

NOTE

This Patient Group Direction is intended for use by commissioned sexual health services only.

It is recognised by the short life working group who developed this PGD that clotrimazole 500mg pessaries are available as a Pharmacy only (P) medicine as well as in a POM packaged preparation. As such this medicine can be purchased from a registered pharmacy premise and therefore individuals could be directed to purchase this preparation rather than it be supplied under a PGD. However, it was recognised that many services are commissioned to provide the medication required by the condition guidelines at the time of the consultation which includes P medicines. Organisations should consult with service commissioners/providers to determine locally if this PGD is required. A PGD will be required if a supply is made of the POM packaged preparation.

Reference Number: 2

Valid from: 1st November 2023

Review date: May 2026

Expiry date: 31st October 2026



**Rotherham Doncaster
and South Humber**

NHS Foundation Trust

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 500mg pessary / vaginal tablet for the treatment of vulvo- vaginal candidiasis in Rotherham, Doncaster, and South Humber (RDaSH) NHS Foundation Trust

Version Number 2.0

Change History	
Version and Date	Change details
Version 1.0	New template
Version 2.0 July 2023	Updated template: updated to include newly reported adverse effects which aligned with those already included. Added formulation of vaginal tablet to reflect one of the presentations.

Reference Number: 2

Valid from: 1st November 2023

Review date: May 2026

Expiry date: 31st October 2026

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


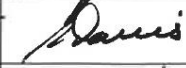

Reference Number: 2

Valid from: 1st November 2023

Review date: May 2026

Expiry date: 31st October 2026

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor	Medical Director		21/09/23
Senior pharmacist	Chief Pharmacist		22/9/23
Senior representative of professional group using the PGD	Director of Nursing and Quality		21/09/23
Person signing on behalf of <u>authorising body</u>	Nurse Consultant	Tina Proctor	21/09/23

Reference Number: 2
 Valid from: 1st November 2023
 Review date: May 2026
 Expiry date: 31st October 2026

Characteristics of staff

Qualifications and professional registration	<p>Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation.</p> <p>Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.</p>
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</p> <p>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.</p> <p>The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults.</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 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.
<p>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.</p>	

Reference Number: 2

Valid from: 1st November 2023

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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>In addition to a single dose clotrimazole pessary, clotrimazole 1% w/w cream should be considered for symptomatic relief - see separate PGD for clotrimazole cream 1%.</p>
<p>Criteria for inclusion</p>	<ul style="list-style-type: none"> • An individual with a confirmed diagnosis of vulvo-vaginal candidiasis who is not appropriate for first-line treatment with oral fluconazole e.g., contraindication or refusal of oral treatment. <p>NOTE – all criteria for inclusion within the BASHH approved national PGD templates for sexual health are based on diagnostic management in line with BASHH guidance. Where services do not have access to diagnostics and treatment is syndromic then the PGD template will need to be locally adapted to reflect local practice being mindful of the BASHH guidance. For example, in this PGD template the following may be considered:</p> <ul style="list-style-type: none"> • 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) who is not appropriate for first-line treatment with oral fluconazole e.g., contraindication or refusal of oral treatment.
<p>Criteria for exclusion</p>	<p>Personal Characteristics</p> <ul style="list-style-type: none"> • Individuals under 13 years of age • 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. • Known or suspected pregnancy <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.

Reference Number: 2

Valid from: 1st November 2023

Review date: May 2026

Expiry date: 31st October 2026

	<p>Medication history</p> <ul style="list-style-type: none"> Individual is taking interacting medicines. Check appendix 1 of current edition of British National Formulary (BNF) for full list. Known allergy/hypersensitivity to clotrimazole or any other imidazole antifungal, or any constituent of the preparation
Cautions including any relevant action to be taken	<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 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	<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.

Description of treatment

Name, strength & formulation of drug	Clotrimazole 500 mg pessary / vaginal tablet
Legal category	P/POM
Route of administration	Vaginal
Off label use	<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 aged 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> <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.</p>

Reference Number: 2

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Dose, frequency, and duration of administration	<ul style="list-style-type: none"> • Insert one pessary using the applicator provided, as high as possible into the vagina when going to bed. This is best achieved when lying back with legs bent up. • Delay PV treatment until menstrual period has ended where appropriate.
Quantity to be supplied	One 500mg clotrimazole pessary per episode of care under the PGD
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	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 & 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 clotrimazole pessaries (but may not reflect all reported side effects):</p> <ul style="list-style-type: none"> • localised skin rash or redness • pruritus, irritation or swelling. • discomfort or burning • vaginal peeling, discharge, or bleeding • pelvic/abdominal pain, nausea
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 medical record. • Report via organisation incident policy.
Written information and further advice to be given to individual	<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 • If adverse reaction to treatment occurs advise individual to contact clinic for further advice • Vaginal intercourse should be avoided whilst using this product. • Do not use tampons, intravaginal douches, spermicides, or other vaginal products while using this product. • 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.

Reference Number: 2

Valid from: 1st November 2023

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	<p>Condition (general):</p> <ul style="list-style-type: none"> • Individuals diagnosed with candidiasis 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 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. • If after 7 days symptoms persist/worsen advise individual to contact their local sexual health service. • Offer condoms and advice on safer sex practices and offer the options for screening for sexually transmitted infections (STIs) where indicated. • Where treatment 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. • If after 7 days symptoms persist/worsen advise individual to contact their local sexual health service
<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 • 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 • 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)

Reference Number: 2

Valid from: 1st November 2023

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	<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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Key references

<p>Key references (accessed February 2023)</p>	<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)
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Appendix A - Registered health professional authorisation sheet

PGD Name/Version: Clotrimazole 500mg pessary / 2

Valid from: 01/11/23 Expiry: 31/10/26

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

Reference Number: 2

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Expiry date: 31st October 2026

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 RDaSH NHS Foundation Trust 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.

This information will be retained by the Chief Pharmacist at RDaSH NHS Foundation Trust.

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