

<b>Document Title:</b>	<b>Patient Group Direction for Doxycycline for the treatment of uncomplicated genital chlamydia trachomatis infection.</b>		
<b>PCT Doc Ref.:</b>		<b>Version No.:</b> 7/2015	
<b>Local Doc Ref.:</b>	PGD		
<b>Author/Owner:</b>	Jacqui Seaton, Head of Medicines Management		
<b>File Reference:</b>	C:\My Documents\Approved PGDs		
<b>Document Overseeing Group:</b>	Medicines Management		
<b>Placement in Framework:</b>			
<b>Approval Level:</b>			
<b>Date of Approval:</b>	June 2015		
<b>Review Date:</b>	December 2018		
<b>Amendment Dates:</b>	<b>Page(s)</b>	<b>Brief Description</b>	
February 2013		Amended review date	
March 2013		Approved for use by NHS T&W Clinical Commissioning Group	
November 2014		Amended review date	
June 2015		Amended review date – No changes made	
June 2018		Amended review date – no changes made	

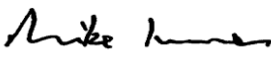

**NB: Always access the electronic version of this PGD to ensure that you are using the most up to date version.**

**The practitioner MUST be authorised by name, under the current version of this PGD before working according to it.**

**Patient Group Direction for Doxycycline for the treatment of uncomplicated genital Chlamydia trachomatis infection.**

**Doxycycline will only be considered as an option for the treatment of uncomplicated genital chlamydia trachomatis infection for clients that have an allergy to Azithromycin.**

**Approved By**

NHS Telford and Wrekin	Name	Signature
CCG Chairman	Mike Innes	
Head of Medicines Management	Jacqui Seaton	

Date of patient group direction approved	June 2015
Date this patient group direction becomes due for review	December 2018

PGD Developed by

Title	Name
Pharmaceutical Adviser	Hitesh Patel

## STAFF CHARACTERISTICS

- Registered nurse with current NMC registration or Registered Pharmacist with current GPhC registration.

### **Specialist competencies or qualifications:**

- The service lead / lead GP has evidence that the health care professional has undertaken training as outlined in the service agreement to carry out clinical assessment of patient leading to confirmation that the patient requires treatment according to the indications listed in the PGD.
- The health care professional must provide evidence of training, appropriate annual updates and continued professional development undertaken to support their competence for administration of this treatment.
- The service lead / lead GP has proof of training by the health care professional on the legal aspects of supply or administration of medicines under a Patient Group Direction
- The service lead / lead GP has assessed the competency (against the organisational competency framework) of the healthcare professional to work to a Patient Group Direction at least every 2 years.
- Must have access to all relevant sources of information e.g. information issued by the Department of Health (DH), British National Formulary (BNF), Summary of Product Characteristics (SPC), and the clinical guideline concerning medicine(s) within this Patient Group Direction (PGD).
- The practitioner needs to re - enforce and update their knowledge and skills in this area of practice with particular reference to changes and national directives
- The registered health care practitioner is professionally accountable for supply or administration under the PGD as defined in their own profession's Code of Professional Conduct and Ethics.

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

**PGDs DO NOT REMOVE INHERANT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY**

**Doxycycline PGD administration form should be used to support supply of treatment against this PGD**

<b>CLINICAL CONDITION</b>	
<b>Clinical need addressed</b>	<ul style="list-style-type: none"> <li>Men and women with confirmed uncomplicated genital Chlamydia trachomatis infection.</li> <li>Sexual contacts of men/women where Chlamydia trachomatis diagnosis made in the index case.</li> </ul> <p>(All sexual contacts must be offered a Chlamydia screen at the point of treatment)</p>
<b>Inclusion criteria</b>	<ul style="list-style-type: none"> <li>The client's medical history supports the clinical indication (confirmed uncomplicated genital Chlamydia trachomatis infection)</li> <li>The client understands and consents to treatment within the Patient Group Direction. (Clients under 16 years must be assessed as meeting Fraser criteria)</li> <li>Client understands that they may be contacted by a health adviser to discuss the need for any sexual partner to be tested / treated</li> </ul>
<b>Exclusion criteria</b> (for full details of interacting medicines refer to current Summary of Product Characteristics (SPC) <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> & BNF)	<p><b>Complicated chlamydial infection including:-</b></p> <ul style="list-style-type: none"> <li>Presence of urinary symptoms</li> <li>Presence of penile discharge in men</li> <li>Presence of vaginal discharge in women</li> <li>Intermenstrual bleeding or change in normal bleeding pattern in women</li> <li>Presence of pelvic pain in women / testicular pain in men</li> </ul> <p><b>Any of the following conditions:-</b></p> <ul style="list-style-type: none"> <li>Presence of concomitant conjunctivitis / joint pains</li> <li>Known hepatic impairment</li> <li>Known porphyria</li> <li>Known myasthenia gravis</li> <li>Known Systemic Lupus Erythematosus.</li> <li>Known HIV infection</li> <li>Recurrent chlamydial infection (Presenting within 3 months of previous treatment)</li> <li><b>Allergies</b></li> <li>Known allergy to doxycycline or tetracycline's</li> </ul> <p><b>Interacting medication</b></p> <p>Patient taking any drug listed in BNF Appendix 1 (interactions with tetracyclines)</p> <p>Clients taking the following medication are excluded from the PGD:</p> <ul style="list-style-type: none"> <li>Antacids</li> <li>Aluminium, calcium, iron, magnesium or zinc salts</li> <li>ACE inhibitors</li> <li>Quinapril</li> <li>Warfarin</li> <li>Antiepileptics</li> </ul>

