

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 fluconazole 150mg capsule for the treatment of vulvo-vaginal candidiasis in University Hospitals Sussex NHS Foundation Trust Sexual Health & Contraception (SHAC) Service**

Version Number 1.0

<b>Change History</b>	
<b>Version and Date</b>	<b>Change details</b>
Version 1.0	New template

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

## PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	1 <sup>st</sup> November 2020
Review date	1 <sup>st</sup> May 2023
Expiry date:	31 <sup>st</sup> October 2023

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 October 2020.

**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
Amanda Cooper	Associate Director Specialist Pharmacy Service
Amy Moore	Principal Pharmacist, HIV, Sexual and Reproductive Health
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	Chair General Training Committee 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 Rita Browne	Consultant in Sexual Health and HIV
Dr Sarah Pillai	Pan London PGD working group
Emma Anderson	Centre for Pharmacy Postgraduate Education (CPPE)
Helen Donovan	Royal College of Nursing
Jo Jenkins (Working Group Co-ordinator)	Specialist Pharmacist (PGDs) Specialist Pharmacy Service
Jodie Crossman	Specialist Nurse. BASHH SHAN SIG Chair
Jodie Walker-Haywood	Specialist Nurse, BASHH Board Nurse Representative, BASHH SHAN SIG Secretary
Leanne Bobb	English HIV and Sexual Health Commissioners Group (EHSHCG)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Portia Jackson	Pharmacist, Cambridgeshire Community Services
Sally Hogan	British Pregnancy Advisory Service (BPAS)
Sandra Wolper	Associate Director Specialist Pharmacy Service
Silvia Ceci	Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service
Tracy Rogers	Associate Director Specialist Pharmacy Service

## PGD approval - meets local need and guidelines

Name	Job title and organization	Signature	Date
<b>Lead author:</b> Reproductive Health PGDs Short Life Working Group	As listed on Page 2/3		
<b>Lead Doctor:</b> Dr Daniel Richardson	Consultant (HIV & GUM), SHAC, UHSussex	Email approval	19/01/2021
<b>Lead pharmacist:</b> Claire Richardson	Lead Pharmacist, HIV & Sexual Health Service, UHSussex	Email approval	20/01/2021
<b>Lead Clinician for area:</b> Dr Debbie Williams	Consultant HIV & SHAC Service, UHSussex	Email approval	21/01/2021
<b>Reviewed by:</b> Dr Juliet Bowie	Associate Specialist, SHAC Service, UHSussex	Email approval	19/01/2021
<b>Representative of other professional group using PGD</b> Wendy Gardiner	Advanced Nurse Practitioner, SHAC Service, UHSussex	Email approval	02/02/2021

## Organisational authorisations

<b>University Hospitals Sussex NHS Foundation Trust authorises this PGD for use by the services or providers listed below:</b>
Sexual Health & Contraception (SHAC) Service.
<b>Limitations to authorisation</b>
Only Registered Nurses who work within the SHAC Service and are signed to the PGD.

Name	Signature & Name	Date
<b>Chair of PGD Group</b>	Joanne Pendlebury – email approval	April 2021
<b>Chief Pharmacist</b>	Mike Cross – email approval	April 2021
<b>Medicines Governance Group chair</b>	Mike Okorie – email approval	April 2021

Local enquiries regarding the use of this PGD may be directed to [uhsussex.pgdgroup@nhs.net](mailto:uhsussex.pgdgroup@nhs.net) or PGD group chair.

Appendix 1 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD.

