



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.

PATIENT GROUP DIRECTION (PGD)

Supply of doxycycline for the treatment of uncomplicated *Chlamydia trachomatis*, epididymo-orchitis, uncomplicated *Mycoplasma genitalium* and non-gonococcal/non-specific urethritis (NSU) by authorised Registered Nurses employed by a GP Practice or community pharmacists working in a pharmacy which is contracted by Hertfordshire County Council to provide the service.

Doxycycline is first line treatment, azithromycin is second line treatment.

Version Number 2.5

Reference: Doxycycline PGD HCC 202010 v2.5

Change History	
Version	Change details
Version 2	<ul style="list-style-type: none"> Page 8 - Treatment inclusion criteria is now 15 years age and above with notification of positive <i>Chlamydia Trachomatis</i> infection evidenced by communication from Sexual Health Hertfordshire. Page 8 – Criteria for Exclusion: ‘Glucose galactose intolerance’ has been changed to Glucose galactose malabsorption’ Page 10 – Drug Interactions: The list of drugs that cause a severe reaction now includes the following drugs: acenocoumarol, acitretin, ciclosporin, warfarin, lithium and phenindione. Appendix A - (Registered Health Professional Authorisation Sheet) amended so that a senior person with designated authority within the provider organisation can sign as authorising manager. Page 6 – Training details added and updated as per PGD application to QA GG Page 7 and page 12- increased detail on use of treatment for <i>Mycoplasma genitalium</i> requiring both azithromycin and doxycycline. Page 9- Cautions – added recommendation to signposting for professionals Page 9 - off-label use: removed comment about use off label Page 11 - added cautionary advisory labels (CALs) from BNF Page 12 - correct drug added Page 14 - key references updated Page 11, 19 - Administrator name removed, email address updated Page 23 - drug forms and dispersible tablets added to form, included detail on supply quantity based on condition diagnosed, batch number box added to form Page 7 - NSU definition updated to include NGU Page 6 - LPC updated to Community Pharmacy Hertfordshire (CPH) Page 6 - safeguarding and Fraser guideline information updated Page 2 - PGD template details updated Page 20 , 23 - Appendix C and D removed




This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

HERTFORDSHIRE PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	17 th March 2022
Review date:	March 2024
Expiry date:	30 th September 2024

This PGD has been based on the national template approved by BASHH (April 2020) and has been peer reviewed by the Hertfordshire PGD working group.

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior Doctor	Joel Bonnet Consultant in Public Health		17-Mar-2022
Senior pharmacist	Rebecca Thomas Senior Pharmacist		17-Mar-2022
Person signing on behalf of authorising body (Public Health Quality and Assurance Governance Group)	David Conrad Director of Public Health Evidence & Improvement Chair of Hertfordshire Public Health Quality and Assurance Governance Group		17-Mar-2022

PGD DEVELOPMENT

HCC Sexual Health PGD Review Group 2020 – Version 1	
Senior Doctor:	Linda Mercy
Senior Pharmacist:	Dipti Patel
Representative of professional group using the PGD:	Helen Musson
Community Pharmacist:	Purvi Barchha
Chair of the QAGG (Public Health Consultant):	David Conrad
Lead Nurse- Sexual Health Herts:	Gillian Miles
Health Improvement Lead- Sexual Health:	Rob Bacon

HCC Sexual Health PGD Review Group 2021/22 – Version 2	
Senior Doctor:	Joel Bonnet
Senior Pharmacist:	Rebecca Thomas
Representative of professional group using the PGD:	Helen Musson
Chair of the QAGG (Director of Public Health Evidence & Improvement):	David Conrad
Health Improvement Lead- Sexual Health:	Rob Bacon
Commissioning Officer:	Helen Cleary

1. Characteristics of staff

Qualifications and professional registration	Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions and working in premises that hold a public health contract with Hertfordshire County Council.
Initial training	<ul style="list-style-type: none"> • The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patient leading to diagnosis of the conditions listed. • Recommended requirement for training would be successful completion of a relevant sexual health module/course accredited or endorsed by the BASHH, CPPE, RCN or a university or advised in the RCN Sexual Health Education directory. • Pharmacists can obtain further learning opportunities in sexual health and Chlamydia from Centre for Pharmacy Postgraduate Education (CPPE). • Nurses are encouraged to complete Health Education England e-learning for healthcare on Sexual and Reproductive Health (e-SRH). • The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent.
Competency assessment	<ul style="list-style-type: none"> • Individuals operating under this PGD must be assessed as competent (see Appendix A). • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions.
Ongoing training and competency	<ul style="list-style-type: none"> • Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required. • Organisational PGD and/or medication training as required by employing organisation.

