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Grampian Highland Orkney Tayside Eileanan Siar Western Isles

Patient Group Direction For The Supply Of Clotrimazole 500mg Pessary By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Tayside And Western Isles

Lead Author: Adapted from the SPS/FSRH National PGD Template by the Medicines Management Specialist Nurse NHSG	**Consultation Group**: See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian

Signature: 		**Signature:** 

NoS Identifier: NoS/PGD/Clotrimazole Pessary/MGPG1354	**Review Date:** February 2025 **Expiry Date:** February 2026	**Date Approved:** February 2023

NHS Grampian, Highland, Orkney, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 2

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	PGD supersedes NoS/PGD/Clotrimazole_Pessary/MGPG1140, Version 1	
Date of change	**Summary of Changes**	**Section heading**
December 2022	2 yearly review of PGD on new NoS PGD template.	
December 2022	Added statements regarding child protection issues.	Inclusion criteria
December 2022	Statement added regarding legal capacity.	Inclusion criteria
December 2022	Added statements regarding child protection.	Inclusion criteria

NoS Identifier: NoS/PGD/Clotrimazole_Pessary/MGPG1354
Keyword(s): PGD Patient Group Direction Clotrimazole Pessary Vulvovaginal Candidiasis Sexual Health Nurse

Policy Statement: It is the responsibility of the individual healthcare professionals and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	December 2022
	Completed:	February 2023
	Approved:	February 2023 (published – March 2023)
	Amended and re-authorised:	Add date

Organisational Authorisations

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

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Ambreen Butt **Health Board:** NHSG **Title:** Sexual Health Consultant **Contact email:** ambreen.butt@nhs.scot **Signature:** …… **Date:** 14/03/2023
Senior representative of the professional group who will provide care under the direction	**Name:** Sara Beveridge **Health Board:** NHST **Title:** Clinical Nurse Specialist **Contact email:** sara.beveridge@nhs.scot **Signature:** …… **Date:** 15/03/2023
Lead author	**Name:** Jodie Allan **Health Board:** NHSG **Title :** Medicines Management Specialist Nurse **Contact email:** jodie.allan@nhs.scot **Signature:** …… **Date:**09/03/2023
Pharmacist	**Name:** Russell Mackay **Health Board:** NHSO **Title :** Lead Clinical Pharmacist **Contact email:** russell.mackay@nhs.scot **Signature:** …… **Date:** 27/03/2023

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		09/03/2023

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		30/03/2023

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	**Title:**
Jodie Allan	**Lead Author:** Medicines Management Specialist Nurse NHSG
Russell Mackay	**Pharmacist:** Lead Clinical Pharmacist NHSO
Dr Ambreen Butt	**Medical Practitioner:** Sexual Health Consultant NHSG
Sara Beveridge	**Senior Representative** Clinical Nurse Specialist NHST
Kimberley MacInnes	Service Manager/Lead Nurse Sexual Health NHSH

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Clinical indication to which this PGD applies

Definition of situation/ Condition	This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to supply clotrimazole 500mg pessary to patients presenting with symptoms of vulvovaginal candidiasis (VVC) i.e. white non-smelly vaginal discharge, vulval itching, soreness or redness who are referred or self-refer to Sexual Health services This PGD should be used in conjunction with individual Board protocols and the recommendations in the current British National Formulary (BNF), British Association for Sexual Health and HIV (BASHH) Guidelines and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	Females aged 13 years or older; • Presenting with symptoms of VVC with or without laboratory confirmed diagnosis. In conjunction with Patient Group Direction for clotrimazole cream 1%. The healthcare professional must use their professional judgement to consider, and where appropriate, act on any child protection and wellbeing issues coming to their attention as a result of providing the service. This should be in line with local child protection procedures and any national or local guidance on under 16s sexual activity. An individual under 16 years of age may give consent for the supply of clotrimazole 500mg pessary, provided they understand fully the benefits and risks involved. The individual should be encouraged to involve a parent/guardian, if possible, in this decision. Where there is no parental involvement and the individual indicates that they wish to accept the supply, supply should proceed, if the healthcare professional deems the individual to have the legal capacity to consent. The Age of Legal Capacity (S) Act 1991, s2 (4) states that 'a person under the age of 16 years shall have legal capacity to consent on their own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending them, they are capable of understanding the nature and possible consequences of the procedure or treatment.

