Patient Group Direction for the administration of : Azithromycin for the treatment of patients with chlamydia/suspected chlamydia, and the sexual contacts of those. Azithromycin for the epidemiological treatment of sexual contacts of epididymo-orchitis and PID.	
Title of patient group direction	Patient group direction for administration or supply of oral azithromycin Stat dose of 1 gram followed by 500mg once daily for a further two days
Approved at	NMP/PGD Group
PGD approved / valid from	September 2018
Review date	June 2021
Expiry date	September 2021
Clinical area(s) where PGD applies	York and North Yorkshire Sexual Health services
Identified Lead for monitoring / review and contact details	Alison Chorlton Lead Nurse

CONSULTATION PROCESS ADOPTED IN DEVELOPING THE PATIENT GROUP DIRECTION (PGD)	
New Document	No
Reviewed Document	Yes
If the PGD is revised what revisions were required and for what reasons e.g. change in medical procedures or change in legislation	Current PGD due for renewal June 2018 Amended on 28.09.2018 in line with BASHH guidelines updated September 2018 Amended October 2018 in line with BASHH guidelines. Amendments to PGD originally approved September 2018 confirmed by Dr Ian Fairley, Alison Chorlton, Paul Jackson, Jennie Booth and Stuart Parkes- October 2018.
List of persons involved in the consultation process. (The group must include a sponsoring clinician, a pharmacist and a senior representative of the professional group. The job title and level of consultation should also be listed).	Dr Ian Fairley Alison Chorlton – Lead Nurse Sexual Health Elizabeth Clarke Advanced Nurse Specialist

CLINICAL CONDITION	
Condition	• Positive or unconfirmed reactive chlamydia result in index patient that decline or unable to take first line doxycycline treatment. • Reported sexual contacts of chlamydia that decline or unable to take first line doxycycline treatment. • Reported sexual contacts of epididymo-orchitis or pelvic inflammatory disease (PID)
Inclusion criteria	• Clients/patients who have had a positive chlamydia screening test or have been identified as a sexual partner of a person with confirmed or suspected chlamydial infection and decline or are unable to take doxycycline treatment. • Pregnant women who consent to azithromycin treatment. • Clients/patients who have tested positive for chlamydia and are experiencing symptoms • Re-treatment of any of the above who have reported vomiting or severe diarrhoea within 2 hours of taking medication. • Re-treatment of any of the above who have reported sexual intercourse with an untreated partner.
Exclusion criteria	• Allergy or hypersensitivity to azithromycin or other macrolide antibiotics. Some brands of azithromycin contain soya or soya lecithin and are therefore contraindicated in individuals with an allergy to soya or peanuts. If individual is allergic, check manufacturer's information for brand being used and if necessary, exclude from PGD • Children 12 years and under • Patients aged 13-15 years who are not Fraser competent • Children under 45 Kg bodyweight • Known history of hepatic impairment or liver disease • Porphyria • Patient declines treatment under PGD • Myasthenia gravis • Congenital or documented QT prolongation • Currently receiving treatment with other active substances known to prolong QT • Electrolyte disturbance, particularly in case of hypokalaemia and hypomagnesaemia • Clinically relevant bradycardia, cardiac arrhythmia or severe cardiac insufficiency.

	hypokalaemia and hypomagnesaemia • Clinically relevant bradycardia, cardiac arrhythmia or severe cardiac insufficiency. • Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption • Severe renal impairment
Action if excluded	First line chlamydia treatment is doxycycline PGD. If doxycycline cannot be used(due to pregnancy/suspected pregnancy, drug interactions, allergies, patient choice) explain reason for exclusion to patient and document in notes. Refer to medical practitioner/prescriber during that clinical session or when next available in clinic. When a medical practitioner/prescriber is not physically present. Defer treatment and discuss by telephone. If patient presents with an acute presentation and no doctor is available refer for immediate assessment in Emergency Department/Urgent Care.
Action for patients not wishing to receive care under the PGD	Refer to non-medical prescriber or medical practitioner during that clinical session or when next available in clinic.

<table>
<tr><th colspan="4">DESCRIPTION OF TREATMENT</th></tr>
<tr><td>Name of Medicine</td><td colspan="3">Azithromycin</td></tr>
<tr><td>Legal Classification</td><td colspan="3">Prescription only medicine (POM)</td></tr>
<tr><td>Licensing information</td><td colspan="3">Pregnant women or women known to be at risk of pregnancy

The individual must be informed that although the use of azithromycin in pregnancy is thought to be safe, there is limited research available. The individual must:
• Be fully informed of the risks and benefits of this treatment
• Be informed that this use is outside the terms of the SPC
• Be informed of the availability of alternative treatment (erythromycin for 1 or 2 weeks)
• Give verbal consent for use outside the terms of the SPC and this must be documented in the clinical record
• Be given the option of seeing an appropriate doctor/ independent non medical prescriber

