



## **PATIENT GROUP DIRECTION**

### **Doxycycline for the treatment of uncomplicated genital Chlamydia trachomatis infection**

For the supply of **Doxycycline on PGD** by **community pharmacists working in** Brighton and Hove and contracted to provide chlamydia treatment as part of the locally commissioned Sexual Health and Contraceptive service.

Direction no: BH 2018 10

Valid from: 1<sup>st</sup> January 2019

Supersedes: All previous Brighton and Hove PGDs for community pharmacist administration of Azithromycin for chlamydia treatment issued before January 2019

Review date: 1<sup>st</sup> June 2020

Expiry date: 31<sup>st</sup> December 2020

This Patient Group Direction (PGD) is to be read, agreed to and signed by all community pharmacists contracted to provide the service. The original copy, signed by all those concerned, should be kept in a designated place within the pharmacy, and be readily accessible for reference and audit purposes.

***Authorised for use in:***

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 the General Pharmaceutical Council (GPhC) Standards for Pharmacy Professionals and Pharmaceutical Society of Northern Ireland (PSNI) Code of Ethics for Pharmacists.

No PGD can envisage every clinical situation. Pharmacists are expected to exercise professional judgement and discretion. In any situation where there is concern a doctor must be consulted.

Individual practitioners must declare that they have read and understood the Patient Group Direction and agree to supply/administer medicines listed only in accordance with the PGD.

The most recent and in date final signed version of the PGD must be used.

The pharmacist must work within the service specification agreed between the employing pharmacy and the commissioning organisation.

User confirmation

Patient group direction effective from 1<sup>st</sup> October 2018

**PROFESSIONALS AUTHORISED TO SUPPLY UNDER THIS PGD**

This document applies only to community pharmacists accredited to supply doxycycline under PGD and who are working within the boundaries of **Brighton and Hove City Council**.

**DECLARATION:** I am a registered pharmacist, employed at

Name of Pharmacy	
Address	
Post Code	

**I have read this Patient Group Direction (PGD) and confirm that:-**

**Qualifications**

I am registered with the General Pharmaceutical Council (GPhC) or Pharmaceutical Society of Northern Ireland (PSNI)

**Specialist qualifications and competencies**

I am competent to provide the chlamydia treatment service as part of the sexual health and contraceptive service because

1. I have completed the **Emergency Contraception and Chlamydia Testing and Treatment Service** Declaration of and Competence (DoC) on the CPPE website. <https://www.cppe.ac.uk/services/declaration-of-competence>
2. I have completed the mandatory CPPE Safeguarding Children and Vulnerable Adults e-learning and passed the associated level 2 assessment
3. I have reviewed the local policies and documentation for this service and references associated with this PGD

**Maintenance of competencies**

I will ensure that I am aware of any changes to the recommendations for this medication and that it is my responsibility to keep up-to-date with continuing professional development and take part in audit on a regular basis.

Name	GPhC/PSNI registration number	Signature	Date

**Signature of Authorising Pharmacist or Pharmacy Manager**

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**Name of Authorising Pharmacist or Pharmacy Manager**

.....

