

**Patient Group Direction for the administration and / or supply of :
: topical and/or intravaginal clotrimazole for vulvovaginal candidiasis**

Title of patient group direction	Topical and/or intravaginal clotrimazole for vulvovaginal candidiasis
Approved at	NMP/PGD Group
PGD approved / valid from	February 2019
Review date	October 2020
Expiry date	February 2022
Clinical area(s) where PGD applies	York and North Yorkshire Sexual Health services
Identified Lead for monitoring / review and contact details	Alison Chorlton ext 5465
CONSULTATION PROCESS ADOPTED IN DEVELOPING THE PATIENT GROUP DIRECTION (PGD)	
New Document	No
Reviewed Document	Yes
If the PGD is revised what revisions were required and for what reasons e.g. change in medical procedures or change in legislation	Fluconazole oral now alternative treatment
List of persons involved in the consultation process. (The group must include a sponsoring clinician, a pharmacist and a senior representative of the professional group. The job title and level of consultation should also be listed).	Dr Ian Fairley Elizabeth Clarke, Advanced Nurse Specialist Alison Chorlton – Lead Nurse Sexual Health

CLINICAL CONDITION	
Condition	<p>Management of uncomplicated vulvovaginal candidiasis suspected and confirmed when oral fluconazole is unsuitable or contraindicated.</p> <p>Management of uncomplicated vulvovaginal candidiasis suspected and confirmed when clotrimazole is the patient's preferred choice.</p>
Inclusion criteria	<p>Direct microscopic visualization of yeast spores or hyphae or positive candida culture or</p> <p>Clinical presentation typical of vulvovaginal candidiasis to include:</p> <ul style="list-style-type: none"> • vulvitis/fissuring • vaginitis with typical curding discharge • symptoms of typical vulvovaginal itching <p>The above criteria reflect the national recommendations made by the British Association for Sexual Health and HIV www.bashh.org.uk</p>
Exclusion criteria	<ul style="list-style-type: none"> • Known allergies to clotrimazole or any ingredient of the products • Complicated presentations, e.g. complicated by secondary bacterial infection and/or bleeding frankly • Recalcitrant vulvovaginitis • Large areas of broken skin/fissuring • Repeated presentations, i.e. received treatment from nurse more than 3 times in last 6 months.
Action if excluded	<p>Refer to Medical Practitioner/prescriber</p> <p>As there may be occasions when a medical practitioner is not physically present within the department, discuss by telephone where possible with medical practitioner.</p> <p>Alternatively arrange immediate assessment in accident and emergency if patient presents with an acute presentation and no doctor is available that</p>

	clinical session.
Action for patients not wishing to receive care under the PGD	Refer to medical practitioner that clinical session or when next available in clinic. As there may be occasions when a medical practitioner is not physically present within the department, discuss by telephone where possible with medical practitioner first, and defer treatment until after this discussion.

DESCRIPTION OF TREATMENT			
Name of Medicine	Clotimazole		
Legal Classification	P		
Licensing information	Is the medicine licensed for the intended use?	YES	
	Does it have a black triangle status?		NO
	Does it have a Risk Minimisation Measures (RMM) recommendation		NO
Form	Intravaginal pessary Cream		
Strength	500mg (pessary) 1% (cream)		
Dose	Intravaginal (pessary) Topical (cream)		
Frequency	Pessary- stat dose at night Cream- 2-3 times daily		
Route	Intravaginal (pessary) Topical (cream)		
Total Treatment Quantity	Single intravaginal pessary with product/patient information leaflet 20g tube of cream with product/patient information leaflet		
Interactions with other medicines (This must include all potentially serious interactions listed in the BNF)	Use appendix 1 of the BNF and manufacturers SPC to identify drugs with a black dot / clinically significant interactions If in doubt, contact Medicines Information for advice		




Adverse Reactions (This should include all the common and potentially serious adverse reactions. It is acceptable to state that the BNF should be referred to for further information)	Urticaria or apparent irritation of skin/mucous membranes in area applied/administered.	Treatment of adverse reactions Discontinue use and seek advice from Sexual Health Clinic, GP, NHS Urgent Care or Emergency Department depending upon severity.
Advice to Patients: Written and Oral advice (This should include the provision of a patient information leaflet)	The following minimum details need to be documented in full in patient's records in relation to initiating treatment under PGD <ul style="list-style-type: none"> • Information regarding aetiology of candidiasis • Information regarding treatment concordance and side effects; supported by patient information leaflet (PIL) • Complete the full course. • Insert pessary in lying position last thing at night and wear protective sanitary wear on underwear throughout and for next 48 hours after completion of course due to likely increased discharge from dissolving pessary. • Apply cream topically to affected area twice daily massaging into affected tissue • Advise to use moisturising emollients which are non-perfumed, non-coloured and soap free as a soap substitute in genital area • Avoid wearing tight fitting synthetic undergarments and clothing • Discussion regarding safer sex in general for future sexual health • For treatment in pregnancy the patient should be advised to discard the applicator and insert the dissolvable tablet manually. • Advise the effect of the cream and/or pessary on latex is unknown, so to avoid reliance on barrier methods of contraception whilst using medication 	
Follow up action	Review with GP if symptoms persist	
Storage	<ul style="list-style-type: none"> • locked medicines cupboard – store below 25 °C • locked briefcase for outreach use 	

