

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

### **Fluconazole 150mg Capsule**

By registered health care professionals for

### **Ano-genital Candidiasis**

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

## **PGD NUMBER 27**

### **1. Change history**

| <b>Version number</b> | <b>Change details</b> | <b>Date</b> |
|-----------------------|-----------------------|-------------|
| 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/<br>Pharmaceutical Adviser                  |      |           |      |
| Senior Paramedic                                             |      |           |      |
| Director of Nursing                                          |      |           |      |
| GP Adviser                                                   |      |           |      |
| Senior Microbiologist<br>(if PGD contains<br>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                                                                                                                                                                                                                                                                                                         |
|-----------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Qualifications and professional registration</b> | <ul style="list-style-type: none"> <li>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</li> <li>Pharmacists must be practising in Manx Care authorised premises i.e. contracted pharmacy premises</li> </ul>                                     |
| <b>Initial training</b>                             | <ul style="list-style-type: none"> <li>Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria</li> <li>Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD</li> <li>Local training in the use of PGDs</li> </ul> |
| <b>Competency assessment</b>                        | Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PG's                                                                                                                                                                                                                        |
| <b>Ongoing training and competency</b>              | 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

|                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Clinical condition or situation to which this PGD applies</b> | Ano-genital candidiasis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Inclusion criteria</b>                                        | <ul style="list-style-type: none"> <li>• Suspected ano-genital candidiasis</li> <li>• Individual with symptoms and signs of ano-genital candidiasis</li> <li>• Second line use/alternative to Clotrimazole cream/pessary</li> <li>• Patients who are 16 and over (under Minor Ailments Scheme)</li> <li>• Males who are 13 and over (under GUM – accordingly to local safeguarding policy)</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Exclusion criteria</b>                                        | <ul style="list-style-type: none"> <li>• Not licensed for use in females under 16 for vaginal candidiasis</li> <li>• Patients under 16 years (under MAS)</li> <li>• Individuals who are hypersensitive to Fluconazole</li> <li>• Individuals who present with more than 4 episodes in 12 months</li> <li>• Individuals with genital sores/ulcers suggestive of other infections</li> <li>• Individuals with pelvic pain</li> <li>• Individuals with acute porphyria</li> <li>• Breastfeeding, pregnancy or at substantial risk of pregnancy</li> <li>• Recurrent or unresolved symptoms of candidiasis within 4 weeks of being treated</li> <li>• Treatment failure within the same episode</li> <li>• Complicated presentations, e.g. complicated by secondary bacterial infection and/or bleeding frankly (under MAS)</li> <li>• Recalcitrant vulvovaginitis</li> <li>• Large areas of broken skin/fissuring</li> </ul> |
| <b>Cautions (including any relevant action to be taken)</b>      | <p>Discuss with appropriate doctor/independent prescriber:</p> <ul style="list-style-type: none"> <li>• For individuals under 13 years of age, follow local safeguarding policy</li> <li>• Offer/signpost for full STI screen</li> <li>• Fluconazole has been associated with prolongation of the QT interval and should be used in caution in patients with Pro-arrhythmic conditions e.g. known QT prolongation, cardiomyopathy, sinus bradycardia, symptomatic arrhythmias, electrolyte disturbances</li> </ul> <p>Consider referral if two or more treated episodes of candidiasis in the last six months. Refer to appropriate doctor or independent prescriber:</p> <ul style="list-style-type: none"> <li>• Consider the possibility of renal impairment and hepatic disease</li> <li>• Susceptibility to QT interval prolongation</li> </ul>                                                                      |

|                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|---------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Arrangements for referral for medical advice</b>     | Patient should be referred to a more experienced clinical practitioner for further assessment                                                                                                                                                                                                                                                                                                                                                                |
| <b>Action to be taken if patient excluded</b>           | Patient should be referred to a more experienced clinical practitioner for further assessment                                                                                                                                                                                                                                                                                                                                                                |
| <b>Action to be taken if patient declines treatment</b> | <ul style="list-style-type: none"> <li>• 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</li> <li>• This information must be documented in the patients' health records</li> <li>• Any patient who declines care must have demonstrated capacity to do so</li> <li>• Where appropriate care should be escalated</li> </ul> |

