

Nottingham University Hospitals NHS Trust

Patient Group Direction for Clotrimazole Cream

Step 1	Clinical Condition or situation to which the patients group direction applies
(i)	<p>Definition of the clinical condition/situation (including criteria for confirmation)</p> <ul style="list-style-type: none"> • Patient known to have vulvovaginal candidiasis (VVC) if symptomatic with vulval itching, soreness or redness; or known to have sub-preputial candidiasis (SPC) if symptomatic with glans penis or preputial itching, soreness or redness.
(ii)	<p>Description of those patients included under the direction</p> <ul style="list-style-type: none"> • Male or female patient who is symptomatic with a laboratory-confirmed culture positive genital <i>Candida species</i> diagnosis. • Male patient who is symptomatic with a microscopically-confirmed diagnosis of <i>Candida sp.</i> as identified by spores and hyphae on dark ground microscopy of a 'wet preparation' of sub-preputial secretions. • Male patient who is symptomatic with a microscopically-confirmed diagnosis of <i>Candida sp.</i> as identified by spores and hyphae on a Gram stained sub-preputial smear. • Female patient who is symptomatic with a microscopically-confirmed diagnosis of <i>Candida sp.</i> as identified by spores and hyphae on dark ground microscopy of a 'wet preparation' of vaginal secretions. • Female patient who is symptomatic with a microscopically-confirmed diagnosis of <i>Candida sp.</i> as identified by spores and hyphae on a Gram stained endo-cervical smear or high vaginal smear. • All must have no contraindications in their medical history to the type of antifungal preparation to be supplied.
(iii)	<p>Description of those patient excluded from treatment under the direction</p> <ul style="list-style-type: none"> • Person under 16 years of age. • Pregnant or risk of pregnancy*. • Known allergy to Clotrimazole, or other Imidazole. • Known diabetes mellitus. • Known human immunodeficiency virus (HIV) infection. • Known recurrent VVC, diagnosis of VVC twice or more in the last 6 months, or treatment for VVC in the last 3 months. • Patient with genital ulcers or skin conditions affecting the genitalia. • Patient complaining of other symptoms. • Patient using other topical skin preparations (other than simple emollients) on the genital area, or using any drug with a potentially hazardous interaction with Clotrimazole, as indicated in the current British National Formulary (BNF). • Reservations/concerns by patient about side effects of the antifungal preparation. • Patient using other topical skin preparations on the genital area. <p><i>* A pregnancy risk exists if menstruation is late and/or vaginal sexual intercourse (VSI) has occurred since the last normal menstrual period and no contraception has been used, or compliance has been incomplete, or its effectiveness has been reduced. Note that a risk also occurs, despite a last normal withdrawal bleed, if 3 or more 30-35 µg Ethinylestradiol or 2 or more 20 µg Ethinylestradiol contraceptive pills, are missed in Week 1 of the pill pack and VSI has occurred, without barrier contraception, within the pill-free interval or Week 1.</i></p>

Step 1 Continued	Clinical Condition or situation to which the patients group direction applies
(iv)	<p>Actions to be taken in the event of exclusion</p> <ul style="list-style-type: none"> • If the exclusions detailed in Step 1 (iii) (other than pregnancy risk, other topical skin preparations on the genital area), refer to doctor. • If at risk of pregnancy as described in Step 1 (iii) or other topical skin preparations on the genital area, seek medical advice.
(v)	<p>Action to be taken if patients do not wish to receive or adhere to care</p> <ul style="list-style-type: none"> • Where the health professional requires advice on the management of the problems or feels the patient's management is outside their sphere of competence, support should be sought from an appropriate medical practitioner. • If patient refuses antifungal preparation refer patient to doctor. If patient refuses to see doctor document in clinic notes. If patient fails to adhere to care seek medical advice.
Step 2	Health professional authorised to supply or administer drugs under the direction
(i)	<p>Professional qualifications required</p> <ul style="list-style-type: none"> • First level nursing qualification. • Sexual Health experience – at least two years of practice within a GU Medicine department seeing unselected male and female patients with the conditions described in Step 1 (ii) pertaining to this direction. • Contraception experience, when supplying to female patients.
(ii) (iii)	<p>Specialist training, experience or competency required</p> <ul style="list-style-type: none"> • Consultant-led training from GU Medicine to ensure that nurses undertaking the Direction have a confident and clear understanding of the limits of the Patient Group Direction and when to refer to a doctor. • Theoretical training will include training on male and female anatomy/physiology/history taking and examination; training on pharmacology/drug interactions/nurse prescribing issues and Patient Group Directions. Training will be by interactive seminars, case studies, simulated scenarios and group discussions. Participation in these and the trainee's responses will be used to evaluate understanding and competency. • In vitro training will include training on male testicular and female pelvic examination. Training will be by practice on a range of in vitro pelvic models. Development of expertise in examination and correct identification of in vitro condition will be used to evaluate understanding and competency. • Practical training will include patient clinical contact for male and female history taking/examination/investigation/discussion of findings and treatment under Patient Group Direction Training will be by observation of senior doctor, supervised practice by senior doctor, case discussions, simulated scenarios, group discussions and tutored clinical experience. Development of expertise in history taking/examination/investigation/discussion of findings; the correct and appropriate identification of clinical conditions and use of Patient Group Direction; and accurate and appropriate record keeping will all be used to evaluate competency.