Additional requirements Pharmacists	<ul style="list-style-type: none"> • The pharmacist must obtain a satisfactory Disclosure & Barring Check (DBS) with Adult & Child Workforce checks. The DBS can be obtained via the pharmacist's employer, an independent provider or Hertfordshire County Council. The DBS should be renewed every 3 years. • Community Pharmacy Hertfordshire (CPH) and Herts County Council strongly encourage Pharmacists that have received the updated DBS check from HCC, to then register for the update service online (https://www.gov.uk/dbs-update-service) • Has undertaken appropriate training for working under PGDs for supply and administration of medicines. • Competence in the assessment of individuals using Fraser competency guidelines. • Is up to date with training and updating in safeguarding children and vulnerable adults. • Knowledge of Child Protection Guidelines/safeguarding for Hertfordshire and how to escalate any concerns (included in PGD, appendix E). • User of PGD is required to follow the flow chart detailed in Appendix C.
Additional requirements Nurses	<ul style="list-style-type: none"> • Has undertaken appropriate training for working under PGDs for supply and administration of medicines. • Competence in the assessment of individuals using Fraser competency guidelines. • Is up to date with training and updating in safeguarding children and vulnerable adults. • Knowledge of Child Protection Guidelines/ safeguarding for Hertfordshire and how to escalate any concerns (included in PGD, appendix E). • Nurse Authorisation Form (see Appendix A) completed and authorised to operate under this PGD. • User of PGD is required to follow the flow chart detailed in Appendix D.
<p>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.</p>	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	<ul style="list-style-type: none"> • Genital, pharyngeal and/or rectal <i>Chlamydia trachomatis</i> infection • Clinical epididymo-orchitis • Non-gonococcal or non-specific urethritis (NGU, NSU). Non-specific urethritis (NSU) refers also to non-gonococcal nonchlamydial (NGU). This PGD refers to NSU to cover NSU and NGU. • Uncomplicated <i>Mycoplasma genitalium</i> infection (prior to a course of doxycycline (see PGD: doxycycline PGD HCC202010v2.5). • Asymptomatic individuals presenting within 2 weeks of sexual contact with an individual with a confirmed diagnosis of with any of the conditions detailed below.
Criteria for inclusion	<ul style="list-style-type: none"> • Individuals (aged 15 years and above) with a positive test for <i>Chlamydia trachomatis</i> infection in the genitals, rectum or pharynx, evidenced by communication from Sexual Health Hertfordshire. • Clinical epididymo-orchitis (where the practitioner is competent in management of men with testicular pain). • Individuals with a microscopic diagnosis of NSU. • Individuals with a positive <i>test for Mycoplasma genitalium</i> (without a clinical diagnosis of pelvic inflammatory disease (PID) in women) as treatment prior to azithromycin (where <i>Mycoplasma genitalium</i> is known to be sensitive to macrolides/of unknown resistance status) - see PGD: Azithromycin PGD 202010v2.5. • Asymptomatic individuals presenting within 2 weeks of sexual contact with an individual with a confirmed diagnosis of chlamydia, NSU, PID or epididymo-orchitis who are unwilling/unable to defer testing after the 2 week window period. • Individuals who present with clear penile discharge where there is no access to microscopy facilities to diagnose NSU. • A single repeat treatment course for individuals who have had sexual intercourse within 7 days of receiving treatment or who have had sex with partner untreated for the above conditions. • Consent given. • Clients under 16 years must be assessed as competent using "Fraser Guidelines".
Criteria for exclusion	<ul style="list-style-type: none"> • Consent not given. • Individuals under 15 years of age. • Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. • Individuals 16 years of age and over and assessed as lacking capacity to consent. <p>Medical history</p> <ul style="list-style-type: none"> • Individuals with clinical proctitis or PID

