurantoin MR Capsules 100mg / tablets 50mg Authorisation

This specimen PGD has been produced in collaboration with the Scottish Antimicrobial Prescribing Group and the Primary Care Community Pharmacy Group to assist NHS Boards in the provision of 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 nitrofurantoin capsules or 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.

Doctor	Dr Laura Ryan	Signature	Lauce lys
Pharmacist	Dr John McAnaw	Signature	Johngerferhan
NHS Scotland Representative	Mr Jim Miller	Signature	for huller
Approved on behalf of	f NHS [insert details] by	/ :	
Medical Director		Signature	
Director of Pharmacy/Senior Pharmacist		Signature	
Clinical Governance Lead		Signature	
Date approved			
Effective from date		Review date	

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

NHS Pharmacy First Scotland PGD Nitrofurantoin Capsules /Tablets Version 2.0 August 2022

Review Date August 2024

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Clinical Situation	
Indication	Acute uncomplicated urinary tract infection (UTI) in non-pregnant females aged 16 years and over.
Inclusion Criteria	 Non-pregnant females, assigned as female at birth who have not had any reassignment procedures, aged 16 years and over. Older women should be fit, ambulatory and self-caring. If no dipstick testing available or patient is over 65 years, patient must present with three or more of the following symptoms: Dysuria Frequency Urgency Suprapubic tenderness or BOTH dysuria and frequency are present. Otherwise: Diagnose a UTI in the presence of two or more urinary symptoms (dysuria, frequency, urgency, visible haematuria or nocturia) and a positive dipstick test result for nitrite. Note: A positive dip stick in women over 65 is not an indication of UTI as asymptomatic bacteriuria is common in older women. A renal function assessment should be considered prior to supplying nitrofurantoin.

Exclusion Criteria	Patients assigned as male at birth
	Females under 16 years Detionte living in long term care facilities
	Patients living in long term care facilities
	Allergy or serious adverse effect from nitrofurantoin or to any
	other components of the preparation
	 If <u>upper</u> urinary tract infection is more likely i.e. flank pain radiating towards the groin, feel systemically unwell (fever
	and chills, rigors, nausea, vomiting), as well as with other
	symptoms of lower UTI. (Patients presenting with such
	symptoms should be urgently referred to GP/OOH)
	Patients over 45 years with unexplained visible haematuria
	without symptoms of UTI
	Visible haematuria which persists or recurs after successful
	treatment of UTI
	Unexplained non-visible haematuria if found on urine dipstick if
	no UTI symptoms present
	Patients over 40 years who present with recurrent UTI with any
	haematuria
	Risk of treatment failure due to one or more of the following:
	Received antibiotic treatment for UTI within 1 month; 2 or more
	UTI episodes in the last 6 months or 3 or more episodes in the
	last 12 months; taking antibiotic prophylaxis for recurrent UTI
	Presence of new unexplained vaginal discharge or itch suggestive
	of other pathology
	Confused
	Patient utilises urethral or suprapubic catheters (either indwelling
	or intermittently)
	Pregnancy – known or suspected
	Known moderate to severe renal impairment (where pharmacists are able to independently access relevant patient records/blood
	are able to independently access relevant patient records/blood results e.g. via Clinical Portal to establish levels of renal
	impairment when required, a supply of treatment can be
	considered. If this is not possible, patient should be referred to
	GP/OOH)
	 History of renal stones / renal colic, abnormal urinary tract e.g.
	vesicoureteric reflux, reflux nephropathy, neurogenic bladder,
	urinary obstruction, stent, recent instrumentation.
	Known severe liver fibrosis/encephalopathy (where pharmacists
	are able to independently access relevant patient records/blood
	results e.g. via Clinical Portal to establish levels of hepatic
	impairment when required, a supply of treatment can be
	considered. If this is not possible, patient should be referred to
	GP/OOH).
	Known haematological abnormalities, blood dyscrasias, known
	porphyria, vitamin B (particularly folate) deficiency known folate
	which has not been corrected, G6PD deficiency, electrolyte
	imbalance

 Known or susceptibility to peripheral neuropathy, or known neurological disorder Current immunosuppression e.g. chemotherapy, long term oral corticosteroids, other immunosuppressant therapies Known interstitial lung disease or poorly controlled respiratory disease Taking any medication which interacts with nitrofurantoin– refer to BNF for full list of interactions. Decline to provide consent or non-capacity to consent.

Cautions /Need for	Any doubt as to inclusion/exclusion criteria being met.
further advice/	
Circumstances when	 Recent hospital in-patient stay (in the previous three
further advice	months) - consider the reason for this admission.
should be sought	 Known previous nitrofurantoin-resistant isolates or multi-
from a doctor	drug-resistant isolates or recent travel to a country with
	known increased incidence of antimicrobial resistance
	Patient over 65 years
	Manage suspected UTI in ambulant women aged 65 years
	and over who are able to look after themselves independently
	with no comorbidities as in those aged under 65 years, taking
	into account the increasing background incidence of
	asymptomatic bacteriuria.
	Diabetes
	Patients with known diabetes are not excluded from treatment
	from community pharmacy. If concerned about recurrent UTIs
	or that this may be a side effect of medication e.g. SGLT2
	inhibitors, please consider signposting for GP practice follow
	up.
	Symptoms of UTI lasting longer than 7 days
	 Prolonged symptoms suggestive of a UTI may be considered
	for treatment, but clinical judgement may be required
	regarding onward referral.
	 Breastfeeding Patients who are breastfeeding and displaying symptoms of
	UTI can be considered for treatment in community pharmacy
	 As a general rule, if a medication is licensed for use in
	paediatrics (neonatal age onward) then it should be safe for
	use in breastfeeding as the dose the infant/child receives via
	the breastmilk will be significantly less than therapeutic doses.
	 National Institute for Health and Care Excellence. British
	National Formulary for Children. Available at:
	NITROFURANTOIN Drug BNFc content published by NICE
	(Accessed 23rd February 2022)
	UK Drugs in Lactation Service states the following:
	 Nitrofurantoin can be used with caution.
	 Small amounts in breast milk, moderate level of
	evidence of use in breastfeeding
	 Avoid in known G6PD deficiency, hyperbilirubinaemia,
	and in jaundiced premature infants because of risk of
	kernicterus
	 Available at: <u>Nitrofurantoin – Medicines – SPS - Specialist</u>
	Pharmacy Service – The first stop for professional medicines
	advice (Accessed 23rd February 2022)
Action if Excluded	Refer to GP Practice/Out-of-hours service and document in Patient
	Medication Record (PMR).

