

Section 1
CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR
DOXYCYCLINE 50mg and 100mg CAPSULES

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

Organisation and service	
Bath & North East Somerset Council	<ul style="list-style-type: none"> Community pharmacists working under the Sexual Health enhanced services contract commissioned by Virgin Care
Period	
Date PGD comes into effect	1st October 2020
Expiry date	30th September 2022
Staff characteristics	
Professional qualifications	Registered Pharmacist with current General Pharmaceutical Council Practising Registration working under the Sexual Health enhanced services contract
Specialist competencies or qualifications	<p>Must fit all the following criteria:</p> <ul style="list-style-type: none"> Have undertaken appropriate training for working under patient group directions for the supply and administration of medicines Have been assessed as competent to work with this PGD Have undertaken training in the role, care and administration of the medicine specified in this PGD, as specified by the individual authorising organisation Have undertaken appropriate continuing professional development around sexual health testing and treatment, and can provide evidence of this CPD, or who have undertaken relevant training, as specified by the relevant authorising organisation Have access to all relevant sources of national and local information e.g. information issued by the Department of Health, British National Formulary (BNF), local clinical protocols and Summary of Product Characteristics (SPC) concerning medicine(s) within this PGD: https://bnf.nice.org.uk/ https://www.medicines.org.uk/emc https://about.medicinescomplete.com/#/

PATIENT GROUP DIRECTION (PGD) FOR
DOXYCYCLINE
50mg and 100mg CAPSULES

<p>Continuing training and education</p>	<p>The practitioner is responsible for and accountable for maintaining and updating their knowledge and skills in this area of practice with particular reference to changes and national directives</p>
<p>Clinical Details</p>	
<p>Indication</p>	<p>For the treatment of chlamydia trachomatis, including rectal and pharyngeal chlamydia infection (NB not ophthalmic infection), or who require epidemiological treatment of chlamydia trachomatis</p> <p>Sexual contact(s) of a client with a positive genital chlamydia result diagnosed through the Avon Chlamydia Screening Office (Unity)</p>
<p>Inclusion criteria</p>	<p>Patients 13 years of age or over (patients under 16 years old must be assessed as Fraser competent) who have provided valid consent to treatment and fulfilling one of the following criteria:</p> <ul style="list-style-type: none"> • Have a laboratory confirmed Chlamydia trachomatis infection or Are a sexual contact in the last six months or the last known contact of the above (epidemiological treatment) • Have a laboratory confirmed <u>rectal</u> Chlamydia trachomatis infection (NB: NOT ophthalmic chlamydia) or • Are a sexual contact in the last six months or the last known contact of the above (epidemiological treatment). • Individuals who have had sexual intercourse within 7 days of receiving treatment for chlamydia or who have had sex with an untreated partner with chlamydia <p>The pharmacy will receive confirmation from the Chlamydia Screening Office that the client tested positive for chlamydia and that doxycycline is the treatment to be used</p> <p>If the client is under 16 discuss the value of parental support and encourage client to inform parent(s). An assessment of the Fraser Guidelines on competency must be made:</p> <ul style="list-style-type: none"> • Mature enough to understand the advice and implications • Cannot be persuaded to discuss with parents

