



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 oral metronidazole for the treatment of Bacterial Vaginosis (BV) or *Trichomonas* vaginalis (TV)

in

Integrated Sexual Health Services (ISHS) Derbyshire Community Health Services

Version Number 2.1

Change History		
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.	

PGD DEVELOPMENT GROUP

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

Reference Number: 216(S) Metronidazole (BV-TV) National Template v2.1





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.

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
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	Specialist Pharmacist PGDs and Medicine Mechanisms, Specialist
Group Co-ordinator)	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

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ORGANISATIONAL AUTHORISATIONS

PATIENT GROUP DIRECTION DEVELOPMENT WORKING GROUP

This PGD has been agreed by doctors, and/or expert clinical practitioners, pharmacist and representative healthcare professionals from the trust stated below for use within Integrated Sexual Health Services (ISHS), University of Derby and Burton Teaching Hospitals Foundation Trust (UHDBFT) and Derbyshire Community Health Services Foundation Trust (DCHSFT)

PATIENT GROUP DIRECTION AUTHORISATION

PGD approved by PGD Working Group on 27th September 2023 (minor change November 2023)

This PGD is authorised for use on behalf of DCHS by the following signatories:

Position of signatory	Name	Signature	Date
Director of Nursing, AHPs & Quality (amendment approved by Deputy Chief Nurse)	Michelle Bateman (Jo Wain)	J.We.	13/12/2023
Head of Medicines Management	Kate Needham	LINGED	13/12/2023
Deputy Medical Director (amendment approved by Medical Director)	Dr Seema Kumari (Ben Pearson)	Benleavon.	13/12/2023
Lead Clinician	Dr Ade Apoola	20 A Apolla	13/12/2023
Specialist in Antimicrobial Therapy	Cerina Nanuan	Quuan	13/12/2023

REVIEWED FOR DCHS BY:		
Date	Name	Position
September	Lisa Walton	ISHS Specialist Nurse Practitioner
2023	Dr Ade Apoola	ISHS Lead Clinician
	Cerina Nanuan	Advanced Pharmacist for IP&C

PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct. Individual practitioners must declare that they have read and understood the Patient Group Direction and agree to supply/administer medication(s) listed only in accordance with the PGD.

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1. Characteristics of staff

Qualifications and	Current contract of employment within a Local Authority or NHS	
professional registration	commissioned service or an NHS Trust/organisation.	
	Registered healthcare professional listed in the legislation as able	
	to practice under Patient Group Directions.	
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.	
	Individual has undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfH PGD elearning programme	
	The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults.	
	For advice on additional local training requirements see section 4: Characteristics of DCHS ISHS Staff.	
Competency assessment	 Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for Bacterial Vaginosis (BV) or <i>Trichomonas Vaginalis</i> (TV) infection testing and/or treatment. Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions 	
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.	

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2. Clinical condition or situation to which this PGD applies

Clinical condition or	Bacterial vaginosis (BV)
situation to which this PGD	Trichomonas vaginalis (TV)
applies	Thenomonas vaginais (1 v)
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.
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
	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.
	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:
	<u>CredibleMeds</u> ; registration required, or <u>Sudden arrhythmic</u>
	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	The 2g single dose should not be given if the individual is
relevant action to be taken	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.
	monitoring requirements.

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	 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). Safeguarding: Where there are any safeguarding concerns refer to local policies for safeguarding adults and children and/or seek advice from the safeguarding lead/team in the organisation. Document the concern and outcome in the healthcare record. DCHS: Safeguarding adults and children policies on DCHS SharePoint. DCHS Safeguarding Team: 01773 850000. East Midland's Children and Young People's Sexual Assault Service (EMCYPSAS): 0800 183 0023 (24-hour service). 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 & formulation of drug	Metronidazole 400 mg.
Tormulation of drug	Metronidazole 200mg or 500mg tablets or oral solution (200mg/5ml) may be issued under this PGD if the 400mg tablets are unavailable.
Legal category	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

