

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 York and North Yorkshire Sexual health services including specialist clinical outreach services

Version Number 1.1

Change History	
Version and Date	Change details
Version 1.0 July 2020	New template
Version 1.1 October 2020	Removed from criteria for inclusion: <i>Any individual with clinical signs suggestive BV or TV</i> <i>Sexual contacts of individuals diagnosed or suspected TV – do not wait for test results to treat. (text struck through removed only)</i> Advisory wording added to inclusion criteria section: NOTE – <i>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.</i>

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 st July 2020
Review date	February 2023
Expiry date:	30 th June 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)/BASHH Bacterial Special Interest Group (BSIG) 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
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 (EHSCHG)
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 (EHSCHG)
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

Reference Number:v1


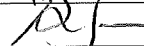



Valid from: May 2022

Review date: February 2023

Expiry date: 30th June 2023

	Pharmacy Service
Tracy Rogers	Associate Director Specialist Pharmacy Service

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor	Dr Ian Fairley, Lead Consultant		26/05/22
Senior pharmacist	Paul Jackson		14/6/22
Senior representative of professional group using the PGD	Steven Evans, ANS		7/7/22
Person signing on behalf of <u>authorising body</u>	Jennie Booth, Lead Nurse Medicines Management		04-08-22
	Stuart Parkes, Chief Pharmacist AP KATE NIXON DEPT CHIEF PHARMACIST		11/8/22

1. Characteristics of staff

Qualifications and professional registration	<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>
Initial training	<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>
Competency assessment	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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. • Completion of PGD awareness session via Trust Learning HUB
<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

Clinical condition or situation to which this PGD applies	<ul style="list-style-type: none"> • Bacterial vaginosis (BV) • <i>Trichomonas vaginalis</i> (TV)
Criteria for inclusion	<ul style="list-style-type: none"> • 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. • Any individual with clinical signs suggestive BV or TV • Sexual contacts of individuals diagnosed <u>or suspected</u> TV – do not wait for test results to treat.
Criteria for exclusion	<p>Personal Characteristics</p> <ul style="list-style-type: none"> • 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 <p>Medical history</p> <ul style="list-style-type: none"> • 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. <p>Medication history</p> <ul style="list-style-type: none"> • Individual is taking interacting medicines. Check appendix 1 of current edition of British National Formulary (BNF) for full list. • Known allergy/hypersensitivity to metronidazole or tinidazole or any of the constituents found within the medication.
Cautions including any relevant action to be taken	<ul style="list-style-type: none"> • 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. • 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	<ul style="list-style-type: none"> • 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.
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3. Description of treatment

Name, strength & formulation of drug	Metronidazole 200mg or 400 mg tablets
Legal category	POM
Route of administration	Oral
Off label use	<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>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.</p> <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>
Dose and frequency of administration	<p><u>Individuals with TV/BV:</u></p> <ul style="list-style-type: none"> • 400mg to be taken twice a day for 7 days or • Single 2g dose (5 tablets all at once) (not in pregnant individuals or HIV positive women with TV)
Quantity to be supplied	<ul style="list-style-type: none"> • Seven-day course: appropriately labelled pack of 400mgx14 tablets/200mgx28 tablets OR • Single dose: appropriately labelled pack of 400mgx5 tablets/200mgx10 tablets

Reference Number:v1
Valid from: May 2022
Review date: February 2023
Expiry date: 30th June 2023

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
Identification & management of adverse reactions	<p>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</p> <p>The following side effects are common with metronidazole (but may not reflect all reported side effects):</p> <ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<p>Medication:</p> <ul style="list-style-type: none"> • 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 afterwards • 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 <p>Condition (general):</p> <ul style="list-style-type: none"> • 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.

Reference Number:v1
Valid from: May 2022
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Expiry date: 30th June 2023

	<p>Condition (specific):</p> <ul style="list-style-type: none"> • Bacterial vaginosis <ul style="list-style-type: none"> ○ 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 ○ Use condoms because the alkalinity of semen causes bacteria in the vagina to release amines • Trichomonas vaginalis <ul style="list-style-type: none"> ○ 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 implications of incomplete treatment
<p>Follow up treatment</p>	<ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ 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
<p>Records</p>	<p>Record:</p> <ul style="list-style-type: none"> • The consent of the individual and <ul style="list-style-type: none"> ○ 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 record action taken. ○ 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

	<ul style="list-style-type: none"> • 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) <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>
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4. Key references

<p>Key references (accessed April 2020)</p>	<ul style="list-style-type: none"> • 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) (2019) Guidelines – Trichomonas Vaginalis https://www.bashhguidelines.org/current-guidelines/vaginal-discharge/trichomonas-vaginalis-2014/ • 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 A - Registered health professional authorisation sheet

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

Valid from: May 2022 Expiry: 30th June 2023

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

<p>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 York & Scarborough Teaching Hospitals NHS Foundation Trust for the above named health care professionals who have signed the PGD to work under it.</p>			
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.

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When the expiry date is exceeded, this PGD ceases to be a legal document. Staff authorisation records must be maintained for 8 years if the PGD relates to adults only, 10 years for implants and 25 years after the expiry date if the PGD relates to children