**PATIENT GROUP DIRECTION (PGD) FOR
DOXYCYCLINE
50mg and 100mg CAPSULES**

	<ul style="list-style-type: none"> • Likely to have had or continue to have sexual intercourse • Physical or mental health likely to suffer if does not receive help or treatment • In the client's best interest to receive contraception advice, treatment or both without parental consent
<p>Exclusion criteria</p>	<p>Patients fulfilling one or more of the following criteria are excluded from treatment under the PGD: (see <i>Action if patient is excluded</i>)</p> <ul style="list-style-type: none"> • The pharmacy has not received confirmation from the Chlamydia Screening Office that the presenting client has tested positive for chlamydia trachomatis • Under 13 years of age • Under 16 years of age who are not Fraser competent. • Taking significantly interacting medicines – check Appendix 1 of current British National Formulary (BNF) • Immunocompromised (including HIV) or taking immunosuppressive therapies. • Females with pelvic pain or suspected PID • Presence of concomitant conjunctivitis and/or joint pain/swelling • Pregnancy (known or suspected) • Breast-feeding • Ophthalmic chlamydia • Known hepatic or renal impairment • Acute/known porphyria • Known allergy or intolerance to doxycycline or any other tetracycline • Known myasthenia gravis • Unable to avoid persistent sunlight • Known to have systemic lupus erythematosus <p>For full details of interacting medicines refer to current SPC and BNF: https://www.medicines.org.uk/emc https://bnf.nice.org.uk/</p>
<p>Action if patient is excluded</p>	<ul style="list-style-type: none"> • Manage as per safeguarding policy • Refer to client's GP or sexual health service e.g. Riverside Clinic within an appropriate timescale • Inform patient of alternative options if appropriate • Contact the Chlamydia Screening Office to advise them that the client is excluded under the PGD • Ensure all actions/decisions are documented in notes

**PATIENT GROUP DIRECTION (PGD) FOR
DOXYCYCLINE
50mg and 100mg CAPSULES**

Action if patient declines	<ul style="list-style-type: none"> Advise client on alternative sources of treatment Refer to client's GP or sexual health service e.g. Riverside Clinic within an appropriate timescale Ensure all actions/decisions are documented in notes
Drug Details	
Name, form & strength of medicine	<p>Doxycycline 50mg capsules Doxycycline 100mg capsules</p>
Legal Status/classification of medicine	Prescription only medicine (POM)
Route/method of administration	<p>Oral</p> <ul style="list-style-type: none"> Doxycycline capsules are to be swallowed whole, not crushed or chewed, with plenty of water, during meals, while sitting or standing. Avoid taking them just before lying down or bedtime Indigestion remedies, iron or zinc supplements are not to be taken at the same time as this medicine. To be taken at least two hours before or two hours after a dose of doxycycline
Dosage; Frequency; Duration of treatment; Maximum or minimum treatment period; Quantity to supply / administer	<p>100mg twice daily (every 12hours) for 7 days supplied as either:</p> <ul style="list-style-type: none"> 28 x 50mg capsules Directions: TWO capsules to be taken TWICE daily 14 or 16 100mg capsules Directions: ONE capsule to be taken TWICE daily

**PATIENT GROUP DIRECTION (PGD) FOR
DOXYCYCLINE
50mg and 100mg CAPSULES**

<p>Cautions</p>	<ul style="list-style-type: none"> Alcohol should be avoided as it may reduce effectiveness of doxycycline Skin becomes more sensitive to sunlight in some clients whilst they are being treated with doxycycline. This sensitivity can continue for two weeks to several minutes after stopping doxycycline
<p>Side effects</p> <p>Side effects (continued)</p>	<p>Potential adverse / undesirable effects include:</p> <p>Common:</p> <ul style="list-style-type: none"> Nausea, vomiting, diarrhoea (antibiotic associated colitis reported occasionally) Dysphagia and oesophageal irritation. Headache Photosensitivity Skin reactions Exacerbation of SLE symptoms Dyspnoea; hypotension; peripheral oedema; tachycardia Other rare side effects include hepatotoxicity, pancreatitis, blood disorders, hypersensitivity reactions, and visual disturbances <p>If adverse reaction(s) occur (ADRs):</p> <ul style="list-style-type: none"> If at any time patient has difficulty breathing, has wheezing, develops swelling, rash or itch, emergency treatment should be sought Otherwise patient to report to own GP or sexual health service. If reported to service: <ul style="list-style-type: none"> Document in patient record Report to GP (only if authorised by patient) Yellow Card to Medicines Control Agency <ul style="list-style-type: none"> all ADRs if preparation has black triangle status ▼ <p>otherwise only if ADR is serious or unusual</p> <p>Please refer to current SPC and BNF for full details of side effects: https://www.medicines.org.uk/emc https://bnf.nice.org.uk/</p>
<p>Advice to patient</p>	<p>Advice relating to treatment of condition/all medicines included in PGD:</p> <ul style="list-style-type: none"> Provide manufacturers patient information leaflet to support advice

