Patient Group Directions

for the supply of

Doxycycline
Azithromycin
Levonorgestrel
Ulipristal

by Community Pharmacists

Valid from: February 2020

Expiry date: February 2022

PGD Reference Number: PH_PGD_02

Version: 2.0

Contents

Patient Group Directions for the supply of Doxycycline, Azithromycin, Levonorgestrel and Ulipristal

These patient group directions (PGDs) are specific written instructions for the supply of the named products to groups of patients within the areas covered by Bristol City Council, North Somerset Council and South Gloucestershire Council.

The majority of clinical care should be provided on an individual basis. The supply of medicines under Patient Group Directions should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability.

Staff Characteristics

This PGD requires that a pharmacist has;

- Registered with the GPhC, met the conditions specified by the Commissioner and completed the Declaration of Competence process for this service.
- Undertaken appropriate training to carry out a clinical assessment of a client who requires treatment according to the indications listed in the PGD, including use of the Fraser and Bichard guidelines as appropriate
- Undertaken appropriate training for working under patient group directions for the supply and administration of medicines
- Made themselves familiar with the information on each drug in the current BNF
- Agreed to be professionally accountable for their practice in accordance with the GPhC. In the exercise of professional accountability there is a requirement to maintain and improve their professional knowledge and competence
- Signed, and retained in-store, a copy of this document

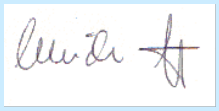
Incident Reporting

- All incidents need to be reported in accordance with the local incident reporting policy.

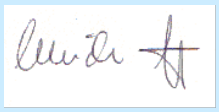
1. Doxycycline PGD Development and Authorisation

	Name and Job Title	Date
Written by	Tom Gregory Medicines Optimisation Pharmacist North Somerset CCG	March 2018
Reviewed by	Michelle Jones Medicines Management Pharmacist Bristol CCG	May 2018

This PGD has been authorised for use in Bristol City Council by:

	Name and Job Title	Signature	Date
Doctor	Dr Lucinda Farmer Education and Training Lead for Unity Sexual Health		20/03/2020
Pharmacist	Debbie Campbell Deputy Director (Medicines Optimisation) NHS BNSSG CCG		19/02/2020
Public Health Representative	Dr Joanna Copping Consultant in Public Health Medicine Bristol City Council		20/03/2020

This PGD has been authorised for use in North Somerset Council by:

	Name and Job Title	Signature	Date
Doctor	Dr Lucinda Farmer Education and Training Lead for Unity Sexual Health		20/03/2020
Pharmacist	Debbie Campbell Deputy Director (Medicines Optimisation) NHS BNSSG CCG		19/02/2020
Public Health Representative	Fiona Miles Public Health Manager North Somerset Council (Public Health Team)		20/03/2020

This PGD has been authorised for use in South Gloucestershire Council by:

	Name and Job Title	Signature	Date
Doctor	Dr Lucinda Farmer Education and Training Lead for Unity Sexual Health		20/03/2020
Pharmacist	Debbie Campbell Deputy Director (Medicines Optimisation) NHS BNSSG CCG		19/02/2020
Public Health Representative	Lindsey Thomas Specialist Public Health Manager South Gloucestershire Council Public Health & Wellbeing Division		02/04/2020

Clinical Details	
Indication	• Male and female clients who have a positive genital chlamydia result following screening by the Unity Chlamydia Screening Service. • Sexual contact of a client with a positive genital chlamydia result diagnosed through the Unity Chlamydia Screening Service.
Inclusion criteria	• Male or female client with a diagnosis of uncomplicated Chlamydia or a sexual contact requiring treatment. • (The pharmacy will receive confirmation from the Unity Chlamydia Screening Office that the client tested positive for chlamydia and that doxycycline is the treatment to be used.) • Age – adults and young people aged 13 years and over, up to and including those aged 24 years* (*In exceptional circumstances, the pharmacist may use their professional judgement to supply to a patient aged 25 years or above provided the patient meets the PGD requirements and has been referred by the Unity Chlamydia Screening Programme) • Young persons under the age of 16 years should be competent under the Lord Fraser guidelines (or have treatment consent from a carer with parental responsibility) • In a female client where the risk of pregnancy is nil or negligible[1]. • To re-treat client who has vomited within 2 hours of treatment of Chlamydia.

[1] Recent publications from the FFPRHC CEU refer to being
"Reasonably certain the woman is not pregnant" and define this as
"has not had intercourse since the last normal menses;
has been correctly and consistently using a reliable method of contraception;
is within the first 7 days of the onset of a normal menstrual period;
is within 4 weeks postpartum for non-lactating women;
is within the first 7 days post-abortion or miscarriage;
is fully or nearly fully breastfeeding, amenorrhoeic and <6 months postpartum.
Pregnancy testing if available adds weight to the exclusion of pregnancy but only if ≥ 3 weeks since the last episode of unprotected sexual intercourse".

Exclusion criteria	• The pharmacy has not received confirmation from the local chlamydia screening office that the presenting client has tested positive for C*hlamydia trachomatis*
	• If the chlamydia screening office have determined that azithromycin is the treatment to be used in this client, please refer to the PGD for the supply of azithromycin
	• No valid consent
	• Age less than 13 years (doxycycline is contraindicated under 12 years)
	• Clients aged 13 -16 years who are not Fraser competent
	• Pregnancy or breast-feeding (For women using the contraceptive pill, compliance and effectiveness in the current and previous cycle should be checked.) *Pregnancy and breastfeeding are absolute contraindications to the use of tetracyclines*
	• Known hypersensitivity to doxycycline or other tetracycline antibiotics (tetracycline, oxytetracycline, lymecycline, minocycline, demeclocycline, tigecycline) or their excipients or serious adverse reactions with previous treatment with doxycycline
	• Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrose-isomaltase insufficiency should not take doxycycline
	• Hepatic impairment or concomitant use of hepatotoxic drugs
	• Patients with myasthenia gravis, systemic lupus erythematosus, or acute porphyria
	• Known or suspected alcohol dependence
	• Male client presenting with ANY symptoms associated with complicated chlamydia infection (acute testicular pain and/ or swelling, penile discharge, urinary symptoms such as stinging when passing urine, concomitant conjunctivitis)
	• Female client presenting with ANY symptoms associated with complicated chlamydia infection (acute lower abdominal/ pelvic pain, intermenstrual or post-coital bleeding, unusual vaginal discharge, urinary symptoms such as stinging when passing urine, concomitant conjunctivitis)
	• Appendix 1 of the latest version of the BNF https://www.medicinescomplete.com/mc/ should be checked for a full, comprehensive list of all potential drug interactions
	• Concurrent use of any potentially interacting drugs which includes the following medications, is an exclusion criteria:
	  • Antiepileptics: carbamazepine, fosphenytoin, phenobarbital, phenytoin, primidone
	  • Coumarin anticoagulants: warfarin, phenindione,

