

This patient group direction (PGD) must only be used by registered health 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)

For the administration or supply of

Clotrimazole 500mg Soft Gel Pessary and/or 2% Cream

By registered health care professionals for

Vulvo-vaginal candidiasis

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 15

1. Change history

Version number	Change details	Date
1	Original PGD ratified	June 2021

2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care [PGD website FAQs](#)

3. PGD development

Refer to the [NICE PGD competency framework for people developing PGDs](#)

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the [NICE PGD competency framework for people authorising PGDs](#)

Job Title	Name	Signature	Date
Medical Director			
Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)			

5. PGD adoption by the provider

Refer to the [NICE PGD competency framework for people authorising PGDs](#)

Job title and organisation	Signature	Date	Applicable or not applicable to area

6. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the [NICE PGD competency framework for health professionals using PGDs](#)

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	<ul style="list-style-type: none"> Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy Pharmacists must be practising in Manx Care authorised premises i.e. contracted pharmacy premises
Initial training	<ul style="list-style-type: none"> Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD Local training in the use of PGDs
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs
Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

7. Clinical Conditions

Clinical condition or situation to which this PGD applies	Vulvo-vaginal candidiasis – first line treatment
Inclusion criteria	<ul style="list-style-type: none"> • Patient with confirmed diagnosis of vulvo-vaginal candidiasis • Symptoms and signs of vulvo-vaginal candidiasis
Exclusion criteria	<p>Discuss with appropriate doctor/independent prescriber:</p> <ul style="list-style-type: none"> • For Patients under 13 years of age, follow local safeguarding policy • Patients who are pre-pubertal • Patients who are hypersensitive to Clotrimazole, any other imidazole antifungals, or any constituent of the preparation • Four or more treated episodes of candidiasis in past 12 months • Patients with genital sores/ulcers suggestive of other infections • Patients with symptoms of pelvic pain • Recurrent or unresolved symptoms of candidiasis within 4 weeks of being treated <p>Clotrimazole Pessaries should not be used if the patient has any of the following symptoms where upon medical advice should be sought:</p> <ul style="list-style-type: none"> • Irregular vaginal bleeding • Abnormal vaginal bleeding or a blood-stained discharge. • Lower abdominal pain or dysuria • Any adverse events such as redness, irritation or swelling associated with the treatment • Fever or chills • Nausea or vomiting • Diarrhoea • foul smelling vaginal discharge
Cautions (including any relevant action to be taken)	<ul style="list-style-type: none"> • Offer a full sexually transmitted infection (STI) screen • If systemic treatment is needed for candidiasis, see Fluconazole PGD • Consider referral if two or more treated episodes of candidiasis in past 6 months • Discuss with appropriate doctor/independent prescriber: • Patients who are pregnant and /or breastfeeding as they may need a longer course • Treatment of Patients who are immunosuppressed • Pessaries and may damage latex condoms and diaphragms
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient excluded	Patient should be referred to a more experienced clinical practitioner for further assessment

Action to be taken if patient declines treatment	<ul style="list-style-type: none"> • A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated
---	--

8. Details of the medicine

Name, form and strength of medicine	Clotrimazole 500mg Soft Gel Pessary and/or 2% Cream
Legal category	Pharmacy Only (P) or Prescription only medicine (POM) depending on brand available
Indicate any <u>off-label use</u> (if relevant)	None
Route/method of administration	<ul style="list-style-type: none"> • Per vagina/topical application • One 500mg pessary should be inserted at night. Using the applicator provided, the pessary should be inserted as high as possible into the vagina
Dose and frequency	<ul style="list-style-type: none"> • Single dose of 500mgs soft gel pessary and/or 2% cream – apply cream topically two or three times daily to affected area • One Pessary to be inserted high into the vagina at night
Quantity to be supplied	<ul style="list-style-type: none"> • One single pack containing 1 x 500mg soft gel pessary and/or 1 x 10g 2% cream • Single dose treatment
Maximum or minimum treatment period	<ul style="list-style-type: none"> • Single treatment – see inclusion criteria • Maximum: One episode of care
Storage	Room temperature
Adverse effects	<ul style="list-style-type: none"> • Abdominal pain • Discomfort • genital peeling • localised skin rash • oedema • paraesthesia • pelvic pain • skin reactions • syncope • vaginal haemorrhage
Records to be kept	The administration of any medication given under a PGD must be recorded within the patient's medical records

9. Patient information

Verbal/Written information to be given to patient or carer	<ul style="list-style-type: none">• Verbal information must be given to patients and or carers for all medication being administered under a PGD• Where medication is being supplied under a PGD, written patient information leaflet must also be supplied• A patient information leaflet is available on request
Follow-up advice to be given to patient or carer	If symptoms do not improve or worsen or you become unwell, seek medical advice immediately

10. Appendix A

References
<ol style="list-style-type: none">1. British National Formulary (BNF) available online: https://bnf.nice.org.uk2. Nursing and Midwifery (2018) "The code" available online: https://www.nmc.org.uk3. Current Health Care Professions Council standards of practice4. General Pharmaceutical Council standards5. The General Optical Council6. Electronic medicines compendium available online: https://www.medicines.org.uk7. BASHH guidelines

11. Appendix B

Health professionals agreed to practice
<ul style="list-style-type: none">• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor• A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves