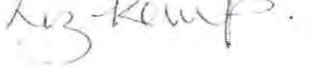
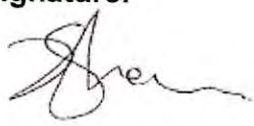
NHS Grampian

Patient Group Direction For The Supply Of Doxycycline Capsules For Treatment Of Uncomplicated Genital Chlamydia Infection By Pharmacists Working Within NHS Grampian

Lead Author:	**Consultation Group:**	**Approver:**
Principal Pharmacist, Pharmacy and Medicines Directorate	See relevant page in the PGD	NHSG Medicines Guidelines and Policies Group **Authorisation:** NHS Grampian

Signature:		**Signature:**
		

NHSG Identifier:	**Review Date:**	**Date Approved:**
NHSG/PGD/Doxy_CP/ MGPG1014	January 2021	January 2019

NHS Grampian have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 1

Revision History:

Reference and approval date of PGD that has been adapted or superseded.	New PGD following changes to the recommendations for the treatment of Chlamydia by BASSH.	
Date of change	**Summary of Changes**	**Section heading**
January 2019	New PGD	

NoS Identifier: NHSG/PGD/Doxy_CP/MGPG1014
Keyword(s): PGD Patient Group Direction Doxycycline, Chlamydia, Community Pharmacy

Policy Statement: It is the responsibility of individual Pharmacist and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of individual safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	October 2018
	Completed:	January 2019
	Approved:	January 2019 (published – February 2019)
	Amended:	

Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

PGD Developed/Reviewed by;

Medical Practitioner	**Name:** Dr Ambreen Butt **Health Board:** NHSG **Title:** Consultant in Sexual Health **Contact email:** ambreenbutt@nhs.net **Signature** .....
Senior representative of the professional group who will provide care under the direction (if different from below)	**Name:** **Health Board:** **Title: Principal** **Contact email:** **Signature** .....
Lead Author	**Name:** Elizabeth Kemp **Health Board:** NHSG **Title :** Principal Pharmacist P&MD **Contact email:** e.kemp@nhs.net **Signature** .....
Pharmacist	**Name:** Sam Reid **Health Board:** NHSG **Title :** Community Pharmacist **Contact email:** Samantha.reid7@nhs.net **Signature** .....

Approved and authorised for use within NHSG by;

Subgroup	Chair Name	Signature	Date Signed
NHS Grampian Medicines Guidelines and Policies Group	Lesley Thomson		February 2019

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	**Title:**
Elizabeth Kemp	**Lead Author:** Principal Pharmacist, Pharmacy and Medicines Directorate
Sam Reid	**Pharmacist:** Community Pharmacy
Dr Ambreen Butt	Consultant in Sexual Health
Frances Adamson	Medicines Management Specialist Nurse
Dr Sarah Wallage	**Medical Practitioner:** Consultant in Sexual Health
Dr Noha El Sakka	Consultant and Service Clinical Director Medical Microbiology and Virology
Suzanne Brittain	Antibiotic Pharmacist

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Clinical indication to which this PGD applies

Definition of situation/condition	This Patient Group Direction (PGD) will authorise pharmacists to supply doxycycline capsules to individuals aged 13 years and over with a laboratory confirmed diagnosis of uncomplicated genital chlamydia infection. It also allows the treatment of asymptomatic sexual contacts of someone with a positive diagnosis of uncomplicated genital chlamydia infection. Sexually active individuals are at risk of sexually transmitted infections. *Chlamydia trachomatis* is the most prevalent bacterial infection. Genital chlamydia infection can cause considerable short and long term morbidity. The sequelae of chlamydia infection include pelvic inflammatory disease, ectopic pregnancy and tubal infertility in females, epididymo-orchitis in males, and reactive arthritis. Doxycycline is a tetracycline antibiotic indicated for the treatment of uncomplicated genital chlamydia infection. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), and individual Summary of Product Characteristics (SmPC).
Inclusion criteria	• Individuals aged 13 years of age and over with a positive chlamydia test and an uncomplicated genital presentation Child protection procedures should be followed in all individuals under the age of 16 – see link below: http://nhsgintranet.grampian.scot.nhs.uk/depts/ChildProtection/Pages/default.aspx Asymptomatic individuals aged 13 years and over who are sexual contacts of someone with a positive chlamydia diagnosis.