	acenocoumarol • Enzalutamide • Oral retinoids: acitretin, alitretinoin, isotretinoin, tretinoin • Rifampicin • Ergot-derivatives: ergotamine and methysergide • Methotrexate • Concomitant penicillin use • Oral typhoid vaccines • Ciclosporin • Summary of Product Characteristics are available at https://www.medicines.org.uk/emc/
Management of excluded patients	• Record the reason for exclusion / referral in the case records. • **Record any advice given.** • Refer to a doctor, independent prescriber or the local sexual health services, and highlight the need to seek further medical advice. • Contact the Chlamydia Screening Office to advise them that the patient is excluded under this PGD.
Action for patients not wishing to receive care under this PGD	• Record the refusal in the case records. • Encourage the client to contact the Unity Chlamydia Screening Service or refer to a doctor or independent prescriber where appropriate, for example; GP or the local sexual health service. • Record any advice given in patient's notes.
Cautions	• Photosensitivity manifesting with exaggerated sunburn is a known side effect of doxycycline. Patients likely to be exposed to direct sunlight or ultraviolet light should be advised that this reaction can occur and that treatment should be discontinued at the first evidence of skin erythema. Patients should be advised to use sunscreens of an appropriate factor and given advice on avoidance of sun exposure. • Absorption interactions: calcium salts, dairy products, oral iron, lanthanum, zinc. Chelation is possible with medicines containing cations and tetracyclines. Patients should be advised to avoid co-administration of medicines containing calcium, iron, lanthanum or zinc for at least two to three hours either side of a doxycycline dose (or maximally separated) • Oesophagitis and oesophageal ulceration has been reported in patients taking doxycycline. This can be mitigated by taking with sufficient fluid and avoiding taking doses immediately before going to bed.

Drug Details	
Name, form & strength of medicine	Doxycycline hyclate 100mg capsules
Legal classification	POM The MHRA have advised that medicines supplied under a PGD would usually be considered to be dispensed medicines and should be labelled accordingly
Route/Method	Oral. Capsules should be swallowed whole with plenty of fluid during meals while sitting upright or standing
Dosage, frequency and duration	100mg twice daily for seven days
Quantity to supply/administer	14 capsules

Side effects	• For a comprehensive list of possible side effects please see the latest BNF, or go to www.medicines.org.uk for the Summary of Product Characteristics, or consult the manufacturer's patient information leaflet
	• Advise the client to contact their GP or a sexual health clinic if the client experiences any adverse effects to the treatment.
	• Any side effects should be recorded in the notes and the client referred to a doctor where necessary.
	• Common side effects include:
	  • Nausea, vomiting and diarrhoea
	  • Oesophageal irritation
	  • Dysphagia
	  • Fungal infection (including overgrowth of non-susceptible organisms)
	  • Back pain
	  • Anxiety
	  • Upper abdominal pain
	  • Dry mouth
	  • Nasopharyngitis or sinusitis (including sinus headache)
	• Use the Yellow Card System to report adverse drug reactions directly to the Committee of Safety in Medicines (CSM). Yellow Cards and guidance on their use are available at the back of the BNF as well as

	on the MHRA website (https://yellowcard.mhra.gov.uk/). • Anaphylaxis Before administering any medication, the possibility of anaphylaxis must be considered and appropriate medical treatment should be available for immediate use in case of anaphylactic reactions. • For further information, please see the resuscitation council guidelines. http://www.resus.org.uk/pages/glalgos.htm http://www.resus.org.uk/pages/reaction.pdf
Advice to patient	• The Pharmacist should check that the client understands the reason for treatment and how the treatment should be taken. The manufacturer's patient information leaflet must be given, and the possibility of side effects discussed • The client should be advised that the capsules should be swallowed whole with plenty of fluid and may be taken with or without food. Administration immediately before bed should be discouraged to reduce the risk of oesophagitis. If gastric irritation occurs, the capsules should be taken with food. There is no evidence that the absorption of doxycycline is significantly affected by food. • Offer verbal and written information on Chlamydia infection and its treatment. (Information on Chlamydia and other sexually transmitted diseases is available from: http://www.fpa.org.uk/helpandadvice/sexuallytransmittedinfectionsstis/chlamydia) • The importance of sexual partner(s) being evaluated and treated should be highlighted. • The client should be advised to abstain from any sexual intercourse (including protected vaginal, anal and oral sex) whilst taking treatment and until client and partner(s) have completed treatment. • In females taking oral contraceptives, if they do experience vomiting or diarrhoea after taking doxycycline, this may lead to contraceptive failure. They should refer to the instruction leaflet that comes with their oral contraceptive pill, to minimise the risk of contraceptive failure. There is no interaction between doxycycline and oral contraceptives; the warning is related to risk of vomiting/diarrhoea after taking doxycycline. • Advise the client that if they vomit within two hours of taking the medication, they may need re-treating and so should contact the chlamydia screening service for advice on 0117 342 9299

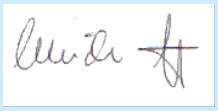
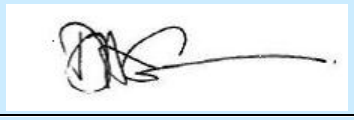
Records and Follow Up	
Referral arrangements	• If clients cannot be treated under this PGD, they should be referred back to the Unity Chlamydia Screening Office, or their GP, or a sexual health service

Records/audit trail	• Record the consultation in the patient's medication records, in line with the service protocol. • Ensure that the documentation meets the service's requirements for audit trail. • Records should include; • Client's name • Address • Date of birth (where possible) • Consent given (including consent to pass information back to the screening office) • Up to date drug/medication history (prescribed, non-prescribed & complementary) • Date and time of administration • Batch number, expiry date and quantity of doxycycline supplied • Dose advised • Name of health professional administering medicine (enrolment on PharmOutcomes is sufficient to identify supplying pharmacist) • Referral arrangements (including self-care) and any advice given • Any exclusions or client refusals • Information or leaflets supplied to the client • Document details of any adverse drug reactions and actions taken • Date and time of supply of doxycycline • Fraser guidelines followed and additional information record sheet completed for all clients under 16 or where competence is in doubt.
Follow up	• As per local arrangements / protocol • Re-treatment may be needed in clients who have not completed the course of treatment or have had unprotected sex with an untreated partner, including within one week of starting treatment if both treated simultaneously. If re-treatment is required refer to the Unity Chlamydia Screening Programme, the client's GP, or local Sexual Health Services.

