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

Patient Group Direction (PGD) For The Supply Of Oral Metronidazole For The Treatment Of Bacterial Vaginosis (BV) Or *Trichomonas Vaginalis* (TV) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Tayside And Western Isles

Lead Author: Adapted from the FSRH/SPS PGD Supply of oral metronidazole for the treatment of Bacterial Vaginosis (BV) or *Trichomonas vaginalis* (TV) version 2.1 Date Published: October 2023		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/Metronidazole/ 1439	**Review Date:** December 2025 **Expiry Date:** June 2026	**Date Approved by NoS:** 25th January 2024

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 2.1

Revision History for NoS:

NoS PGD that has been adapted and/or superseded	New PGD adapted from FSRH/SPS PGD Supply Of Oral Metronidazole For The Treatment Of Bacterial Vaginosis (BV) or *Trichomonas Vaginalis* (TV) supersedes Patient Group Direction For The Administration/Supply Of Metronidazole Tablets NoS/PGD/Metronidazole/MGPG1143, Version 1

Date of change	Summary of Changes	Section heading
October 2023	Reference to NoS Appendix 1 and 2.	Authorisation
October 2023	Statement added in about nurses being registered by the NMC.	Professional registration
October 2023	Removed SPS advised training and added TURAS NoS PGD training link added.	Initial Training
October 2023	Added in statement about capacity under the age of 13 and the legislation statement added.	Criteria for inclusion
October 2023	NICE Competency framework statement removed.	Competency assessment
October 2023	Added statement about recording on systems.	Records
October 2023	Added statement about valid consent.	Criteria for Inclusion
October 2023	Added statement about no consent	Criteria for exclusion
October 2023	Added Statement about active or chronic sever peripheral and central nervous system disease as per SPC.	Criteria for exclusion

FSRH/SPS most recent changes

Version and Date	Change details
Version 1.0 July 2020	New template.
Version 1.1 October 2020	Removed from criteria for inclusion: Any individual with clinical signs suggestive BV or TV. Sexual contacts of individuals diagnosed or suspected TV – do not wait for test results to treat (text struck through removed only). Advisory wording added to inclusion criteria section: **Note** - All criteria for inclusion within the BASHH approved national PGD templates for sexual health are based on diagnostic management in line with BASHH guidance. Where services do not have access to diagnostics and treatment is syndromic then the PGD template will need to be locally adapted to reflect local practice being mindful of the BASHH guidance.

Version 1.2 August 2022	TV treatment updated in line with updated BASHH guidance.
Version 2.0 April 2023	Updated template: Additional clarification regarding interacting medicines. Small formatting/wording changes to align with other SPS sexual health PGD templates.
Version 2.1 October 2023	Updated PGD development group members. Cockayne syndrome added to exclusions. Statement added regarding risk of prolongation of QT interval with interacting drugs added to exclusions and reflected in interactions section.

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.

Authorisation

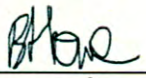
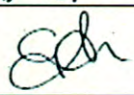
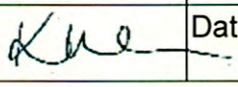
This specimen Patient Group Direction (PGD) template has been produced by SPS/FSRH and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may supply medicines under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SPC) for all medicines supplied in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Supply of the medicines has to be by the same practitioner who has assessed the patient under the PGD.

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.

This PGD has been produced for NoS by:					
Doctor	Dr Bridie Howe	Signature		Date Signed	24/01/2024
Pharmacist	Gayle Anderson	Signature		Date Signed	25/01/2024
Nurse	Kimberley MacInnes	Signature		Date Signed	25/01/2025

Approved for use within NoS by:

NoS Group Chair	**Signature**	**Date Signed**
Lesley Coyle		22/01/2024

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Adam Coldwells – Interim Chief Executive		25/01/2024

Version 2.1 – Approved for NoS from 25th January 2024

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	July 2023
Review date	December 2025
Expiry date:	June 2026

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)/BASHH Bacterial Special Interest Group (BSIG) in February 2023.

Name	Designation
Ali Grant	Highly Specialist Clinical Pharmacist: HIV, Sexual and Reproductive Health
Alison Crompton	Community pharmacy
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	Vice President, General Training Faculty of Sexual and Reproductive Healthcare (FSRH)
Dr John Saunders	Consultant in Sexual Health and HIV
Dr Rachael Jones	Consultant in HIV and Sexual Health, Chelsea and Westminster NHS Foundation Trust
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)
Heather Randle	Royal College of Nursing
Jo Jenkins	Lead Pharmacist PGDs and Medicine Mechanisms, Specialist Pharmacy Service
Rosie Furner (Working Group Co-ordinator)	Specialist Pharmacist PGDs and Medicine Mechanisms, Specialist Pharmacy Service
Portia Jackson	Pharmacist, Cambridgeshire Community Services
Sally Hogan	British Pregnancy Advisory Service (BPAS)
Sandra Wolper	Associate Director, Medicines Use and Safety, Specialist Pharmacy Service
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service