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	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: According to local protocol: Single 2g dose (e.g.5x400mg 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 – 400 mg 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 400mgx5 tablets (or if unavailable - 200mgx10 tablets/1x100ml bottle of 200mg/5ml liquid) OR Five-day course (400mg): appropriately labelled pack of 400mgx10 tablets (or if unavailable 200mgx20 tablets/1x100ml bottle of 200mg/5ml liquid) OR Seven-day course (400mg): appropriately labelled pack of 400mgx14 tablets (or if unavailable 200mgx28 tablets/2x100ml bottles of 200mg/5ml liquid) OR Seven-day course (500mg): appropriately labelled pack of 500mgx14 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 or the product SPC Seek advice from an appropriate clinician/Medicines Advisory Service if required. Individuals concurrently prescribed the following medications are excluded from treatment under this PGD and must be referred to an appropriate prescriber: 5 fluorouracil ciclosporin busulfan lithium

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	 phenobarbital phenytoin 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)
Identification & 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 organisation incident policy.
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):

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	 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: test of cure only if symptoms persist confirmation of compliance with treatment retaking the sexual history to explore the possibility of re-infection pursuing partner notification and health promotion
Records	Property of the individual and The consent of the individual and If individual is under 13 years of age record action taken If individual is under 16 years of age document capacity using Fraser guidelines. If not competent

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record action taken.
If individual over 16 years of age and not competent, record action taken dual not treated under PGD record action taken of individual, address, date of birth tact details where appropriate not past and present medical and sexual history, genetication history. ation or microbiology finding/s where relevant. The power allergies and nature of reaction of registered health professional of medication supplied supply supplied years about the medication including side effects, and when and what to do if any concerns given, including advice given if excluded or declines and adverse drug reactions and actions taken certal arrangements made poply outside the terms of the product marketing seation ed that supplied via Patient Group Direction (PGD) arould be signed and dated (or a password controlled end securely kept for a defined period in line with local should be clear, legible and contemporaneous. all individuals receiving treatment under this PGD
should be clear, legible and contemporaneous.

4. Characteristics of DCHS ISHS Staff

Qualifications	A registered nurse working within ISHS who is deemed competent by their clinical line manager and authorised by their professional lead to undertake the clinical assessment of a patients leading to the identification of those suitable for management under this PGD.
Additional Local Training	Has undertaken the local training programme on the process, responsibilities and scope of PGDs. Has undertaken local training based on the use of this PGD Has undertaken training in recognition of and treatment of anaphylaxis including basic life support in the 12 months. Has undertaken Safeguarding Children Level 3 training in the last 12 months.

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	Has undertaken Safeguarding Adults Level 2 training in the last 3			
	years.			
Continuing Training &	Evidence of Continuing Professional Development in ISHS nurse			
Education	role.			
	The nurse should be aware of any change to the recommendations for the medicines listed.			
	It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the			
	limitations of individual scope of practice.			

5. Key references

Key references (accessed	Electronic Medicines Compendium
January 2023, September	http://www.medicines.org.uk/
2023)	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/
	Specialist Pharmacy Service (SPS) Identifying risk factors for
	developing a long QT interval
	https://www.sps.nhs.uk/articles/identifying-risk-factors-for-
	developing-a-long-qt-interval/#:~:text=QT

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Appendix A - Registered health professional authorisation sheet

PGD Name/Version: 216(S) Metronidazole (BV-TV) National Template v2.1

Valid from: December 2023 Expiry: 30 June 2026

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.

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.					
Name	Designation	Signature	Date		

Authorising manager

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 Derbyshire Community Health Services for the above named health care professionals who have signed the PGD to work under it.

Name	Designation	Signature	Date

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.

PGD Authorisation Forms shall be maintained and retained by the Service Manager who is responsible for the safe storage of the records.

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