Exclusion criteria	• Under the age of 13 Children under the age of 13 years should not be treated under this PGD. (The Child Protection Team must be contacted for children of 12 years and under who present having had sexual intercourse). • Pregnancy or a risk of pregnancy • Breast feeding • Men and women complaining of symptoms suggestive of an STI prior to a confirmed chlamydia diagnosis • Allergy to doxycycline or any other tetracycline antibiotic (Consider if individual would be eligible for treatment with Azithromycin) • Known anaphylactic hypersensitivity to any of the excipients • Severe hepatic impairment • Taking medicines that interact with Doxycycline (see current BNF Appendix 1 for full list or the SmPC • Suspected **complicated** chlamydia infection. Women with a positive Chlamydia result complaining of pelvic pain/pain during vaginal sex and men with a positive Chlamydia test complaining of testicular pain must be referred to a GP or sexual health clinic • Individuals, who following a diagnosis and treatment for uncomplicated genital chlamydia infection report having unprotected vaginal, anal or oral sex with an untreated partner likely to have chlamydia infection. • Porphyria • Individuals with Myasthenia Gravis • Individuals with Systemic Lupus Erythematosus • Individuals with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrose-isomaltase insufficiency should not take doxycycline.
Precautions and special warnings	Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines, including doxycycline. 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. Use doxycycline with caution in individuals with alcohol dependence.

Action if excluded from treatment	Consider Azithromycin PGD. If this is not applicable then medical advice should be sought – refer to General Practitioner (GP)/Consultant (relevant medical practitioner) or a sexual health clinic. The reason why the individual was excluded under the PGD will be documented in the appropriate individual record.
Action if treatment is declined	The individual/person with parental responsibility should be advised of the risks and consequences of not receiving treatment. Refer to GP/Consultant (relevant medical practitioner) or sexual health clinic. Record outcome in Medication Record if appropriate, or individual's relevant record.
Consent	Prior to the supply of the medicine(s), valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.

Description of treatment available under the PGD

Name form and strength of medicine	Doxycycline 100mg Capsules.
Legal status	Doxycycline 100mg Capsules are a Prescription-only Medicine (PoM). In accordance with the MHRA all medicines **supplied** under a PGD **must** either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply.
Dosage/Maximum total dose	100mg twice a day Maximum total dose to be supplied is 14 x 100mg capsules.
Frequency of dose/Duration of treatment	Twice daily for seven days.
Maximum or minimum treatment period	Seven days treatment.

Route/Method of administration	Oral. The capsules should be swallowed with plenty of fluid.
Quantity to be supplied	Supply one box pre-packed of 14 x 100mg capsules.
Storage requirements	PVC/Alu blisters: Do not store above 25°C. Store in the original packaging to protect from moisture.
Follow-up (if applicable)	If the individual returns following side effects resulting in stopping treatment or following completed treatment and still complaining of symptoms, they should be referred to GP/Consultant (relevant medical practitioner) or a sexual health clinic. Their Individual Medication Record should be updated to record this.
Advice (Verbal)	Advise individual/person with parental responsibility what to expect and what to do for minor and major reactions. Cautionary and Advisory labels 6, 9,11 & 27 apply: • Do not take indigestion remedies or medicines containing iron or zinc, 2 hours before or after you take this medicine • Space the doses evenly throughout the day. Keep taking the medicine until the course is complete or you are told to stop • Protect your skin from sunlight – even on a bright but cloudy day. Do not use sun beds. • Take with a full glass of water Individuals should be advised take capsules whilst sitting or standing and well before going to bed. Individuals should also be advised to abstain from having oral, anal or vaginal sex, even with a condom, until they, and their current partners, have completed treatment and for 1 week after completing treatment. Individuals should receive information regarding chlamydia infection at the time of antibiotic treatment, and must be advised to notify any sexual partners. If serious adverse or persistent effects occur, the individual/ person with parental responsibility should be advised to contact their GP/Accident and Emergency department/NHS24.