	<ul style="list-style-type: none"> <li>• Atovaquone</li> <li>• Ciclosporin</li> <li>• Ergotamine</li> <li>• Retinoids</li> <li>• Tripotassium dicitratobismuthate</li> <li>• Sulcralfate</li> </ul> <ul style="list-style-type: none"> <li>• Known or suspected pregnancy</li> <li>• Breast feeding</li> <li>• Client under 16 years who is felt not to meet Fraser criteria</li> </ul>
<b>Caution / need for further advice</b>	
<b>Management of excluded patients</b>	<ul style="list-style-type: none"> <li>• Refer all clients with above contra-indications to the GUM clinic (or their GP) as soon as possible.</li> <li>• Discuss with client reasons for exclusion and document</li> </ul>
<b>Action for patients not wishing to receive care under this PGD</b>	<ul style="list-style-type: none"> <li>• Give client opportunity to discuss non-concordance.</li> <li>• Refer to client's own GP or GUM clinic.</li> <li>• Ensure client is aware of implications of not having treatment</li> </ul>

Treatment and Drug details	
<b>Name form and strength of medicine</b>	Doxycycline capsule 100mg BD for 7 days.
<b>Legal classification</b>	<ul style="list-style-type: none"> <li>• POM – Prescription only medicine.</li> </ul>
<b>Black triangle warning</b> Suspected adverse reactions. Should be reported using the Yellow Card reporting scheme ( <a href="http://www.yellowcard.gov.uk">www.yellowcard.gov.uk</a> ).	<ul style="list-style-type: none"> <li>• No</li> </ul>
<b>Method of obtaining supply</b>	<ul style="list-style-type: none"> <li>• Licensed supplier</li> <li>• Community Pharmacies</li> </ul>
<b>Site for treatment</b>	Accredited Community Pharmacies GP Practice's
<b>Route / method</b>	Oral
<b>Dose</b>	100mg twice daily for 7 days
<b>Number of times treatment may be administered</b>	<ul style="list-style-type: none"> <li>• Once only, in any three month period.</li> <li>• Clients presenting within three months from previous treatment should be referred to GUM.</li> </ul>
<b>Quantity to be supplied or administered</b>	14 x 100mg Capsules
<b>Side effects</b> <i>Full details of side effects are available in the SPC.</i> <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> <i>Suspected adverse reactions to drugs including vaccines should be reported on the yellow card</i>	Refer to GP where patient is unable to complete antibacterial due to adverse effects  <b>Common side effects include :</b> nausea; vomiting; diarrhoea; dysphagia and oesophageal irritation

<p>available at the back of the BNF. Also at <a href="http://www.yellowcard.gov.uk">www.yellowcard.gov.uk</a></p>	<p><b>Rare side effects include:</b> hepatotoxicity, pancreatitis, blood disorders, photosensitivity, rash and intracranial hypertension.</p>
<p><b>Labelling Requirements</b></p>	<ul style="list-style-type: none"> <li>• Medication should be issued directly to client</li> <li>• Pack must be individually labelled</li> <li>• Labels must have the following information. <ul style="list-style-type: none"> <li>➤ Client name</li> <li>➤ Date of supply</li> <li>➤ Full details of medication supplied</li> <li>➤ Quantity</li> <li>➤ Directions for use</li> <li>➤ Address of Pharmacy / clinic</li> <li>➤ Contact details Pharmacy / clinic</li> <li>➤ The words 'keep out of children's reach' or words of similar meaning.</li> </ul> </li> </ul>
<p><b>Advice to patient / carer</b></p>	<ul style="list-style-type: none"> <li>• Capsules should be swallowed whole with plenty of fluids during meals whilst sitting or standing.</li> <li>• Avoid exposure to sunlight or sunlamps.</li> <li>• Warn of risk of gastro intestinal upset and skin rashes.</li> <li>• Give leaflet on condom use and safer sex and Chlamydia</li> <li>• Client should be advised that they will be contacted by a health advisor for partner notification.</li> <li>• Client should be advised to abstain from unprotected sex (vaginal/anal/oral and genital contact) during treatment and should to continue to refrain from unprotected sex until partner has completed treatment.</li> </ul>
<p><b>Follow up</b></p>	<ul style="list-style-type: none"> <li>• No follow up required unless reaction to medication in which case the patient should be referred to the GP</li> <li>• If symptoms persist the patient should be reviewed by a doctor/senior nurse in 2 weeks.</li> </ul>
<p><b>Suspected Adverse reactions</b></p>	<ul style="list-style-type: none"> <li>• Patient presenting with suspected adverse drug reaction should be referred to a doctor for further investigations.</li> <li>• All adverse reactions should be reported to the MHRA, using the yellow ADR card system available in the BNF. <a href="http://www.yellowcard.mhra.gov.uk">www.yellowcard.mhra.gov.uk</a></li> </ul>
<p><b>Error reporting</b></p>	<ul style="list-style-type: none"> <li>• Any incidents or near miss issues must be reported via the organisation's internal reporting system.</li> </ul>

<p><b>RECORD KEEPING</b></p>	
<p><b>Documentation needed / treatment records to be kept for audit purposes</b></p> <p><i>A computer or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes.</i></p>	<ul style="list-style-type: none"> <li>• Patient's name, address, date of birth</li> <li>• Manufacturer / brand of product, batch number, expiry date</li> <li>• Record of informed consent</li> <li>• Date of supply</li> <li>• Quantity supplied</li> <li>• Advice given to client</li> <li>• Details of staff who supplied (sign and print name)</li> <li>• Details of any adverse drug reactions, and action taken</li> <li>• Reconciliation – stock balances should be reconcilable with receipts, administration, records and disposal on a patient by patient basis.</li> </ul>

## REFERENCES

	BNF Current Edition
	SIGN Guidance Management of genital Chlamydia trachomatis infection. 2000
	National Chlamydia Screening Programme for England – core requirements 3 edition 2006 DH
	Doxycycline Product SPC <a href="http://www.medicines.org.uk">www.medicines.org.uk</a>
	BASHH Clinical Effectiveness Group (2010). Standards for the management of sexually transmitted infections. <a href="http://www.bashh.org/about/bashh_publications">http://www.bashh.org/about/bashh_publications</a>

## Register of practitioners qualified to administer and / or supply

### Doxycycline under this Patient Group Direction

Name of clinical manager / GP Lead	
Signature of clinical manager / GP Lead	Date:
A copy of this page should be retained by the authorising manager for 25 years for audit purposes	
Please state clinical area where this PGD is in use	

#### Healthcare professional individual declaration

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

- **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.
- All practitioners operating in accordance with this PGD should have a current, signed copy of it readily available for reference.
- If a practitioner is asked to supply, or administer a medicine not covered by this or any other PGD then a patient specific direction is required from a doctor, dentist or independent prescriber.

Name of professional (please print)	Signature	Authorising Manager (must sign against each entry)	Date of authorisation

**Healthcare professionals working under a PGD must have received appropriate training and been assessed as competent to administer/supply the medicine referred to in the PGD. The clinical lead should review competency of authorised practitioner/s at least annually. Training certificates must be available for inspection.**

**Authorisation to use this PGD does not remove inherent professional responsibility and accountability**

**A copy of this authorisation form must be printed off, signed and dated by the healthcare professional authorised to use this PGD. This should be retained by the service provider (e.g. GP practice) and readily available for inspection (e.g. CQC).**



## Appendix 1

### **The Fraser Guidelines (in the context of treatment for STI)**

- The young person understands the advice and has sufficient maturity to understand what is involved.
- That the doctor/nurse could not persuade the young person to inform their parents, nor allow the doctor/nurse to inform them.
- That the young person would be very likely to begin or continue having sexual intercourse with or without treatment for the infection.
- That without treatment, the young person's physical or mental health would suffer.
- That it would be in the young person's best interest to give such advice or treatment without parental consent.
- Under 16s have a right to confidentiality whether asking for advice on STIs or any medical treatment.

(Adapted from the Family Planning Association Fact-sheet No 12, 1997)