

This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

PATIENT GROUP DIRECTION (PGD)

Supply of clotrimazole 1% cream for the symptomatic relief of vulvo-vaginal candidiasis or candidal balanoposthitis in Integrated Sexual Health Services (ISHS) Derbyshire Community Services

Version Number 2.0

Change History	
Version and Date	Change details
Version 1.0	New template
Version 2.0 July 2023	Updated template; added newly reported adverse effects Addition of management of candidal balanoposthitis

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	November 2023
Review date	May 2026
Expiry date:	October 2026

This PGD template has been peer reviewed by the Sexual Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the British Association for Sexual Health and HIV (BASHH) in May 2023.

This section **MUST REMAIN** when a PGD is adopted by an organisation.

Name	Designation
Ali Grant	Highly Specialist Clinical Pharmacist: HIV, Sexual and Reproductive Health
Alison Crompton	Community pharmacy
Andrea Smith	Community pharmacy
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Reference Number: [PGD 230\(S\) Clotrimazole Cream National Template V2.0](#)

Valid from: 1 November 2023

Review date: May 2026

Expiry date: 31 October 2026

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Sally Hogan	British Pregnancy Advisory Service (BPAS)
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ORGANISATIONAL AUTHORISATIONS

PATIENT GROUP DIRECTION DEVELOPMENT WORKING GROUP
This PGD has been agreed by doctors, and/or expert clinical practitioners, pharmacist and representative healthcare professionals from the trust stated below for use within
Integrated Sexual Health Services (ISHS)
University of Derby and Burton Teaching Hospitals Foundation Trust (UHDBFT)
and Derbyshire Community Health Services Foundation Trust (DCHSFT)

PATIENT GROUP DIRECTION AUTHORISATION

PGD approved by PGD Working Group on 27th September 2023

This PGD is authorised for use on behalf of DCHS by the following signatories:

Position of signatory	Name	Signature	Date
Director of Nursing, AHPs & Quality	Michelle Bateman		11/10/2023
Head of Medicines Management	Kate Needham		11/10/2023
Deputy Medical Director	Dr Seema Kumari		11/10/2023
Lead Clinician	Dr Ade Apoola		11/10/2023
Specialist in Antimicrobial Therapy	Cerina Nanuan		11/10/2023

REVIEWED FOR DCHS BY:		
Date	Name	Position
September 2023	Lisa Walton Dr Ade Apoola Cerina Nanuan	ISHS Specialist Nurse Practitioner Consultant (ISHS) IP&C Pharmacist

PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct. Individual practitioners must declare that they have read and understood the Patient Group Direction and agree to supply/administer medication(s) listed only in accordance with the PGD.

1. Characteristics of staff

Qualifications and professional registration	Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation. Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
Initial training	<p>The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of an individual leading to diagnosis of the conditions listed.</p> <p>Individual has undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfh PGD elearning programme Recommended requirement for training would be successful completion of a relevant sexual health module/course accredited or endorsed by the BASHH, CPPE, RCN or a university or advised in the RCN Sexual Health Education directory. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults.</p> <p>For advice on additional local training requirements see Section 4: Characteristics of DCHS ISHS Staff.</p>
Competency assessment	<ul style="list-style-type: none"> • Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for vulvo-vaginal candidiasis and candidal balanoposthitis infection testing and/or treatment. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
Ongoing training and competency	<ul style="list-style-type: none"> • Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required. • Organisational PGD and/or medication training as required by employing Trust/organisation.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