Approved date: April 2021

Expiry date: 31<sup>st</sup> October 2023

## 1. Characteristics of staff

<b>Qualifications and professional registration</b>	<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>
<b>Initial training</b>	<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 patient leading to diagnosis of the conditions listed.</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> <p>Register and complete PGD training module (certificate can be printed out as evidence) <a href="https://portal.e-lfh.org.uk/">https://portal.e-lfh.org.uk/</a> (3 yearly)</p> <p>Has undertaken training appropriate to recognise and manage allergic/anaphylactic reactions.</p> <p>Has undertaken appropriate Trust approved resuscitation training.</p>
<b>Competency assessment</b>	<ul style="list-style-type: none"> <li>• Individuals operating under this PGD must be assessed as competent (see Appendix A) using SHAC Service Sexual Health Competency framework or complete a self-declaration of competence for vulvo-vaginal candidiasis infection testing and/or treatment.</li> <li>• Staff operating under this PGD are encouraged to review their competency using the <a href="#">NICE Competency Framework for health professionals using patient group directions</a></li> </ul>
<b>Ongoing training and competency</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Organisational PGD and/or medication training as required by employing Trust/organisation, including:             <ul style="list-style-type: none"> <li>➤ PGD e-learning 3 yearly</li> <li>➤ Up to date with mandatory training.</li> </ul> </li> </ul>
<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>	

## 2. Clinical condition or situation to which this PGD applies

<b>Clinical condition or situation to which this PGD applies</b>	<ul style="list-style-type: none"> <li>• Vulvo-vaginal candidiasis</li> </ul>
<b>Criteria for inclusion</b>	<ul style="list-style-type: none"> <li>• An individual with a confirmed diagnosis of vulvo-vaginal candidiasis;</li> <li>• Where microscopy is not available, 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).</li> </ul>
<b>Criteria for exclusion</b>	<p><b>Personal Characteristics</b></p> <ul style="list-style-type: none"> <li>• Individuals under 13 years of age;</li> <li>• Individuals who are pre-pubertal;</li> <li>• Individuals under 16 years of age and assessed as not competent using Fraser Guidelines;</li> <li>• Individuals 16 years of age and over and assessed as not competent to consent using local safeguarding guidelines;</li> <li>• Known or suspected pregnancy.</li> </ul> <p><b>Medical history</b></p> <ul style="list-style-type: none"> <li>• 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;</li> <li>• Individuals with genital sores/ulcers suggestive of other infections/conditions;</li> <li>• Individuals with pelvic pain where pelvic inflammatory disease (PID) has not been excluded;</li> <li>• Individuals with abnormal vaginal bleeding where cause has not been identified;</li> <li>• Recurrent or unresolved symptoms of candidiasis within 4 weeks of being treated;</li> <li>• Individuals who are immunosuppressed and may require further assessment and systemic treatment;</li> <li>• Individuals with acute porphyria;</li> <li>• Past or current history of cardiac rhythm disturbance;</li> <li>• Patients with hypokalemia and advanced cardiac failure;</li> <li>• Known liver impairment;</li> </ul> <p><b>Medication history</b></p> <ul style="list-style-type: none"> <li>• Individual is taking interacting medicines (check appendix 1 of current edition of British National Formulary (BNF) for full list);</li> <li>• Individuals with a known allergy to fluconazole or to related azole compounds or any of the constituents found within the formulation.</li> </ul>
<b>Cautions including any relevant action to be taken</b>	<ul style="list-style-type: none"> <li>• If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented;</li> <li>• 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);</li> <li>• Discuss with appropriate medical/independent non-medical</li> </ul>

	prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain.
<b>Action to be taken if the individual is excluded or declines treatment</b>	<ul style="list-style-type: none"> <li>• If declined ensure individual is aware of the need for treatment and the potential consequences of not receiving treatment;</li> <li>• Record reason for decline in the consultation record;</li> <li>• Explain the reasons for exclusion to the individual and document in the consultation record;</li> <li>• Where required refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options.</li> </ul>