Advice (Written)	The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual/person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.
Identifying and managing possible adverse reactions	Common side effects: • GI side effects including nausea, vomiting, diarrhoea and abdominal discomfort • Sensitivity to sunlight • Headache • Tinnitus. Individuals experiencing signs of an allergic reaction or headache with blurred vision should stop taking capsules and should be advised to contact their GP or seek medical advice via NHS 24 **This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.** **BNF/BNFC**: https://www.bnf.org **SmPC/PIL/Risk Minimisation Material:** https://www.medicines.org.uk/emc/ http://www.mhra.gov.uk/spc-pil/index.htm https://www.medicines.org.uk/emc/rmm-directory If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Report any severe reactions or reactions to any ▼medicines using the Yellow Card System. https://yellowcard.mhra.gov.uk/
Facilities and supplies required	The following should be available at sites where the medicine is to be administered: • Appropriate storage facilities • An acceptable level of privacy to respect individual's right to confidentiality and safety • Access to a working telephone • Access to medical support (this may be via the telephone) • Clean and tidy work areas, including access to hand washing facilities or alcohol gel • Copy of the current PGD for the medicine specified in the PGD.

Characteristics of staff authorised to supply medicine(s) under PGD

Professional qualifications	Pharmacists whose name is currently on the register held by the General Pharmaceutical Council (GPhC).
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual/person with parental responsibilities capacity to understand the nature and purpose of medicine(s) supply in order to give or refuse consent • Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual • Having undertaken appropriate training to carry out clinical assessment of individuals leading to a diagnosis that requires treatment according to the indications listed in the PGD.
Ongoing training and competency	**All professionals working under this PGD must:** • Have undertaken PGD training as required/set out by NHSG • Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct • Have knowledge and familiarity of the following; o SmPC for the medicine(s) to be supplied in accordance with this PGD.
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintain up to date record of all staff authorised to supply the medicine(s) specified in this direction.

Documentation

Authorisation of supply	Pharmacists working within NHS Grampian can be authorised to supply the drug specified in this PGD by the Director of Pharmacy.

	All authorised staff are required to read the PGD and sign the Agreement to Supply Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board and/or agreed locally.
Record of supply	An electronic or paper record for recording the screening of individuals and the subsequent supply of the medicine(s) specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum: • Date and time of supply • Individuals name and CHI • Exclusion criteria, record why the medicine was not supplied • Record that valid consent to treatment under this PGD was obtained • The name, dose, form, route of the medicine(s) supplied • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who supplied the medicine(s) • Record of any adverse effects (advise individuals GP/relevant medical practitioner). Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • Consent forms • Individual's GP records if appropriate • Secondary Care Medical Notes • Occupational health systems • Individual service specific systems. **N.B.** In addition a Universal Claim Form for Unscheduled Care (CPUS) should be completed for the supply.
Audit	All records of the medicine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.

References	Electronic Medicines Compendium http://www.medicines.org.uk Doxycycline 100mg Capsules (Kent Pharmaceuticals) – Date of revision of text 06/12/18, accessed 08/01/19. British National Formulary and the British National Formulary for Children https://www.bnf.org accessed 23/10/18.

Appendix 1

Healthcare Professional Agreement to Supply Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to supply the medicine(s) contained within the following Patient Group Direction:

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I have completed the appropriate training to my professional standards enabling me to supply the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

Appendix 2

Healthcare Professionals Authorisation to Supply Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administer the medicine(s) under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to administer the medicine(s) under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.
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Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**