University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Administration & Supply of Clotrimazole 1% Cream By Registered Nurses in Ward 3 (Kings Lodge)at FNCH

Documentation details

Reference no:	UHDB172
Version no:	1
Valid from:	21/04/2022
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Expiry date:	20/04/2025

Change history

Version number	Change details	Date
1.	New template	February 2022

Glossary

Abbreviation	Definition

1. PGD template development (PGD Working Group)

PGD Working Group Membership (minimum requirement of consultant, pharmacist and a registered professional who can work under a PGD, or manages the staff who do). If this is a review of existing PGD, replace previous names with the individuals involved for this version

Name	Designation
Dr Uditha Jayatunga	Rehabilitation Consultant
Maradel Rahman	Senior Sister
Colin Ward	Lead Pharmacist, Cancer, Diagnostics and Clinical Support

Where an antimicrobial is included, confirm the name, designation and date of the antimicrobial pharmacist who has reviewed this version

Name of antimicrobial pharmacist	Designation	Date Reviewed
n/a	n/a	n/a

2. Organisational authorisations

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

University Hospitals of Derby & Burton NHS Foundation Trust authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
Ward 3 (Kings Lodge) Florence Nightingale Community Hospital
Limitations to authorisation
This organisation does not authorise the use of this PGD by staff not employed by UHDB

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer *Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)*	James Hooley	**Signed copy held by Pharmacy**	**21/04/2022**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Lead Pharmacist, Cancer, Diagnostics and Clinical Support	Colin Ward	**Signed copy held by Pharmacy**	07/04/2022
Rehabilitation Consultant *Doctor*	Dr Uditha Jayatunga	**Signed copy held by Pharmacy**	06/04/2022
Senior Sister *Registered Professional representing users of the PGD*	Maradel Rahman	**Signed copy held by Pharmacy**	06/04/2022

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

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD.

3. Characteristics of staff

Qualifications and professional registration	Registered Nurse with a current NMC registration
Initial training	- Completion of all Essential-to-role training as outlined in the UHDB PGD policy. - Individual has read and understood full content of this PGD and signed authorisation (section 7) - Completion of Medicines Management Drug Assessment
Competency assessment	Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions 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 - if any training needs are identified these should be discussed with either authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be provided as required.
Ongoing training and competency	Annual Medicines Safety Training (essential to role) Review/repeat initial training above when this PGD is revised
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Female patients presenting with Vulvo-Vaginal candidiasis **NOTE:** The clotrimazole 1% cream is for symptomatic relief only and is not a treatment in itself.
Criteria for inclusion	Patients over 16 years presenting with the one or more of the following • An individual 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)
Criteria for exclusion	Personal Characteristics • 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 Medication history • 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	Contact with mucous membranes should be avoided
Action to be taken if the patient is excluded	Refer to medical staff for review and prescribing an alternative agent if appropriate. Record reasons for exclusion in patient notes Advise patient on alternative treatment

Action to be taken if the patient or carer declines treatment	Advise patient on alternative treatment Document refusal, action taken and advice given in nursing documentation Refer to medical staff if appropriate
Arrangements for referral for medical advice	Swab may be required to confirm infection. Liaise with medical team.

5. Description of treatment

Name, strength & formulation of drug	Clotrimazole 1% Cream (TTO pack)
Legal category	P
Route / method of administration	Topical
Indicate any off-label use (if relevant)	*n/a*
Dose and frequency of administration	Apply 1% cream sparingly to vulval area only two to three times a day
Duration of treatment	Continue until 48 hours after symptoms have resolved. Maximum duration 14 days.
Quantity to be supplied (leave blank if PGD is administration ONLY)	One 20g tube of clotrimazole 1% cream to be given without a prescription. Add patient name, date and any other details required on the pre-pack label supplied from pharmacy.
Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC.
Drug interactions	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Adverse reactions	The following side effects are reported with topical clotrimazole (but may not reflect all reported side effects): • Localised skin reactions: ○ rash ○ redness ○ pruritus ○ irritation ○ oedema ○ mild stinging/burning ○ blisters ○ peeling/exfoliation • Allergic reactions: ○ syncope ○ hypotension ○ dyspnoea ○ urticaria

	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use.
Written information to be given to patient or carer	Give marketing authorisation holder's patient information leaflet (PIL) provided with the product.
Patient advice / follow up treatment	Monitor for sensitivity reactions; Verbal advice on why drug administered, action of the drug and subsequent management of condition. Patient information leaflet covering risks / side-effects; Advice given on application of the cream. May cause local irritation and slight burning – discontinue if irritation cannot be tolerated. Give advice on preventative measures to avoid re-occurrence i.e. good personal hygiene, to avoid wearing tight clothing, and the use of local irritants such as bubble baths, perfumed toiletries, biological washing powders etc. Damages latex condoms and diaphragms for up to 5 days after application. Seek further medical advice if no improvement in condition within 7 days.
Records	Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following: • name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • name of registered health professional • name of medication supplied/administered • date of supply/administration • dose, form and route of supply/administration • quantity supplied/administered • batch number and expiry date (if applicable e.g. injections and implants) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • Confirm whether supplied and/or administered and that this was done via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled e-records). All records should be clear, legible and contemporaneous. If you are not recording in ePMA (or other electronic system which has ability to generate audit reports) then a record of all individuals

	receiving treatment under this PGD should also be in the clinical area for audit purposes as per UHDB PGD policy.

6. Key references

Key references	• 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 • https://medusa.wales.nhs.uk

7. Registered health professional authorisation sheet

PGD Name [version]: **FNCH – Ward 3 – Clotrimazole 1% cream [v1]**
PGD ref: **UHDB172**
Valid from: 21/04/2022 **Expiry date: 20/04/2025**

Before signing check that the document you have read is published on Koha or is an in-date hard-copy with all necessary authorisations signed in section 2. The Name/Version/Ref of the document you have read MUST match this authorisation form.

Registered health professional
By signing this patient group direction you are indicating that
a) You agree to and understand all content and commit to only work within this framework.
b) You have completed any core PGD e-Learning or training records on My Learning Passport or within your department.
c) You meet the staff characteristics and have completed any additional learning/competency outlined in Section 3 of this PGD.

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 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 / Assessor

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 University Hospitals of Derby & Burton 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 must be retained by a manager in the clinical department where the PGD is in-use to serve as a record of those registered health professionals authorised to work under this PGD.