	<ul style="list-style-type: none"> • Individuals with confirmed Lymphogranuloma venereum (LGV) or a contact of LGV. • Breast feeding • Known pregnancy • Known hepatic impairment • Known severe renal impairment • Presence of concomitant conjunctivitis and/or joint pain/swelling • Acute porphyria • Myasthenia gravis • Systemic Lupus Erythematosus (SLE) • Individuals with oesophagitis and oesophageal ulcerations. • Sucrose or fructose intolerance. • Glucose galactose malabsorption. • Sucrose-isomaltase insufficiency. <p>Medication history</p> <ul style="list-style-type: none"> • Any concurrent interacting medicine(s) – see Section 4 Drug interactions • Known allergy or hypersensitivity to doxycycline, other tetracycline antibiotics or to any component of the product - see Summary of Product Characteristics
Cautions including any relevant action to be taken	Discuss with appropriate medical/ independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain.
Action to be taken if the individual is excluded or declines treatment	<ul style="list-style-type: none"> • If declined ensure individual is aware of the need for treatment and the potential consequences of not receiving treatment. • Explain the reasons for exclusion to the individual and document in the consultation record. • Record reason for decline in the consultation record. • Consider if azithromycin can be used as second line (see separate PGD). • Where required refer the individual back to Sexual Health Hertfordshire.

3. Description of treatment

Name, strength & formulation of drug	Doxycycline 50mg or 100mg capsules or 100mg dispersible tablets.
Legal category	POM
Route of administration	Oral
Off label use	Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where medicines have been assessed by pharmacy/Medicines Management in

	accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with pharmacy/Medicines Management.
Dose and frequency of administration	100mg twice daily. Individuals with a diagnosis of uncomplicated <i>Mycoplasma genitalium</i> infection to follow doxycycline course with azithromycin antimicrobial therapy according to resistance profile. (see PGD - Azithromycin PGD 202010v2.5)
Duration of treatment	All diagnosis except epididymo-orchitis - 7 days Epididymo-orchitis – 14 days
Quantity to be supplied	7 day supply - appropriately labelled pack of 28x50mg, 14x100mg capsules or 14x100mg dispersible tablets. For 14 supply - appropriately labelled pack/s (as above) to a total quantity of 56x50mg, 28x100mg capsules or 28x100mg dispersible tablets. All medicines supplied to a patient under this PGD must comply with the EC labelling and leaflet directive i.e.: must be fully labelled and include an appropriate Patient Information Leaflet.
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	All concurrent medications should be reviewed for interactions. The interactions listed as severe in the BNF are: <ul style="list-style-type: none"> • Acitretin • Alitretinoin • Isotretinoin • Tretinoin • Acenocoumarol • Ciclosporin • Lithium • Phenindione • Warfarin A detailed list of all drug interactions is available in the BNF www.bnf.org or the product SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk .
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org . The following side effects are common with doxycycline (but may not reflect all reported side effects):

	<ul style="list-style-type: none"> • Hypersensitivity reactions • Headache • Nausea • Vomiting • Rashes including maculopapular and erythematous rashes, exfoliative dermatitis, erythema. • Photosensitivity skin reactions.
Management of and reporting procedure for adverse reactions	<ul style="list-style-type: none"> • Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report via organisation incident policy. • Report to Hertfordshire County Council via PHcommissioning@hertfordshire.gov.uk.
Written information and further advice to be given to individual	<ul style="list-style-type: none"> • Give patient information leaflet (PIL) provided with the original pack. Explain mode of action, side effects, and benefits of the medicine • Individuals diagnosed with <i>Chlamydia trachomatis</i> /NSU/<i>Mycoplasma genitalium</i> treatment should be offered information (verbal, written and/or digital) about their diagnosis and management. • 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. • Advise to avoid exposure to direct sunlight or ultraviolet light. • Advise not to take antacids or preparations containing calcium, iron, zinc and magnesium salts 2 hours before or after taking doxycycline. • Space the doses evenly throughout the day. Keep taking this medicine until the course is finished or unless told to stop. • Dispersible tablets should be dissolved or mixed with water before taking. • Discuss implications of incompletely treated/untreated infection of self or partner. • Advise to abstain completely from sexual intercourse (even with condoms) including oral sex, during treatment and until treatment course completed and until partner(s) treatment completed. Where not achievable advise on use of condoms. • Discuss risk of re-infection, and further transmission of infection, if after treatment sexual intercourse takes place with an untreated partner/s. • Discuss partner/s notification and issue contact slips if appropriate • Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs) • Where treatment not supplied via a sexual health clinic ensure the individual has contact details of Hertfordshire sexual health services.