Step 2 Continued	Health professional authorised to supply or administer drugs under the direction
(ii) continued (iii)	<p>Specialist training, experience or competency required continued</p> <ul style="list-style-type: none"> • Where the nurse does not possess, or has limited contraception experience, theoretical and practical training in contraception as relevant to PGD use will be given. Training will be by an interactive seminar, simulated scenarios, problem-based learning, observation of an experienced doctor or nurse and case discussions. Participation in these and the trainee's responses will be used to evaluate understanding and competency. • A reflective diary will be kept. • On-going personal learning and consultant-provided teaching, including individual case reviews and scenarios, will be used to maintain and update skills. • For some nurses who will not be undertaking patient genital examinations or investigations these sections and the anatomy/physiology sections may be omitted from the training package but all other elements will be included.
(iv)	<p>Continuing education requirements</p> <ul style="list-style-type: none"> • Audit of practice. • Case note review.
Step 3	Description of medicine(s) to which the direction applies
(i)	<p>Names of the medicines to be supplied and administered</p> <p>Clotrimazole Cream.</p>
(ii)	<p>Legal status</p> <p>Licensed – P.</p>
(iii)	<p>Dose(s) of medication, including criteria for varying or adjusting the dose</p> <p>1% Cream applied topically BD to TDS x 7 days (20g). No dose variation.</p>
(iv)	<p>Method or route</p> <p>Topical to genital area.</p>
(v)	<p>Frequency of administration</p> <p>BD to TDS x 7 days (20g).</p>
(vi)	<p>Total dosage and number of times treatment can be administered</p> <p>Once during current episode by nurse prior to seeking medical advice.</p>
(vii)	<p>Minimum or maximum period over which medicine should be administered</p> <p>Standard 7 day period.</p>
(viii)	<p>Information about follow-up</p> <p>A follow-up appointment is not required for patients who are appropriate for treatment under the PGD unless severe local burning or irritation occur after using the cream in which case the patient should return promptly for review. The patient should be advised to return if any symptoms persist and that they will be contacted by the clinic if any tests prove positive requiring further treatment.</p>

