

Patient Group Direction For The Supply Of Doxycycline Capsules By Nurses For The Treatment Of Uncomplicated Genital Chlamydia Infection, Uncomplicated Mycoplasma Genitalium And Non-Gonococcal/Non-Specific Urethritis Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Adapted from the SPS/FSR PGD Supply of Doxycycline for the treatment of	<b>Consultation Group</b> : See relevant page in the PGD	Approver: NoS PGD Group
uncomplicated chlamydia trachomatis, uncomplicated Mycoplasma genitalium or non-gonococcal/non- specific urethritis, Version 2.0, Date published April 2023		Authorisation: NHS Grampian

Signature:	Signature:
flax	- Ster

NoS Identifier: NoS/PGD/Doxy_Nurses/ 1416	Review Date: September 2025	Date Approved: September 2023
	Expiry Date: March 2026	

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles 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 2

#### **Revision History For NoS:**

Reference a approval da that has be and/or supe	ate of PGD en adapted	New PGD adapted from National PGD template and supersedes NoS/PGD/Doxy_Nurses/MGPG1157, Version 1	
Date of change	Summary of Changes		Section heading
May 2023	Updated to I	NoS template Version 9.	
May 2023	Statement added about consent under the age of 16 and assess the capacity of a child under the 1991 cct for that procedure or treatment.		Inclusion Criteria
May 2023	Statement added about who should be contacted if Exclus the individual is 13 years of age.		Exclusion Criteria
May 2023	Myasthenia gravis added as per national template. Exclusion C		Exclusion Criteria
May 2023	Tretinoin added as per BNF advice to avoid. Exclusion		Exclusion Criteria
May 2023	5		Precautions and special warnings
May 2023	Acenocoumarol, Ciclosporin and Phenindione added to list as per BNF.		Precautions and special warnings
May 2023	Statement added about referral if individual is under 13 years of age.		Action if excluded from treatment
May 2023	Avoid alcohol when taking doxycycline added as per SMPC.		Advice (verbal)
May 2023	Optional furt Nurses and	her training added for Sexual Health Midwives.	Specialist competencies
May 2023	Updated as	per national template and BNF.	Identifying and managing possible adverse reactions
June 2023		emoved about fructose intolerance, actose malabsorption or sucrose- nsufficiency.	Exclusion criteria

**NoS Identifier:** NoS/PGD/Doxy\_Nurses/1416, Version 2

**Keyword(s):** PGD Patient Group Direction doxycycline chlamydia urethritis mycoplasma genitalium nurse

**Policy Statement:** It is the responsibility of the individual healthcare professionals 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 safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	May 2023
	Completed:	June 2023
	Approved: Amended and re-	September (published – October 2023)
	authorised:	

Patient Group Direction For Use Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

# **Organisational Authorisations**

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

PGD Developed/Reviewed by;

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	Date: 25/10/2023
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Patient Group Direction For Use Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

#### Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		25/10/2023
1		

#### Authorised and executively signed for use within NoS Boards by;

Signature	Date Signed
1 Histor	11/11/2023

#### Management and Monitoring of Patient Group Direction

#### **PGD Consultative Group**

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

Name:

Title:

Lead Author: Medicines Management Specialist Nurse NHSG
Pharmacist: Area Antimicrobial Pharmacist Microbiology NHSH
Medical Practitioner: Consultant Sexual Health NHSG
Senior Representative: Lead Nurse/Service Manager Highland Sexual Health
Head of Community Pharmacy Services NHSH
Clinical Nurse Specialist Sexual Health
Senior Charge Nurse Sexual Health NHSH
Sexual Health Nurse Team Leader NHSG

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#### **Clinical indication to which this PGD applies**