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Depending on availability either of the 2 treatment choices can be used Description of Treatment

Name of Medicine	Nitrofurantoin	
Form/Strength	100 mg MR capsules	
Route of	Oral	
administration		
Dosage	100 mg	
Frequency	Twice a day (12 hourly) (with or just after food)	
Duration of treatment	3 days	
Quantity to	6 x 100 mg MR capsules	
supply/administer		
▼ additional	No	
monitoring		
Legal Category	POM (Prescription Only Medicine)	
Is the use outwith the SPC	No	
Storage requirements	As per manufacturer's instructions	
	Store below 25°C in a cool dry place	
Additional information	None	

Description of Treatment

Description of Treatment	
Name of Medicine	Nitrofurantoin
Form/Strength	50 mg tablets
Route of	Oral
administration	
Dosage	50 mg
Frequency	Four times a day (with or just after food)
Duration of treatment	3 days
Quantity to	12 x 50 mg tablets
supply/administer	
▼ additional	No
monitoring	
Legal Category	POM (Prescription Only Medicine)
Is the use outwith the SPC	No
Storage requirements	As per manufacturer's instructions
	Store below 25°C in a cool dry place
Additional information	None

Warnings including possible adverse reactions and management of these	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 administering medication under this Patient Group Direction. This can be accessed on <u>www.medicines.org.uk</u>
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, 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 <u>http://yellowcard.mhra.gov.uk/</u>

	 Advise patient on ways to prevent re-infection – e.g. double voiding, voiding after sexual intercourse. Paracetamol and ibuprofen may relieve dysuric pain and discomfort. Ensure patient is aware that if symptoms worsen, they experience significant flank pain, become systemically unwell, or develop a fever, they should seek medical advice that day. Advise patient to seek further medical advice, if symptoms do not resolve after 3 days, if symptoms return or drug side effects are severe. Advise patient with haematuria which persists or recurs after successful treatment of UTI to contact their GP for follow up. Advise patient to stop taking immediately and seek medical advice if develops pulmonary, hepatic, haematological or neurological reactions e.g. breathing difficulties, abdominal pain discomfort, bruising and bleeding and seek advice from GP, OOH or NHS 24. Advise patient that their GP will be informed the next working day that antibiotics have been supplied or appropriate referral has been made. Advise patient that if they require to seek further advice from the Out-of-hours service they should make staff aware of their nitrofurantoin treatment.
	Information on medicines can be found at <u>https://www.medicines.org.uk/emc/browse-medicines</u> or https://www.gov.uk/pil-spc
Monitoring	Not applicable
Follow-up	Not applicable
Additional Facilities	 The following should be available where the medication is supplied: An acceptable level of privacy to respect patient's right to confidentiality and safety. Access to medical support (this may be via the telephone). Approved equipment for the disposal of used materials.
	 Clean and tidy work areas, including access to hand washing facilities. Access to current BNF (online version preferred).

Characteristics of staff authorised under the PGD

Professional	Registered pharmacist with current General Pharmaceutical Council (GPhC) registration.
qualifications	Under PGD legislation there can be no delegation. Supply of
	the medication has to be by the same practitioner who has
	assessed the patient under this PGD.
Specialist competencies or	Has successfully completed NES Pharmacy e-learning module on "Urinary Tract Infections for NHS Pharmacy First Scotland".
qualifications	https://learn.nes.nhs.scot/33556/pharmacy/cpd-resources/urinary-tract-
	infections-utis-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 relevant nitrofurantoin Summary of Product Characteristics (SPC).
Continuing education and training	Has read current guidance on the management of urinary tract infections e.g.PHE/NICE,SIGN,SAPG
	Health Improvement Scotland. SIGN 160: Management of suspected bacterial lower urinary tract infection in adult women. A national clinical guideline. September 2020. Available at <u>sign-160-uti-0-1 web-version.pdf</u> (accessed 20 th January 2022)
	Health Improvement Scotland: Scottish Antimicrobial Prescribing Group (SAPG). <i>Urinary Tract Infections</i> . Available at: <u>Urinary</u> <u>tract infections (sapg.scot)</u> (accessed 20 th January 2022)
	Aware of local treatment recommendations.
	Attends approved training and training updates as appropriate. Undertakes CPD when PGD or NES Pharmacy module updates.

Audit Trail	
Audit Trail Record/Audit Trail	 All records must be clear, legible and in an easily retrieval format. Pharmacists must record in Patient Medication Record (PMR). The following records should be kept (paper or computer based) and are included in the patient assessment form: Patient's name/parent/guardian/person with parental responsibility, address, date of birth and consent given Patient's CHI number Contact details of GP (if registered) Presenting complaint and diagnosis Details of medicine supplied The signature and printed name of the healthcare professional who supplied the medicine.
	 Advice given to patient (including side effects) The 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) The patient's GP, where known, should be provided with a copy of the client assessment form for the supply of nitrofurantoin 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-y2020602.pdf (Accessed on 29th November 2021)

Additional references	British National Formulary (BNF) current edition
	Electronic Medicines Compendium. <i>Nitrofurantoin SPC</i> . Available at <u>Home - electronic medicines compendium (emc)</u> (Accessed 24 th February 2022)
	Public Health England. <i>Summary of antimicrobial prescribing guidance.</i> May 2021. Available at: <u>Summary of antimicrobial prescribing guidance (publishing.service.gov.uk)</u> (Accessed 24 th February 2022)
	National Institute for Clinical Excellence / Public Health England. Summary of antimicrobial prescribing guidance – managing common infections. Jan 2022. Available at: <u>Antimicrobial prescribing</u> <u>table (bnf.org)</u> (accessed 24 th February 2022)
	Public Health England. <i>Diagnosis of urinary tract infections.</i> October 2021. Available at: <u>Diagnosis of urinary tract</u>
	infections - quick reference tool for primary care (publishing.service.gov.uk) (accessed 24 th February 2022)
	Royal College of General Practitioners. TARGET Urinary tract infection resource suite. Available at: Urinary tract infection
	resource suite: Patient facing materials (rcgp.org.uk) (Accessed 24 th February 2022)
	Health Protection Scotland. Scottish Urinary Tract Infection Network. Available at: <u>HPS Website - Scottish Urinary Tract Infection Network</u> (accessed 24 th February 2022)
	Faculty of Sexual and Reproductive Health. Clinical Guidance – Drug Interactions with Hormonal Contraception. Jan 2019. Available at:
	https://www.fsrh.org/standards-and-guidance/documents/ceu- clinical-guidance-drug-interactions-with-hormonal/fsrh-guidance- drug-interactions-hormonal-contraception-jan-2019.pdf
	(Accessed on 23rd February 2022)