Gonorrhoea unlicensed indication per BNF/SPC (Off label)</td></tr>
<tr><td></td><td>Is the medicine licensed for the intended use?</td><td>YES</td><td></td></tr>
<tr><td></td><td>Does it have a black triangle status?</td><td></td><td>NO</td></tr>
<tr><td></td><td>Does it have a Risk Minimisation Measures (RMM) recommendation</td><td></td><td>NO</td></tr>
<tr><td>Form</td><td colspan="3">Tablets/ capsules
or
Oral suspension (if patient unable to swallow tablets/capsules)</td></tr>
<tr><td>Strength</td><td colspan="3">250mg tablets/capsules
or
200mg/5mL suspension when reconstituted with water</td></tr>
<tr><td>Dose</td><td colspan="3">Stat dose of 1 gram followed by 500mg once daily for a further two days</td></tr>
<tr><td>Frequency</td><td colspan="3"></td></tr>
</table>

	As above	
Route	Oral	
Total Treatment Quantity	One course (3 days treatment)	
Interactions with other medicines (This must include all potentially serious interactions listed in the BNF)	See Appendix 1 in British National Formulary (BNF) under macrolides • Antacids (azithromycin must be taken at least 1 hour before or 2 hours after antacids) • Colchicine (risk of colchicine toxicity) • Warfarin and other oral anticoagulants (no additional monitoring is required with stat doses of azithromycin) • Ergotamine derivatives (because of the theoretical possibility of ergotism, azithromycin and ergot derivatives should not be co administered) • Digoxin (possibility of raised digoxin levels) • Ciclosporin (ciclosporin levels should be monitored and the dose adjusted accordingly) **If in doubt, contact Medicines Information for advice tel 5960**	
Adverse Reactions	• Sudden breathlessness, wheezing, swelling, rash or itching • Nausea, dyspepsia, abdominal discomfort • Diarrhoea, dizziness, headache, numbness or pins	**Treatment of adverse reactions** • SEEK URGENT MEDICAL ADVICE • advise to avoid antacids within 2 hours of taking antibiotic • If any side effect becomes serious then seek medical advice

	and needles, visual disturbances, deafness, tiredness, weakness • Vomiting or severe diarrhoea within 2 hours of taking.	• Will require re-treatment
Advice to Patients: Written and Oral advice (This should include the provision of a patient information leaflet)	• Capsules/tablets should be swallowed whole with a drink of water • Follow manufacturer's guidelines with regard to any requirement to delay taking before/after food • Advise of possible side effects as listed in PIL • If any severe diarrhoea or vomiting is induced within 2 hours of ingesting the medicine - return to clinic as absorption will have been insufficient to achieve bactericidal levels of absorption • Advice regarding avoiding any form of sexual contact until self and partner/s is also fully treated, to avoid risk of reinfection. Abstinence needs to extend until 7 days after both self and sexual partner/s are fully treated if taking azithromycin or throughout course of any other antibiotic • Partner notification will be undertaken in line with national recommendations • Discussion regarding safer sex in general for future sexual health • Encourage screening for other STI's if required • Advise a repeat chlamydia test if a new sexual partner and on a yearly basis if under 25 years • Provide written information regarding treatment concordance and side effects; supported by patient information leaflet (PIL) and 'advice after treatment' leaflet • It is recommended to discard breast milk during treatment and up until 2 days after discontinuation of treatment. Nursing may be resumed thereafter. • Provide written information regarding aetiology of chlamydia, transmission, and implications for partial/non-treatment; with supporting leaflet and/or principles of epidemiological treatment	

	for sexual contacts being treated, as appropriate • Information regarding PID and/or epididymo-orchitis for asymptomatic sexual contacts thereof as appropriate • Refer to relevant care pathways • Inform pregnant women that it is not licensed in pregnancy but is in BASHH/WHO guidance
Follow up action	Telephone compliance check in 7-10 days,only if required, whereby patient may be discharged by telephone if they have been fully compliant and concordant, a follow-up return visit only required if: o Persistent or new symptoms are established during the telephone compliance discussion o Non-concordance with treatment is established during the telephone compliance discussion o A risk of re-infection is established during the telephone compliance discussion
Storage	• Locked medicines cupboard – store below 25 °C • Locked briefcase for outreach use
Records to be Kept	**The following minimum details need to be documented in full in patient's records in relation to initiating treatment under PGD** • Date/time of record entry • Drug name and strength • Dose, form and quantity supplied • Route of administration • Time of administration if appropriate • Advice given to patients • Name/job title of staff administering/supplying medicine(and signature if written records) • Details of any adverse drug reactions or side effects • Details of any problems reported with compliance and action advised/taken • Any communication with other health care providers • Postal treatment record in the patient records (if supplied this way) as per postal treatment • If the patient is pregnant her treatment must be documented in her maternity (green) notes or write to her GP.