1. Characteristics of staff

Qualifications and professional registration	Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation. Registered nurses and midwives as recognised by the Nursing and Midwifery Council (NMC).
Initial training	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. 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 as advised in the RCN Sexual Health Education directory. Have undertaken NoS PGD module training on TURAS Learn. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults.
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix 1 and Appendix 2) or complete a self-declaration of competence for Bacterial Vaginosis (BV) or *Trichomonas Vaginalis* (TV) infection testing and/or treatment.
Ongoing training and competency	• 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.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	• Bacterial Vaginosis (BV). • *Trichomonas vaginalis* (TV).
Criteria for inclusion	• Any individual diagnosed with TV or BV. • Sexual contacts of individuals diagnosed TV – do not wait for test results to treat. • Individuals treated for TV who have had sexual intercourse within 7 days of receiving treatment. • An individual under 16 years of age may give consent for the supply of metronidazole, 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. • Valid consent.
Criteria for exclusion	**Personal Characteristics** • Individuals under 13 years of age. • Individuals under 16 years of age and assessed as not competent using Fraser Guidelines. • Individuals 16 years of age and over and assessed as not competent to consent using local safeguarding guidelines. • No valid consent. **Medical history** • Two or more treated episodes of BV in the past 6 months without confirmation of diagnosis by microscopy. • TV – positive test of cure where reinfection and non-concordance has been excluded. • Pelvic pain/suspected pelvic inflammatory disease (PID). • Known moderate to severe hepatic impairment. • Porphyria. • Alcohol dependence or with general alcohol consumption, a refusal to cease from drinking alcohol during treatment and 48 hours after completion.

	• Active or chronic severe peripheral and central nervous system disease. • Cockayne syndrome. **Medication history** • Any concurrent interacting medicine(s) – see Drug Interactions section. • Concomitant use of another medication known to cause QT prolongation (e.g. haloperidol, sotalol, terfenadine, pimozide) (For further information recommended resources include: CredibleMeds; registration required, or Sudden arrhythmic death syndrome (SADS) - Drugs to avoid). • Known allergy/hypersensitivity to metronidazole or tinidazole or any of the constituents found within the medication.
Cautions including any relevant action to be taken	• The 2g single dose should **not** be given if the individual is **pregnant** - use alternative regimen as detailed in dosage section below. • If used by an individual who is **breast feeding** the single 2g dose of metronidazole is considered to be compatible with breastfeeding. • Individuals prescribed warfarin should be advised that concomitant use of metronidazole may affect their INR levels and more frequent INR monitoring may be advised – individuals should be advised to contact the anticoagulant service monitoring their treatment to seek advice on monitoring requirements. • If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. • 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). • Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain.
Action to be taken if the individual is excluded or declines treatment	• If declined ensure individual is aware of the need for treatment and the potential consequences of not receiving treatment. • Record reason for decline in the consultation record. • Explain the reasons for exclusion to the individual and document in the consultation record. • Where required refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options.

3. Description of treatment

Name, strength and formulation of drug	Metronidazole 200mg tablets and 400mg tablets.
Legal category	Prescription Only Medicine (POM)
Route of administration	Oral
Off label use	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). **Individuals who are pregnant** – SPC does not recommend use in first trimester of pregnancy however BASHH guidelines states that meta-analysis have concluded that there is no evidence of teratogenicity (malformation of the embryo) from the use of metronidazole during the first trimester of pregnancy. 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. 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.
Dose and frequency of administration	**Individuals with BV:** • Single 2g dose (e.g. 5 x 400mg tablets all at once) (not in pregnant individuals) OR • 400mg to be taken twice a day for 5 days OR • 400mg to be taken twice a day for 7 days

	Individuals with TV: • First line – 400mg to be taken twice daily for 7 days • Second line (individuals unlikely to adhere with 7 day regime but who are not pregnant) - single 2g dose **Women living with HIV diagnosed with TV:** • 400mg to be taken twice a day for 7 days
Quantity to be supplied	• Single dose (2g): appropriately labelled pack of 400mg x 5 tablets OR • Five-day course (400mg): appropriately labelled pack of 400mg x 10 tablets or 200mg x 20 tablets OR • Seven-day course (400mg): appropriately labelled pack of 400mg x 14 tablets or 200mg x 28 tablets
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	All concurrent medications should be reviewed for interactions. A detailed list of all drug interactions is available in the BNF www.bnf.org or the product SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk Individuals concurrently prescribed the following medications are excluded from treatment under this PGD: • 5 fluorouracil • ciclosporin • busulfan • lithium • phenobarbital • phenytoin
Identification and management of adverse reactions	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org The following side effects are frequently reported with metronidazole but do not reflect all reported side effects: • nausea • vomiting • gastrointestinal disturbance • diarrhoea • abdominal pain