**Practitioners not listed are not authorised to practice under this PGD.**

**1. Clinical conditions or situation to which the direction applies.**

<p><b>Indication</b></p>	<p>Treatment of uncomplicated genital Chlamydia trachomatis infection.</p>
<p><b>Criteria for inclusion</b></p>	<ul style="list-style-type: none"> <li>• Individual (or sexual contacts of individual) with a positive, asymptomatic diagnosis of genital chlamydia trachomatis infection evidenced by contact slip, text message or other written confirmation from the Chlamydia Screening Programme (CSP).</li> <li>• Individuals who have had sexual intercourse with an untreated partner within 7 days of receiving treatment</li> <li>• Individuals who did not complete the 7 day treatment course</li> <li>• The individual must be able to give informed consent to treatment.</li> <li>• If the individual is under 16 years old, they must be assessed as Fraser competent (see Appendix 1) or if not assessed as Fraser Competent accompanied by one or both parents, or a legal guardian and consents to the treatment being given.</li> <li>• If under 13 years of age, follow the local safeguarding children policy.</li> </ul>
<p><b>Criteria for exclusion</b></p>	<p><b>Personal Characteristics</b></p> <ul style="list-style-type: none"> <li>• Individuals aged under 16 years who are assessed as <b>not</b> competent using Fraser Guidelines</li> <li>• Individual is under 13 years old</li> <li>• Individual without capacity to consent</li> <li>• Individual wishes to see a doctor</li> </ul> <p><b>Medical History</b></p> <ul style="list-style-type: none"> <li>• Pregnancy</li> <li>• Breastfeeding</li> <li>• Severe hepatic impairment</li> <li>• Severe renal impairment</li> <li>• Presence of urinary symptoms</li> <li>• Presence of penile discharge, epididymitis or testicular pain in men</li> <li>• Presence of vaginal discharge in women</li> <li>• Presence of concomitant conjunctivitis and /or joint pain/swelling</li> <li>• Fever</li> <li>• Females with pelvic pain or suspected pelvic Inflammatory Disease (PID)</li> <li>• Porphyria</li> <li>• Myasthenia Gravis</li> <li>• Individual is being treated for HIV</li> <li>• Known Systemic Lupus Erythematosus</li> <li>• Individuals with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrase-isomaltase insufficiency should not take doxycycline.</li> </ul>

	<p><b>Medication History</b></p> <ul style="list-style-type: none"> <li>Known allergy or hypersensitivity to Doxycycline or other tetracycline antibiotics (refer to a current BNF for the full list) or any constituent of the medication refer to section 6.1 of the Summary of Product Characteristics (SPC)</li> </ul> <p><b>Interacting medicines-</b> Examples are included below.</p> <p><b>Check Appendix 1 of a current BNF or the SPC for Doxycycline section 4.5 for the full list.</b></p> <ul style="list-style-type: none"> <li>Phenobarbital, carbamazepine, primidone and phenytoin increase the metabolism of doxycycline</li> <li>Warfarin. There have been reports of prolonged prothrombin time in patients taking warfarin and doxycycline.</li> <li>Methoxyflurane. The concurrent use of tetracyclines and methoxyflurane has been reported to result in fatal renal toxicity. See section 4.5 of SPC</li> <li>Ciclosporin. Doxycycline may increase plasma concentrations.</li> <li>Methotrexate. Increased risk of methotrexate toxicity</li> <li>Retinoids, concomitant use should be avoided</li> </ul>
<p><b>CAUTIONS:</b> Need for further advice or action to be taken</p>	<ul style="list-style-type: none"> <li>The use of drugs of the tetracycline class during tooth development (pregnancy, infancy and childhood to the age of 12 years) may cause permanent discolouration of the teeth (yellow-grey-brown). See section 4.3 of SPC for further information.</li> <li>Doxycycline is contra-indicated in <b>pregnancy</b>. The risks associated with the use of tetracyclines during pregnancy are predominantly due to effects on teeth and skeletal development.</li> <li>Tetracyclines are excreted into milk and are therefore contra-indicated in nursing mothers. (See above about use during tooth development).</li> <li>Patients likely to be exposed to direct sunlight or ultraviolet light should be advised that a photosensitivity reaction can occur with tetracycline drugs.</li> </ul>
<p><b>Action if excluded</b></p>	<ul style="list-style-type: none"> <li>Signpost/refer to Sexual Health and Contraception (SHAC) service or GP as soon as possible with information about further options. Link to SHAC website <a href="http://brightonsexualhealth.com">http://brightonsexualhealth.com</a></li> <li>If complicated Chlamydia infection suspected refer to Sexual Health and Contraception (SHAC) service.</li> <li>Discuss with the individual the reasons for exclusion and document.</li> <li>A Best Interest assessment should be undertaken by an authorised prescribing practitioner for individuals who lack capacity to consent. <a href="http://www.legislation.gov.uk/ukpga/2005/9/contents">http://www.legislation.gov.uk/ukpga/2005/9/contents</a></li> <li>If child is &lt; 13 years follow the Local Safeguarding children policy. <a href="http://www.brightonandhovelscb.org.uk/">http://www.brightonandhovelscb.org.uk/</a></li> <li>Safeguarding concerns (for children aged 13 to 18) identified at presentation should be referred to the Local Safeguarding Children Board.</li> </ul>