**PATIENT GROUP DIRECTION (PGD) FOR
DOXYCYCLINE
50mg and 100mg CAPSULES**

	<ul style="list-style-type: none"> • Take at regular intervals (as per directions) and complete the whole course of medication. Take medication at 12 hourly intervals. • Encourage the patient not to miss any doses. If they do miss a dose, advise them to take it as soon as they remember unless it is nearly time for their next dose, in which case advise the patient to leave out the missed dose. Advise the patient never take two doses at the same time to make up. • Swallow whole with plenty of water and with food whilst sitting or standing to avoid risk of oesophageal ulceration • Avoid direct exposure to sunlight and ultra-violet light. • Advise patient not to take tablets containing zinc or iron or indigestion remedies at the same time as doxycycline. Leave a 2-hour gap either side of dose if possible. Antacids, calcium, iron, magnesium salts and zinc preparations decrease absorption of doxycycline • Advice on reporting side-effects and contact information in the event of severe side effects (see <i>side-effects</i>) <ul style="list-style-type: none"> ○ Advise about possible candidiasis when taking antibiotics ○ Warn of possible gastro-intestinal upset or skin rash • Advise the client to avoid sex and alcohol until treatment of self and partners has been completed, symptoms have resolved and all other results are negative • Male clients: excessive self-examination of the penis should be avoided. • Advise of need to treat sexual partners and follow partner notification protocol • Discuss and encourage safer sex and condom availability including B&NES Ccard • Leaflet on chlamydia to be given to client as appropriate • All clients diagnosed with chlamydia should receive sexual health advice and information on how to access testing for other STIs (such as Riverside Clinic, www.safebanes.com etc.)
<p>Follow up actions</p>	<ul style="list-style-type: none"> • Re-treatment may be needed in clients who have not completed the course of treatment, or have had unprotected sex with an untreated partner, including within one week of starting treatment if both treated simultaneously. If re-treatment is required contact Chlamydia Screening Office, the client's GP or Riverside Clinic

Audit trail	
Records/audit trail	<ul style="list-style-type: none">• Date• Patient's name, address, date of birth and consent given by client/parent/guardian• Contact details of GP (if registered)• Indication for use• Dose form administered (tablets or capsules)• Batch number• Expiry date• Date of administration• Patient information leaflet(s) offered• Advice given to client/parent/guardian (including side effects)• Referral arrangements (including self-care)• Name and designation of healthcare professional who administered or supplied the medication.• Details of any adverse drug reaction and actions taken including documentation in the patient's medical record• Any additional advice sought from a doctor or other healthcare professional

References used for this PGD

NICE Good Practice Guidance (MPG2) [Patient Group Directions \(02 August 2013\); Updated March 2017](#)

BASHH guideline [Update on the treatment of Chlamydia trachomatis \(CT\) infection](#) (September 2018) BASSH Clinical Effectiveness Group

BASHH guideline [Update on the treatment of Chlamydia trachomatis \(CT\) infection](#) (September 2018) BASSH Clinical Effectiveness Group

BASHH guideline [National Guideline for the Management of Genital Tract Infection with Chlamydia Trachomatis](#) (2015)

BASHH guideline [Management of Suspected Sexually Transmitted Infections in Children and Young People](#) (2010)

This PGD is based on the Doxycycline PGD developed by Virgin Care, April 2019, and was drawn up in consultation with:

Name	Speciality
Paul Moloney	Lead Pharmacist, Virgin Care B&NES
Dr Arnold Fernandes	Consultant in Genitourinary Medicine and Contraception, The Riverside Clinic, Royal United Hospital NHS Foundation Trust
Jayne Elton	Lead Nurse Practitioner, The Riverside Clinic, Royal United Hospital NHS Foundation Trust
Monika Kolbuk	Pharmacy Cluster Manager, Jhoots Pharmacy
Melanie Green	Head of Medicines Management, B&NES Clinical Commissioning Group
Richard Brown	Chief Officer, Avon Local Pharmaceutical Committee
Paul Sheehan	Public Health Commissioning and Development Manager, Bath and North East Somerset Council