Definition of situation/ Condition	<ul> <li>This Patient Group Direction (PGD) will authorise nurses to supply doxycycline capsules to individuals aged 13 years and over with a laboratory confirmed diagnosis of uncomplicated chlamydia infection (any site) or uncomplicated mycoplasma genitalium infection.</li> <li>It also allows treatment of non-gonococcal (NGU) or non-apositio unotheritie (NSU) on microacent.</li> </ul>	
	specific urethritis (NSU) on microscopy.	
	Treatment under this PGD may also be given to asymptomatic individuals presenting within 2 weeks of sexual contact with an individual with a confirmed diagnosis of any of the conditions detailed above.	
	This PGD should be used in conjunction with the individual Board protocols and the recommendations in the current British Association for Sexual Health and HIV ( <u>BASHH</u> ) relevant guidelines, British National Formulary ( <u>BNF</u> ), British National Formulary for Children ( <u>BNFC</u> ), and the individual Summary of Product Characteristics ( <u>SmPC</u> ).	
Inclusion criteria	<ul> <li>Individuals aged 13 years and over.</li> <li>Individuals with a positive test for chlamydia trachomatis infection in the genitals, rectum or pharynx.</li> <li>Individuals with a positive test for mycoplasma genitalium (without a clinical diagnosis of pelvic inflammatory disease (PID) in women) as treatment prior to further antimicrobial therapy where mycoplasma genitalium is known to be sensitive to macrolides or is of unknown resistance status.</li> <li>Individuals with a microscopic diagnosis of NGU or NSU.</li> <li>Asymptomatic individuals (regular or casual partners) presenting within 2 weeks of sexual contact with an individual with a confirmed diagnosis of chlamydia, NSU/NGU PID or epididymo-orchitis. These individuals can be treated at the time of presentation in line with local clinic guidelines. Asymptomatic individuals presenting after 2 weeks can be treated at clinician's discretion in line with local clinic guidelines.</li> <li>Individuals who require a single repeat treatment course as they have had sexual intercourse within the 7 day treatment course with a partner untreated for the above conditions.</li> </ul>	

	Prior to the supply of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy. An individual under 16 years of age may give consent for the supply of doxycycline capsules, provided they understand fully the benefits and risks involved. The individual should be encouraged to involve a parent/guardian, if possible, in this decision. Where there is no parental involvement and the individual indicates that they wish to accept the supply, supply should proceed, if the healthcare professional deems the individual to have the legal capacity to consent. The Age of Legal Capacity (S) Act 1991, s2 (4) states that 'a person under the age of 16 years shall have legal capacity to consent on their own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending them, they are capable of understanding the nature and possible consequences of the procedure or treatment.	
	Legal advice from the NHS in Scotland states that if a healthcare professional has been trained and professionally authorised to undertake a clinical assessment which is normally that of a medical practitioner, then that health care professional can be considered to have the necessary power.	
Exclusion criteria	<ul> <li>Individuals under 13 years of age*.</li> <li>Under 16 years of age and judged to be incapable of understanding the nature and possible consequences of procedures or treatment as per Age of Legal Capacity (Scotland) Act 1991 (commonly referred to as Fraser competency).</li> <li>Individuals 16 years of age and over and assessed as lacking capacity to consent.</li> <li>Confirmed lymphogranuloma venereum (LGV) or a contact with LGV.</li> </ul>	
	Medical History	
	<ul> <li>Individuals with PID. Symptoms of PID: <ul> <li>Lower abdominal tenderness which is usually bilateral</li> <li>Fever &gt;38°C</li> </ul> </li> <li>Men who have proctitis. Symptoms of proctitis: <ul> <li>A frequent or continuous feeling that you need to have a bowel movement</li> <li>Rectal bleeding, rectal mucous and/or rectal pain</li> <li>A feeling of rectal fullness</li> </ul> </li> </ul>	

