

Patient Group Direction for the administration of : oral doxycycline for the treatment of patients with chlamydia/suspected chlamydia, non-gonococcal urethritis (NGU) and the sexual contacts thereof, and for the epidemiological treatment of sexual contacts of epididymo-orchitis and pelvic inflammatory disease (PID)	
Title of patient group direction	Oral doxycycline 100mg
Approved at	NMP/PGD Group
PGD approved / valid from	September 2018
Review date	June 2021
Expiry date	September 2021
Clinical area(s) where PGD applies	York and North Yorkshire Sexual Health services
Identified Lead for monitoring / review and contact details	Alison Chorlton Lead Nurse
CONSULTATION PROCESS ADOPTED IN DEVELOPING THE PATIENT GROUP DIRECTION (PGD)	
New Document	No
Reviewed Document	Yes
If the PGD is revised what revisions were required and for what reasons e.g. change in medical procedures or change in legislation	Current PGD due for renewal June 2018
List of persons involved in the consultation process. (The group must include a sponsoring clinician, a pharmacist and a senior representative of the professional group. The job title and level of consultation should also be listed).	Dr Ian Fairley Alison Chorlton – Lead Nurse Sexual Health Elizabeth Clarke Advanced Nurse Specialist

CLINICAL CONDITION	
Condition	<ul style="list-style-type: none"> • Positive or equivocal/unconfirmed reactive chlamydia result in index patient • Male diagnosed with non-gonococcal urethritis(NGU) • Reported sexual contact with a person with any of the conditions above • Sexual contacts of epididymo-orchitis or pelvic inflammatory disease(P.I.D)
Inclusion criteria	<ul style="list-style-type: none"> • First line treatment for patients who have had a positive chlamydia screening test or have been identified as a sexual partner of a person with confirmed or suspected chlamydial infection • First line treatment for male with non-specific urethritis diagnosed by direct microscopic visualization of > 5 polymorphonuclear cells on gram stain over 5 high power fields (x1000 magnification) • Clients/patients who have tested positive for chlamydia and present with symptoms but who are unable to attend sexual health services for further assessment and management • Clients/patients who have tested positive for chlamydia and present with symptoms whose condition has been discussed with a competent practitioner prior to treatment
Exclusion criteria	<ul style="list-style-type: none"> • Client/patients who themselves directly present with the complicated conditions pelvic inflammatory disease (PID) and epididymo-orchitis • Pregnancy, breastfeeding or at risk of pregnancy • Allergy or hypersensitivity to doxycycline, tetracycline antibiotics or any of the excipients of the doxycycline capsules • Client/patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrose-isomaltase insufficiency should not take doxycycline. • Client/ patient has already taken doxycycline but it was not effective/tolerated • Myasthenia gravis or systemic lupus erythematosus • Children aged 12 or under • Client/patients aged 13-15 who are not Fraser competent • Known hepatic disease (formal diagnosis or abnormal

	<p>blood results)</p> <ul style="list-style-type: none"> • Known renal impairment (formal diagnosis or abnormal blood results) • Known porphyria • Patients who decline treatment under a PGD
Action if excluded	<ul style="list-style-type: none"> • Consider if azithromycin PGD can be used. • If azithromycin cannot be used, explain reason for exclusion to patient and document in records. • Refer to medical practitioner/prescriber that clinical session or when next available in clinic, • As there may be occasions when a medical practitioner is not physically present within the department, discuss by telephone where possible with medical practitioner. • Alternatively arrange immediate assessment in accident and emergency if patient presents with an acute presentation and no doctor is available that clinical session.
Action for patients not wishing to receive care under the PGD	<ul style="list-style-type: none"> • Refer to medical practitioner that clinical session or when next available in clinic. • As there may be occasions when a medical practitioner is not physically present within the department, discuss by telephone where possible with medical practitioner first, defer treatment until after this discussion is possible for patients not wishing to receive care under the PGD.