Section 2

**MANAGERIAL CONTENT OF PATIENT GROUP DIRECTION FOR
DOXYCYCLINE 50mg and 100mg CAPSULES**

This patient group direction must be agreed to and signed by all health care professionals involved in its writing and who use it. The Authorising Organisations lead should hold the original signed copy. The PGD must be easily accessible in the clinical setting

Authorisation

**Specialist Medical
Clinician:**
Dr. Arnold Fernandes

Name: DR. ARNOLD FERNANDES

Signature:  Date: 1st October 2020

Consultant in Genitourinary Medicine and Contraception,
The Riverside Clinic, Royal United Hospital NHS Foundation
Trust

Lead Pharmacist:
Paul Moloney

Name: PAUL MOLONEY

Signature:  Date: 1st October 2020

Lead Pharmacist, Virgin Care Ltd

**Organisational
Authorisation:**
Dr. Bruce Laurence

Name: DR. BRUCE LAURENCE

Signature:  Date: 1st October 2020

Director of Public Health, B&NES Council

Individual Authorisation

**YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS
PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT**

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**

Note to Authorising Managers: Authorised staff should be provided with an individual copy
of the clinical content of the PGD and a copy of the authorisation sheet showing their
authorisation.

I have read and understood the Patient Group Direction and agree to supply this medicine
only in accordance with this PGD.

Name of Professional	Signature	Authorising Manager	Date

Name of pharmacy / pharmacies:

PATIENT GROUP DIRECTION (PGD) FOR
DOXYCYCLINE
50mg and 100mg CAPSULES

Appendix 1

Self-assessment of competencies for supply/administration of **DOXYCYCLINE 50mg and 100mg CAPSULES** under patient under patient group direction

Name of Professional	Pharmacy / Pharmacies	Date

With reference to

- a) PGD for **DOXYCYCLINE 50mg and 100mg CAPSULES**
 - b) Patient Information Leaflet
- and** to be used in conjunction with
- c) references contained within the PGD

Eligibility to Practice

The Practitioner will:

- a) have a good working knowledge of why **DOXYCYCLINE 50mg and 100mg CAPSULES** are recommended
- b) have completed my organisations approved training on Patient Group Directions demonstrate the following competencies when administering/supplying the named medicine **DOXYCYCLINE 50mg and 100mg CAPSULES**

Knowledge		Signature & date
1	Identify local and national policies, Patient Group Direction and procedures used in the administration/supply of the above named medicine	
2	Describe the mode of action of the above named medicine	
3	Describe the clinical indications under which the patient is eligible for treatment	
4	Describe the contraindications/exclusions to the use of the above named medicine	
5	Explain the circumstances under which further advice from the doctor would be sought and arrangements for referral.	
6	Describe the administration process for the above named medicine including dose and site	
7	Describe any possible side effects or interactions of the above named medicine	
8	Discuss the relevant warnings and patient information to be given	
9	Explain the record keeping required in your area of work	
10	Undertake Continual Professional Development relevant to the above named medicine and the clinical area to which this PGD relates. Request updates to the PGD when changes to guidance necessitate this	

Abbreviations used in this Patient Group Direction

B&NES	Bath and North East Somerset
BNF	British National Formulary
CCG	Clinical Commissioning Group
CSP	Chlamydia Screening Programme
GP	General Practitioner
HIV	Human Immunodeficiency Virus
MHRA	Medicines and Healthcare products Regulatory Agency
PID	Pelvic Inflammatory Disease
PGD	Patient Group Direction
POM	Prescription Only Medicine
SPC	Summary of Product Characteristics
STI	Sexually Transmitted Infection(s)