2. Clinical condition or situation to which this PGD applies

<p>Clinical condition or situation to which this PGD applies</p>	<ul style="list-style-type: none"> • Vulvo-vaginal candidiasis <p>NOTE: The clotrimazole 1% cream is for symptomatic relief only and is not a treatment in itself. Clotrimazole 1% w/w cream for use in vulvo-vaginal candidiasis should be considered in addition to either single dose oral fluconazole or a single dose clotrimazole pessary - see separate PGDs for fluconazole oral capsules or clotrimazole pessaries.</p> <ul style="list-style-type: none"> • Candidal balanoposthitis
<p>Criteria for inclusion</p>	<ul style="list-style-type: none"> • An individual aged 13 years or over with a confirmed diagnosis of vulvo-vaginal candidiasis <p>OR</p> <ul style="list-style-type: none"> • An individual aged 16 years or over with a confirmed diagnosis of candidal balanoposthitis
<p>Criteria for exclusion</p>	<p>Personal Characteristics</p> <ul style="list-style-type: none"> • Individuals under 13 years of age (vulvo-vaginal candidiasis) or under 16 years of age (candidal balanoposthitis) • Individuals who are pre-pubertal • Individuals under 16 years of age and assessed as not competent using Fraser Guidelines • Individuals 16 years of age and over and assessed as not competent to consent using local safeguarding guidelines <p>Medical history</p> <ul style="list-style-type: none"> • Individuals with four or more treated episodes of candidiasis (2 or more confirmed by microscopy) in the preceding 12 months – refer to prescriber/specialist service • Individuals with genital sores/ulcers suggestive of other infections/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 • Known or suspected pregnancy • For balanoposthitis – individual has severe symptoms (including ulceration or inability to retract the foreskin) <p>Medication history</p> <ul style="list-style-type: none"> • Known allergy/hypersensitivity to clotrimazole or any other imidazole antifungal, or any constituent of the preparation
<p>Cautions including any relevant action to be taken</p>	<ul style="list-style-type: none"> • If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. • If the presenting individual is under 13 years of age the healthcare professional should speak to local safeguarding

	<p>lead and follow the local safeguarding policy (note under 13 years of age excluded from treatment under this PGD). Safeguarding: Where there are any safeguarding concerns refer to local policies for safeguarding adults and children and/or seek advice from the safeguarding lead/team in the organisation. Document the concern and outcome in the healthcare record. DCHS: Safeguarding adults and children policies on DCHS SharePoint. DCHS Safeguarding Team: 01773 850000. East Midland's Children and Young People's Sexual Assault Service (EMCYPAS): 0800 183 0023 (24-hour service).</p> <ul style="list-style-type: none"> • Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain.
<p>Action to be taken if the individual is excluded or declines treatment</p>	<ul style="list-style-type: none"> • If declined ensure individual is aware of the need for treatment and the potential consequences of not receiving treatment. • Record reason for decline in the consultation record. • Explain the reasons for exclusion to the individual and document in the consultation record. • Where required refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options.

3. Description of treatment

<p>Name, strength & formulation of drug</p>	<p>Clotrimazole 1% w/w cream</p>
<p>Legal category</p>	<p>P</p>
<p>Route of administration</p>	<p>Topical</p>
<p>Off label use</p>	<p>Best practice advice is given by BASHH and is used as the reference guidance in this PGD and may vary from the Summary of Product Characteristics (SPC).</p> <p>This PGD may include off label use as some manufacturers' SPCs exclude the age groups detailed below. Practitioners should check details for the brand they are supplying:</p> <ul style="list-style-type: none"> ○ Individuals under 16 years of age ○ Individuals age 60 years or over <p>Medicines should be stored according to the conditions detailed in the storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where medicines have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label supply under this PGD. The responsibility for the decision to release the affected drugs for use lies with pharmacy/Medicines Management.</p>

	Where a medicine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence.
Dose, frequency and duration of administration	<p>Vulvo-vaginal candidiasis Apply 1% cream sparingly to vulval area only two to three times a day until 48 hours after symptoms have resolved. Maximum duration 14 days.</p> <p>Candidal balanoposthitis Apply twice a day for up to 14 days</p>
Quantity to be supplied	One 20g tube of clotrimazole 1% cream
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	<p>Whilst there are no clinically significant interactions listed within this PGD all concurrent medications should be reviewed for interactions.</p> <p>A detailed list of all drug interactions is available in the BNF www.bnf.org or the product SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk</p>
Identification & management of adverse reactions	<p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org</p> <p>The following side effects are frequently reported with topical clotrimazole (but may not reflect all reported side effects):</p> <p>Localised skin reactions:</p> <ul style="list-style-type: none"> ○ rash ○ redness ○ pruritus / urticaria ○ irritation ○ oedema ○ mild stinging/burning ○ blisters ○ peeling/exfoliation <p>Allergic reactions:</p> <ul style="list-style-type: none"> ○ syncope ○ hypotension ○ dyspnoea ○ urticaria
Management of and reporting procedure for adverse reactions	<ul style="list-style-type: none"> • Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the individual's clinical record. • Report via organisation incident policy.