	<ul> <li>Men who have a positive chlamydia result but have signs or symptoms of epididymo-orchitis: <ul> <li>Testicular tenderness</li> <li>Testicular swelling</li> </ul> </li> <li>Breastfeeding</li> <li>Pregnancy</li> <li>Severe hepatic impairment</li> <li>Severe renal impairment</li> <li>Individuals with Myasthenia Gravis</li> <li>Presence of concomitant conjunctivitis and/or joint pain/swelling</li> <li>Acute porphyria</li> <li>Systemic Lupus Erythematosus (SLE)</li> <li>Individuals with oesophagitis and oesophageal ulcerations</li> <li>Individuals complaining of symptoms suggestive of an Sexually Transmitted Infection (STI) prior to a confirmed chlamydia diagnosis.</li> </ul>
	<ul> <li>Any concurrent interacting medicine(s) – All concurrent medications should be reviewed for interactions. The interactions listed as severe in Appendix 1 of the BNF are:         <ul> <li>Acenocoumarol</li> <li>Acitretin</li> </ul> </li> </ul>
	<ul> <li>Alitretinoin</li> <li>Ciclosporin</li> <li>Isotretinoin</li> <li>Lithium</li> <li>Phenindione</li> <li>Tretinoin</li> <li>Warfarin</li> <li>Known allergy or hypersensitivity to doxycycline, other tetracycline antibiotics or to any component of the product - see <u>Summary of Product Characteristics</u></li> </ul>
	<ul> <li>Where there is no valid consent.</li> <li>*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).</li> </ul>
Precautions and special warnings	Individuals for whom no valid consent has been received. Any gender based violence, child protection and welfare issues should be referred through the appropriate channels.

	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	Medical advice must be sought – refer to relevant medical practitioner.
	Inform/refer to the relevant medical practitioner if individual declines treatment, and/or provide them with information about further options.
	For anyone presenting for treatment under this PGD aged under 13 years, the local child protection team must be contacted. Consultation with sexual health services or their GP should be prioritised.
	Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	Inform/refer to the relevant medical practitioner if individual declines treatment.
	Document that the supply was declined, the reason and advice given in appropriate clinical records.

### Description of treatment available under the PGD

Name form and strength of medicine	Doxycycline 50mg or 100mg capsules or 100mg dispersible tablets.
Legal status	Doxycycline is a Prescription-only Medicine (POM) In accordance with the MHRA all medicines <b>supplied</b> under a PGD <b>must</b> 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.
Is the use out with the SmPC?	Not licensed for treatment of Mycoplasma genitalium.

	[]
Dosage/Maximum total dose	100mg twice a day.
	Maximum total dose of <b>1.4g</b> .
Frequency of dose/Duration of treatment	Twice daily for seven days.
Maximum or minimum treatment period	Seven days.
Route/Method of administration	Oral.
	The capsules should be swallowed with plenty of fluid.
	It is important not to lie down for at least thirty minutes after taking doxycycline capsules, so that the capsule can move as swiftly as possible into the stomach and prevent irritation of the throat or oesophagus.
Quantity to be	Supply one box pre-packed of 14 x 100mg capsules.
supplied	Supply one box pre-packed of 28 x 50mg capsules.
	Supply two boxes pre-packed of 8 x 100mg dispersible tablets.
	<b>Note</b> - Remaining 2 tablets should be returned to community pharmacy for disposal.
Storage requirements	Store below 25°C. Store in the original packaging to protect from moisture.
Additional Information	None.
Follow-up (if applicable)	Individuals with a definite diagnosis of uncomplicated <i>Mycoplasma genitalium</i> infection where the doxycycline course is to be followed by a second antimicrobial (according to the resistance profile), the second antimicrobial course should be started immediately after completing the doxycycline course. If the 2 <sup>nd</sup> antimicrobial course is not started within this timeframe the individual should be referred to a specialist practitioner. Follow local individual board protocol for chlamydia follow up and partner notification.

