

**CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR
ASYMPTOMATIC CHLAMYDIA TRACHOMATIS INFECTION
Doxycycline 100mg capsules**

Version Control

This document is only valid on the day it was printed




The current version of this document can be found on Pharmoutcomes and the LPC website
<http://www.southstaffslpc.co.uk/services/emergency-hormonal-contraception/>

Revision History

Version	Date	Author	Change description
1.0 / 2022	Feb 2022	Andrew Pickard	New PGD

Authorisation

This document requires authorisation by the following individuals:

Management			
PGD Author	Andrew Pickard, Pharmacy Advisor - NHS England & Improvement Midlands (Staffordshire and Shropshire)		
Authorisation			
Name and Designation	Organisation	Signature	Date
Richard Harling – Lead Doctor	Staffordshire County Council		30/03/2022
Dr Arabinda Kundu – Consultant/Clinical Director in Sexual Health	Midlands Partnership Foundation Trust		15/03/2022
Andrew Pickard - Pharmacy Advisor	NHS England & Improvement Midlands		07/03/22

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.

Staff Characteristics	
1. Professional qualifications to be held by staff undertaking PGD	<ul style="list-style-type: none"> Community pharmacists authorised by Central Health Solutions under contract to Staffordshire County Council to provide a Chlamydia Treatment Service as per the Service Specification.
2. Competencies required to be held by staff undertaking this PGD	<ul style="list-style-type: none"> Has a clear understanding of the legal requirements to operate a PGD Overview Patient group directions Guidance NICE Competent to follow and administer PGD showing clear understanding of indications for treatment (and subsequent actions to be taken), and the treatment itself. Has a clear understanding of the drug to be administered including side effects and contraindications. All clinicians operating within the PGD have a personal responsibility to ensure their on-going competency by continually updating their knowledge and skills.
3. Specialist qualifications, training, experience and competence considered relevant to the clinical condition treated under this PGD	<ul style="list-style-type: none"> The community pharmacist must be registered with the General Pharmaceutical Council. Completion of the current CPPE training packages on Sexual Health in Pharmacies Sexual health in pharmacies : CPPE and Safeguarding Vulnerable Adults and Children Safeguarding children and adults at risk: a guide for the pharmacy team : CPPE Completion of the CPPE learning pack – Combating CSE: An e-learning resource for healthcare professionals is required Combating CSE - An e-learning resource for healthcare professionals: CPPE Attendance at a local training event(s) approved by Staffordshire County Council is recommended where these are organised, but this is not a prerequisite for delivering this service.

**CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR ASYMPTOMATIC
CHLAMYDIA TRACHOMATIS INFECTION
Doxycycline 100mg capsules**

Clinical Details	
Indication	Asymptomatic genital chlamydia trachomatis infection and sexual contacts of confirmed chlamydia trachomatis infection. The use of doxycycline is considered first line treatment for asymptomatic chlamydia infection.
Aims	To reduce the risks of short and longer term complications associated with chlamydia infection such as pelvic inflammatory disease and tubal infertility.
Inclusion Criteria	<ul style="list-style-type: none"> • Informed consent is given • Individuals aged 15 years and over who have a positive genital chlamydial result following screening, and when azithromycin cannot be used. • Sexual contacts of individuals aged 15 years and over with a positive genital chlamydial result, and when azithromycin cannot be used. • Retreatment in case of possible reinfection if intercourse has taken place within the recommended 7 days of abstinence during treatment.
Exclusion Criteria	<p>Women</p> <ul style="list-style-type: none"> • Pregnant/suspected pregnancy/breastfeeding • Suspected pelvic inflammatory disease • Pelvic pain which has recent onset • Symptoms suggestive of other STIs such as unusual vaginal discharge <p>Men</p> <ul style="list-style-type: none"> • Known or suspected proctitis/prostatitis • New or unusual testicular pain • Urethritis • Symptoms suggestive of other STIs such as penile discharge <p>Women and Men</p> <ul style="list-style-type: none"> • Informed consent not given • Individuals under 15 years of age • Known or suspected hypersensitivity to doxycycline or other tetracycline antibiotics, or to any of the excipients • Moderate to severe impaired liver function • Previous history of porphyria • Myasthenia gravis or systemic lupus erythematosus • Known or suspected sero-reactive arthritis • Known or suspected conjunctivitis • Sucrose intolerance such as glucose galactose malabsorption • Clinically significant interaction(s) with other medication <p>Please refer to current BNF https://bnf.nice.org.uk/ and SPC for full details https://www.medicines.org.uk/emc/</p>

<p>Supply to young persons</p>	<p>If a young person (aged <16 years) requests treatment for chlamydia, then they must be assessed for competency. If they are deemed as being 'Fraser Competent' then a supply can be made, but this must be documented in the records.</p> <p>If the young person is not deemed to be 'Fraser Competent' advice must be sought from First Response Team on: 0800 1313126 (or the Emergency Duty Team on 0345 6042886 outside of office hours). Practitioners should discuss with First Response the remaining need for the child to have treatment for chlamydia.</p> <p>Further guidance can be found at: Gillick competence and Fraser guidelines NSPCC Learning</p> <p>Pharmacists must be aware of, and comply with the relevant safeguarding expectations from Staffordshire Safeguarding Board regarding sexual activity in young people: Safeguarding Practice Guidance - Staffordshire Safeguarding Children Board (staffsscb.org.uk)</p> <p>If a child under 13 years requests treatment for chlamydia, and there is a reasonable concern that sexual activity has taken place, the pharmacist should always contact the First Response team on 0800 1313 126 (or the Emergency Duty Team on 0345 6042886 outside of office hours) and there must always be a presumption that the case will be referred to the Children's Social Care Services in the area where the child lives. A record of the referral should be maintained in the pharmacy.</p> <p>If you think the child or young person is in immediate danger telephone 999</p>
<p>Management of excluded individuals</p>	<ul style="list-style-type: none"> • Explain reason for exclusion with the individual and document in patient records and/or PharmOutcomes • Refer to Sexual Health Clinic or the individuals GP
<p>Management of individuals requiring referral</p>	<ul style="list-style-type: none"> • Female with pelvic pain, consider immediate referral to Sexual Health Clinic. If pain severe, refer to local A&E department • Symptoms suggestive of other STI – consider immediate referral to Sexual Health Clinic • Male with scrotal pain, consider immediate referral to local A&E department • If vomiting occurs within 3 hours of taking initial dose, refer to Sexual Health Clinic or GP for re-evaluation. • Document referral details in patient records and/or PharmOutcomes

Treatment and Drug Details	
Name, form & strength of medicine	Doxycycline 100mg capsules
Legal classification	Prescription Only Medicine (POM)
Storage	Store below 25°C
Route/method	Oral
Dosage/frequency/duration of treatment	<p>Doxycycline 100mg capsules twice daily for 7 days.</p> <p>The capsules should be swallowed with plenty of fluid in either the resting or standing position and well before going to bed for the night to reduce the likelihood of oesophageal irritation and ulceration.</p> <p>A second course of treatment may be offered in the case of possible re-infection if the client has not abstained from sexual intercourse during the 7 days of treatment.</p>
Quantity to supply/administer	14 capsules
Labelling requirements	As the individual will be taking the medication away with them in order to complete the course, it must be supplied to them with the same labelling and other information which they would otherwise receive if the medicine had been supplied against a prescription. The wording 'Supplied via PGD' should also be added to the label.
Cautions	<ul style="list-style-type: none"> • May cause skin sensitivity to sunlight, therefore avoid direct exposure to sunlight and ultra-violet light. Doxycycline should be discontinued immediately and appropriate therapy instituted if serious skin reactions occur • Blurred vision may occur with doxycycline, so clients should avoid driving or operating machinery if they experience this side effect. • <i>Benign intracranial hypertension</i> has been associated with the use of tetracyclines including doxycycline. This is usually transient, however cases of permanent visual loss secondary to benign intracranial hypertension have been reported with tetracyclines including doxycycline. If visual disturbance occurs during treatment, prompt ophthalmologic evaluation is warranted. • <i>Clostridium difficile</i>-associated diarrhoea (CDAD) has been reported with use of nearly all antibacterial agents including doxycycline, and may range in severity from mild diarrhoea to fatal colitis. CDAD must be considered in all individuals who present with diarrhoea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents • <i>Pseudomembranous colitis</i> has been reported with nearly all antibacterial agents, including doxycycline, and has ranged in severity from mild to life-threatening. It is important to consider this diagnosis in individuals

	<p>who present with diarrhoea subsequent to the administration of antibacterial agents.</p>
<p>Side effects/Adverse Reactions</p>	<ul style="list-style-type: none"> • Gastrointestinal adverse effects, such as nausea, vomiting, and diarrhoea. • Less frequently, doxycycline may cause photosensitivity. • Tinnitus <p>If an individual taking doxycycline develops headache and visual disturbance, the drug should be stopped immediately, and they should be referred for prompt ophthalmologic evaluation.</p> <p>Please refer to current BNF http://bnf.org/bnf and SPC www.medicines.org.uk/emc for full details</p> <p>All serious adverse reactions must be reported to MHRA via the Yellow Card System www.yellowcard.mhra.gov.uk . An individual presenting with a suspected serious ADR should be referred to their GP.</p>
<p>Drug interactions</p>	<ul style="list-style-type: none"> • Phenobarbital, carbamazepine, phenytoin, and primidone — metabolism of doxycycline may be accelerated by these drugs, leading to a reduced plasma concentration. • Rifampicin — may cause a reduction in doxycycline levels, leading to undertreatment. • Antacids, oral zinc, iron salts or bismuth preparations — can reduce the absorption of tetracyclines. Dosages should be maximally separated • Penicillin – bactericidal action may be impaired so avoid giving doxycycline alongside penicillin • Methoxyflurane – reports of fatal renal toxicity • Retinoids – increased risk of benign intracranial hypertension • Cyclosporin - doxycycline may increase the plasma concentration of ciclosporin. Co-administration should only be undertaken with appropriate monitoring • Methotrexate - doxycycline increases the risk of methotrexate toxicity; prescribe with caution to patients on methotrexate. <p>Please refer to current BNF http://bnf.org/bnf and SPC www.medicines.org.uk/emc for full details</p>
<p>Advice/follow up treatment</p>	<ul style="list-style-type: none"> • Take and read patient information leaflet. • Take dose at regular intervals, twice daily for 7 days and complete the course. • The capsules should be swallowed with plenty of fluid in either the resting or standing position and well before going to bed for the night to reduce the likelihood of

	<p>oesophageal irritation and ulceration.</p> <ul style="list-style-type: none"> • Avoid antacids, and zinc or iron supplements for at least 2 hours before and after treatment. • Avoid strong sunlight or sunbeds during treatment, and stop medication if erythema occurs. • Individual and/or partner to abstain completely from sexual contact (even with a condom) during the 7 days of treatment. • If the individual is taking oral contraception or using contraceptive patches; <ul style="list-style-type: none"> ○ advise to continue to take contraceptive as usual ○ additional contraceptive precautions should be taken for 7 days after completion of course ○ if these 7 days run beyond the end of a packet, the next packet should be started immediately without a break/ or the next patch used. In the case of ED tablets, the inactive ones should be omitted, and a new pack started. • Discuss implications of incomplete treatment of individual or partner • Advise on common side effects and management, including if vomiting occurs within 3 hours of initial dose • All individuals with confirmed chlamydia infection should be encouraged to be screened for other sexually transmitted infections. • All individuals with confirmed chlamydia infection should be advised to contact their local sexual health clinic for partner notification purposes. • Individuals should be advised to attend for STI screening at a GUM clinic at least one week after completion of treatment • Provide contact details for sexual health clinic.
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<p>Supply</p>	<p>Individuals should be provided with the patient information leaflet and local guide to the Sexual Health Clinic.</p> <p>Sexual Health Clinics in Staffordshire are run by Midlands Partnership NHS Foundation Trust (MPFT)</p> <p>To find out opening times in north Staffordshire (districts of Newcastle under Lyme and Staffordshire Moorlands) Telephone: 0300 7900 165</p> <p>To find out opening times in southern Staffordshire (districts of Cannock, East Staffordshire, Lichfield, South Staffordshire, Stafford and Tamworth) Telephone 0300 124 5022</p> <p>Alternatively, opening times for MPFT clinics across Staffordshire can be found here: Home - Open Clinic</p> <p>All individuals, whether supplied with treatment or not should be given the local guide to Sexual Health Services.</p>
<p>Records/audit trail</p>	<ul style="list-style-type: none"> • In discussion with the individual enter consultation details onto the relevant module within PharmOutcomes or complete the paper proforma if unable to access PharmOutcomes at the time of the consultation. • Informed verbal consent should be obtained (for individuals aged under 16 years, Fraser guidelines should be followed) • Electronic patient records and/or the completed paper proforma should be retained for adults for a period of 10 years after attendance and for children until the child is 25 years old. Computerised patient medication records are recommended to be kept. • If the individual is excluded, a record of the reason for exclusion must be documented within PharmOutcomes, and any specific advice that has been given. • If a safeguarding referral is made, a record of the referral must be maintained in the pharmacy
<p>Adverse drug reactions</p>	<p>All serious adverse reactions must be reported to MHRA via the Yellow Card System www.yellowcard.mhra.gov.uk . An individual presenting with a suspected serious ADR should be referred to their GP.</p>
<p>Date last reviewed: February 2022</p>	<p>Date for next review: February 2024</p>
<p>Expiry date: 31st March 2024</p>	<p>Version No: 1.0 / 2022</p>

References	<p>Electronic Medicines Compendium - Home - electronic medicines compendium (emc)</p> <p>Electronic BNF - BNF British National Formulary - NICE</p> <p>BASHH - 2015 UK national guideline for the management of infection with <i>Chlamydia trachomatis</i> https://www.bashhguidelines.org/current-guidelines/urethritis-and-cervicitis/chlamydia-2015/</p> <p>CKS – Chlamydia (uncomplicated genital) 2021 https://cks.nice.org.uk/topics/chlamydia-uncomplicated-genital/</p>
Glossary	<p>BNF – British National Formulary</p> <p>SPC – Summary of Product Characteristics</p> <p>PIL – Patient Information Leaflet</p> <p>PGD – Patient Group Direction</p> <p>CKS – Clinical Knowledge Summaries</p> <p>BASHH – British Association for Sexual Health and HIV</p>

Operation of this PGD is the responsibility of the commissioner and service providers.

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

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Contractors who are commissioned to provide the service will be notified of any amendments, and provided with updated documentation for use by individual practitioners.

Central Health Solutions under contract to Staffordshire County Council authorise this PGD for use by accredited Community Pharmacists delivering the service from community pharmacies that meet the requirements as outlined in the service specification and that have been commissioned by Central Health Solutions.

This page must be completed and retained by each individual Pharmacist who intends to work in accordance with this PGD.

Professional Responsibility and Declaration

- I have successfully completed the relevant training as outlined in the Service Specification and this Patient Group Direction
- I agree to maintain my clinical knowledge appropriate to my practice in order to maintain competence to deliver this service
- I am a registered pharmacist with the General Pharmaceutical Council
- I confirm that indemnity insurance is in place to cover my scope of practice
- 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 of professional (please print)	Signature	Date of signing

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY