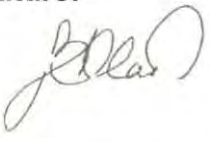
NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Patient Group Direction For The Supply Of Clotrimazole 1% Cream For The Symptomatic Relief Of Vulvo-Vaginal Candidiasis Or Candidal Balanoposthitis By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Adapted from SPS/BASHH Patient Group Direction (PGD) Supply Of Clotrimazole 1% Cream For The Symptomatic Relief Of Vulvo-Vaginal Candidiasis Or Candidal Balanoposthitis, Version 2 - Date Published: July 2023		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature: 		**Signature:** 
NoS Identifier: NoS/PGD/Clotrimazole_C/ 1657	**Review Date:** May 2026 **Expiry Date:** October 2026	**Date Approved by NoS:** 28th November 2025

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 2.0

Revision History for NoS:

NoS PGD that has been superseded	PGD supersedes NoS/PGD/Clotrimazole_Cream/MGPG1353, Version 2 (NoS Version)

Date of change	Summary of Changes	Section heading
May 2025	SPS Version 1.0 unpublished by NoS.	
May 2025	Title change to keep in line with SPS PGD title.	
May 2025	Reference to NoS Appendix 1 and 2.	Authorisation
May 2025	Statement added in about nurses being registered by the NMC.	Professional registration
May 2025	Removed SPS advised training and added TURAS NoS PGD training and safeguarding training link added.	Initial Training
May 2025	Added in statement about capacity under the age of 13 and the legislation statement added.	Criteria for inclusion
May 2025	NICE Competency framework statement removed.	Competency assessment
May 2025	Statement added about over labelled stock.	Legal
May 2025	Added clinical systems utilised.	Records
November 2025	Reference to fluconazole removed as no NoS PGD currently	Throughout

FSRH/SPS most recent changes

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.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Authorisation

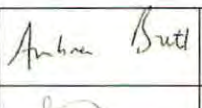
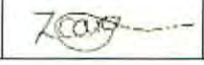
This specimen Patient Group Direction (PGD) template has been produced by SPS/BASHH and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may supply medicines 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 manufacturer's product information/Summary of Product Characteristics (SmPC) for all medicines supply 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 medicines has to be by the same practitioner who has assessed the patient under the PGD.

All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1).

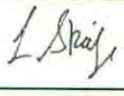
A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

This PGD has been produced for NoS by:					
Doctor	Dr Ambreen Butt	Signature		Date Signed	09/09/2025
Pharmacist	Joanne Adam	Signature		Date Signed	29/10/2025
Nurse	Zara Cargill	Signature		Date Signed	23/09/2025

Approved for use within NoS by:

NoS Group Chair	**Signature**	**Date Signed**
Lesley Coyle		26/11/2025

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Laura Skaife-Knight		28/11/2025

Version 2 – Approved for NoS from 28th November 2025.

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
Carmel Lloyd	Royal College of Midwives
Chetna Parmar	Pharmacist adviser, Umbrella
Clare Livingstone	Royal College of Midwives
Deborah Redknapp	English HIV and Sexual Health Commissioners Group (EHSHCG)
Dipti Patel	Local authority pharmacist
Dr Achyuta Nori	Consultant in Sexual Health and HIV
Dr Cindy Farmer	Vice President, General Training Faculty of Sexual and Reproductive Healthcare (FSRH)
Dr John Saunders	Consultant in Sexual Health and HIV
Dr Kathy French	Pan London PGD working group
Dr Rachael Jones	Consultant in HIV and Sexual Health, Chelsea and Westminster NHS Foundation Trust
Dr Rita Browne	Consultant in Sexual Health and HIV
Dr Sarah Pillai	Associate Specialist
Emma Anderson	Centre for Pharmacy Postgraduate Education (CPPE)
Heather Randle	Royal College of Nursing
Jo Jenkins	Lead Pharmacist PGDs and Medicine Mechanisms, Specialist Pharmacy Service
Portia Jackson	Pharmacist, Cambridgeshire Community Services
Rosie Furner (Working Group Co-ordinator)	Governance Pharmacist, Medicines Use and Safety, Specialist Pharmacy Service
Sally Hogan	British Pregnancy Advisory Service (BPAS)
Sandra Wolper	Associate Director, Medicines Use and Safety, Specialist Pharmacy Service
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service

Characteristics of staff

Qualifications and professional registration	Registered nurses within sexual health services recognised by the Nursing and Midwifery Council (NMC).
Initial training	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. Have undertaken NoS PGD module training on TURAS Learn. 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.
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix 1 and Appendix 2) or complete a self-declaration of competence for vulvo-vaginal candidiasis and candidal balanoposthitis infection testing and/or treatment.
Ongoing training and competency	• 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.	

Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	• Vulvo-vaginal candidiasis **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 a single dose clotrimazole pessary - see separate PGD for clotrimazole pessaries. • Candidal balanoposthitis
Criteria for inclusion	• An individual aged 13 years or over with a confirmed diagnosis of vulvo-vaginal candidiasis. • An individual with symptoms of vulvo-vaginal candidiasis confirmed on examination or via symptoms reported by the individual (including vulvo-vaginal itching, erythema, fissures, abnormal thick lumpy “cottage cheese” vaginal discharge). **Or** • An individual aged 16 years or over with a confirmed diagnosis of candidal balanoposthitis. • Symptoms suggestive of balanoposthitis confirmed on examination of the individual (including: discharge from the glans/behind the foreskin, itching, inability to fully retract the foreskin, erythema, purpura, scaling, fissures. • NOTE - Aged 13 years and over. All individuals under the age of 18 years - follow local young person’s risk assessment or equivalent local process. • An individual under 16 years of age may give consent for the supply of Clotrimazole 1% w/w cream, provided they understand fully the benefits and risks involved. The individual should be encouraged to involve a parent/guardian, if possible, in this decision. Where there is no parental involvement and the individual indicates that they wish to accept the supply, supply should proceed, if the healthcare professional deems the individual to have the legal capacity to consent. The Age of Legal Capacity (S) Act 1991, s2 (4) states that ‘a person under the age of 16 years shall have legal capacity to consent on their own behalf to any surgical, medical or dental procedure or treatment where, in the

	opinion of a qualified medical practitioner attending them, they are capable of understanding the nature and possible consequences of the procedure or treatment'.
Criteria for exclusion	**Personal Characteristics** • 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. **Medical history** • 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). **Medication history** • Known allergy/hypersensitivity to clotrimazole or any other imidazole antifungal, or any constituent of the preparation.
Cautions including any relevant action to be taken	• 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 lead and follow the local safeguarding policy (**Note:** under 13 years of age excluded from treatment under this PGD).

	• Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain.
Action to be taken if the individual is excluded or declines treatment	• 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.

Description of treatment

Name, strength and formulation of drug	Clotrimazole 1% w/w cream
Legal category	P In accordance with the MHRA all medicines supplied under a PGD must either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply.
Route of administration	Topical
Off label use	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). 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: • Individuals under 16 years of age. • Individuals age 60 years or over. 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. 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	**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. **Candidal balanoposthitis** Apply twice a day for up to 14 days.
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	Whilst there are no clinically significant interactions listed within this PGD all concurrent medications should be reviewed for interactions. 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
Identification and management of adverse reactions	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 The following side effects are frequently reported with topical clotrimazole (but may not reflect all reported side effects): **Localised skin reactions:** • rash • redness • pruritus/urticaria • irritation • oedema

	• mild stinging/burning • blisters • peeling/exfoliation. **Allergic reactions:** • syncope • hypotension • dyspnoea • urticaria.
Management of and reporting procedure for adverse reactions	• 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.
Written information and further advice to be given to individual	**Medication:** • 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 of Vulvo-Vaginal Candidiasis only and is not a treatment in itself. Consider use in conjunction with the pessary. • 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. **Condition (general):** • 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 their GP/Accident and Emergency department/NHS24. • 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.
Follow up treatment	• 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 their GP/Accident and Emergency department/NHS24.
Records	**Record:** • The consent of the individual and o If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken o 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 • 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). Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy. 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. Depending on the clinical setting where supply is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • NaSH – Sexual Health Electronic Patient Record • BadgerNet – Digital Maternity Notes • HEPMA • Individual's GP records if appropriate • Individual service specific systems.

Key references

Key references (accessed February 2023)	• 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 Balano-posthitis (2008) balano_posthitis_2008.pdf (bashh.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)

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 1 - Healthcare Professional Agreement to Supply Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to supply the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Supply Of Clotrimazole 1% Cream For The Symptomatic Relief Of Vulvo-Vaginal Candidiasis Or Candidal Balanoposthitis By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2

I have completed the appropriate training to my professional standards enabling me to supply the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2 - Healthcare Professionals Authorisation to Supply Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to supply the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to supply the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that supply is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
Patient Group Direction For The Supply Of Clotrimazole 1% Cream For The Symptomatic Relief Of Vulvo-Vaginal Candidiasis Or Candidal Balanoposthitis By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Patient Group Direction For The Supply Of Clotrimazole 1% Cream For The Symptomatic Relief Of Vulvo-Vaginal Candidiasis Or Candidal Balanoposthitis By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date