Step 3 Continued	Description of medicine(s) to which the direction applies
(ix)	<p>Advice available for the patient and carers (including written advice)</p> <ul style="list-style-type: none"> • Read the patient product information leaflet supplied before using the cream. Sensitively ensure patient is able to read and understand, if not then cover details verbally. • Wash the affected skin and dry thoroughly before applying the cream. • Apply the cream thinly and evenly to the affected area two to three times daily and rub in gently. • Avoid sexual intercourse (SI) until symptoms have subsided as, although VVC and SPC are not sexually transmitted infections, SI may cause irritation. • Advice about concurrent use of other topical skin preparations on the genital area • Advice about personal hygiene and skin care. • Advice about avoidance of tight-fitting or synthetic clothing and possible allergens eg soap, bubble bath. • Warn of the risk of mild local burning or irritation after using the cream. If this is severe the cream should be discontinued and the patient should return promptly for review. • Warn of the risk of damage to latex contraceptives. They should be avoided for at least 5 days after using the cream.
(x)	<p>Instructions on identifying, managing and reporting possible adverse outcomes</p> <p>Advice to patients on reporting any adverse outcomes or side effects to the appropriate medical practitioner to gain further advice. Report and refer to Consultant in-charge. A Nottingham University Hospitals NHS Trust (NUHT) drug incident form must be completed and procedure guidelines followed. All serious adverse reactions must be reported under the National yellow card system.</p>
(xi)	<p>Description of circumstances in which further advice should be sought from a doctor</p> <p>As indicated in Step 1 (iv) and (v), and Step 3 (xv).</p>
(xii)	<p>Arrangements for referral to medical staff</p> <p>To contact consultant covering the clinic or discuss with a senior doctor in clinic.</p>
(xiii)	<p>Facilities and supplies which should be available at sites where care by group protocol will be provided</p> <p>Clotrimazole 1% Cream topically BD to TDS x 7 days (20g) as a pre-pack, with a patient product information leaflet, will be supplied by NUHT Pharmacy Department under the supervision of the pharmacist according to agreed stock levels. These will be stored in a locked cupboard. Advice to health professional on the issue of drugs supplied and any additions to be made to the label will be given by the pharmacist as necessary.</p>
(xiv)	<p>Details of treatment records required</p> <ul style="list-style-type: none"> • Counselling as per Nurse Supply of Clotrimazole Cream Patient Group Direction. This needs to be recorded, dated and signed in full in the clinic notes. • Supply Clotrimazole 1% Cream topically BD to TDS x 7 days (20g), with a patient product information leaflet. Ensure tube is labelled with the name of the patient and date of supply. • Date and sign audit sheet.

Step 3 Continued	Description of medicine(s) to which the direction applies
(xv)	<p>Side-effects, contra-indications and any relevant concurrent medication considerations</p> <ul style="list-style-type: none"> • Contra-indications – known allergy to Clotrimazole or other Imidazole. • Side effects - mild local burning or irritation; risk of damage to latex contraceptives. For infrequent side effects see current BNF. • Concurrent medication - Check all concurrent medication with the patient and in the current BNF before supplying Clotrimazole. Refer to a doctor if the patient is taking any medication, which may interact with the intended treatment. • The current BNF can be accessed in either its paper format or electronic format using the hyperlink http://www.bnf.org
Step 4	Professionals involved in patient group direction development
(i)	<p>Names job title and signatures of those involved in drawing up the direction</p> <p>Signature: See attached letter Date: See attached letter</p>
(ii)	<p>Signature of the individual(s) who will supply or administer the named medications under this direction</p> <p>Name See attached sheet Signed See attached sheet Date __/__/__</p>
(iii)	<p>Signature of all consultants authorising the use of the direction</p> <p>Name See attached letter Signed See attached letter Date __/__/__ & email communication & email communication</p> <p>Name _____ Signed _____ Date __/__/__</p> <p>Name _____ Signed _____ Date __/__/__</p> <p>Name _____ Signed _____ Date __/__/__</p>
(iv)	<p>Signature of Clinical Governance lead on behalf of Trust</p> <p>Name _____ Signed _____ Date __/__/__</p>
(v)	<p>Professional Advisory groups who have approved the direction</p> <p>Therapeutics Committee (secretary) Signed _____ Date __/__/__</p> <p>_____ Signed _____ Date __/__/__</p> <p>_____ Signed _____ Date __/__/__</p>
(vi)	<p>Signature of the Manager who has authorised the direction</p> <p>Name See attached letter Job Title See attached letter Date __/__/__ & email communication & email communication</p>
(vii)	<p>Description of the audit trail/tool to be used and statement of records to be kept for audit purposes</p> <p>Monitoring during routine pharmacy reviews and record keeping audits. All clinical notes will be kept as per NUHT Medical Records Recommendations. Audit of administration with pharmacy and Clinical Audit Department, NUHT.</p>

Step 4 Continued	Professionals involved in patient group direction development
(viii)	<p>Will a prescription be written and at what point will it be countersigned?</p> <p>The nurse will not write a prescription but will complete an audit sheet at the point of supply.</p>
(ix)	<p>Date Direction comes into force ___/___/___ Review /Date: ___/___/___ (usually 2 years)</p>