1.0 March 2020 2.0 August 2021 2.0 August 2022 1.0 Inte following sections have been updated: 2.0 August 2022 2.0 August 2022 1.0 The following sections have been updated: 2.0 August 2022 2.0 August 2022 2.0 August 2022 1.0 The following sections have been updated: 2.0 August 2022 2.0 August 2022 2.0 August 2022 2.0 Removal of upper age limit 7 2.0 Clarification that "older women should be fit, ambulatory and self-caring" and that "a positive dip stick in women over 65 is not an indication of UTI as asymptoms when testing urine with dipstick 2.0 Dyber age limit removed 3.0 Upper age limit removed 4.0 Clarification of definition of "upper" UTI 5.1 Haematuria – specific criteria now apply 6.2 Clarification of definition of vaginal discharge/itch 0.2 Clarification of definition of impairment 0.3 Clarification of definition of impairment 0.4 Clarification of defini	Version	Date	Summary of Changes	
 2022 Addition of covering statement regarding validity of PGD when approaching date for review of content Indication Removal of upper age limit Inclusion criteria Clarification that "older women should be fit, ambulatory and self-caring" and that "a positive dip stick in women over 65 is not an indication of UTI as asymptomatic bacteriuria is common in older women." Inclusion criteria Upper age limit removed Clarification that patients living in long term care facilities are excluded Clarification of definition of "upper" UTI Haematuria – specific criteria now apply Clarification of definition of vaginal discharge/itch Clarification of definition of mumosuppression Clarification of definition of minunosuppression Clarification of definition of associated actions required for patients avith renal or hepatic impairment Clarification of definition of additional information for patients over 65 years, with diabetes, symptoms lasting more than 7 days, breastfeeding Advice to patient Update to information for patients Action if patient is excluded Removal of requirement to record in Pharmacy Care Record (PCR) Action if patient declines Inclusion of ink to NHS Inform for guidance on self-care (Record (PCR)) Action if patient declines Inclusion of inclusions Update link to training module Removal of requirement to record in PCR Clarification that notification for should be sent to GP for patients being referred as well as those being treated by community pharmacy. 	1.0		Version 1.0 Original PGD	
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 Update to information on retention of records 			 Updated link to training module Record/audit trail Removal of requirement to record in PCR Clarification that notification form should be sent to GP for patients being referred as well as those being treated by community pharmacy. 	



National Patient Group Direction (PGD)

Supply of Trimethoprim Tablets Version – 2.0

The purpose of the PGD is to allow management of acute uncomplicated urinary tract infection (UTI) in non-pregnant females aged 16 years and over, by registered pharmacists within Community Pharmacies.

This PGD authorises pharmacists delivering the NHS Pharmacy First Scotland Service Level Agreement to supply trimethoprim to non-pregnant females aged 16 years and over presenting with symptoms of an acute uncomplicated urinary tract infection (UTI) who meet the criteria for inclusion under the terms of the document.

Change History – see table at end of document for more details

Change to eligibility

- 1. Eligible age range extended to 16 years and over
- 2. Haematuria can now be considered for treatment in community pharmacy under certain circumstances (some exclusions still apply)
- 3. Diabetes patients with diabetes can now be considered for treatment in community pharmacy
- 4. Symptoms of UTI lasting longer than 7 days can now be considered for treatment in community pharmacy with guidance to report to GP practice
- 5. Breastfeeding can now be considered for treatment in community pharmacy
- 6. Presence of vaginal discharge or itch can now be considered for treatment unless "presence of new, unexplained vaginal discharge or itch suggestive of other pathology"

Clarification for community pharmacy network

- 7. Pregnancy clarified to include those planning a pregnancy in next 3 months
- 8. Renal impairment clarified as known "moderate to severe"
- 9. Folate deficiency clarified as known folate deficiency "which has not been corrected"
- 10. Hepatic insufficiency clarified as "severe known liver fibrosis / encephalopathy"
- 11. Immunosuppressed clarified as "current immunosuppression e.g. chemotherapy, long term oral corticosteroids, other immunosuppressant therapies

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PGD Trimethoprim Tablets

Authorisation

- This specimen PGD has been produced in collaboration with the Scottish Antimicrobial Prescribing Group and the Primary Care Community Pharmacy Group to assist NHS Boards in the provision of 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 trimethoprim 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.

Doctor	Dr Laura Ryan	Signature	e have lys
Pharmacist	Dr John McAnaw	Signature	e Johg Mg Law
NHS Scotland Representative	Mr Jim Miller	Signature	for halles
Approved on behalf	f of NHS [insert details]] by:	
Medical Director		Signature	
Director of Pharmacy/Senior Pharmacist		Signature	
Clinical			
Governance Lead		Signature	
Date Approved		_	
Effective from Date		Review Date	

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

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Clinical Situation

Indication	Acute uncomplicated urinary tract infection (UTI) in non-pregnant females aged 16 years and over.
Inclusion Criteria	Non-pregnant females, assigned as female at birth who have not had any reassignment procedures, aged 16 years and over.
	Older women should be fit, ambulatory and self-caring.
	If no dipstick testing available or over 65 years of age, patient must present with three or more of the following symptoms:
	Dysuria
	Frequency
	Urgency
	Suprapubic tenderness
	• or BOTH dysuria and frequency are present.
	Otherwise:
	Diagnose a UTI in the presence of two or more urinary symptoms (dysuria, frequency, urgency, visible haematuria or nocturia) and a positive dipstick test result for nitrite.
	Note: A positive dip stick in women over 65 is not an indication of UTI as asymptomatic bacteriuria is common in older women.

Exclusion Criteria	Patients assigned as male at birth
	Patients under 16 years
	Patients living in long term care facilities
	• Allergy or serious adverse effect from co-trimoxazole,
	trimethoprim or to any other components of the medication
	• If <u>upper</u> urinary tract infection is more likely i.e. flank pain
	radiating towards the groin, feel systemically unwell (fever and
	chills, rigors, nausea, vomiting), as well as with other symptoms
	of lower UTI. (Patients presenting with such symptoms should
	be urgently referred to GP/OOH)
	 Patients over 45 years with unexplained visible haematuria without
	symptoms of UTI
	 Visible haematuria which persists or recurs after successful treatment
	of UTI
	 Unexplained non-visible haematuria if found on urine dipstick if no UTI
	symptoms present
	 Patients over 40 years who present with recurrent UTI with any
	haematuria
	 Risk of treatment failure due to one or more of the following: Received
	antibiotic treatment for UTI within 1 month; 2 or more UTI episodes in
	the last 6 months or 3 or more episodes in the last 12 months; taking
	antibiotic prophylaxis for recurrent UTI
	 Presence of new unexplained vaginal discharge or itch suggestive of
	other pathology
	Confused
	 Patient utilises urethral or suprapubic catheters (either indwelling or
	intermittently)
	Known abnormality of the urinary tract
	 Pregnancy – known or suspected (and including those intending to
	become pregnant within the next 3 months)
	Known moderate to severe renal impairment (where pharmacists are
	able to independently access relevant patient records/blood results
	e.g. via Clinical Portal to establish levels of renal impairment when
	required, a supply of treatment can be considered. If this is not
	possible, patient should be referred to GP/OOH)
	Known haematological abnormalities, porphyria/known folate
	deficiency which has not been corrected
	Known severe known liver fibrosis/encephalopathy (where
	pharmacists are able to independently access relevant patient
	records/blood results e.g. via Clinical Portal to establish levels of
	hepatic impairment when required, a supply of treatment can be
	considered. If this is not possible, patient should be referred to
	GP/OOH.)
	 Known hyperkalaemia, megaloblastic anaemia, galactose intolerance,
	the Lapp lactose deficiency or glucose-galactose malabsorption
	 Current immunosuppression e.g. chemotherapy, long term oral
	corticosteroids, other immunosuppressant therapies
	 Taking any medication which interacts with trimethoprim – refer to
	BNF for full list of interactions
	 Decline to provide consent or non-capacity to consent.

