NHS
Cornwall and Isles of Scilly

Patient group direction for the supply of a fluconazole 150mg capsule and clotrimazole 1% cream by community pharmacists for the first line management of vulvo-vaginal candidiasis

Documentation details

Reference no: PGD05
Version no: 2.2
Valid from: 1 April 2025
Review date: 1 December 2026
Expiry date: 31 March 2027

Change history

Version number	Date	Details
1	11 Jan 2022	New PGD
1.1	4 Feb 2022	Clarified duration of treatment with clotrimazole cream
2	February 2023	Transfer to ICB stationery Renumber to PGD05 Review of PGD
2.1	29 April 2024	Added patient advice regarding fluconazole and pregnancy in line with updated SmPC
2.2	January 2025	Reviewed (unchanged). Links updated as needed.

Patient group direction development

Date template comes into effect: April 2025
Version no: 2.2
Valid from: 1 April 2025
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Patient group direction working group

January 2025 review (version 2.1)		
Name and role	**Job title**	**Organisation**
Chris Burgin Pharmacist and lead reviewer	Pharmaceutical advisor	NHS Cornwall and Isles of Scilly Integrated Care Board (ICB)
Amanda Fidelis Pharmacist	Senior clinical pharmacist	NHS Cornwall and Isles of Scilly Integrated Care Board (ICB)
Dr Rob White	General practitioner	NHS Cornwall and Isles of Scilly Integrated Care Board (ICB)

This patient group direction (PGD) was developed by a working group involving pharmacists from NHS Cornwall and Isles of Scilly integrated care board (CIOS ICB) and GP clinical leads from CIOS ICB. Version 2.0 approved by medicines optimisation programme board (MOPB), February 2023. Adapted from the SPS template.

Organisational authorisations

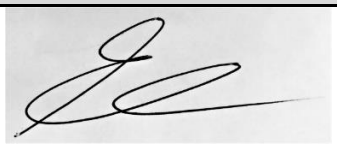
The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

CIOS ICB authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services: Community pharmacies contracted to provide the CIOS ICB community pharmacy PGD service for minor ailments.

Limitations to authorisation: None.

Approved by	Name	Signature	Date of email approval
Chief pharmacist NHS Cornwall and Isles of Scilly Integrated Care Board	Marco Motta		12 February 2025

Approved by	Name	Signature	Date of email approval
Chief medical officer NHS Cornwall and Isles of Scilly Integrated Care Board	Dr Chris Reid		6 March 2025
Chief nursing officer & chief operating officer NHS Cornwall and Isles of Scilly Integrated Care Board	Susan Bracefield		20 March 2025

Local enquiries regarding the use of this PGD may be directed to ciosicb.prescribing@nhs.net

Individual registered health professionals must be authorised by name to work to this PGD. This should be recorded on the authorisation sheet at the end of this document.

Characteristics of staff

Qualifications and professional registration

Registered professional with one of the following bodies:

- Pharmacists registered with the General Pharmaceutical Council (GPhC)

Initial training

- Must be authorised by name as an approved practitioner under the current terms of this PGD before working to it
- Has undertaken appropriate training and been assessed and declared competent to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this PGD
- Must be competent in the use of PGDs (see NICE competency framework for health professionals using PGDs)
- Must have access to the PGD and associated online resources

Competency assessment

All pharmacists operating under this PGD are required to complete a declaration of competence for minor ailments via the Centre Pharmacy Postgraduate Education (CPPE) website and complete the declaration of competence on PharmOutcomes.

Staff operating under this PGD are encouraged to attend specific commissioning organised training events on minor ailments and complete the CPPE common clinical conditions e-learning.

Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD.

Ongoing training and competency

Practitioners must ensure they are up to date with relevant issues and clinical skills relating to the management of vulvo-vaginal candidiasis, with evidence of appropriate continued professional development (CPD).

Pharmacists will be required to complete an annual declaration of competence via the CPPE website and PharmOutcomes.

The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.

Clinical condition or situation to which this PGD applies

Condition or situation: First line treatment of vulvo-vaginal candidiasis as per NICE guidelines, including topical imidazole where there are vulval symptoms.