	<ul> <li>Individuals who have not had a full STI screen (or who did not have chlamydia diagnosed in a sexual health clinic) should be advised to attend an appropriate service for a full STI screen.</li> <li>Routine follow-up for uncomplicated chlamydia following treatment with doxycycline is unnecessary, except in the following situations where local protocols should be followed:</li> <li>Where poor compliance is suspected.</li> <li>Where symptoms persist.</li> </ul>
	testing positive for rectal chlamydia in line with local clinic protocols.
Advice (Verbal)	Advise individual what to expect and of the possible side effects and their management.
	<ul> <li>Additionally:</li> <li>Do not take indigestion remedies or medicines containing iron or zinc, 2 hours before or after you take this medicine.</li> <li>Space the doses evenly throughout the day. Keep taking the medicine until the course is complete or you are told to stop.</li> <li>Protect your skin from sunlight – even on a bright but cloudy day. Do not use sun beds.</li> <li>Take with a full glass of water or milk.</li> <li>Avoid alcohol when taking doxycycline – as may decrease half-life of doxycycline.</li> <li>Individuals should be advised take capsules whilst sitting or standing and well before going to bed.</li> <li>Individuals should receive information regarding chlamydia, NSU/NGU or <i>Mycoplasma genitalium</i> infection at the time of antibiotic treatment, and must be advised to notify any sexual partners, and issue contact slips if appropriate.</li> <li>Discuss implications of incompletely treated/untreated infection of self or partner.</li> <li>Individuals should also be advised to abstain from having oral, anal or vaginal sex, even with a condom for the duration of treatment and until their current partners (if they have one), have completed treatment, or until they are symptom free if they have ongoing symptoms after completing prescribed treatment.</li> </ul>

	Discuss risk of re-infection, and further transmission of infection, if after treatment sexual intercourse takes place with an untreated partner(s).
	Discuss partner notification and issue contact slips if
	appropriate. Offer condoms and advice on safer sex practices and possible need for screening for STIs.
	Where treatment not supplied via a sexual health clinic ensure the individual has contact details of local sexual health services.
	If serious adverse or persistent effects occur, the individual should be advised to contact their GP/Emergency department/NHS24.
Advice (Written)	The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.
Identifying and managing possible adverse reactions	The following side effects are common with doxycycline (but may not reflect all reported side effects):         Hypersensitivity reactions         Headache         Nausea         Vomiting         Photosensitivity skin reactions         Rash including maculopapular, erythematous or exfoliative rashes and Henoch-Schonlein purpura         Urticaria         Hypotension         Pericarditis         Tachycardia         Dyspnoea         Peripheral oedema.         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/products/bnf-online/         SmPC/PIL/Risk Minimisation Material:         https://www.medicines.org.uk/emc/         https://www.medicines.org.uk/emc/

	If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Report any severe reactions using the Yellow Card System. <u>https://yellowcard.mhra.gov.uk/</u>
Facilities and supplies required	<ul> <li>The following are to be available at sites where the medicine is to be supplied:</li> <li>Appropriate storage facilities</li> <li>An acceptable level of privacy to respect individual's right to confidentiality and safety</li> <li>Access to a working telephone</li> <li>Access to medical support (this may be via the telephone)</li> <li>Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel</li> <li>A copy of this current PGD in print or electronically.</li> </ul>

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

Professional qualifications	Registered nurses as recognised by the Nursing and Midwifery Council (NMC).
Specialist competencies	<ul> <li>Approved by the organisation as:</li> <li>Competent to assess the individual's capacity to understand the nature and purpose of the medicine supply in order to give or refuse consent.</li> <li>Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual.</li> <li>Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD.</li> <li>Competent to undertake supply of the Medicine.</li> <li>Competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions.</li> <li>Competent to work under this PGD and authorised by name as an approved person to work under the terms of the PGD.</li> <li>Sexual Health Nurses and Midwives.</li> <li>Optional further sexual health training:</li> <li>Education and Training - Faculty of Sexual and Reproductive Healthcare (fsrh.org)</li> </ul>

Ongoing training and competency	<ul> <li>All professionals working under this PGD must:</li> <li>Have undertaken NoS PGD module training on <u>TURAS</u> Learn.</li> <li>Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct. Note: All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of the medicine. If any training needs are identified these should be discussed with those responsible for authorisation to act under the PGD.</li> <li>Have knowledge and familiarity of the following;</li> <li><u>SmPC</u> for the medicine(s) to be supplied in accordance with this PGD.</li> </ul>
Responsibilities of professional manager(s)	<ul> <li>Professional manager(s) will be responsible for;</li> <li>Ensuring that the current PGD is available to all staff providing care under this direction.</li> <li>Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.</li> <li>Maintain up to date record of all staff authorised to supply the medicine(s) specified in this direction.</li> </ul>

### Documentation

Authorisation of supply	Sexual Health Nurses working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to supply the medicine(s) specified in this PGD by their Professional Line Manager/Consultant/Practice GPs. All authorised staff are required to read the PGD and sign the Agreement to Supply Medicines Under PGD ( <u>Appendix 1</u> ). A Certificate of Authorisation ( <u>Appendix 2</u> ) 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.
Record of supply	An electronic or paper record must be completed to allow audit of practice. An electronic/HEPMA record of the screening and subsequent supply, or not of the medicine(s) specified in this PGD should be made in accordance with individual Health Board electronic/HEPMA recording processes.

	<ul> <li>If a paper record is used for recording the screening of individuals and the subsequent supply or not of the medicine(s) specified in this PGD, it should include as a minimum:</li> <li>Date and time of supply</li> <li>Individuals name and CHI</li> <li>Exclusion criteria, record why the medicine was not supplied (if applicable)</li> <li>Record that valid consent to treatment under this PGD was obtained</li> <li>The name, dose, form, route (batch number, expiry date and anatomical site where appropriate for injectable medicines) of the medicine(s) administered/supplied</li> <li>Advice given, including advice given if excluded or declined treatment under this PGD</li> <li>Signature and name in capital letters of the healthcare professional who supplied the medicine, and who undertook the assessment of the individual's clinical suitability for the administration/supply of the medicine</li> <li>Record of any adverse effects and the actions taken (advise individuals' GP/relevant medical practitioner).</li> <li>Depending on the clinical setting where supply is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate:</li> <li>NaSH – Sexual Health Electronic Patient Record</li> <li>Individual service specific systems.</li> <li>Local policy should be followed with respect to sharing information with the individual's General Practitioner.</li> <li>All records should be clear, legible and contemporaneous and in an easily retrievable format.</li> </ul>
Audit	All records of the medicine(s) 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 supplied under a PGD.
References	Electronic Medicines Compendium <u>http://www.medicines.org.uk</u> Doxycycline 100mg Capsules (Sovereign Medical) – Date of revision of text 21/04/20, accessed 02/05/23.

British National Formulary and British National Formulary for Children <u>https://www.bnf.org/products/bnf-online/</u> accessed 02/05/23. BASHH CEG September 2018 – <u>Update on the treatment of</u> <u>Chlamydia trachomatis (CT) infection</u>
BASSH UK National <u>Guideline on the management of non-</u> gonococcal urethritis
British Association for Sexual Health and HIV national guideline for the management of infection with <i>Mycoplasma</i> genitalium



Appendix 1

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

Working within: e.g. Area, Practice

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

#### Patient Group Direction For The Supply Of Doxycycline Capsules By Nurses For The Treatment Of Uncomplicated Genital Chlamydia Infection, Uncomplicated Mycoplasma Genitalium And Non-Gonococcal/Non-Specific Urethritis Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2

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 supply the medicine(s) under this PGD is responsible for ensuring that they are 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 supply the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that supply is carried out within the terms of the direction, and according to their 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

Patient Group Direction For The Supply Of Doxycycline Capsules By Nurses For The Treatment Of Uncomplicated Genital Chlamydia Infection, Uncomplicated Mycoplasma Genitalium And Non-Gonococcal/Non-Specific Urethritis Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date