Cautions /Nood for	Any doubt as to inclusion/exclusion criteria being met.
Cautions /Need for further advice/	Any doubt as to inclusion/exclusion criteria being met.
Circumstances when	Patient over 65 years
further advice should be sought from a doctor	 Manage suspected UTI in ambulant women aged 65 years and over who are able to look after themselves independently with no comorbidities as in those aged under 65 years, taking into account the increasing background incidence of asymptomatic bacteriuria.
	Diabetes
	• Patients with known diabetes are not excluded from treatment from community pharmacy. If concerned about recurrent UTIs or that this may be a side effect of medication e.g. SGLT2 inhibitors, please consider signposting for GP practice follow up.
	Symptoms of UTI lasting longer than 7 days
	 Prolonged symptoms suggestive of a UTI may be considered for
	treatment, but clinical judgement may be required regarding onward referral.
	Breastfeeding
	 Patients who are breastfeeding and displaying symptoms of UTI can be considered for treatment in community pharmacy As a general rule, if a medication is licensed for use in paediatrics
	(neonatal age onward) then it should be safe for use in breastfeeding as the dose the infant/child receives via the breastmilk will be significantly less than therapeutic doses.
	National Institute for Health and Care Excellence. <i>British National</i>
	Formulary for Children. Available at TRIMETHOPRIM Drug BNF
	content published by NICE (accessed 20 th January 2022) -
	 Trimethoprim is licensed for use in the neonatal period onwards. UK Drugs in Lactation Service states the following:
	 Trimethoprim can be used with caution. Limited published evidence of safety, small amounts in
	 Limited published evidence of safety, small amounts in breast milk, for short-term use only due to risk of folate
	deficiency, monitor infant for gastro-intestinal
	disturbances and oral candida infection, especially if used
	in high doses, although these effects are unlikely to occur.
	• Available at: <u>Trimethoprim – Medicines – SPS - Specialist</u>
	Pharmacy Service – The first stop for professional
	medicines advice (accessed 20th January 2022)
Action if Excluded	Refer to GP Practice/Out-of-hours service and document in Patient
	Medication Record (PMR)

Action if Patient Declines	Note that self-care should be considered as an option depending on symptom severity.
	If patient declines treatment, advise on self-care to relieve symptoms and advise to return to pharmacy if symptoms fail to resolve within 3 days or if symptoms worsen.
	Patients can be directed to NHS Inform for guidance on self-care at: <u>Urinary tract infection (UTI) - Illnesses & conditions NHS inform</u> (accessed 20 th January 2022)
	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 Patient Medication Record (PMR) if appropriate.
Description of Treat	ment

Description of Treatment

Name of Medicine	Trimethoprim
Form/Strength	200 mg (or 2 x 100 mg) Tablets
Route of	Oral
administration	
Dosage	200 mg
Frequency	Twice a day (12 hourly)
Duration of treatment	3 days
Maximum or minimum	Maximum 3 days (1200 mg)
treatment period	
Quantity to	6 x 200 mg tablets or 12 x 100 mg tablets
supply/administer	
Black triangle	No
(🛡 additional	
monitoring	
required	
Legal Category	POM (Prescription Only Medicine)
Is the use outwith the SPC	Νο
Storage requirements	As per manufacturer's instructions Store
	below 25°C in a cool dry place
Additional information	None

Warnings including possible adverse reactions and management of these	The most frequent adverse effects at usual dose are pruritus and skin rash (in about 3 to 7% of patients). These effects are generally mild and quickly reversible on withdrawal of the drug.
	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 administering medication under this Patient Group Direction. This can be accessed on <u>www.medicines.org.uk</u>
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, use the Yellow Card System to report adverse drug reactions. Yellow Cards and guidance on its use are available at the back of the BNF or online at http://yellowcard.mhra.gov.uk/

Advice to Patient/carer including written	 Advise patient about the importance of hydration in relieving symptoms. Offensive smelling urine/cloudy – may be suggestive of
information	 dehydration Increasing fluid intake to around 2.5 L per day (6-8 mugs containing approximately 350 ml) is thought to reduce UTI by dilution and flushing of bacteriuria. (While no evidence was identified for benefit, increasing fluid intake with water in women with urinary symptoms is a low-cost intervention without evidence of harm that may provide
	symptomatic relief) Provide a cystitis/UTI patient information leaflet and discuss contents with patients. <u>Cystitis- Patient Leaflet BMJ Best Practice</u> (accessed 2 nd May 2022) The patient information leaflet contained in the medicine should be
	made accessible to the patient. Where this is unsuitable, sufficient information should be given to the patient in a language that they can understand.
	 Inform patient of possible side effects and their management and who to contact should they become troublesome.
	 Explain the benefits and risks of taking antibiotics for this condition.
	 If on combined oral contraception, no additional contraceptive precautions are required unless vomiting or diarrhoea occur. (See reference section for Faculty of Reproductive and Sexual Healthcare Guidance)
	• Advise patient of self-management strategies including maintaining a good fluid intake, wearing loose fitting underwear/clothing, wearing
	 cotton underwear and avoidance of vaginal deodorants. Advise patient on ways to prevent re-infection – e.g. double voiding, voiding after sexual intercourse.
	 Paracetamol and ibuprofen may relieve dysuric pain and discomfort.
	• Ensure patient is aware that if symptoms worsen, they experience significant flank pain, become systemically unwell, or develop a favor, then they should sock medical advice that day.
	 fever, then they should seek medical advice that day. Advise patient to seek further medical advice, if symptoms do not resolve after 3 days, if symptoms return or drug side effects are
	 severe. Advise patient with haematuria which persists or recurs after successful treatment of UTI to seek further medical advice for follow
	 up. Advise patient to discontinue treatment if rash develops and seek medical advice.
	 Advise patient that their GP will be informed the next working day that antibiotics have been supplied or appropriate referral has been made.
	 Advise patient that if they require to seek further advice from the Out-of-hours service they should make staff aware of their trimethoprim treatment. Information on medicines can be found at
	https://www.medicines.org.uk/emc/browse-medicines or_ https://www.gov.uk/pil-spc

Monitoring	Not applicable	
Follow-up	Not applicable	
Additional Facilities	The following should be available where the medication is supplied:	
	 An acceptable level of privacy to respect patient's right to confidentiality and safety. 	
	 Access to medical support (this may be via the telephone). Approved equipment for the disposal of used materials. Clean and tidy work areas, including access to hand washing 	
	facilities.Access to current BNF (online version preferred).	

Characteristics of staff authorised under the PGD

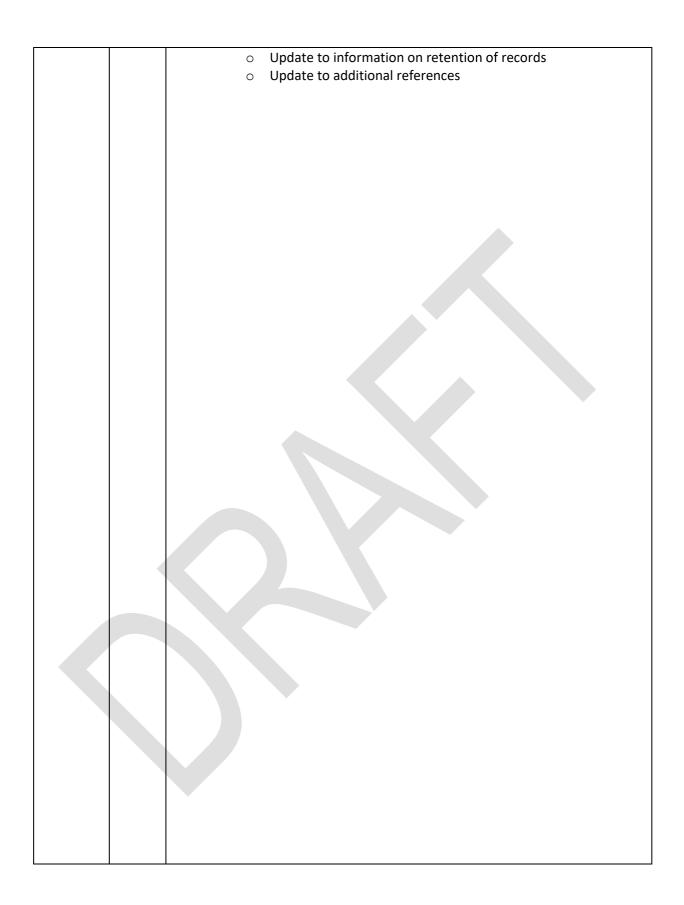
Professional	Registered pharmacist with current General Pharmaceutical Council (GPhC)
qualifications	registration. Under PGD legislation there can be no delegation. Supply of the
	medication has to be by the same practitioner who has
	assessed the patient under this PGD.
Specialist competencies or qualifications	Has successfully completed NES Pharmacy e-learning module on "Urinary Tract Infections for NHS Pharmacy First Scotland". https://learn.nes.nhs.scot/33556/pharmacy/cpd-resources/urinary-tract-
	infections-utis-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 trimethoprim Summary of Product Characteristics (SPC).
Continuing education and training	Has read current guidance on the management of urinary tract infections e.g. PHE/NICE,SIGN,SAPG
	Health Improvement Scotland. SIGN 160: Management of suspected bacterial lower urinary tract infection in adult women. A national clinical guideline. September 2020.
	Available at <u>sign-160-uti-0-1_web-version.pdf</u> (accessed 20 th January 2022)
	Health Improvement Scotland: Scottish Antimicrobial Prescribing Group (SAPG). <i>Urinary Tract Infections</i> . Available at: <u>Urinary tract</u> <u>infections (sapg.scot)</u> (accessed 20 th January 2022)
	Aware of local treatment recommendations.
	Attends approved training and training updates as appropriate. Undertakes CPD when PGD or NES Pharmacy module updates.

Audit Trail	
Audit Trail Record/Audit Trail	 All records must be clear, legible and in an easily retrieval format. Pharmacists must record in Patient Medication Record (PMR) The following records should be kept (paper or computer based) and are included in the patient assessment form: Patient's name/parent/guardian/person with parental responsibility, address, date of birth and consent given Patient's CHI number Contact details of GP (if registered) Presenting complaint and diagnosis Details of medicine supplied The signature and printed name of the healthcare professional who supplied the medicine. Advice given to patient (including side effects) The 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
	 The patient's GP, where known, should be provided with a copy of the GP notification form for the supply of trimethoprim 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 normar 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 St HSC-Scotland-Records-Management-Code-of-Practice-2020-v20200602.pdf (Accessed on 29th November 2021)

Additional references	British	National	Formulary	(BNF)	current	edition
			npendium. <i>Trime</i> npendium (emc)	•		
	Summary infection	y of antimicrob	linical Excellence <i>pial prescribing g</i> vailable at: <u>Antim</u> v 2022)	uidance – m	anaging com	mon
	October quick ref	2021. Availabl	<i>Diagnosis of urir</i> e at: <u>Diagnosis o</u> r primary care (p r 2022)	<u>f urinary tra</u>	ct infections	<u>-</u>
	infection r	esource suite. A tient facing ma	al Practitioners. vailable at: <u>Urinar</u> aterials (rcgp.org	ry tract infec	tion resource	<u>}_</u>
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Version history

Version	Date	Summary of Changes		
1.0	March 2020	Version 1.0 Original PGD		
2.0	2020 August 2022	 The following sections have been updated: Addition of covering statement regarding validity of PGD when approaching date for review of content Indication Removal of upper age limit Inclusion criteria Clarification that "older women should be fit, ambulatory and self-caring" and that "a positive dip stick in women over 65 is not an indication of UTI as asymptomatic bacteriuria is common in older women." Inclusion of visible haematuria in list of symptoms when testing urino with diastick 		
		 urine with dipstick Exclusion criteria Upper age limit removed Clarification that patients living in long term care facilities are excluded Clarification of definition of "upper" UTI Haematuria – specific criteria now apply Clarification of definition of vaginal discharge/itch Clarification of catheter use Pregnancy – now includes women who intend to become pregnant in next 3 months Clarification of definition of immunosuppression Clarification of definition of immunosuppression Clarification of additional information for patients over 65 years, with diabetes, symptoms lasting more than 7 days, breastfeeding Advice to patient Update to information for patients Action if patient is excluded Removal of requirement to record in Pharmacy Care Record (PCR) Action of patient declines Inclusion of link to NHS Inform for guidance on self-care Removal of requirement to record in PCR 		
		 Specialist competencies or qualifications Updated link to training module Record/audit trail Removal of requirement to record in PCR Clarification that notification form should be sent to GP for patients being referred as well as those being treated by community pharmacy. 		





Patient Group Direction (PGD)

Supply of Fusidic Acid 2% Cream Version – 2.0

The purpose of the PGD is to allow management of impetigo in adults and children by registered pharmacists in Community Pharmacies.

This PGD authorises pharmacists delivering the NHS Pharmacy First Scotland Service Level Agreement to supply Fusidic acid 2% cream to adults and children presenting with symptoms of impetigo who meet the criteria for inclusion under the terms of the document.

NICE Guideline 153¹ recommends that hydrogen peroxide 1% cream should be considered as first line treatment for patients with localised non-bullous impetigo who are not systemically unwell or at high risk of complications. Hydrogen peroxide 1% cream (Crystacide) is listed on the NHS PFS Approved List.

Please refer to your local Health Board policy for first line treatment of impetigo.

Change History – see table at end of this document for more details

- Removal of lower age limit
- Minor changes to inclusion criteria
- Minor changes to exclusion criteria
- Clarification of symptoms
- Additional safety netting advice included

If this PGD is past the review date, the content shall remain valid until such time that the review is complete and a new version has been published. <u>It is the responsibility of the person using the PGD</u> to ensure they are using the most recent issue.

1. National Institute for Health and Care Excellence. *Guideline 153 Impetigo : antimicrobial prescribing*. February 2020. Available at: Impetigo: antimicrobial prescribing (nice.org.uk) (accessed 16th June 2022)

PGD Fusidic Acid Cream 2%

Authorisation

This specimen Patient Group Direction (PGD) has been produced in collaboration with the Scottish Antimicrobial Prescribing Group and the Primary Care Community Pharmacy Group to assist NHS Boards in the provision of 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 Fusidic Acid 2% cream 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	Dr Laura Ryan	Signature	hance Ryc
Pharmacist	Dr John McAnaw	Signature	John July 4 man
NHS Scotland Representative	Mr Jim Miller	Signature	for how the
Approved on behalf	of NHS [insert detai	ils] by:	
Medical Director		Signature	
Director of Pharmacy/Senior Pharmacist		Signature	
Clinical Governance Lead		Signature	
Date approved			
Effective from date		- Review date	
NUS Dearmoon First Soc	tland		

Clinical Situation

Clinical Situation	Treatment of minor stanbylococcal skin infections (Importion)	
Indication Inclusion Criteria	Treatment of minor staphylococcal skin infections. (Impetigo)	
Inclusion Chiena	 Adults and children with minor/localised, uncomplicated skin infection The rash consists initially of vesicles with erythematous base which easily rupture and are seldom observed. The exudate dries to form yellow-gold or yellow-brown crust which gradually thickens Informed consent by patient or parent/carer Patient must be present at consultation 	
Exclusion Criteria	 Widespread skin infection. History of MRSA colonisation or infection Has had impetigo treated with an antibiotic (including fusidic acid 2% cream) within the last 3 months. Patient systemically unwell Allergy to any component of the cream. Patient/carer refuses treatment. Presenting with any underlying skin condition on the same area of the body as impetigo. 	
Cautions /Need for further advice/ Circumstances when further advice should be sought from a doctor	 Any doubt as to inclusion/exclusion criteria being met. Lesions present near the eye – care should be taken when applying cream near to the eye. Patients under one year of age – in some cases, impetigo management may require oral (or sometimes IV) antibiotics, especially in neonates. These children may need clinical review therefore appropriate safety-netting advice is essential e.g. if not improving, see GP. 	
Action if Excluded	Refer to GP Practice/Out-of-hours (OOH) service and document in Patient Medication Record (PMR)	
Action if Patient Declines`	If patient declines treatment, advise on self-care to relieve symptoms and advise to see their GP if symptoms fail to resolve within 5 days or if symptoms worsen. Advise to contact NHS 24 if becoming systemically unwell or rapidly spreading to large areas of body during OOH period. 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 Patient Medication Record (PMR) if appropriate.	
	Record outcome in Patient Medication Record (PMR) if appropriate.	

Description of Treatment

Name of Medicine	Fusidic Acid	
Form/Strength	2% Cream	
Route of	Topical	
administration		
Dosage	Apply gently to lesions	
Frequency	Apply three or four times daily	
Duration of treatment	5 days	
Maximum or minimum	Use for a maximum of 5 days. Maximum of one supply in three	
treatment period	months.	
Quantity to	1 x 15g	
supply/administer		
▼ additional	No	
monitoring		
Legal Category	POM (Prescription Only Medicine)	
Is the use outwith the SPC	No	
Storage requirements	As per manufacturer's instructions	
	Store below 25°C in a cool dry place	
Additional information	None	

Warnings including possible adverse reactions and management of these	Side effects with this product are rare however hypersensitivity reactions may occur. 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 administering medication under this PGD. This can be accessed on <u>Home -</u> <u>electronic medicines compendium (emc)</u>
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 (e.g. via SBAR). Where appropriate, use the Yellow Card System to report adverse drug reactions. Yellow Cards and guidance on its use are available at the back of the BNF or online at http://yellowcard.mhra.gov.uk/
Advice to Patient/carer including written information	 Wash hands before and after applying cream. Where possible remove scabs by bathing with warm water before applying the cream. Impetigo is a very infectious condition. Important to prevent infection spreading by using own flannels and towels (hot wash after use). Do not scratch or pick spots.

	 If applicable, suggest applying cream three times daily on school days (before school, after school and evening) and four times daily at other times. Inform school of condition. Advise that child should be excluded from school until the lesions are crusted and healed or 48 hours after commencing antibiotic treatment. Do not share cream with anyone else. Do not apply to breast if patient is breastfeeding. Inform of possible side effects and their management. 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	If the skin infection spreads or there is no improvement after 5 days, seek medical advice from GP. If patient becomes systemically unwell or rapidly spreading to large areas of body during OOH period seek medical advice from NHS 24.
Additional Facilities	 The following should be available where the medication is supplied: An acceptable level of privacy to respect patient's right to confidentiality and safety. Access to medical support (this may be via the telephone). Clean and tidy work areas, including access to hand washing facilities. Access to current BNF (online version preferred).

Characteristics of staff authorised under the PGD

Professional qualifications	Registered pharmacist with current General Pharmaceutical Council (GPhC) registration.
•	Under PGD legislation there can be no delegation. Supply of
	the medication has to be by the same practitioner who has
	assessed the patient under this PGD.
Specialist	Has successfully completed NES Pharmacy "Impetigo for NHS
competencies or	Pharmacy First Scotland" e-learning module.
qualifications	Available at:
	https://learn.nes.nhs.scot/34440/pharmacy/cpd-resources/impetigo-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 Fusidic Acid Cream Summary of Product
	Characteristics (SPC).
Continuing advantion	Los road aurrent guidenes on the management of impetias
Continuing education and training	Has read current guidance on the management of impetigo Aware of local treatment recommendations.
and training	Attends approved training and training updates as appropriate.
	Undertakes CPD when PGD or NES Pharmacy module updates.