Criteria for inclusion

- An individual with reported symptoms including:
    - Vulval or vaginal itching (often the defining symptom)
    - Vulval or vaginal soreness and irritation
    - Vaginal discharge (usually white, 'cheese-like', and non-malodorous)
    - Superficial dyspareunia
    - Dysuria (pain or discomfort during urination)

Criteria for exclusion

- Women aged under 16 or over 60 years
- Known or suspected pregnancy
- Individuals with 4 or more treated episodes of candidiasis in the preceding 12 months, or 2 or more treated episode in the preceding 6 months.
- Individuals with genital sores or ulcers suggestive of other infections or conditions
- Individuals with pelvic pain where pelvic inflammatory disease (PID) has not been excluded
- Individuals with abnormal vaginal bleeding where cause has not been identified
- Recurrent or unresolved symptoms of candidiasis within 4 weeks of being treated
- Individuals who are immunosuppressed and may require further assessment and systemic treatment
- Individuals with acute porphyria
- Past or current history of cardiac rhythm disturbance
- Patients with hypokalemia and advanced cardiac failure
- Known liver impairment
- Doubt over diagnosis
- Individual is taking interacting medicines. Check appendix 1 of current print edition of British National Formulary (BNF) for full list, or online
- Individuals with a known allergy to fluconazole or to related azole compounds or any of the constituents found within the formulation
- Individuals with a known allergy to clotrimazole or any other imidazole antifungal, or to any of the constituents found within the formulation

Cautions including any relevant action to be taken
Discuss with appropriate medical or independent non-medical prescriber any medical condition or medication of which the pharmacist is unsure or uncertain.

Action to be taken if the patient is excluded
- Explain the reasons for exclusion to the individual
- Record reasons for exclusion and any action(s) taken
- Advise patient on alternative treatment
- Refer to a prescriber if appropriate (for example GP or NHS 111 or out of hours (OOH) services)
- Give safety-netting advice

Action to be taken if the patient declines treatment
- Ensure the individual is aware of the need for treatment and the potential consequences of not receiving treatment
- Document the reasons for declining, advice given and the decision reached
- Advise patient on alternative treatment if appropriate
- Refer to a prescriber if appropriate
- Give safety-netting advice

Arrangements for referral for medical advice
Advise people with vuvlo-vaginal candidiasis to seek medical help if symptoms worsen rapidly significantly at any time, or symptoms have not improved after completing a course of treatment.

Description of treatment – fluconazole 150mg capsule

Name, strength and formulation of drug
Fluconazole 150mg capsule

Legal category
Prescription only medicine (POM)

Route and method of administration
Oral

Indicate any off-label use (if relevant)
Not applicable

Dose and frequency of administration
Single 150mg dose

Duration of treatment
1 dose

Quantity to be supplied
1 capsule

Storage
Stock must be stored in conditions in line with the summary of product characteristics (SPC)

Drug interactions

- Fluconazole has a number of drug-drug interactions which may be clinically significant and all concurrent medications should be reviewed for interactions
- Where a significant interaction is identified which may require dosage amendment or additional monitoring refer to appropriate medical or independent non-medical prescriber
- A detailed list of all drug interactions is available in the BNF online or the product SmPC, which is available from the electronic medicines compendium (EMC) website www.medicines.org.uk

Increased risk of adverse reactions

A detailed list of adverse reactions is available in the SmPC, which is available from the EMC website www.medicines.org.uk and BNF www.bnf.org

Identification and management of adverse reactions

- The following side effects are commonly reported with fluconazole (but may not reflect all reported side effects): headache, abdominal pain, diarrhoea, nausea, vomiting, rash
- This list is not exhaustive; refer to BNF or SPC for full details

Description of treatment – clotrimazole 1% cream

Name, strength and formulation of drug

Clotrimazole 1% cream

Legal category

Pharmacy (P) medicine

Route and method of administration

Topical

Indicate any off-label use (if relevant)