## 8. Details of the medicine

|                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|--------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Name, form and strength of medicine</b>             | Fluconazole 150mg capsule                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Legal category</b>                                  | Pharmacy (P)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Indicate any <u>off-label use</u> (if relevant)</b> | Use in under 16 years                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Route/method of administration</b>                  | Oral                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Dose and frequency</b>                              | One single dose of 150mg                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Quantity to be administered and/or supplied</b>     | One single dose of 150mg                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Maximum or minimum treatment period</b>             | One dose per episode                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Storage</b>                                         | Room temperature                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Adverse effects</b>                                 | <ul style="list-style-type: none"> <li>• agranulocytosis</li> <li>• alopecia</li> <li>• cardio-respiratory distress</li> <li>• diarrhoea</li> <li>• dizziness</li> <li>• dyslipidaemia</li> <li>• flatulence</li> <li>• gastrointestinal discomfort</li> <li>• headache</li> <li>• hepatic disorders</li> <li>• hypokalaemia</li> <li>• leucopenia</li> <li>• neutropenia</li> <li>• nausea</li> <li>• oedema</li> <li>• QT interval prolongation</li> <li>• severe cutaneous adverse reactions (SCARs)</li> <li>• thrombocytopenia</li> <li>• torsade de pointes</li> <li>• skin reactions</li> <li>• seizure</li> <li>• taste altered</li> <li>• vomiting</li> </ul> |
| <b>Records to be kept</b>                              | The administration of any medication given under a PGD must be recorded within the patient's medical records                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

## 9. Patient information

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|-------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Verbal/Written information to be given to patient or carer</b> | <ul style="list-style-type: none"><li>• Verbal information must be given to patients and or carers for all medication being administered under a PGD</li><li>• Where medication is being supplied under a PGD, written patient information leaflet must also be supplied</li><li>• A patient information leaflet is available on request</li></ul> |
| <b>Follow-up advice to be given to patient or carer</b>           | 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"><li>1. British National Formulary (BNF) available online: <a href="https://bnf.nice.org.uk">https://bnf.nice.org.uk</a></li><li>2. Nursing and Midwifery (2018) "The code" available online: <a href="https://www.nmc.org.uk">https://www.nmc.org.uk</a></li><li>3. Current Health Care Professions Council standards of practice</li><li>4. General Pharmaceutical Council standards</li><li>5. The General Optical Council</li><li>6. Electronic medicines compendium available online: <a href="https://www.medicines.org.uk">https://www.medicines.org.uk</a></li><li>7. Current BASSH Guidelines</li><li>8. Nobles' Hospital Antimicrobial formulary</li><li>9. Clinical Knowledge Summaries (2017) <a href="http://cks.nice.org.uk/candida-female-genital">http://cks.nice.org.uk/candida-female-genital</a></li><li>10. Summary of Product Characteristics: Fluconazole 150mg capsule. <a href="http://www.medicines.org.uk/emc/product/6086">http://www.medicines.org.uk/emc/product/6086</a></li><li>11. The effectiveness and safety of oral treatments for vaginal candidiasis in pregnancy are uncertain and these treatments should not be offered. <a href="https://www.nice.org.uk/donotdo/the-effectiveness-and-safety-of-oral-treatments-for-vaginal-candidiasis-in-pregnancy-are-uncertain-and-these-treatments-should-not-be-offered-2">https://www.nice.org.uk/donotdo/the-effectiveness-and-safety-of-oral-treatments-for-vaginal-candidiasis-in-pregnancy-are-uncertain-and-these-treatments-should-not-be-offered-2</a></li><li>12. NICE Clinical Guidance (CG62) (2019) Antenatal care for uncomplicated pregnancies <a href="https://www.nice.org.uk/guidance/CG62">https://www.nice.org.uk/guidance/CG62</a></li><li>13. Addison, B, Brown, A, Edwards, R, and G Gray. 2012. Minor illness or Major Disease? 2012</li></ol> |

## 11. Appendix B

| Health professionals agreed to practice                                                                                                                                                                                                                                                                                                                                             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li>• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor</li><li>• 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</li></ul> |