	<ul style="list-style-type: none"> <li>Follow local safe guarding arrangements for vulnerable adults when appropriate. <a href="https://www.brighton-hove.gov.uk/content/social-care/keeping-people-safe/help-adults-risk-abuse-or-neglect">https://www.brighton-hove.gov.uk/content/social-care/keeping-people-safe/help-adults-risk-abuse-or-neglect</a></li> </ul>
<p><b>Action if patient declines treatment</b></p>	<ul style="list-style-type: none"> <li>Advise about risks of infection and disease complications and document advice given.</li> <li>Inform or refer to SHAC as appropriate and document the advice given.</li> <li>Ensure patient is aware of implications of not having treatment.</li> </ul>
<p><b>Reference to national / local policies or guidelines</b></p>	<ul style="list-style-type: none"> <li>Access to BNF current edition or online</li> <li>Summary of Product Characteristics (SPC) for doxycycline 100mg capsules <a href="https://www.medicines.org.uk/EMC/medicine/23950/SPC/Doxycycline+Capsules+BP+100mg/">https://www.medicines.org.uk/EMC/medicine/23950/SPC/Doxycycline+Capsules+BP+100mg/</a></li> <li>Patient Information Leaflet (PIL) <a href="https://www.medicines.org.uk/emc/product/4063/pil">https://www.medicines.org.uk/emc/product/4063/pil</a></li> <li>General Pharmaceutical Council (GPhC) Standards for Pharmacy Professionals.</li> <li>Pharmaceutical Society of Northern Ireland (PSNI) Code of Ethics for Pharmacists.</li> </ul>

## 2. Description of Treatment

<b>Name, strength &amp; formulation of drug</b>	Doxycycline 100mg capsules
<b>Legal status</b>	Prescription only medicine (POM)
<b>Storage of products</b>	Cool, dry place.
<b>Dose, frequency &amp; quantity</b>	<p><b>Adults and young people over &gt; 12years</b></p> <ul style="list-style-type: none"> <li>• 100mg twice a day for 7 days (14 capsules)</li> <li>• Take with or after food</li> </ul>
<b>Supply and labelling requirements</b>	<ul style="list-style-type: none"> <li>• Supply 14 capsules and label as per POM requirements. A record should be made on the Patient Medication Record (PMR)</li> <li>• The patient information leaflet (PIL) must be given to the patient</li> </ul>
<b>Number of times treatment may be administered</b>	<ul style="list-style-type: none"> <li>• Treatment can be provided once (excluding patients that are re-infected before the treatment is completed or who fail to complete the 7 day course -see Inclusion Criteria)</li> </ul>
<b>Identification &amp; Management of Adverse Reactions</b>	<p><b>Common:</b></p> <ul style="list-style-type: none"> <li>• Nausea, vomiting, diarrhoea, oesophageal irritation and dysphagia.</li> </ul> <p><b>Less common</b></p> <ul style="list-style-type: none"> <li>• Loss of appetite</li> <li>• Sore tongue</li> <li>• Rash caused by photosensitivity</li> <li>• Sleep disturbance</li> <li>• Confusion</li> <li>• Hypersensitivity reactions and tinnitus</li> </ul> <p><b>Refer to the current Summary of Product Characteristics (SPC) of relevant product and current BNF for a full list and further information.</b></p>
<b>Patient advice /Follow up treatment</b>	<ul style="list-style-type: none"> <li>• Advise to swallow the capsules whole with plenty of fluids during meals, while sitting or standing and well before bedtime to prevent irritation to the oesophagus.</li> <li>• Refer to the PIL and advise patient to read it before starting treatment.</li> <li>• Inform individual of possible side effects and their management.</li> <li>• Individuals should be advised that they will not be clear of chlamydia until the 7 day treatment has been completed</li> <li>• Sexual contact (including oral sex) with partner should be avoided until partner has also completed the 7 day treatment</li> <li>• Advise individuals that all sexual partners in the last 6 months will need to have testing and treatment.</li> <li>• Do not take indigestion remedies concurrently – avoid antacids and calcium, magnesium and iron salts two hours before and one hour after taking doxycycline.</li> <li>• Individuals likely to be exposed to direct sunlight or ultraviolet light should be advised that this reaction can occur with tetracycline drugs and treatment should be discontinued at the first evidence of skin erythema.</li> </ul>