Additional Facilities	<p>Following items to be available at site where PGD is operated:</p> <ul style="list-style-type: none"> • Doxycycline capsules and dispersible tablets • Patient information leaflets • Current edition of British National Formulary/access to intranet
Follow up treatment	<ul style="list-style-type: none"> • The individual should be advised to seek medical advice in the event of an adverse reaction. • Individuals with a definite diagnosis of uncomplicated <i>Mycoplasma genitalium</i> infection to follow doxycycline course with azithromycin antimicrobial therapy which should be started immediately after completing the doxycycline course. Where this is not achieved it must be started with 2 weeks of the doxycycline course being completed. If the 2nd antimicrobial course is not started within this timeframe the individual should be referred to a specialist practitioner. • Follow local protocol for Chlamydia follow up and partner notification. • Client to be advised to abstain from sexual intercourse (genital, anal or oral sex, even with a condom), until one week after client and partner have been treated. If the partner(s) receive a one-week course of treatment rather than single dose therapy then sexual intercourse should be avoided until the end of the course or if the partner(s) choose testing only, until the partner(s) have a negative test. • Client to be advised to screen again 6 weeks to 3 months after treatment. • Client to be given sexual health advice and reminded of the risk of reinfection. • Client should be advised to request another screen, visit a Sexual Health Hertfordshire clinic, or their GP, if they develop any symptoms, or there has been a risk of reinfection. • Emphasise to client the importance of informing all sexual partners of the positive diagnosis so that they can be screened and treated. • Advise annual screening is recommended for sexually active people under the age of 25, or sooner if they change sexual partner. • Advise clients, who have been treated, not to screen again for six weeks due to the risk of false positive results. • Individuals who have not had a full STI screen should be advised to attend an appropriate service for a full STI screen. • Routine follow-up for uncomplicated Chlamydia following treatment with doxycycline is unnecessary, except in the following situations where local protocols should be followed: <ul style="list-style-type: none"> ○ Pregnancy ○ Where poor compliance is suspected ○ Where symptoms persist ○ Where LGV is suspected.
Records	<p>Record:</p> <ul style="list-style-type: none"> • The consent of the individual • If individual not treated under PGD record action taken

	<ul style="list-style-type: none"> • Name of individual, postcode, date of birth • GP contact details where appropriate • Relevant past and present medical and sexual history, including medication history. • Examination or microbiology finding/s where relevant. • Any known allergies and nature of reaction • Name of registered health professional • Name of medication supplied • Date of supply • Dose supplied • Quantity supplied including batch number and expiry date in line with local procedures. • Advice given, including advice given if excluded or declines treatment • Details of any adverse drug reactions and actions taken • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Any referral arrangements made • Any supply outside the terms of the product marketing authorisation • If under 16 years of age, document Fraser competency • Recorded that supplied via Patient Group Direction (PGD) • Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy. • All records should be clear, legible and contemporaneous. • A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy. <p>Nurses: complete appropriate forms (see appendix B) for client and/or partner treated and forward via email to Hertfordshire Chlamydia Screening Service (see appendix B for contact details).</p> <p>Pharmacists: In discussion with the patient, enter treatment details onto the Public Health Designated Database (currently PharmOutcomes) to ensure payment within 10 days of the consultation date.</p>
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4. Key references