Records to be Kept	<p>The following minimum details need to be documented in full in patient's records in relation to initiating treatment under PGD</p> <ul style="list-style-type: none"> • Date/time of record entry • Drug name and strength • Dose and form • Route of administration • Time of administration if appropriate • Advice given to patients, including written information. • name/job title of staff administering/supplying medicine (and signature if written records) • Details of any adverse drug reactions or side effects • Details of any problems reported with compliance and action advised/taken • Consent to treatment under PGD • That treatment was supplied under a PGD Any communication with other health care providers • If the patient is pregnant her treatment must be documented in her maternity (green) notes or her GP written to.
Audit Arrangements	As per current Trust PGD Policy

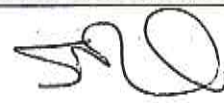
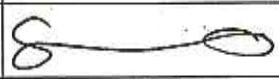
References	<p>Manufacturers SPC</p> <p>National guidelines for the management of vulvovaginal candidiasis in adults, 2007, British Association for Sexual Health and HIV, www.bashh.org</p> <p>Nursing and Midwifery Council, updated advice sheet for Record Keeping, July 2009, www.nmc.org.uk</p> <p>The British National Formulary, www.bnf.org.uk</p>
Competency Requirements (attach any competency frameworks / documents)	<p>Completion of a local Sexual Health training programme for the administration of clotrimazole under PGD within Sexual Health services. This will require/include:</p> <ul style="list-style-type: none"> • Clinical competence in sexual history taking, the clinical examination/assessment and genital screening required to enable the accurate diagnosis and treatment of vulvovaginal candidiasis. • Knowledge base of the interactions of clotrimazole with other drugs, and other exclusions and contra-indications for issuing clotrimazole. • Competence in the above will be demonstrated by the undertaking of a local clinical competency based training and assessment programme. • Assessment will be undertaken by the Lead Sexual Health nurse or designated PGD assessor, who will both be fully competent and either practising as an independent prescriber themselves, or practicing in accordance with this PGD. • Receiving Clinical Supervision and/or audit of case notes on an ongoing basis. • Evidence of continuing professional development in Sexual Health and/or the Sexual Health nurse role. • Minimum of 6 months experience of working in Sexual Health in the preceding 3 years. • Competence in the use of PGDS. • Trust PGD awareness session or Trust HUB e-learning. • Regular attendance and participation in the tri-annually educational clinical governance/audit day at York Sexual Health Services. <p>Maintain professional accountability with the Nursing and Midwifery Council (NMC) and ensure continuing professional development.</p>

**AUTHORISATION OF THE PATIENT GROUP DIRECTION (PGD) FOR ADMINISTRATION
OF: topical and/or intravaginal clotrimazole for vulvovaginal candidiasis**

PGD Development / Review Team – responsible for PGD content

Title	Name	Signature	Date
Lead Author	Steve Evans/Alison Chorlton		29.1.18.
Clinical Director Lead Approval	Ian Fairley		05-02-19
Directorate Pharmacy Lead Approval	Paul Jackson		21/2/19

PGD Approved by the NMP/PGD Group

Title	Name	Signature	Date
NMP Lead / Lead Nurse Medicines Management	Jennie Booth		22.02.2019
Chief Pharmacist / Deputy Chief Pharmacist	Stuart Parkes		22/2/19

Authorisation to work within the PGD

This patient group direction must be agreed to and signed by all health care professionals involved in its use.

The PGD must be easily accessible in the clinical setting.

Notes to the NMP/PGD Authorising staff

- Do not proceed unless this document carries the signatures of the development / review team (Lead Author, Lead Clinical Director and Directorate Lead Pharmacy)
- You are responsible for fulfilling the legal requirement that a senior person from the profession ensures that only fully competent, qualified and trained professionals operate under this PGD
- Using a PGD is not a form of prescribing

Staff authorised to work under this PGD

Ward / Department	Sexual Health
Professionals to whom this Patient Group Direction applies	Qualified nurses who work within Yorclinic sexual health and have completed the agreed training programme

I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct when working for this Trust:

Name (Capitals)	Sign	Job Title	Authorising Manager	Date

When the review date is exceeded, this PGD ceases to be a legal document

TEMPLATE DOCUMENTATION CONTROL

The template documentation control refers to the PGD template not the completed PGD.
Do not alter this section.

Author:	Jennie Booth, Lead Nurse Medicines Management Carol Belt, Principal Pharmacy Technician Stuart Parkes, Deputy Chief Pharmacist
Owner:	NMP/PGD Group
Date of issue:	February 2018
Version:	3
Approved by	NMP/PGD Group
Review date:	February 2021