	• That azithromycin was given under a PGD • The outcome of the compliance discussion needs to be recorded in full in the patient's notes
Audit Arrangements	As per current trust PGD policy
References	• National guidelines for the management of gonorrhoea in adults, 2011, British Association for Sexual Health and HIV, www.bashh.org • National guidelines for the management of chlamydia trachomatis genital tract infection, 2015, British Association for Sexual Health and HIV, www.bashh.org • National guidelines for the management of non-gonococcal urethritis, May 2017, British Association for Sexual Health and HIV, www.bashh.org • National guidelines for the management of pelvic inflammatory disease, 2018, British Association for Sexual Health and HIV, www.bashh.org • National guidelines for the management of epididymo-orchitis (2010) British Association for Sexual Health and HIV, www.bashh.org • Nursing and Midwifery Council, Standards for Medicines Management 2007, minor updates 2015 , www.nmc.org.uk • The British National Formulary, www.bnf.org.uk • Nursing and Midwifery Council, The Code for nurses and midwives. March 2015 www.nmc.org.uk **(refers to record keeping)** • National Chlamydia Screening Programme Chlamydia Screening Standards www.chlamydiascreening.nhs.uk

	• The electronic Medicines Compendium (eMC) www.medicines.org.uk/EMC/default.aspx • Stockley's Drug interactions- web version
Competency Requirements (attach any competency frameworks / documents)	Completion of a local training programme for the administration of azithromycin under PGD within sexual health services. This will require/include: • Clinical competence in sexual history taking • Competence in undertaking clinical examination/assessment and genital screening to enable the accurate diagnosis and treatment of chlamydia infection if required. • The ability to recognize which sexual contacts will require epidemiological treatment in line with national guidelines. • Knowledge base of the interactions of azithromycin with other drugs, and other exclusions and contra-indications for issuing azithromycin • Competence in the above will be demonstrated by the undertaking of a local clinical competency based training and assessment programme, evidenced by completion of theoretical study including e-learning and clinical experience within sexual health. • Assessment will be undertaken by the Lead Sexual Health nurse or designated PGD assessor, who will both be fully competent and either practising as an independent prescriber themselves, or practicing in accordance with this PGD. • Receiving clinical supervision and/or audit of case notes on an ongoing basis • Commitment to continuing professional development identified through clinical supervision and appraisal • Evidence of continuing professional development in sexual health • 5 study days or the equivalent in hours, of study related to the field of sexual health; every 3 years. • Regular attendance and participation in the Tri annual educational clinical governance • *Maintain professional accountability with the Nursing and Midwifery Council (NMC) and ensure continuing professional development.*

	• Attendance at a Trust/clinic PGD awareness session or Trust HUB e-learning

AUTHORISATION OF THE PATIENT GROUP DIRECTION (PGD) FOR ADMINISTRATION OF: Azithromycin			
PGD Development / Review Team – responsible for PGD content			
Title	**Name**	**Signature**	**Date**
Lead Author	Alison Chorlton		10.7.18
Clinical Director Lead Approval	Ian Fairley		31/7/18.
Directorate Pharmacy Lead Approval	Paul Jackson		21/8/18 25/10/18
PGD Approved by the NMP/PGD Group			
Title	**Name**	**Signature**	**Date**
			1.10.2018
NMP Lead / Lead Nurse Medicines Management	Jennie Booth		24.08.2018
Chief Pharmacist / Deputy Chief Pharmacist	Stuart Parkes		1/10/2018 24/8/18.

Authorisation to work within the PGD

This patient group direction must be agreed to and signed by all health care professionals involved in its use.

The PGD must be easily accessible in the clinical setting.

Notes to the NMP/PGD Authorising staff

- Do not proceed unless this document carries the signatures of the development / review team (Lead Author, Lead Clinical Director and Directorate Lead Pharmacy)
- You are responsible for fulfilling the legal requirement that a senior person from the profession ensures that only fully competent, qualified and trained professionals operate under this PGD
- Using a PGD is not a form of prescribing

Staff authorised to work under this PGD	
Ward / Department	Sexual Health
Professionals to whom this Patient Group Direction applies	Qualified nurses who work within sexual health and have completed the agreed training programme

I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct when working for this Trust:

Name (Capitals)	Sign	Job Title	Authorising Manager	Date
This is to be completed when the PGD has been approved	This is to be completed when the PGD has been approved	This is to be completed when the PGD has been approved	This is to be completed when the PGD has been approved	This is to be completed when the PGD has been approved

When the review date is exceeded, this PGD ceases to be a legal document	
TEMPLATE DOCUMENTATION CONTROL	
The template documentation control refers to the PGD template not the completed PGD. **Do not alter this section.**	
Author:	Jennie Booth, Lead Nurse Medicines Management Carol Belt, Principal Pharmacy Technician Stuart Parkes, Deputy Chief Pharmacist
Owner:	NMP/PGD Group
Date of issue:	February 2018
Version:	3
Approved by	NMP/PGD Group
Review date:	February 2021