	<p>Individuals should be advised to avoid exposure to sunlight or sun lamps.</p> <ul style="list-style-type: none"> <li>• Individuals known to be taking part in high-risk sexual activity should be treated and advised to consult SHAC or GP/nurse.</li> <li>• Individuals that develop unusual or persistent side effects or symptoms of sexually transmitted infections should be recommended to consult their GP/nurse or SHAC.</li> <li>• Include routine follow-up advice of local services where a full sexual health check can be conducted.</li> <li>• Advise individuals that the CSP will contact them in 7 days to review the treatment and discuss any follow-up if necessary</li> <li>• Refer individuals to the Family Planning Association website for further information and a patient information leaflets on chlamydia <a href="https://www.fpa.org.uk/sites/default/files/chlamydia-information-and-advice.pdf">https://www.fpa.org.uk/sites/default/files/chlamydia-information-and-advice.pdf</a></li> </ul>
<p><b>Reporting procedure of Adverse Reactions</b></p>	<ul style="list-style-type: none"> <li>• Any serious reaction should be reported to the Medicines and Healthcare Products Agency (MHRA) through the yellow card scheme in the normal manner. It is the responsibility of the healthcare professional identifying a suspected ADR to report it. Yellow cards are available in the back of the BNF or obtained via Freephone 0808 100 3352 or online at <a href="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a></li> <li>• All cases of suspected adverse drug reactions should be documented in the patient's medical records. The GP should always be informed.</li> <li>• The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so.</li> </ul>
<p><b>Records</b></p>	<p>In all cases, data collected for the individuals clinical record and other relevant documentation should include:</p> <ul style="list-style-type: none"> <li>• Name, address, date of birth, CSP code</li> <li>• If individual is under 16 years of age document competency using Fraser guidelines</li> <li>• If individual is under 13 years of age record action taken.</li> <li>• Drug name, manufacturer of product, batch number and expiry date of product</li> <li>• Dose and quantity supplied</li> <li>• Date supplied and by whom</li> <li>• Informed consent of the individual</li> <li>• Advice given to individual (including side effects)</li> <li>• Whether partner/contact was treated today</li> <li>• Confirmation that advice was given to abstain from all sexual contact for 7 days after the last contact has been treated.</li> <li>• Details of any adverse drug reaction and action taken.</li> <li>• Any referral arrangements</li> </ul> <p>Details of each supply under this PGD (as above) should be sent to the Chlamydia Screening programme using PharmOutcomes at the time of the consultation.</p> <p>All records will be kept for 10 years after last attendance, or up to the patient's 26th birthday if longer than 10 years away.</p>

	<ul style="list-style-type: none"> <li>• A computer or manual record of all individuals treated under this Patient Group Direction should also be kept for audit purposes within each pharmacy.</li> <li>• The consultation should be submitted on the PharmOutcomes system and claims for payment will be generate as defined in the service specification.</li> </ul>
<b>Audit Trail</b>	Documentation (manual or computerised) to enable immediate access to the details of individuals receiving this medication must exist.