Not applicable

Dose and frequency of administration

Apply two or three times a day

Duration of treatment

To be applied as needed for a maximum of 7 days

Quantity to be supplied

20g tube

Storage

Stock must be stored in conditions in line with the summary of product characteristics (SPC)

Drug interactions

- All concurrent medications should be reviewed for interactions
- Where a significant interaction is identified which may require dosage amendment or additional monitoring refer to appropriate medical or independent non-medical prescriber
- A detailed list of all drug interactions is available in the BNF online or the product SmPC, which is available from the EMC website www.medicines.org.uk

Increased risk of adverse reactions

A detailed list of adverse reactions is available in the SmPC, which is available from the EMC website www.medicines.org.uk and BNF www.bnf.org

Identification and management of adverse reactions

- The following side effects are commonly reported with clotrimazole (but may not reflect all reported side effects): abdominal pain, genital peeling or bleeding, pruritus, rash, oedema, erythema and discomfort or burning
- This list is not exhaustive; refer to BNF or SPC for full details

Management of and reporting procedure for adverse reactions

- Healthcare professionals and patients or carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme
- Record all adverse drug reactions (ADRs) in the patient's medical record (and inform the patient's GP)
- Report via organisation incident policy

Written information to be given to patient or carer

- The marketing authorisation holders' patient information leaflets provided with the products if treatment is to be supplied and advise patient to read the leaflet
- Patient information on vulvo-vaginal candidiasis can be viewed and printed from the NHS website and patient.info

Patient advice and follow up treatment

- Provide advice on using the medication:
    - Advise that clotrimazole cream may cause damage to latex condoms; the effectiveness of such contraceptives may be reduced, it is advised to use alternative precautions during and for at least 5 days after using this product
- Provide advice on measures to relieve symptoms:
    - Use simple emollients as a soap substitute to wash and/or moisturize the vulval area
    - Avoid contact with potentially irritant soap, shampoo, bubble bath, or shower gels, wipes, and daily or intermenstrual 'feminine hygiene' pad products
    - Avoid vaginal douching
    - Avoid wearing tight-fitting and/or non-absorbent clothing, which may irritate the area
    - Avoid use of complementary therapies such as application of yoghurt, topical or oral probiotics, and tea tree or other essential oils
- The patient should be advised to seek medical advice in the event of an adverse reaction
- If after 7 days symptoms persist or worsen advise the patient to contact their GP
- Patients planning on becoming pregnant should be advised to wait at least a week after stopping fluconazole before undertaking unprotected sexual intercourse, due to a very low increased risk of miscarriage.

Records

- Completion of PGD checklist on PharmOutcomes.
- Completion of patient medication record.
- Label the pack being supplied appropriately:
    - Dose, form and route of supply or administration
    - Quantity supplied or administered
    - Supplied via PGD
- Record details of any adverse drug reactions and actions taken

- Referral arrangements (including self-care)
- Batch number and expiry date (if applicable)
- Completion of consent form and completion of the audit claim on PharmOutcomes
- Records should be signed and dated (or a password controlled e-records).
- All records should be clear, legible and contemporaneous
- A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy

Audit trail

- PMR entry
- Patient's GP should be notified using the notification form on PharmOutcomes within 48 hours of supply for inclusion in the patients notes

Key references

- NICE CKS – Candida – female genital
- NHS UK – Thrush in man and women
- CIOS ICB management of infection guidelines
- Patient.info – vaginal thrush
- BNF – fluconazole monograph
- BNF – clotrimazole monograph
- Electronic Medicines Compendium (EMC)
- NICE PGD medicines practice guideline [MPG2]
- Specialist Pharmacy website

Registered health professional authorisation sheet

PGD: Patient group direction for the supply of a fluconazole 150mg capsule and clotrimazole 1% cream by community pharmacists for the first line management of vulvo-vaginal candidiasis

Valid from: 1 April 2025
Expiry: 31 March 2027

Before signing this PGD, check that the document has had the necessary authorisations above. Without these, this PGD is not lawfully valid.

Authorisation

By signing this patient group direction, you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.

Name	Designation	Signature	Date
Click or tap here to enter text.			
Click here to enter text.			
Click here to enter text.			
Click here to enter text.			

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.