Audit Trail	
Record/Audit Trail	 All records must be clear, legible and in an easily retrieval format. Pharmacists must record in Patient Medication Record (PMR). The following records should be kept (paper or computer based) and are included in the patient assessment form: Patient's name/parent/guardian/person with parental responsibility, address, date of birth and consent given Patient's CHI number Contact details of GP (if registered) Presenting complaint and diagnosis Details of medicine supplied The signature and printed name of the healthcare professional who supplied the medicine. Advice given to patient (including side effects) Whether the patient met the inclusion criteria and whether the exclusion criteria were assessed Details of any adverse drug reaction and actions taken including documentation in the patient's medical record Referral arrangements (including self-care) The patient's GP, where known, should be provided with a copy of the client assessment form for the supply of fusidic acid or appropriate referral on the same, or next available working day. These records should be retained in accordance with national guidance ² (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 Socitish Government. Scottish Government Records Management. Edinburgh 2020. Available at SG-HSC-Scottand-Records Management. Code-ol-Practice-2020. vol200602.pdf (Accessed on 29 th November2021)
Additional references	British National Formulary (BNF) current edition Fusidic Acid Cream SPC

Version history

Version	Date	Summary of Changes
1.0	April 2020	Version 1.0 New PGD
2.0	August 2022	 The following sections have been updated: Addition of statement regarding first line treatment of non- bullous impetigo for patients who are not systemically unwell or at high risk of complications – refer to local Health Board policy on use of hydrogen peroxide 1% cream (Crystacide) Addition of covering statement regarding validity of PGD when approaching date for review of content Removal of lower age limit of 2 years Changes to inclusion criteria to clarify symptoms of impetigo Amendment of exclusion criteria from multiple site to widespread infection Removal of "concern about non-compliance with topical treatment" exclusion Update to guidance for children at school to minimise risk of spread of infection Addition of guidance on follow up required when patient becomes systemically unwell during OOH period

Patient Group Direction for the treatment of acute uncomplicated urinary tract infection (UTI) in non-pregnant female patients over 16 years of age

Patient assessment form

Patient Name:	Click or tap here to enter text.	Date of Birth /CHI:	Click or tap here to enter text.
Date of assessment:	Click or tap to enter a date.	Patient is aware that GP will informed:	Yes 🗆 No 🗆

Patient clinical picture and related appropriate actions

Symptom assessment		No	Actions
Symptom of dysuria (pain or burning when passing urine)			Consider treatment if three or more of the following
Symptom of frequency (needing to pass urine more often than usual			symptoms present: Dysuria Frequency
Symptom of urgency (little warning of the need to pass urine)			 Urgency Suprapubic tenderness Or if BOTH dysuria and
Symptom of suprapubic tenderness (pain/tenderness in lower abdomen)			frequency present. Support the diagnostic process with dipstick testing if available
	ſ		
Frank haematuria (blood in urine)			If unexplained or specific exclusion criteria apply – do not treat and REFER to GP/OOH If likely to be related to UTI – treatment may be provided
Vaginal discharge or irritation			If new/unexplained – do not treat and REFER for STI assessment
Clinical features		No	Actions
Do symptoms suggest upper UTI (these may include loin pain, fever <u>></u> 38°C, rigors or systemically very unwell)?			If YES, do not treat and REFER urgently (same day) due to risk of upper UTI or sepsis
Duration of symptoms > 7 days?			If YES, treatment may be provided Ensure GP is notified that follow up may be required
Has the patient had a UTI requiring an antibiotic within the last 28 days?			If YES, do not treat and REFER due to risk of resistant organisms

Does the patient have recurrent UTI? (≥ 2 episodes in last 6 months or ≥ 3 episodes in last year?		If YES, do not treat and REFER due to need for urine culture
Does patient take prophylactic antibiotics for treatment of UTI?		If YES, do not treat and REFER
Urinary catheter in situ or use of intermittent self-catheterisation?		If YES, do not treat and REFER
Is the patient currently immunosuppressed? E.g. auto-immune disease, chemotherapy, long term corticosteroids or other immunosuppressant medication?		If YES, do not treat and REFER
Pregnant – known or suspected? Planning to become pregnant in next 3 months if treating with trimethoprim?		If YES, do not treat and REFER
Breastfeeding?		If YES, treatment may be provided
Diabetes?		If YES, treatment may be provided. Refer to GP if concern over recurrent UTI or if UTI is potentially caused by side effect of medication
Confused or dehydrated?		If YES, do not treat and REFER
Known moderate to severe renal impairment or abnormality of the urinary tract or ureteric stent?		If YES, do not treat and REFER
Is the patient on any interacting medications (e.g. warfarin/trimethoprim). See current BNF/SPC for details		If YES, do not treat and REFER
Known haematological abnormalities, porphyria, folate deficiency which is uncorrected, glucose-6- phosphate deficiency?		If YES, do not treat and REFER
Known electrolyte imbalance?		If YES, do not treat and REFER
Known severe liver fibrosis / encephalopathy?		If YES, do not treat and REFER
Patient has known blood disorders such as leucopenia, megaloblastic anaemia, thrombocytopenia, agranulocytosis, or methaemoglobinaemia?		If YES, do not treat and REFER

Treatment options

Follow NHS board's first line formulary choice – this is trimethoprim in most boards.

Ideally nitrofurantoin should only be used if you have access to information about current renal function. However, if no recent eGFR is available but the patient has no history of renal problems, nitrofurantoin may be used (See Appendix 1).

Clinical features affecting therapeutic choice	Trimethoprim	Nitrofurantoin	
Clinically significant drug interactions with existing medication	AVOID if significant interaction exists with current medication		
Known interstitial lung disease or poorly controlled respiratory disease	SUITABLE	AVOID due to difficulty in recognising pulmonary fibrosis secondary to nitrofurantoin	
Current use of alkalinising agents	SUITABLE	AVOID or advise to stop alkalinising agent	
Allergy or adverse effect to trimethoprim	AVOID	SUITABLE	
Allergy or adverse effect to nitrofurantoin	SUITABLE	AVOID	

Preparation options and supply method

Medicine and strength	Regimen - Health Board specific	Supply method
Nitrofurantoin 50 mg tablets	ONE tablet FOUR times daily x 12	
Nitrofurantoin MR 100 mg capsules	ONE capsule TWICE daily x 6	PGD via UCF
Trimethoprim 100 mg tablets	TWO tablets TWICE daily x 12	
Trimethoprim 200 mg tablets	ONE tablet TWICE daily x 6	
Symptomatic management only	Appropriate analgesia	UCF or OTC or existing supply

Advice	Provided (tick as
How to take medication	appropriate)
Expected duration of symptoms - to seek medical assistance if symptoms worsen or are not resolving within 3 days	
Nitrofurantoin only – stop taking immediately and seek medical assistance if symptoms of pulmonary reaction develop (e.g. cough, dyspnoea, fever, chills)	
Ensure adequate fluid intake (approx. 2.5L per day but avoid very large amounts due to risk of inadequate bladder contact with antibiotic). Fluid intake should result in urine being a pale straw colour.	
Symptomatic (use of analgesia)	
Prevention of UTI - Hygiene / toilet habits (do not 'hold on' – go to the toilet when you need to)	
If patient has haematuria – seek medical assistance if haematuria persists or returns after successful treatment of UTI	
Patient information leaflet relating to medication is given to patient	

Communication

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

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 acute Urinary Tract Infection (UTI) in patients over 16 years

Notification of assessment and 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 UTI:	
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 enter text.
	Click or tap here to enter text.	GPhC number Circk or tap here to enter text.
Postcode	Click or tap here to enter text.	DateClick or tap to enter a date.