	Legal advice from the NHS in Scotland states that if a healthcare professional has been trained and professionally authorised to undertake a clinical assessment which is normally that of a medical practitioner, then that health care professional can be considered to have the necessary power to assess the capacity of a child under the 1991 Act, for that procedure or treatment. If under 13 years of age this PGD cannot be used and the healthcare professional should speak to the local Child Protection lead if any concerns and follow the local child protection policy, otherwise refer to GP or paediatrics. Prior to the supply of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.
Exclusion criteria	• Under 13 years of age (the healthcare professional should speak to the local Child Protection lead if any concerns and follow the local child protection policy, otherwise refer to GP or paediatrics) • Under 16 years of age and assessed as not competent to consent to treatment using Fraser guidelines or parent or guardian not present to give consent • Known or suspected allergy to clotrimazole or any of the excipients • Pregnancy • Breast feeding • Prior treatment with clotrimazole for same episode • Recurrent vulvovaginal candidiasis (more than 2 episodes in previous 6 months) • Known to be immunosuppressed and may require further assessment and systemic treatment • Clinical history and/or symptoms suggest sexually transmitted disease (STD) **Note:** If the individual is aged <16 years of age assess the requirement for child protection referral • Genital ulceration or skin condition affecting the genitalia • Females with any of the following symptoms; o irregular vaginal bleeding o abnormal bleeding or blood stained discharge o vulval or vaginal ulcers, blisters or sores o lower abdominal pain or dysuria o fever or chills o nausea or vomiting o diarrhoea o foul smelling vaginal discharge. Individuals for whom no valid consent has been received.

Precautions and special warnings	Laboratory tests have suggested that, when used together, clotrimazole pessary may cause damage to latex contraceptives. Consequently the effectiveness of such contraceptives may be reduced. Females should be advised to use alternative precautions for at least five days after using this product.
Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner. Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	Inform/refer to the relevant medical practitioner if individual declines treatment. Document that the supply was declined, the reason and advice given in appropriate clinical records.

Description of treatment available under the PGD

Name form and strength of medicine	Clotrimazole 500mg Pessary.
Legal status	Clotrimazole 500mg pessary is available as a Pharmacy Medicine (P) or Prescription only Medicine (POM) pack presentation.
Is the use out with the SmPC?	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 (SmPC). This PGD may include off label use as some manufacturers' SmPCs exclude the age groups detailed below. Practitioners should check details for the brand they are supplying: • Individuals under 16 years of age • Individuals age 60 years or over. Where a medicine is recommended off-label, ensure as part of the consent process, informing the individual that the medicine is being offered in accordance with national guidance but that this is outside the product licence. In accordance with the MHRA all medicines **supplied** under a PGD **must** either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply.

Dosage/Maximum total dose	One 500mg pessary **The maximum total dose to be supplied under this PGD is 500mg (one pessary).**
Frequency of dose/Duration of treatment	1 x clotrimazole 500mg pessary at night.
Maximum or minimum treatment period	One treatment.
Route/Method of administration	Vaginal
Quantity to be supplied	Supply one 500mg pessary.
Storage requirements	Do not store above 25°C.
Additional Information	N/A
Follow-up (if applicable)	No routine follow up required, individual should be advised to return if symptoms persist or recur.
Advice (Verbal)	• Advise individual what to expect and of the possible side effects and their management • Explanation of what candidiasis infection is, how it is treated and actions to take to avoid further episodes of infection • Advise woman to pass urine prior to insertion of pessary • Insert pessary high into vagina using the applicator provided at night before sleeping and leave to dissolve • Avoid using during menstruation as pessary will not be as effective at this time • Avoid sexual intercourse (SI) until symptoms have subsided as SI may cause irritatio. • Avoid tight fitting and synthetic clothing and possible allergens, e.g. soap • Encourage to shower rather than bath and use soap substitutes for washing the vulval area • Warn of potential risk of damage to latex condoms and diaphragms. They should be avoided for at least 5 days after using pessary • Warn of risk of reaction, occasional local irritation and/or mild burning may occur, treatment should be discontinued if severe