DESCRIPTION OF TREATMENT			
Name of Medicine	Doxycycline		
Legal Classification	Prescription only medicine (POM)		
Licensing information			
	Is the medicine licensed for the intended use?	YES	
	Does it have a black triangle status?		NO
	Does it have a Risk Minimisation Measures (RMM) recommendation		NO
Form	Capsules		
Strength	100mg		
Dose	100mg twice daily		
Frequency	12 hours apart		
Route	Oral		
Total Treatment Quantity	Total of 14x 100mg capsules with product/patient information leaflet (7 day course)		
Interactions with other medicines (This must include all potentially serious interactions listed in the BNF)	See Appendix 1 in British National Formulary (BNF) under tetracyclines <ul style="list-style-type: none"> • Warfarin and other oral anticoagulants (enhanced anticoagulant effect) • Retinoids (e.g. acitretin/isotretinoin -avoid concomitant use, risk of benign intracranial hypertension) • Methotrexate(may result in an increased risk of methotrexate toxicity) If in doubt, contact Medicines Information for advice tel 5960		
Adverse Reactions	<ul style="list-style-type: none"> • Sudden breathlessness, wheezing, swelling, rash or 	Treatment of adverse reactions – SEEK URGENT MEDICAL ADVICE	





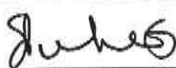
	<p>itching</p> <p>Nausea, dyspepsia, abdominal discomfort, diarrhoea</p> <p>Vomiting within 2 hours of taking doxycycline on more than one occasion</p> <p>Photosensitivity</p>	<ul style="list-style-type: none"> • Advise take tablets with or immediately after food, with plenty of fluid, while sitting or standing • Discontinue drug if gastrointestinal side effects are severe and return for assessment to sexual health or NHS walk-in, GP or A & E depending upon severity. • Seek advice from sexual health services as absorption may have been inadequate • Advise to apply sun screen liberally, wear protective headwear and clothing and to avoid exposure of skin to direct sunlight, sunlamps – stop treatment/see doctor if skin problems arise
<p>Advice to Patients: Written and Oral advice (This should include the provision of a</p>	<ul style="list-style-type: none"> • Information regarding PID and/or epididymo-orchitis for asymptomatic sexual contacts thereof • Information regarding aetiology of chlamydia/NGU, transmission, and implications for partial/non- 	

<p>patient information leaflet)</p>	<p>treatment; with supporting leaflet and/or principles of epidemiological treatment for sexual contacts being treated.</p> <ul style="list-style-type: none"> • Information regarding treatment concordance and side effects; supported by patient information leaflet (PIL) • Swallow capsules whole with plenty of fluids with or after a meal emphasizing risk of possible GI disturbance • Do not take at same time as antacid preparations, need to be taken 2 to 3 hours apart • Do not take at same time as preparations containing aluminium, calcium, magnesium, zinc or antacids– take 2 to 3 hours apart • Avoid direct exposure of skin to direct sunlight or sun lamps • Take at regular intervals and complete the full prescribed course • Advice regarding avoiding any form of sexual contact until self and partner/s is also fully treated, to avoid risk of reinfection. Abstinence needs to extend until 7 days after both self and sexual partner/s are fully treated • Discussion regarding safer sex in general for future sexual health • Partner notification will be undertaken in line with national recommendations
<p>Follow up action</p>	<p>Telephone compliance check in 7-10 days if required, whereby patient may be discharged by telephone if they have been fully compliant and concordant, a follow-up return visit only required if:</p> <ul style="list-style-type: none"> ○ Persistent or new symptoms are established during the telephone compliance discussion ○ Non-concordance with treatment is established during the telephone compliance discussion ○ A risk of re-infection is established during the telephone compliance discussion
<p>Storage</p>	<ul style="list-style-type: none"> • locked medicines cupboard – store below 25 °C • Locked briefcase for outreach use

Records to be Kept	<p>Document the following in the patients notes:</p> <ul style="list-style-type: none"> • Any reason for exclusion, including action taken • If the patient has refused treatment under the PGD, any advice given or cautions taken • That the drug had been administered under a PGD • Date and time of administration • Name, form, strength and dose of drug administered • Route of administration • Time of administration if appropriate • Advice given to patients • Signature of staff administering/supplying medicine • Details of any adverse drug reactions or side effects • Form of documentation (patients casenotes, letters etc) • Any communication with other health care professionals • If a postal treatment, record in the patient records this was sent as per postal treatment pathway. • The outcome of the compliance discussion needs to be recorded in full in the patient's notes • If the patient is pregnant her treatment must be documented in her maternity (green) notes or her GP written to. <p>The record must be signed by the nurse responsible for the administration/supply.</p>
Audit Arrangements	As per current Trust PGD Policy
References	<p>National guidelines for the management of chlamydia trachomatis genital tract infection, (2015-updated September 2018), British Association for Sexual Health and HIV, www.bashh.org</p> <p>National guidelines for the management of non-gonococcal urethritis, 2015-updated May 2017, British Association for Sexual Health and HIV, www.bashh.org</p> <p>National guidelines for the management of pelvic</p>