<p>Written information and further advice to be given to individual</p>	<p>Medication:</p> <ul style="list-style-type: none"> • Give manufacturer information leaflet (PIL) provided with the original pack. Explain mode of action, side effects, and benefits of the medicine • Advise that the clotrimazole 1% cream is for symptomatic relief only and is not a treatment in itself. Consider use in conjunction with the pessary or oral fluconazole • If adverse reaction to treatment occurs advise individual to contact clinic for further advice • Advise that this product 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. • Instruct individuals not to smoke or go near naked flames due to risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it. <p>Condition (general):</p> <ul style="list-style-type: none"> • Individuals diagnosed with candidiasis or candidal balanoposthitis should be offered information (verbal, written and/or digital) about their diagnosis and management • Provide verbal and written or online information on possible triggers for candidiasis or candidal balanoposthitis including avoiding using local irritants such as perfumed soap and encouraging use of emollients externally. • Give reassurance that candidiasis is not a sexually transmitted infection • If sexual partner is symptomatic advise they should access sexual health screening • Symptoms should resolve within 14 days but if symptoms do not begin to improve, or worsen during this time, seek further advice from the service or a relevant clinician • Offer condoms and advice on safer sex practices and offer the options for screening for sexually transmitted infections (STIs) where indicated. • Where treatment is not supplied via a sexual health clinic ensure the individual has contact details of local sexual health services if required.
<p>Follow up treatment</p>	<ul style="list-style-type: none"> • The individual should be advised to seek medical advice in the event of an adverse reaction. • Symptoms should resolve within 14 days but if symptoms do not begin to improve, or worsen during this time, seek further advice from the service or a relevant clinician
<p>Records</p>	<p>Record:</p> <ul style="list-style-type: none"> • The consent of the individual and <ul style="list-style-type: none"> ○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken. ○ If individual over 16 years of age and not competent, record action taken • If individual not treated under PGD record action taken • Name of individual, address, date of birth

	<ul style="list-style-type: none"> • GP contact details where appropriate • Relevant past and present medical and sexual history, including medication history. • Examination or microbiology finding/s where relevant. • Any known allergies and nature of reaction • Name of registered health professional • Indication for treatment • Name of medication supplied • Date of supply • Dose supplied • Quantity supplied including batch number and expiry date in line with local procedures. • Advice given, including advice given if excluded or declines treatment • Details of any adverse drug reactions and actions taken • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Any referral arrangements made • Any supply outside the terms of the product marketing authorisation • Recorded that supplied via Patient Group Direction (PGD) <p>Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy.</p> <p>All records should be clear, legible and contemporaneous.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>
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4. Characteristics of DCHS ISHS Staff

Qualifications	A registered nurse working within ISHS who is deemed competent by their clinical line manager and authorised by their professional lead to undertake the clinical assessment of a patients leading to the identification of those suitable for management under this PGD.
Additional Local Training	<p>Has undertaken the local training programme on the process, responsibilities and scope of PGDs.</p> <p>Has undertaken local training based on the use of this PGD.</p> <p>Has undertaken training in recognition of and treatment of anaphylaxis including basic life support in the 12 months.</p> <p>Has undertaken Safeguarding Children Level 3 training in the last 12 months.</p> <p>Has undertaken Safeguarding Adults Level 2 training in the last 3 years.</p>

Continuing Training & Education	<p>Evidence of Continuing Professional Development (CPD) in ISHS nurse role.</p> <p>The nurse should be aware of any change to the recommendations for the medicines listed.</p> <p>It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice.</p>
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5. Key references

Key references (accessed February 2023)	<ul style="list-style-type: none"> • Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline “Patient Group Directions” https://www.nice.org.uk/guidance/mpg2 • NICE Clinical Knowledge Summaries - https://cks.nice.org.uk • Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines • British Association for Sexual Health and HIV national guideline for the management of vulvovaginal candidiasis (updated 2021) British Association for Sexual Health and HIV national guideline for the management of vulvovaginal candidiasis (2019) (bashhguidelines.org) • British Association for Sexual Health and HIV national guideline for the management of Balanoposthitis (2008) 2062.pdf (bashhguidelines.org) • MHRA: Emollients: new information about risk of severe and fatal burns with paraffin-containing and paraffin-free emollients (2018) Emollients: new information about risk of severe and fatal burns with paraffin-containing and paraffin-free emollients - GOV.UK (www.gov.uk)
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Appendix A - Registered health professional authorisation sheet

PGD Name/Version: PGD 230(S) Clotrimazole Cream National Template V2.0

Valid from: 1 November 2023 **Expiry:** 31 October 2026

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

Registered health professional

By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs 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 Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Derbyshire Community Health Services for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

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

PGD Authorisation Forms shall be maintained and retained by the Service Manager who is responsible for the safe storage of the records