Key references (accessed March 2022)	<ul style="list-style-type: none"> • Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2
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	<ul style="list-style-type: none"> • BASHH CEG September 2018 – Update on the treatment of <i>Chlamydia trachomatis</i> (CT) infection https://www.bashhguidelines.org/media/1191/update-on-the-treatment-of-chlamydia-trachomatis-infection-final-16-9-18.pdf • BASHH National Guidelines on the management non-gonococcal urethritis (2015) www.bashhguidelines.org/media/1051/ngu-2015.pdf • BASHH National Guidelines on the management infection with <i>Mycoplasma genitalium</i> (2018) www.bashhguidelines.org/media/1198/mg-2018.pdf • Royal Pharmaceutical Society Safe and Secure Handling of Medicines (December 2018) https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines • Centre of Pharmacy Post Graduate Education – Self declaration of Competency https://www.cppe.ac.uk/services/docs/chlamydia%20testing%20and%20treatment.pdf • Health Education England, E-learning for healthcare: Sexual and Reproductive Health (e-SRH) https://portal.e-lfh.org.uk/Component/Details/628669
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5. APPENDICES

A- Registered health professional authorisation sheet (NURSES AND PHARMACISTS)
B- Patient treatment form for index/partner/contact (NURSES ONLY)
C- Management of Chlamydia Treatment protocol (PHARMACISTS ONLY)
D- Management of Chlamydia Treatment protocol (NURSES ONLY)
E- Safeguarding flowchart (NURSES AND PHARMACISTS)

Appendix A (NURSES AND PHARMACISTS)	Registered health professional authorisation sheet
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PGD Reference: Doxycycline PGD HCC 202010 v2.5:

Supply of doxycycline for the treatment of uncomplicated *Chlamydia trachomatis*, epididymo-orchitis, uncomplicated *Mycoplasma genitalium* and non-gonococcal/non-specific urethritis (NSU) by authorised Registered Nurses employed by a GP Practice or community pharmacists working in a pharmacy which is contracted by Hertfordshire County Council to provide the service.

Valid from: 17th March 2022 Expiry: 30th September 2024

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered Health Professional

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

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	Designation	Signature	Date

Authorising manager

I confirm that the registered health professionals named above are suitably declared trained and competent to work under this PGD. I give authorisation on behalf of:

Pharmacy / Surgery name

F Code / E Code

for the above named health professionals who have signed the PGD to work under it.

Name	Designation	Signature	Date

Notes to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

A signed copy should be given to each healthcare professional and should also be readily available within the pharmacy/GP Practice.

Appendix B NURSES ONLY	PATIENT TREATMENT FORM (For Index, Partner or Contact)
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Hertfordshire Chlamydia Screening Service
Southgate Health Centre
Stevenage
Herts
SG1 1HB

Tel: 0208 102 4894
Email: CLCHT.CHLAMYDIASCREENINGSERVICE@NHS.NET

PLEASE RETURN THE COMPLETED FORM TO ENSURE PAYMENT UNDER THE SLA

Site Details

Site Code:		Treatment Site:	
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Patient Details

Date		D.O.B		Lab No	
Name					
Symptomatic:					

Pregnancy Risk: Allergies:

DO NOT ISSUE A PRESCRIPTION - USE MEDICATION PROVIDED BY HCSP

Medication Given

Doxycycline 100mg twice daily for 7 or 14 days (1st Line)

Azithromycin 1g stat and then 500mg daily for 2 days (2nd line)

When azithromycin is recommended off-label consider, as part of the consent process, the patient should be informed that the drug is being offered in accordance with national guidance but that this is outside the product licence.

	Batch Number:	
	Expiry Date:	
	Date Administered:	