	• If serious adverse or persistent effects occur, the individual should be advised to contact their GP/Accident and Emergency department/NHS24 • Individuals/carers should be advised to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme.
Advice (Written)	The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.
Identifying and managing possible adverse reactions	Serious adverse reactions rarely occur. Genital peeling, pruritus, rash, oedema, erythema, discomfort, burning, irritation, pelvic pain, vaginal haemorrhage and abdominal pain. **This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.** **BNF/BNFC**: https://www.bnf.org/products/bnf-online/ https://www.bnf.org/products/bnf-online/ **SmPC/PIL/Risk Minimisation Material:** https://www.medicines.org.uk/emc/ http://www.mhra.gov.uk/spc-pil/index.htm https://www.medicines.org.uk/emc/rmm-directory If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Report any severe reactions using the Yellow Card System. https://yellowcard.mhra.gov.uk/
Facilities and supplies required	The following are to be available at sites where the medicine is to be supplied: • Appropriate storage facilities • An acceptable level of privacy to respect patient's right to confidentiality and safety • Access to a working telephone • Access to medical support (this may be via the telephone) • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • Condoms • A copy of this current PGD in print or electronically.

Characteristics of staff authorised to supply medicine(s) under PGD

Professional qualifications	Registered nurses and midwives as recognised by the Nursing and Midwifery Council (NMC).
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's capacity to understand the nature and purpose of the medicine supply in order to give or refuse consent • Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual • Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD • Competent to undertake supply of the medicine • Competent to work under this PGD and authorised by name as an approved person to work under the terms of the PGD.
Ongoing training and competency	**All professionals working under this PGD must:** • Have undertaken NoS PGD module training on TURAS Learn • Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct. **Note:** All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of the medicine. If any training needs are identified these should be discussed with those responsible for authorisation to act under the PGD • Have knowledge and familiarity of the following; o SmPC for the medicine(s) to be supplied in accordance with this PGD.
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintain up to date record of all staff authorised to supply the medicine(s) specified in this direction.

Documentation

Authorisation of supply	Nurses and midwives working within NHS Grampian, Highland, Orkney, Tayside and Western Isles can be authorised to supply the medicine(s) specified in this PGD by their Professional Line Manager/Consultant/Practice GPs. All authorised staff are required to read the PGD and sign the Agreement to Supply Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.
Record of supply	An electronic or paper record must be completed to allow audit of practice. An electronic/HEPMA record of the screening and subsequent supply or not of the medicine(s) specified in this PGD should be made in accordance with individual Health Board electronic/HEPMA recording processes. If a paper record is used for recording the screening of individuals and the subsequent supply, or not of the medicine(s) specified in this PGD, it should include as a minimum: • Date and time of supply • Individuals name and CHI • Exclusion criteria, record why the medicine was not supplied (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, dose, form, route of the medicine(s) supplied • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who supplied the medicine, and who undertook the assessment of the individual's clinical suitability for the supply of the medicine • Record of any adverse effects and the actions taken (advise individuals' GP/relevant medical practitioner). Depending on the clinical setting where supply is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • NaSH – Sexual Health Electronic Patient Record • Individual service specific systems.

	Local policy should be followed with respect to sharing information with the individual's General Practitioner. All records should be clear, legible and contemporaneous and in an easily retrievable format.
Audit	All records of the medicine(s) specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines supplied under a PGD.
References	Electronic Medicines Compendium http://www.medicines.org.uk Canesten® 500mg Pessary – Date of revision of text 15/09/21, accessed 14/12/22. British National Formulary and British National Formulary for https://www.bnf.org/products/bnf-online/ accessed 14/12/22. British Association for Sexual Health and HIV national guideline for the management of vulvovaginal candidiasis (2019) https://www.bashhguidelines.org/media/1223/vvc-2019.pdf

NHS Grampian NHS Highland NHS Orkney NHS Tayside NHS Eileanan Siar Western Isles

Appendix 1

Healthcare Professional Agreement to Supply Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to supply the medicine(s) contained within the following Patient Group Direction:

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I have completed the appropriate training to my professional standards enabling me to supply the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

NHS Grampian NHS Highland NHS Orkney NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2

Healthcare Professionals Authorisation to Supply Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to supply the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to supply the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that supply is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
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Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**