	• an unpleasant taste in the mouth may occur which will continue throughout the duration of treatment but will resolve once treatment finishes.
Management of and reporting procedure for adverse reactions	• 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: http://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report via DATIX reporting.
Written information and further advice to be given to individual	**Medication:** • Give patient information leaflet (PIL) provided with the original pack. Explain mode of action, side effects, and benefits of the medicine. • Advise that no alcohol should be taken for the duration of the treatment and for 48 hours after the course has been completed. • Advise to swallow the tablets whole with plenty of water and to take with or after food. • If adverse reaction to treatment occurs advise individual to contact clinic for further advice. • Individuals who are breast feeding should be advised that metronidazole can cause breast milk to have a bitter taste which may cause some difficulties with feeding. • Seek advice from a pharmacist/nurse or doctor if any new medications are prescriber or started during the metronidazole course including those medications purchased over the counter. **Condition (general):** • Individuals diagnosed with BV/TV should be offered information (verbal, written and/or digital) about their diagnosis and management. • Offer condoms and advice on safer sex practices and offer the options for screening for sexually transmitted infections (STIs). • Where treatment not supplied via a sexual health clinic ensure the individual has contact details of local sexual health services. **Condition (specific):** **Bacterial Vaginosis** • If symptoms persist/worsen advise individual to contact clinic.

	• Avoid local excessive washing, bubble baths, soaps, douching - advise use of emollient as a soap substitute. • BV is not an STI. • No screening or treatment of partner(s) is required. • Give general advice including information about possible triggers for BV. • Advise that regular condom use may reduce the frequency of BV recurrence. ***Trichomonas vaginalis*** • TV is an STI. • Screening and treatment of partner(s) is required. • Abstain completely from sexual intercourse (even with condom) including oral sex, for 7 days and for 7 days after partner(s) treated, and follow up is complete. • Warn of risk of re-infection and further transmission of infection, if sexual intercourse takes place within 7 days of treatment starting or with an untreated partner. • Discuss partner notification and issue contact slips if appropriate. • Discuss implications of incomplete treatment.
Follow up treatment	• The individual should be advised to seek medical advice in the event of an adverse reaction. • Follow local protocol for follow up and partner notification. • **Individuals with *Trichomonas Vaginalis* (TV):** should be advised to re-attend a sexual health clinic (face to face or remotely) 4 weeks following treatment for: o test of cure only if symptoms persist o confirmation of compliance with treatment o retaking the sexual history to explore the possibility of re-infection o pursuing partner notification and health promotion.
Records	• The consent of the individual and o If individual is under 13 years of age record action taken o If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken o If individual over 16 years of age and not competent, record action taken • If individual not treated under PGD record action taken. • Name of individual, address, date of birth. • GP contact details where appropriate. • Relevant past and present medical and sexual history, including medication history. • Examination or microbiology finding/s where relevant.

	• Any known allergies and nature of reaction. • Name of registered health professional. • Name of medication supplied. • Date of supply. • Dose supplied. • Quantity supplied including batch number and expiry date in line with local procedures. • Advice given, including advice given if excluded or declines treatment. • Details of any adverse drug reactions and actions taken. • Advice given about the medication including side effects, benefits, and when and what to do if any concerns. • Any referral arrangements made. • Any supply outside the terms of the product marketing authorisation. • Recorded that supplied via Patient Group Direction (PGD). Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy. All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy. 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 • BadgerNet – Digital Maternity Notes • HEPMA • Individual's GP records if appropriate • Individual service specific systems.

4. Key references

Key references (accessed January 2023)	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2

	• British Association for Sexual Health and HIV (BASHH) (2021) Guidelines – *Trichomonas Vaginalis* https://www.bashhguidelines.org/media/1310/tv-2021.pdf • British Association for Sexual Health and HIV (BASHH) (2019) Guidelines – Bacterial Vaginosis https://www.bashhguidelines.org/current-guidelines/vaginal-discharge/bacterial-vaginosis-2012/ • NICE Clinical Knowledge Summaries - https://cks.nice.org.uk • Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines • Metronidazole – is it safe to use with breastfeeding? https://www.sps.nhs.uk/articles/metronidazole-is-it-safe-to-use-with-breastfeeding/

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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:

Patient Group Direction (PGD) For The Supply Of Oral Metronidazole For The Treatment Of Bacterial Vaginosis (BV) Or *Trichomonas Vaginalis* (TV) Within NHS Grampian, Highland, Orkney, Tayside And Western Isles, Version 2.1

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: _____

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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 he or she is 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 he or she understands and is 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 his or her individual code of professional practice and conduct.
Patient Group Direction (PGD) For The Supply Of Oral Metronidazole For The Treatment Of Bacterial Vaginosis (BV) Or *Trichomonas Vaginalis* (TV) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Tayside And Western Isles, Version 2.1
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

Patient Group Direction (PGD) For The Supply Of Oral Metronidazole For The Treatment Of Bacterial Vaginosis (BV) Or *Trichomonas Vaginalis* (TV) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Tayside And Western Isles, Version 2.1					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**