Partner Information

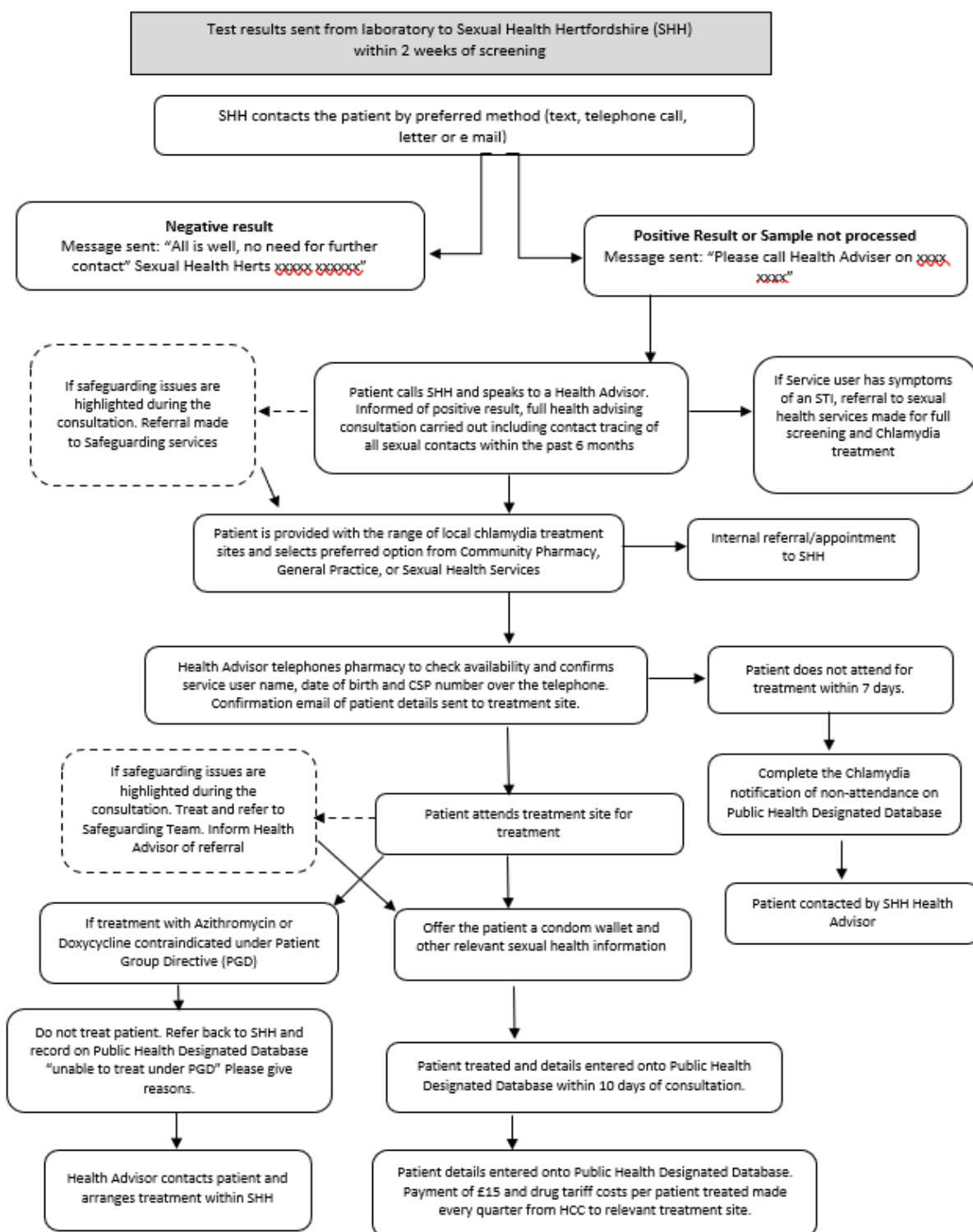
Partner Name	
Partner D.O.B	
Has partner been treated?	Yes/No
Where were they treated	