### 3. Description of treatment

<b>Name, strength &amp; formulation of drug</b>	Fluconazole 150mg capsule
<b>Legal category</b>	P/POM
<b>Route of administration</b>	Oral
<b>Off label use</b>	<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"> <li>○ Individuals under 16 years of age</li> <li>○ Individuals age 60 years or over</li> </ul> <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>
<b>Dose, frequency and duration of administration</b>	Single 150mg dose permissible under this PGD.
<b>Quantity to be supplied</b>	One 150mg capsule.
<b>Storage</b>	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
<b>Drug interactions</b>	<p><b>Fluconazole has a number of drug-drug interactions which may be clinically significant and <u>all concurrent medications should be reviewed for interactions.</u></b></p> <p><b>Where a significant interaction is identified which may</b></p>

	<p><b>require dosage amendment or additional monitoring refer to appropriate medical/independent non-medical prescriber.</b></p> <p>A detailed list of all drug interactions is available in the BNF <a href="http://www.bnf.org">www.bnf.org</a> or the product SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>
<b>Identification &amp; management of adverse reactions</b>	<p><b>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> and BNF <a href="http://www.bnf.org">www.bnf.org</a></b></p> <p>The following side effects are commonly reported with fluconazole (but may not reflect all reported side effects):</p> <ul style="list-style-type: none"> <li>• Headache</li> <li>• Abdominal pain, diarrhoea, nausea, vomiting</li> <li>• Rash</li> </ul>
<b>Management of and reporting procedure for adverse reactions</b>	<ul style="list-style-type: none"> <li>• 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: <a href="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a></li> <li>• Record all adverse drug reactions (ADRs) in the patient's medical record;</li> <li>• Report via organisation incident policy.</li> </ul>
<b>Written information and further advice to be given to individual</b>	<p><b>Medication:</b></p> <ul style="list-style-type: none"> <li>• Give patient information leaflet (PIL) provided with the original pack;</li> <li>• Explain mode of action, side effects, and benefits of the medicine;</li> <li>• If adverse reaction to treatment occurs advise individual to contact clinic for further advice.</li> </ul> <p><b>Condition (general):</b></p> <ul style="list-style-type: none"> <li>• Individuals diagnosed with candidiasis should be offered information (verbal, written and/or digital) about their diagnosis and management;</li> <li>• Provide verbal and written or online information on possible triggers for candidiasis;</li> <li>• Give reassurance that candidiasis is not a sexually transmitted infection;</li> <li>• If sexual partner is symptomatic advise they should access sexual health screening;</li> <li>• If after 7 days symptoms persist/worsen advise individual to contact the SHAC Service to arrange virtual or physical review with a healthcare professional;</li> <li>• Offer condoms and advice on safer sex practices and offer the options for screening for sexually transmitted infections (STIs) where indicated;</li> <li>• Where treatment not supplied via a sexual health clinic ensure the individual has contact details of local sexual health services if required.</li> </ul>
<b>Follow up treatment</b>	<ul style="list-style-type: none"> <li>• The individual should be advised to seek medical advice in the event of an adverse reaction;</li> </ul>

	<ul style="list-style-type: none"> <li>• If after 7 days symptoms persist/worsen advise individual to contact the SHAC Service to arrange virtual or physical review with a healthcare professional.</li> </ul>
<p><b>Records</b></p>	<p><b>Record:</b></p> <ul style="list-style-type: none"> <li>• The consent of the individual and <ul style="list-style-type: none"> <li>○ If individual is under 13 years of age record action taken;</li> <li>○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken;</li> <li>○ If individual over 16 years of age and not competent, record action taken;</li> </ul> </li> <li>• If individual not treated under PGD record action taken;</li> <li>• Name of individual, address, date of birth;</li> <li>• GP contact details where appropriate;</li> <li>• Relevant past and present medical and sexual history, including medication history;</li> <li>• Examination or microbiology finding/s where relevant;</li> <li>• Any known allergies and nature of reaction;</li> <li>• Name of registered health professional;</li> <li>• Name of medication supplied;</li> <li>• Date of supply;</li> <li>• Dose supplied;</li> <li>• Quantity supplied including batch number and expiry date in line with local procedures;</li> <li>• Advice given, including advice given if excluded or declines treatment;</li> <li>• Details of any adverse drug reactions and actions taken;</li> <li>• Advice given about the medication including side effects, benefits, and when and what to do if any concerns;</li> <li>• Any referral arrangements made;</li> <li>• Any supply outside the terms of the product marketing authorisation;</li> <li>• Recorded that supplied via Patient Group Direction (PGD).</li> </ul> <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>