	<p>inflammatory disease 2018, British Association for Sexual Health and HIV, www.bashh.org</p> <p>National guidelines for the management of epididymo-orchitis 2010 British Association for Sexual Health and HIV, www.bashh.org</p> <p>Nursing and Midwifery Council, The Code for nurses and midwives. March 2015 www.nmc.org.uk (refers to record keeping)</p> <p>The British National Formulary, www.bnf.org.uk</p>
<p>Competency Requirements (attach any competency frameworks / documents)</p>	<p>Completion of a local sexual health training programme for the administration of doxycycline under PGD within sexual health services. This will require/include:</p> <ul style="list-style-type: none"> • Clinical competence in sexual history taking • Competence in undertaking clinical examination/assessment and genital screening to enable the accurate diagnosis and treatment of chlamydia and NSU infection if required. • The ability to recognize which sexual contacts will require epidemiological treatment in line with national guidelines. • Knowledge base of the interactions of doxycycline with other drugs, and other exclusions and contra-indications for issuing doxycycline • Competence in the above will be demonstrated by the undertaking of a local clinical competency based training and assessment programme, evidenced by completion of theoretical study including e-learning and clinical experience within sexual health. • Assessment will be undertaken by the Lead Sexual Health nurse or designated PGD assessor, who will both be fully competent and either practising as an independent prescriber themselves, or practicing in accordance with this PGD. • Receiving Clinical Supervision and/or audit of case notes on an ongoing basis • Commitment to continuing professional development identified through Clinical Supervision and appraisal

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| | <ul style="list-style-type: none"> • Evidence of continuing professional development in sexual health. • 5 study days or the equivalent in hours, of study related to the field of sexual health; every 3 years. • Regular attendance and participation in the Tri-annual educational clinical governance sessions. • Maintain professional accountability with the Nursing and Midwifery Council (NMC) and ensure continuing professional development. • Attendance at trust/clinic PGD awareness session • educational clinical governance • Maintain professional accountability with the Nursing and Midwifery Council (NMC) and ensure continuing professional development. • Attendance at Trust/clinic PGD awareness session or Trust HUB e-learning |
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AUTHORISATION OF THE PATIENT GROUP DIRECTION (PGD) FOR THE SUPPLY OF: Doxycycline			
PGD Development / Review Team – responsible for PGD content			
Title	Name	Signature	Date
Lead Author	Arden Cromm		10.7.18
Clinical Director Lead Approval	Jan Farley		1/8/18
Directorate Pharmacy Lead Approval	Dul Jackson		21/8/18
PGD Approved by the NMP/PGD Group			
Title	Name	Signature	Date
NMP Lead / Lead Nurse Medicines Management	Jennie Booth		24.08.2018
Chief Pharmacist / Deputy Chief Pharmacist	Stuart Parkes		24/8/18.
Authorisation to work within the PGD This patient group direction must be agreed to and signed by all health care professionals involved in its use. The PGD must be easily accessible in the clinical setting.			
Notes to the NMP/PGD Authorising staff <ul style="list-style-type: none"> Do not proceed unless this document carries the signatures of the development / review team (Lead Author, Lead Clinical Director and Directorate Lead Pharmacy) You are responsible for fulfilling the legal requirement that a senior person from the profession ensures that only fully competent, qualified and trained professionals operate under this PGD Using a PGD is not a form of prescribing 			

Staff authorised to work under this PGD				
Ward / Department		Sexual health		
Professionals to whom this Patient Group Direction applies		Qualified nurses who work within sexual health and have completed the agreed training programme		
<p><i>I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct when working for this Trust:</i></p>				
Name (Capitals)	Sign	Job Title	Authorising Manager	Date

When the review date is exceeded, this PGD ceases to be a legal document

TEMPLATE DOCUMENTATION CONTROL

The template documentation control refers to the PGD template not the completed PGD.
Do not alter this section.

Author:	Jennie Booth, Lead Nurse Medicines Management Carol Belt, Principal Pharmacy Technician Stuart Parkes, Deputy Chief Pharmacist
Owner:	NMP/PGD Group
Date of issue:	February 2018
Version:	3
Approved by	NMP/PGD Group
Review date:	February 2021