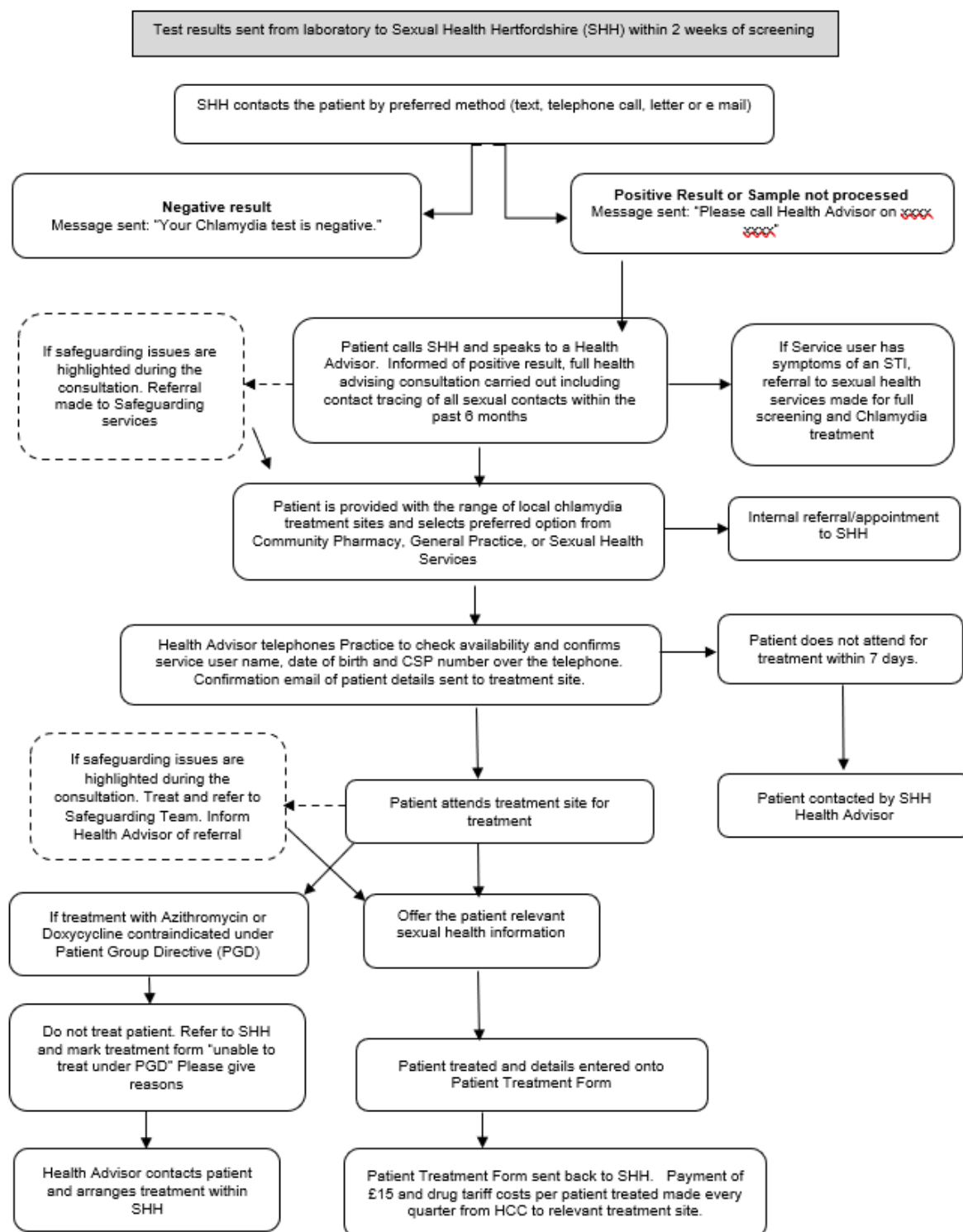
PLEASE ADVISE NO SEXUAL CONTACT FOR 7 DAYS POST TREATMENT

Prescriber Details

Prescriber Signature:	
Prescriber Name:	Date:
Prescriber Job Title:	

**IF YOU HAVE ANY QUERIES PLEASE CALL - ADMINISTRATOR ON 0208 102 4894
or EMAIL CLCHT.CHLAMYDIASCREENINGSERVICE@NHS.NET**

APPENDIX C (PHARMACISTS ONLY)**Management of Chlamydia Treatment Protocol****Management of Chlamydia Treatment Protocol (Pharmacists)**

APPENDIX D (NURSES ONLY)**Management of Chlamydia Treatment Protocol****Management of Chlamydia Treatment in Primary Care Protocol (Nurses Only)**

APPENDIX E (NURSES AND PHARMACISTS)	SAFEGUARDING FLOWCHART
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If you have concerns regarding an adult who is being abused or neglected, call 0300 123 4042 (open 24 hours a day). For more information visit:

<https://www.hertfordshire.gov.uk/services/adult-social-services/report-a-concern-about-an-adult/professionals-request-social-care/professionals-make-an-social-care-referral.aspx>

If there are concerns regarding a child being abused or neglected, follow the steps in the "Recognise, Respond and Refer" flowchart below.