Following assessment (Tick as appropriate)

Presenting symptoms						
Dysuria 🗌		Urgency 🗆		Haematuria 🗌		
Frequency 🗌		Polyuria 🗆 S		Suprapub	Suprapubic tenderness	
Urine dipstick results (op	tional)					
Nitrite '+'ve 🛛	Leuc	cocyte '+'ve 🔲 🛛 🛛 🛛 🖂		e 🗆	Not taken 🛛	
Your patient has been give	en a 3	Trimethoprim 200 mg tablets				
day course of:		Nitrofurantoin 100 mg MR				
		capsules				
		Nitrofurantoin 50 mg tablets				
Your patient is unsuitable	for trea	tment via PGD for th	ne following			
reasons and has been referred:						
Click or tap here to enter text.						
Follow up by GP practice required for the following reasons:				_		
Click or tap here to enter text.						

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.

NHS Pharmacy First Scotland UTI PGDs v2.0 May 2022

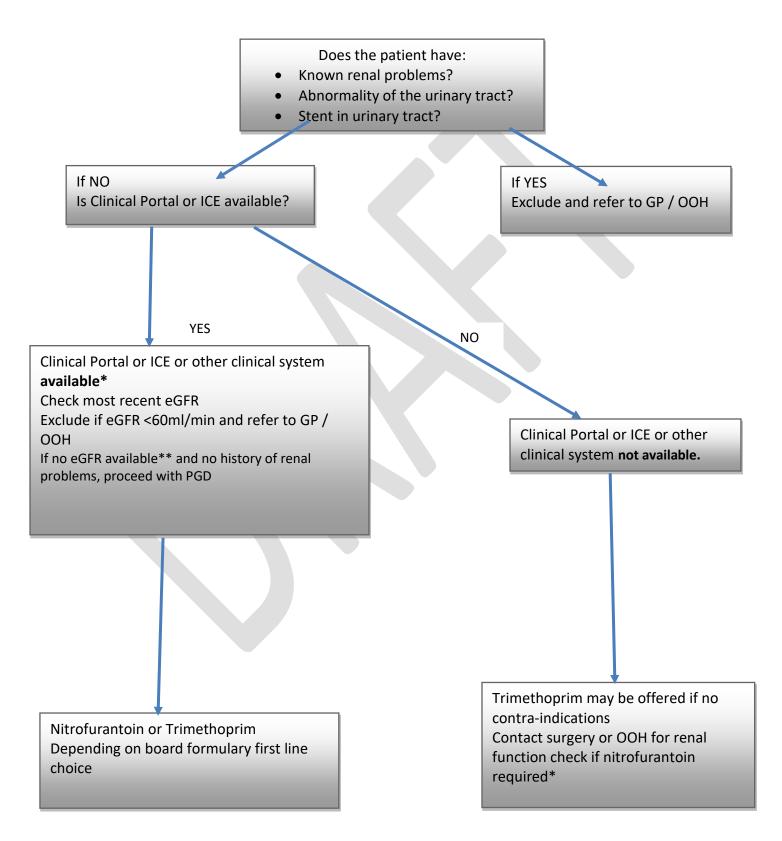
(Due for review May 2024)

Appendix 1.

For boards using nitrofurantoin, a renal function assessment is required.

*eGFR must be >60ml/min for use of the nitrofurantoin PGD

**If eGFR is not available on Clinical Portal or ICE or other clinical system available because such a test appears never to have been performed, it can be assumed there has been no history or suspicion of renal problems and supply can be made if clinically appropriate.



Patient Group Direction for the treatment of adults and children presenting with symptoms of impetigo

Patient assessment form

Patient Name:	Click or tap here to enter text.	Date of Birth /CHI:	Click or tap here to enter text.
Date of assessment:	Click or tap to enter a date.	Patient consents to GP being informed:	Yes 🗆 No 🗆

Patient clinical picture and related appropriate actions

Symptom assessment	Yes	No	Actions
Rash typical of impetigo? (Initially presents as vesicles with erythematous base which easily rupture with exudate drying to form a yellow/gold or yellow/brown crust which gradually thickens).			If NO, consider alternative diagnosis and proceed appropriately. If YES, may be suitable to receive Fusidic acid cream under PGD.
Clinical features	Yes	No	Actions
Has already tried Hydrogen Peroxide (Crystacide) 1% cream to treat lesions?			If NO, consider recommending this as first step of treatment. If YES, may be suitable to receive Fusidic acid under PGD.
Widespread skin infection?			If NO (minor/localised, uncomplicated area of infection only) may be suitable to receive Fusidic acid under PGD. If YES (widespread, extensive lesions), REFER to GP.
History of MRSA colonisation or infection?			If YES, REFER to GP.
Had impetigo treated with any form of antibiotics within the last 3 months?			If YES, REFER to GP.
Patient systemically unwell?			If YES, REFER to GP or OOH if appropriate.
Known allergy to any component of the cream?			If YES, REFER to GP.
Presenting with any underlying skin condition on the same area of the body as impetigo?			If YES, REFER to GP.

Preparation options and supply method

Medicine and strength	Regimen - Health Board specific	Supply method
Fusidic acid 2% cream (1 x 15 g)	Apply gently to affected area THREE or FOUR times daily for 5 days	PGD via UCF

Patient advice checklist

Advice	Provided (tick as appropriate)
Wash hands before and after applying cream	
Where possible, remove scabs by bathing with warm water before applying the cream	
Impetigo is a very infectious condition. Important to prevent infection spreading by using own flannels and towels (hot wash after use)	
Do not scratch or pick spots	
Suggest applying creams THREE times daily on school days (before school, after school and evening) and FOUR times daily at other times	
Inform school of condition – advise that child should be excluded from school until the lesions are crusted and healed or 48 hours after commencing antibiotic treatment	
If infection spreads or there is no improvement after 5 days, seek medical advice from GP	
If patient becomes systemically unwell or infection is rapidly spreading to large areas of body during OOH period, seek medical advice from NHS 24.	
Do not share cream with anyone else	
Do not apply to breast if patient is breastfeeding	
Inform patient of possible side effects of medication and their management	
Provide patient information leaflet	

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 adults and children presenting with symptoms of

NHS Pharmacy First Scotland UTI PGDs v2.0 May 2022

impetigo Notification of assessment and 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.	
01	s attended this pharmacy for	
assessment and potentia	al treatment of impetigo:	
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 ox tap here to enter text.
	Click or tap here to enter text.	GPhC number elick or tap here to enter text.
Postcode	Click or tap here to enter text.	DateClick or tap to enter a date.

Following assessment (Tick as appropriate)

Presenting symptoms	
Rash typical of impetigo (Initially presents as vesicles with erythematous base which easily rupture with exudate drying to form a yellow/gold or yellow/brown crust which gradually thickens – minor/localised lesions)	
Treatment	
Your patient has been supplied with 1 x 15 g Fusidic acid cream	
(Apply gently to affected area THREE or FOUR times daily for 5 days)	
Your patient is unsuitable for treatment via PGD for the following reasons and has been referred: Click or tap here to enter text.	

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 D	Date
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