## Audit

<b>Plan for audit,</b> It is essential for PGD renewal that audits have occurred.	Service audit to be completed using the recommended UHSussex PGD audit template. N. B. Individual PGD users should keep records to audit their own use of PGDs / procedures.
<b>Frequency</b>	Minimum of once in lifetime of PGD 2 years after start date of PGD to inform PGD review.
<b>Nominated lead to manage audit</b>	Advanced Nurse Practitioner/Clinical Nurse Specialist, SHAC Service will manage Service PGD audit process and support / guide those completing the audit. SHAC Nurse(s) who use the PGD will complete the service audit.

## 4. Key references

<b>Key references (accessed April 2020)</b>	<ul style="list-style-type: none"> <li>• Electronic Medicines Compendium <a href="http://www.medicines.org.uk/">http://www.medicines.org.uk/</a></li> <li>• Electronic BNF <a href="https://bnf.nice.org.uk/">https://bnf.nice.org.uk/</a></li> <li>• NICE Medicines practice guideline “Patient Group Directions” <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li> <li>• NICE Clinical Knowledge Summaries - <a href="https://cks.nice.org.uk">https://cks.nice.org.uk</a></li> <li>• Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 <a href="https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines">https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines</a></li> <li>• British Association for Sexual Health and HIV national guideline for the management of vulvovaginal candidiasis (2019) <a href="https://www.bashhguidelines.org/current-guidelines/vaginal-discharge/vulvovaginal-candidiasis-2019/">https://www.bashhguidelines.org/current-guidelines/vaginal-discharge/vulvovaginal-candidiasis-2019/</a></li> <li>• Learning for Health <a href="https://portal.e-lfh.org.uk/">https://portal.e-lfh.org.uk/</a></li> <li>• UHSussex policies and procedures:             <ul style="list-style-type: none"> <li>➤ C085 – Policy for Patient Group Directions: accessed on UH Sussex intranet <a href="https://www.bsuh.nhs.uk/search/?q=c085+policy+for+patient+group+directions">https://www.bsuh.nhs.uk/search/?q=c085+policy+for+patient+group+directions</a></li> <li>➤ SHAC Service Standard Operating Procedure for supply of medicines following telephone / video consultations.</li> </ul> </li> </ul>
---	--

## Appendix A - Registered health professional authorisation sheet

PGD Name/Version: Supply of fluconazole 150mg capsule for the treatment of vulvo-vaginal candidiasis (Version 1.0)

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.

<b>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.</b>			
<b>Name</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>

### Authorising manager

<b>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 <u>University Hospitals Sussex NHS Foundation Trust</u> for the above named health care professionals who have signed the PGD to work under it.</b>			
<b>Name</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>

### 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.

## SHAC SERVICE RETENTION OF PGD AUTHORISATION RECORDS

Records of the authorisation of nurses for the use of this PGD are stored as follows:

- **HARD COPY:** A paper copy of the signature sheet will be kept with the PGD in the PGD Master Copy File in the SHAC Nurse Management Office (if hard copy retained).
  
- **ELECTRONIC RECORD:**
  - A scanned copy of each authorisation sheet is saved on to the service specific file.
  
  - An electronic record of SHAC Nurse authorisation for this PGD is recorded on the SHAC Service PGD Assessment Record database which is stored on to the service specific file.
  
- **INDIVIDUALS:**
  - Individual nurses are provided with the PGD assessment sheet which details the assessment process for PGD approval for their own records.
  
  - A copy of this document is stored in the individual nurses' Personal File.