### 3. Characteristics of Staff

<b>Qualifications required</b>	Pharmacists must be registered with the General Pharmaceutical Council or Pharmaceutical Society of Northern Ireland.
<b>Additional requirements</b>	<ul style="list-style-type: none"> <li>• Be employed within a community pharmacy providing chlamydia treatment as part of the locally commissioned Sexual Health and Contraceptive service.</li> <li>• Completion of the accreditation and training requirements detailed in the locally commissioned Sexual Health and Contraceptive Service Specification.</li> <li>• Are aware of local safeguarding children and vulnerable adult policies and contact information.</li> <li>• Have reviewed the local policies and documentation for this service and references associated with this PGD.</li> <li>• Up-to-date knowledge relating to the clinical condition covered by the PGD, the medicine and its use for the indication specified in the PGD.</li> </ul>
<b>Continued training requirements</b>	<ul style="list-style-type: none"> <li>• Participation in Continuing Professional Development</li> <li>• The pharmacist should ensure she/he is aware of any changes to the recommendations for the treatment of chlamydia and the SPC for doxycycline 100mg capsules</li> </ul>

#### 4. PGD Development

<i>Developed &amp; produced by:</i>	Name	Signature	Date
Pharmaceutical Advisor/Named reviewer	Janet Rittman		3/11/18
Clinical Quality and Patient Safety Manager	Alison Cannon		10.12.18

This patient group direction has been approved on behalf of Brighton and Hove City Council and Brighton and Hove CCG by:

<i>Approved by:</i>	Name	Signature	Date
Director of Public Health BHCC	Alistair Hill		14.01.2019
Clinical Chair for BH CCG	Dr David Supple		05/12/18

#### 5. References

UK National guideline for the management of infection with Chlamydia trachomatis (2015) <https://www.bashh.org/guidelines>

British National Formulary (BNF) online <https://www.bnf.org/products/bnf-online/>

London Sexual Health Programme- PGD for the supply of treatment for uncomplicated genital chlamydia trachomatis V 2.1

<https://www.sps.nhs.uk/articles/contraception-and-sti-community-pharmacy-pgd-templates-london/>

The Pharmaceutical Society of Northern Ireland (PSNI), The code of ethics for pharmacists in Northern Ireland <http://www.psni.org.uk/about/code-of-ethics-and-standards/>

General Pharmaceutical Council Standards for Pharmacy Professionals May 2017 [https://www.pharmacyregulation.org/sites/default/files/standards\\_for\\_pharmacy\\_professionals\\_may\\_2017\\_0.pdf](https://www.pharmacyregulation.org/sites/default/files/standards_for_pharmacy_professionals_may_2017_0.pdf)

National Institute for Health and Care Excellence (NICE) Patient Group Directions (March 2017)

<https://www.nice.org.uk/Guidance/MPG2>

Summary of product characteristics (SPC) for Doxycycline 100mg Capsules

<https://www.medicines.org.uk/emc/product/4063/smpc>

## Appendix 1

### **Under 16s- Fraser Guidelines**

While the Fraser Guidelines below relate specifically to contraceptive advice or treatment, the principles are applicable to other sexual health services for young people under 16. A young person's age should not be a barrier to them accessing condoms.

A young person is competent to consent to contraceptive advice or treatment if:

- The young person understands the professionals' advice
- The professional cannot persuade the young person to inform his or her parents or allow the professional to inform the parents that he or she is seeking contraceptive advice.
- The young person is very likely to begin or continue having intercourse with or without the contraceptive treatment.
- Unless he or she receives contraceptive advice or treatment, the young person's physical or mental health or both are likely to suffer.
- The young person's best interests require the professional to give contraceptive advice, treatment or both without parental consent.

#### Reference

Faculty of Sexual and Reproductive Healthcare: Clinical Effectiveness Unit. March 2010.

Contraceptive Choices for Young People, Accessed 2/7/2018

<https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-young-people-mar-2010/>