2. Azithromycin PGD Development and Authorisation

	Name and Job Title	Date
Written by	Tom Gregory Medicines Optimisation Pharmacist North Somerset CCG Updated Elizabeth Jonas Senior Medicines Optimisation Pharmacist BNSSG CCG	March 2018 October 2018
Reviewed by	Kate Ellis Lead Pharmacist North Somerset Community Partnership CIC	May 2018

This PGD has been authorised for use in Bristol City Council by:

	Name and Job Title	Signature	Date
Doctor	Dr Lucinda Farmer Education and Training Lead for Unity Sexual Health		20/03/2020
Pharmacist	Debbie Campbell Deputy Director (Medicines Optimisation) NHS BNSSG CCG		19/02/2020
Public Health Representative	Dr Joanna Copping Consultant in Public Health Medicine Bristol City Council		20/03/2020

This PGD has been authorised for use in North Somerset Council by:

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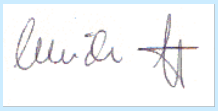
Doctor	Dr Lucinda Farmer Education and Training Lead for Unity Sexual Health		20/03/2020
Pharmacist	Debbie Campbell Deputy Director (Medicines Optimisation) NHS BNSSG CCG		19/02/2020
Public Health Representative	Fiona Miles Public Health Manager North Somerset Council (Public Health Team)		20/03/2020

This PGD has been authorised for use in South Gloucestershire Council by:

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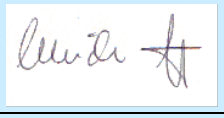
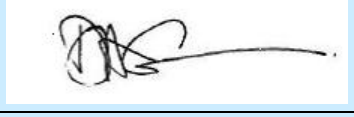
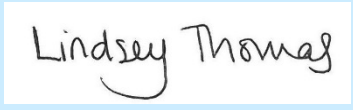
Doctor	Dr Lucinda Farmer Education and Training Lead for Unity Sexual Health		20/03/2020
Pharmacist	Debbie Campbell Deputy Director (Medicines Optimisation) NHS BNSSG CCG		19/02/2020
Public Health Representative	Lindsey Thomas Specialist Public Health Manager South Gloucestershire Council Public Health & Wellbeing Division		02/04/2020

Clinical Details	
Indication	• Male and female clients who have a positive genital chlamydia result following screening by the Unity Chlamydia Screening Programme. • Sexual contact of a client with a positive genital chlamydia result diagnosed through the Chlamydia Screening Programme.
Inclusion criteria	• Male or female client with a diagnosis of uncomplicated Chlamydia or a sexual contact requiring treatment. • (The pharmacy will receive confirmation from the Chlamydia Screening Office that the client tested positive for chlamydia and that azithromycin is the treatment to be used.) • Age – adults and young people aged 13 years and over, up to and including those aged 24 years* (*In exceptional circumstances, the pharmacist may use their professional judgement to supply to a patient aged 25 years or above provided the patient meets the PGD requirements and has been referred by the Unity Chlamydia Screening Programme) • Young persons under the age of 16 years should be competent under the Lord Fraser guidelines (or have treatment consent from a carer with parental responsibility) • In a female client the risk of pregnancy is nil or negligible2. • To re-treat client who has vomited within 2 hours of taking azithromycin for the treatment of Chlamydia.

[2] Recent publications from the FFPRHC CEU refer to being
"Reasonably certain the woman is not pregnant" and define this as
"has not had intercourse since the last normal menses;
has been correctly and consistently using a reliable method of contraception;
is within the first 7 days of the onset of a normal menstrual period;
is within 4 weeks postpartum for non-lactating women;
is within the first 7 days post-abortion or miscarriage;
is fully or nearly fully breastfeeding, amenorrhoeic and <6 months postpartum.
Pregnancy testing if available adds weight to the exclusion of pregnancy but only if ≥ 3 weeks since the last episode of unprotected sexual intercourse".

Exclusion criteria	• The pharmacy has not received confirmation from the local chlamydia screening office that the presenting client has tested positive for chlamydia trachomatis
	• No valid consent
	• Age less than 13 years
	• Clients aged 13 -16 years who are not Fraser competent
	• Weight less than 45kg
	• Known hypersensitivity to azithromycin or other macrolide antibiotics (erythromycin, clarithromycin or spiramycin) or their excipients or serious adverse reactions with previous treatment with azithromycin
	• Hepatic disease
	• Renal impairment
	• Patients with myasthenia gravis or systemic lupus erythematosus
	• Pregnancy or breast-feeding (For women using the contraceptive pill, compliance and effectiveness in the current and previous cycle should be checked.)
	• History of cardiac disease or predisposition to QT interval prolongation (including electrolyte disturbances)
	• Known HIV infection
	• Known or suspected alcohol dependence
	• Male client presenting with ANY symptoms associated with complicated chlamydia infection (acute testicular pain and/ or swelling, penile discharge, urinary symptoms such as stinging when passing urine, concomitant conjunctivitis)
	• Female client presenting with ANY symptoms associated with complicated chlamydia infection (acute lower abdominal/ pelvic pain, intermenstrual or post-coital bleeding, unusual vaginal discharge, urinary symptoms such as stinging when passing urine, concomitant conjunctivitis)
	• Concurrent use of any potentially interacting drugs which includes the following medications, is an exclusion criteria:
	  • Ciclosporin
	  • Coumarin type oral anticoagulants; warfarin, acenocoumarol (nicoumalone) or phenindione.
	  • Digoxin
	  • Theophylline
	  • Nelfinavir
	  • Rifabutin
	  • Reboxetine
	  • Mizolastine
	  • Colchicine

	• Cabergoline • Bromocriptine • Artemether with Lumefastrine • Quetiapine • Ritonavir • Oral typhoid vaccine • Ergot derivatives; ergotamine or proprietary products containing ergotamine, e.g. “Cafergot”, “Migril”. • Also concomitant use of drugs that prolong the QT interval such as; amiodarone, cisapride, amitryptyline or sumatriptan. • The latest version of the BNF www.medicinescomplete.com should be checked for a full, comprehensive list of all potential drug interactions and go to www.medicines.org.uk (search under ‘azithromycin’) and view Summary of Product Characteristics (SPC) for further information.
Management of excluded patients	• Record the reason for exclusion / referral in the case records. • Record any advice given. • Inform the Unity Chlamydia Screening Office that treatment has not been supplied. • Refer to a doctor, independent prescriber or the local sexual health services, and highlight the need to seek further medical advice. • For male clients with scrotal pain or women with acute pelvic pain, emphasise the importance of seeking prompt advice from another healthcare professional. • If weight less than 45kg and Azithromycin the most appropriate treatment refer to Unity sexual health for a review of the most appropriate dose. (0117 3426900)
Action for patients not wishing to receive care under this PGD	• Emphasise the importance of treatment and potential risks if not treated, for example; infertility, risks to sexual partners. • Record the refusal in the case records. • Encourage the client to contact the Unity Chlamydia screening office or refer to a doctor or independent prescriber where appropriate, for example; GP or the local sexual health service. • Record any advice given in patient’s notes.

Cautions	• Drug interactions See exclusion section and the current edition of the BNF or product SPC for full details of interactions. • Concurrent use of the following require special advice for the patient; Antacids see “Advice to patient” section Combined hormonal contraception • Weight less than 45kg – is excluded from this PGD (see management of excluded patients above) • Soya or peanut allergy If tablets are used note that they contain soya lecithin which may be a source of soya protein and therefore, should not be taken by clients allergic to soya or peanuts due to the risk of hypersensitivity reactions.

Drug Details	
Name, form & strength of medicine	Azithromycin tablets (250mg or 500mg) (Azithromycin capsules 250mg may be used if tablets are not available)
Legal classification	POM The MHRA have advised that medicines supplied under a PGD would usually be considered to be dispensed medicines and should be labelled accordingly
Route/Method	Oral
Dosage	1g single dose followed by 500mg daily for 2 days Maximum dose: as above * See cautions section and excluded section
Frequency	Daily
Duration of treatment	Three days
Maximum or minimum treatment period	Three days
Quantity to supply/administer	4 x 500mg tablets or 8 x 250mg tablets (8 x 250mg capsules may be used if tablets are not available)
Side effects	• Azithromycin is well tolerated with a low incidence of side effects. The most common side effect is nausea. Other occasional side effects include loss of appetite, vomiting and diarrhoea. These usually settle by themselves and the client should be reassured. Also other effects include; convulsions, headaches, taste perversions, dizziness, drowsiness or rarely anaphylaxis can occur. • For a comprehensive list of possible side effects please see the latest BNF, or go to www.medicines.org.uk (search under 'azithromycin'). • Advise the client to contact their GP or a sexual health clinic if the client experiences any adverse effects to the treatment. • Any side effects should be recorded in the notes and the client referred to a doctor where necessary. • Use the Yellow Card System to report adverse drug reactions directly to the Committee of Safety in Medicines (CSM). Yellow Cards and guidance on their use are available at the back of the BNF as well as on the MHRA website (https://yellowcard.mhra.gov.uk/). • Anaphylaxis Before administering any medication, the possibility of anaphylaxis must be considered and appropriate medical treatment should be available for immediate use in case of anaphylactic reactions.

	• For further information, please see the resuscitation council guidelines. http://www.resus.org.uk/pages/glalgos.htm http://www.resus.org.uk/pages/reaction.pdf
Advice to patient	• The Pharmacist should check that the client understands the reason for treatment and how the treatment should be taken. The manufacturer's patient information leaflet should be given. • That the dose is unlicenced but advised nationally (by the British Association for Sexual Health and HIV - BASHH) for the treatment of Chlamydia. • The client should be advised that the tablets may be taken with food if the client wishes. If capsules are used these should be swallowed whole on an empty stomach taking the medication at least 1 hour before food or 2 hours after food. • Warn of side effects such as gastro-intestinal upset and skin rash. • Offer verbal and written information on Chlamydia infection and its treatment. (Information on Chlamydia and other sexually transmitted diseases is available from: http://www.fpa.org.uk/helpandadvice/sexuallytransmittedinfectionsstis/chlamydia) • The importance of sexual partner(s) being evaluated and treated should be highlighted. • The client should be advised to abstain from any sexual intercourse (including protected vaginal, anal and oral sex) whilst taking treatment and until partner(s) have completed treatment and waited 7 days following treatment with Azithromycin. • Discuss interactions where appropriate and if taking antacids highlight that the client should be advised to take the medication at least one hour before or two hours after the antacid and may find it easier to take just before bed. • In females taking oral contraceptives, if they do experience vomiting or diarrhoea after taking azithromycin, this may lead to contraceptive failure. They should refer to the instruction leaflet that comes with their oral contraceptive pill, to minimise the risk of contraceptive failure. There is no interaction between azithromycin and oral contraceptives; the warning is related to risk of vomiting/diarrhoea after taking azithromycin. • Advise the client that if they vomit within two hours of taking the medication, it is likely they will need to retake the dose and so should return to the pharmacy or to visit their GP or the local Sexual Health Service to discuss re-treatment.

Records and Follow Up	
Referral arrangements	• As per local arrangements / protocol and Unity Chlamydia Screening Programme Protocol

Records/audit trail	• Record the consultation in the patient's medication records, in line with the service protocol.
	• Ensure that the documentation meets the service's requirements for audit trail.
	• Records should include;
	  • Client's name
	  • Address
	  • Date of birth (where possible)
	  • Consent given
	  • Up to date drug/medication history (prescribed, non-prescribed & complementary)
	  • Date and time of administration
	  • Batch number, expiry date and quantity of azithromycin supplied
	  • Dose advised
	  • Name and signature of health professional administering medicine
	  • Referral arrangements (including self-care) and any advice given
	  • Any exclusions or client refusals
	  • Information or leaflets supplied to the client
	  • Document details of any adverse drug reactions and actions taken
	  • Date and time of administration of azithromycin
	• Fraser guidelines followed and additional information record sheet completed for all clients under 16 or where competence is in doubt.
	• Diagnosis and suitability for treatment under PGD confirmed with Unity Chlamydia Screening Programme where not ascertained in full by staff operating under the PGD.

Follow up	• As per local arrangements / protocol • Re-treatment may be needed in clients who have not completed the course of treatment or have had unprotected sex with an untreated partner, including within one week of starting treatment if both treated simultaneously. • If re-treatment is required refer to the Unity Chlamydia Screening Programme, the client's GP, or local Sexual Health Services.

3. Levonorgestrel PGD Development and Authorisation

	Name and Job Title	Date
Written by	Tom Gregory Medicines Optimisation Pharmacist North Somerset CCG	March 2018
Reviewed by	Kate Ellis Lead Pharmacist North Somerset Community Partnership CIC	May 2018
Reviewed by	Michelle Jones Senior Medicines Optimisation Pharmacist BNSSG CCG	November 2019

This PGD has been authorised for use in Bristol City Council by:

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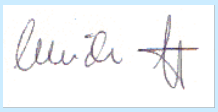
Doctor	Dr Lucinda Farmer Education and Training Lead for Unity Sexual Health		20/03/2020
Pharmacist	Debbie Campbell Deputy Director (Medicines Optimisation) NHS BNSSG CCG		19/02/2020
Public Health Representative	Dr Joanna Copping Consultant in Public Health Medicine Bristol City Council		20/03/2020

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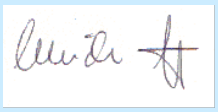
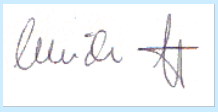
Doctor	Dr Lucinda Farmer Education and Training Lead for Unity Sexual Health		20/03/2020
Pharmacist	Debbie Campbell Deputy Director (Medicines Optimisation) NHS BNSSG CCG		19/02/2020
Public Health Representative	Fiona Miles Public Health Manager North Somerset Council (Public Health Team)		20/03/2020

This PGD has been authorised for use in South Gloucestershire Council by:

	Name and Job Title	Signature	Date
Doctor	Dr Lucinda Farmer Education and Training Lead for Unity Sexual Health		20/03/2020
Pharmacist	Debbie Campbell Deputy Director (Medicines Optimisation) NHS BNSSG CCG		19/02/2020
Public Health Representative	Lindsey Thomas Specialist Public Health Manager South Gloucestershire Council Public Health & Wellbeing Division		02/04/2020

Clinical Details	
Indication	• Emergency contraception (EC) in females presenting up to, and including, 96 hours after unprotected or inadequately protected sexual intercourse (UPSI) • EC providers should advise women that the copper intrauterine device (Cu-IUD) is the most effective method of EC and should be considered by ALL women who have had UPSI and do not want to conceive. • It can be inserted up to 5 days after the first unprotected sexual intercourse (UPSI) in a natural menstrual cycle, or up to 5 days after the earliest likely date of ovulation (whichever is later). • Ulipristal emergency contraception (UPA-EC) should be considered first line if UPSI is likely to have taken place during the 5 days prior to ovulation (high risk) – see ulipristal PGD page 32
Inclusion criteria	• Valid informed consent • Young persons under age 16 should be competent under Fraser Guidelines (or have treatment consent from a Carer with parental responsibility). • Any female aged up to, and including, 24 years who presents up to, and including, 72 hours after UPSI and is at risk of pregnancy (refer to Cautions and further information for reasons why UPSI may have occurred). • Any female aged up to, and including, 24 years who presents between 72 hours and up to, and including 96 hours where ulipristal PGD is contraindicated. This includes the following situations o recent progestogen use (including levonorgestrel EC use) in the last 7 days o the individual is breastfeeding and does not wish to discard the breast milk for seven days o the individual wishes to immediately "quick start on-going contraception or there is an increased risk of pregnancy from further UPSI if there is a delay in commencing ongoing contraception o concurrent use of liver enzyme inducer o severe asthma controlled by oral glucocorticoids o known hypersensitivity to any constituent of ulipristal • In exceptional circumstances, the Pharmacist may use their professional judgement to supply to vulnerable patients over 24 years if patients are not able to access emergency contraception via other routes. • To retreat a patient who has vomited within three hours of taking LNG-EC and is still within 96 hours of UPSI
Exclusion criteria	• No informed consent for treatment provided • The patient wishes to see a doctor • This episode of UPSI occurred more than 96 hours ago • Known hypersensitivity to levonorgestrel or any ingredient contained in the product

	• Current known pregnancy (confirmed with a positive pregnancy test by patient, provider or other healthcare provider) • Less than 21 days post-partum • Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD) • Acute porphyria (see current BNF for more detail) • Unexplained or unusual menstrual bleeding • Acute severe liver disease • Current breast cancer • Acute episode of Inflammatory Bowel Disease or Crohn's Disease. These conditions may affect the absorption of oral EC. Women whose disease is active should be advised that insertion of an IUD would be the most effective emergency contraception for them and referred accordingly • Taking any of the interacting drugs listed in Interactions, with the exception of enzyme-inducing drugs where a 3mg dose may be given • Patients who have taken UPA-EC in the last 5 days • Where the patient wishes to take UPA-EC for this episode of UPSI on the basis that it is more effective than LNG-EC, especially where UPSI has occurred in the 5 days prior to predicted ovulation.

Cautions and further information	Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC).
	
	• This PGD includes off label use in the following conditions
	  ○ Use between 72 and 96 hours post UPSI
	  ○ Increased dose for individuals with BMI over 26kg/m^2 or weight over 70kg
	  ○ Severe hepatic impairment
	  ○ Individuals with previous salpingitis or ectopic pregnancy
	  ○ Lapp-lactase deficiency
	  ○ Hereditary problems of galactose intolerance
	  ○ Glucose-galactose malabsorption
	
	Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence
	
	• Cu-IUD insertion should always be considered as a more effective alternative when emergency contraception is required
	• In women with BMI >26kg/m2 or weight >70kg, it is not known if LNG-EC or UPA-EC is more effective. Insertion of an intrauterine device is not affected by weight and should be considered first-line. If this is not acceptable or suitable, then a 3mg dose of LNG-EC may be used as per dosage schedule.
	• In women who are fully breastfeeding and remain amenorrhoeic (lactational amenorrhoea), contraception including EC is not required for 6

Cautions and further information continued	months after delivery. However, contraception is required if full breastfeeding ceases, menstruation returns or at 6 months – whichever occurs soonest. Women who do not fully meet the criteria for lactational amenorrhoea require contraception from Day 21 after delivery • Women who breastfeed shoud be advised that available limited evidence indicates that LNG-EC has no adverse effects on breastfeeding or on their infants. However, exposure of the infant to levonorgestrel can be reduced if the women takes the tablet immediately after feeding and avoids nursing for at least 8 hours. • LNG-EC can be offered to a women if she has had UPSI earlier in the same cycle as well as within the last 4 days, as evidence suggests that LNG-EC does not disrupt an existing pregnancy and is not associated with foetal abnormality. Use of LNG-EC in pregnancy is unlicensed but is supported by FSRH and this should be explained to the patient. • If a woman requiring oral EC for UPSI in the last 4 days has also had (or may also have had) UPSI more than 21 days ago AND has not had a normal menstrual period since the earlier UPSI, a high-sensitivity urine pregnancy test (able to detect hCG levels around 20mIU/ml) should be done before LNG-EC is taken • If a woman has already taken LNG-EC once or more in a cycle she can be offered LNG-EG again after further UPSI in the same cycle and this is supported by the FSRH as there is no evidence that LNG-EC will disrupt existing pregnancy or increase the risk of foetal abnormality if taken in very early pregnancy. Repeated administration of LNG-EC is well tolerated and can continue to delay ovulation for some time. • Active trophoblastic disease – seek advice from Unity Sexual Health Service • Past ectopic pregnancy – seek advice from Unity Sexual Health • The SPC for Levonelle® states that it is not recommended in patients with severe hepatic dysfunction. The FSRH have sought expert opinion on the issue and concluded that pregnancy poses a significant risk in women with severe impairment and the use of single dose of levonorgestrel 1500 micrograms is therefore acceptable. **Supplied in advance of need** There may be individual circumstances in which it is considered that advance supply of oral emergency contraception is appropriate. If LNG-EC is requested in advance of need signpost individuals to the appropriate service. **Safeguarding** With all people, but particularly with the young or vulnerable, be satisfied that sexual intercourse has been consensual and is not occurring in an abusive relationship. If non-consensual sex or sexual abuse is suspected, follow local safeguarding policy. If under 13 years of age, follow local safeguarding policy **UPSI may have occurred as a result of any of the following;**

	• No contraception used • Barrier method failure e.g. slipped or split condoms, diaphragm or cap inserted incorrectly or dislodged during intercourse or found to be torn/ damaged or removed too early • Prolonged oral contraceptive pill or patch or ring free interval including vomiting or diarrhoea due to medication and/or illness leading to a prolonged contraceptive pill or patch or ring free interval • Complete or partial expulsion of an intrauterine contraceptive device (IUCD) including mid-cycle IUCD removals • Late or missed Depo-Provera contraceptive injection. i.e. last injection administered more than 14 weeks ago • The risk of pregnancy in the fourth year of use of the implant Nexplanon and in the sixth year of the intrauterine system Mirena is low, and levonorgestrel may be considered in this situation. • Concomitant use of drugs that induce liver enzyme activity with COCs, contraceptive patches and combined vaginal rings, POPs or progestogen only implant or within 28 days of stopping them The following list of enzyme inducing drugs is derived from the FSRH guideline 'Drug Interactions with Hormonal Contraception' Jan 2017: o Antiepileptics e.g. Carbamazepine, Eslicarbazepine, Oxcarbazepine, Phenobarbital, Phenytoin, Primidone, Rufinamide, Topiramate, Perampanel, Fosphenytoin o Anti-infectives e.g. Rifabutin, Rifampicin, Griseofulvin o Anti-retroviral treatments e.g. Ritonavir, Ritonavir-boosted protease inhibitors, Efavirenz, Nevirapine. o Antidepressants e.g. St John's Wort (Hypericum perforatum) Bosentan, Modafinil, Aprepitant o Refer to the current BNF and FSRH guideline for Drug Interactions (2017) when the presenting female takes other medication.
Management of excluded patients	• Discuss reasons for exclusion • Refer patient to a GP or the sexual health clinic as appropriate for further discussion and treatment • If more than 96 hours but less than 120 hours (5 days) since the latest episode of UPSI alternative methods that should be discussed with the woman include: • Cu-IUD can be inserted up to 120 hours after the first episode of UPSI or within 5 days of the earliest expected date of ovulation. Refer to the local sexual health clinic or a GP with emergency coil fitting services • UPA-EC is licensed for use up to 120 hours following UPSI. Use of any progestogen-containing contraception, including LNG-EC taken in the 7 days prior, may reduce the efficacy of UPA-EC • Document reason for exclusion in client's record including any advice given, and suggested referral destination

Action for patients not wishing to receive care under this PGD	• Refer to local sexual health service or their usual GP • Document treatment declined in client's record including the reason for declining treatment if known, any advice given included suggested referral destination

Drug Details	
Name, form & strength of medicine	Levonorgestrel 1500 microgram tablets
Legal classification	POM - Prescription Only Medication
Route	Oral
Dosage	• One tablet to be taken as a single dose as soon as possible and no later than 96 hours after UPSI (dose can be repeated if vomiting occurs within three hours of first dose – see inclusion criteria). • Two tablets to be taken as a single dose as soon as possible, and not later than 96 hours after UPSI for women taking liver enzyme inducing drugs or taking liver inducing enzymes in the last 28 days if they are ineligible or do not wish to have an intrauterine emergency method (dose can be repeated if vomiting occurs within three hours of first dose – see inclusion criteria). See page 8 for further information on enzyme inducing drugs. • Two tablets to be taken as a single dose for women with a BMI of >26kg/m2 or who weigh >70kg whom an IUD is inappropriate or unacceptable (dose can be repeated if vomiting occurs within three hours of first dose – see inclusion criteria). A copper IUD is not affected by weight and BMI and women should be signposted to an appropriate provider for fitting of an IUD if appropriate and acceptable to the patient
Maximum treatment period	• The treatment is a single dose. • Although multiple supplies are possible to the same client within the same cycle, they should be fully assessed each time a supply is requested. This is not a substitute for ongoing contraception, and signposting advice should be given to all clients, regardless of how many times they have accessed emergency contraception
Duration of treatment	Single dose to be consumed on the premises at the time of consultation and supervised by the pharmacist
Quantity	1 x 1500 microgram tablet Or 2 x 1500 microgram tablets as detailed above Even though the product is being supplied for the patient to consume on-site, these are all Prescription Only Medicines and should be labelled accordingly
Obtaining supplies	Community pharmacists operating this PGD use their pharmacy supplies and are reimbursed at Drug Tariff price Available as; Emerres (Morningside) Upostelle (Consilient) Levonelle (Bayer)

	Please note that the Levonelle One-Step is the over-the-counter product and costs considerably more, so should not be supplied under this PGD
Side effects	• The patient should be provided with advice about side effects. In particular both written and verbal advice should be given about vomited tablets. The patient information leaflet must be supplied • LNG-EC is generally well tolerated, but the patient may experience the following (see BNF/SPC for full list): **Very Common (>1/10)** • Bleeding not related to menses, headache, nausea, low abdominal pain, fatigue • Common (>1/100, <1/10) • Vomiting, delay of bleeding >7 days, irregular bleeding and spotting, dizziness, diarrhoea, breast tenderness **Very rare (<1/10,000)** • Rash, urticaria, pruritus, face oedema • Bleeding patterns may be temporarily disturbed, but most women will have their next menstrual period within 7 days of the expected time. • Any adverse event that may be attributable to the EC should be documented in the patients clinical notes and reported following local incident reporting procedures • Any serious adverse event that may be attributable to the EC should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) using the yellow card scheme https://yellowcard.mhra.gov.uk/ • If vomiting occurs within three hours of taking the tablets, a second dose will be required as soon as possible, see inclusion criteria. • If the client vomits within three hours following administration of a dose but is subsequently outside of the 96 hour window for treatment (i.e. it is now >96-99 hours following UPSI), a repeat dose is unlikely to be effective, and they should be referred to a sexual health service or their GP for fitting of an IUD. **Anaphylaxis** • Before administering any medication, the possibility of anaphylaxis must be considered and appropriate medical treatment should be available for immediate use in case of anaphylactic reactions. • For further information, please see the resuscitation council guidelines. http://www.resus.org.uk/pages/glalgos.htm http://www.resus.org.uk/pages/reaction.pdf
Interactions	• Enzyme-inducing drugs reduce efficacy of EC, so an emergency Cu-IUD would be preferable as it is not affected by enzyme-inducing drugs. If an IUD is declined or while awaiting IUD fitting, a 3mg dose should be given where the woman is currently taking or has used enzyme inducing drugs in

Interactions continued	the last 28 days. (3mg is an unlicensed dose, but recommended by the FSRH in these situations) • The following list of enzyme inducing drugs is derived from the FSRH guideline 'Drug Interactions with Hormonal Contraception' March 2017. It is not a complete list. **Anticonvulsants** • Carbamazepine, Eslicarbazepine, Oxcarbazepine, Phenobarbital, Phenytoin, Primidone, Rufinamide, Topiramate **Antibiotics** • Rifabutin, Rifampicin **Anti-viral treatments** • Ritonavir, Ritonavir-boosted atazanavir, Ritonavir-boosted tipranavir, Ritonavir-boosted saquinavir, all other ritonavir-boosted protease inhibitors (darunavir, nelfinavir, fosamprenavir, lopinavir) Efavirenz, Nevirapine. See www.hiv-druginteractions.org for further details on interactions with this group of medicines **Others** • St John's Wort (Hypericum perforatum), Bosentan, Modafinil, Aprepitant, Sugammadex **Other potential Drug Interactions** • Ciclosporin – metabolism may be inhibited leading to potential toxicity. Discuss with patients GP. • Anticoagulants – Warfarin and phenindiones effect may be unpredictably altered. Advise INR check within 7 days and inform patients GP. • Selegiline – Selegiline levels may increase. Avoid concomitant use. Discuss with patients GP. • Tizanidine – progestogens possibly increase plasma concentration of tizanidine potentially leading to toxicity. Avoid concomitant use. • Ulipristal –Seek local sexual health service advice regarding suitable treatment options for the client. The effectiveness of UPA-EC could theoretically be reduced if a woman has taken progestogen (including LNG-EC) in the 7 days prior to taking UPA-EC • Sugammadex – Administration of a bolus dose of sugammadex is considered to be equivalent to a missed dose of an oral contraceptive • Severe malabsorption syndromes – such as Crohn's disease, or removal of sections of intestines might impair the absorption and the efficacy of levonorgestrel – advise patient to seek advice regarding treatment with IUCD from the local sexual health service or a GP with emergency coil fitting service. • Current breast cancer – Advise patients of possible disease interaction and the availability of alternative treatment with emergency IUCD fitting. The above list of drug and disease interactions is not exhaustive. For full interaction information please refer to a current version of the BNF or Summary of Product Characteristics.

Advice to patient	• Inform clients that the Cu-IUD is the preferred first line EC treatment for all suitable individuals due to its low documented failure rates. (This is a recommendation from the FSRH). The Cu-IUD can be inserted up to 120 hours after the first episode of UPSI or within 5 days of the earliest expected date of ovulation. • The pregnancy risk from a single act of intercourse is highest (between 20-30%) in the days just before and just after ovulation. Counting the first day of menstrual bleeding as day 1, the pregnancy risk is low before day 7 and after day 17 inclusive in a 28-day cycle • Failure rates – data suggests that LNG-ECis effective up to 96 hours and that delay in treatment up to this time did not appear to affect efficacy • The possible mechanisms of action should be explained to the client as some methods may not be acceptable, depending on individual beliefs about the onset of pregnancy and abortion. (FSRH Emergency Contraception, December 2017) • LNG-EC inhibits ovulation, delaying or preventing follicular rupture and causing luteal dysfunction. If taken prior to the start of the LH surge, LNG-EC inhibits ovulation for the next 5 days, until sperm from the UPSI for which it was taken are no longer viable. • In the late follicular phase, however, LNG-EC becomes ineffective while UPA-EC is still able to delay ovulation. • Neither LNG-EC or UPA-EC are effective post-ovulation • Inform patient that the majority of women will go on to ovulate later in the cycle and are therefore at risk of pregnancy from subsequent UPSI. Women should be made aware of this risk regarding ongoing contraception • Give client a copy of the manufacturers patient information leaflet and the FPA leaflet on emergency contraception – discuss as required especially any difference in missed pill advice between the manufacturer's PIL and the FPA leaflets (developed in conjunction with FSRH) • The patient should be provided with advice about side effects. In particular both written and verbal advice should be given about what to do if vomiting occurs within three hours of treatment • If using levonorgestrel 1500 micrograms beyond 72 hours and up to 96 hours (4 days) inform clients this is an off-licence evidence-based use. Make sure that they are aware that an Cu-IUD is more effective than LNG-EC in preventing pregnancy, particularly after 96 hours • Advise client that she could still become pregnant. Her period may arrive earlier or heavier than normal and stress that this supply only treats this episode of UPSI. If menstrual periods are delayed by more than 7 days or is lighter than usual or she is concerned about changes to her period, the client should be advised to have a pregnancy test and seek medical advice from her GP or local sexual health service

Advice to patient continued	• There is no guarantee of a normal outcome to any pregnancy. However there is no evidence of EC causing birth defects or pregnancy complications if it fails • The possibility of an ectopic pregnancy should be considered particularly in women with a previous ectopic pregnancy, fallopian tube surgery or pelvic inflammatory disease. Inform women to seek medical advice if there is any moderate to severe lower abdominal pain after taking LNG-EC • Advise the use of barrier methods until onset of the next period or the OCP/contraceptive patches are effective again, discuss future contraceptive need and give information pack that contains free condoms • Patient should be advised to make a follow up appointment with her GP or local sexual health service as soon as is practical to ensure that the method has worked and to discuss on-going contraception • As part of raising awareness around sexually transmitted infections and to increase Chlamydia screening uptake, all clients presenting for LNG-EC should be informed that it does not protect against sexually transmitted infections and should be offered a Chlamydia screening kit and advised how to submit it for testing
Records and Follow Up	
Referral arrangements	• If clients cannot be treated under this PGD, or wish to have an emergency IUD fitted, they can be referred to Unity Sexual Health (referral proforma can be accessed via PharmOutcomes)

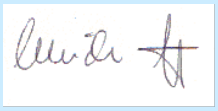
Records/ audit trail	• Record the supply in the patient's medication records, and the below information onto PharmOutcomes in line with the service protocol. Following the PharmOutcomes template will result in all of the required information being recorded
	• Records should include;
	  • Client's name
	  • Address
	  • Date of birth (where possible)
	  • Consent given
	  • Up to date drug/medication history (prescribed, non-prescribed & complementary)
	  • Date and time of administration
	  • Dose supplied
	  • Batch number, expiry date and quantity of Ulipristal supplied
	  • Name and pharmacist supplying and administering medicine
	  • Referral arrangements (including self-care) and any advice given
	  • Any exclusions or client refusals.
	  • Information or leaflets supplied to the client
	• Document details of any adverse drug reactions and actions taken

	• Fraser guidelines followed and additional information record sheet completed for all clients under 16 or where competence is in doubt. • Note: It is strongly recommended that the client takes the dose of levonorgestrel at the time of the consultation. If this is not the case, the reason why should be recorded in the clients record.
Follow up	• Advise a follow up appointment with their GP or local sexual health service in 3 to 4 weeks to ensure that the method has worked. • If the patient does not have a period within 3 to 4 weeks of taking emergency contraception, or their period is unusually light, short or painful, or they have abdominal pain, they should take an early morning sample of urine with them to that appointment. • Patient should be advised to contact their GP or local sexual health service at any time to discuss on-going contraception. • All clients presenting for emergency contraception should be supplied with a screening kit for chlamydia. If sexually transmitted infection is suspected, refer the patient to their GP or local sexual health service

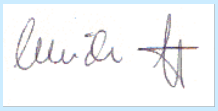
4. Ulipristal PGD Development and Authorisation

	Name and Job Title	Date
Written by	Tom Gregory Medicines Optimisation Pharmacist North Somerset CCG	March 2018
Reviewed by	Michelle Jones Senior Medicines Optimisation Pharmacist BNSSG CCG	May 2018, November 2019

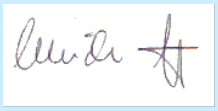
This PGD has been authorised for use in Bristol City Council by:

	Name and Job Title	Signature	Date
Doctor	Dr Lucinda Farmer Education and Training Lead for Unity Sexual Health		20/03/2020
Pharmacist	Debbie Campbell Deputy Director (Medicines Optimisation) NHS BNSSG CCG		19/02/2020
Public Health Representative	Dr Joanna Copping Consultant in Public Health Medicine Bristol City Council		20/03/2020

This PGD has been authorised for use in North Somerset Council by:

	Name and Job Title	Signature	Date
Doctor	Dr Lucinda Farmer Education and Training Lead for Unity Sexual Health		20/03/2020
Pharmacist	Debbie Campbell Deputy Director (Medicines Optimisation) NHS BNSSG CCG		19/02/2020
Public Health Representative	Fiona Miles Public Health Manager North Somerset Council (Public Health Team)		20/03/2020

This PGD has been authorised for use in South Gloucestershire Council by:

	Name and Job Title	Signature	Date
Doctor	Dr Lucinda Farmer Education and Training Lead for Unity Sexual Health		20/03/2020
Pharmacist	Debbie Campbell Deputy Director (Medicines Optimisation) NHS BNSSG CCG		19/02/2020
Public Health Representative	Lindsey Thomas Specialist Public Health Manager South Gloucestershire Council Public Health & Wellbeing Division		02/04/2020

Clinical Details	
Indication	• Emergency contraception (EC) in females presenting within 120 hours of unprotected or inadequately protected sexual intercourse (UPSI). Ulipristal should be considered first line if UPSI is likely to have taken place during the 5 days prior to ovulation (high risk). • EC providers should advise women that the copper intrauterine device (Cu-IUD) is the most effective method of EC and should be considered by ALL women who have had UPSI and do not want to conceive. • It can be inserted up to 5 days after the first (unprotected sexual intercourse (UPSI) in a natural menstrual cycle, or up to 5 days after the earliest likely date of ovulation (whichever is later).
Inclusion criteria	• Valid informed consent • Young persons under age 16 should be competent under Lord Fraser guidelines (or have treatment consent from a Carer with parental responsibility) • Any female, up to and including 24 years, who presents up to and including, 120 hours after UPSI and is at risk of pregnancy (refer to Cautions and Further Information section for reason why UPSI may have occurred). • In exceptional circumstances, the Pharmacist may use their professional judgement to supply to vulnerable patients over 24 years if patients are not able to access emergency contraception via other routes. • To retreat a patient who has vomited within three hours of taking the tablet and is still within 120 hours of UPSI
Exclusion criteria	• No informed consent for treatment provided • The patient wishes to see a doctor • This episode of UPSI occurred more than 120 hours ago • Known hypersensitivity or intolerance to Ulipristal Acetate or any component of the product • Current known pregnancy (confirmed with a positive pregnancy test by patient, provider or other healthcare provider) • Less than 21 days post-partum • Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD) • Non-active or active acute porphyria (see BNF for more detail) • Unexplained or unusual menstrual bleeding • Breast feeding – not advised • Severe asthma controlled by oral steroids – Ulipristal not suitable • Acute episode of Inflammatory Bowel Disease or Crohn's Disease. These conditions may affect the absorption of UPA-EC. Women whose disease is active should be advised that insertion of an IUD would be

	the most effective emergency contraception for them and referred accordingly • Patients who have taken a progestogen-containing drug in the week prior to UPA-EC (consider referral for Cu-IUD fitting or levonorgestrel PGD) • Female client has taken enzyme-inducing drugs in the last 28 days (consider referral for Cu-IUD fitting or levonorgestrel PGD)
Cautions and Further Information	• Referral for Cu-IUD insertion should always be considered as a more effective alternative when EC is required. • This PGD includes off label use in the following conditions o Lapp-lactase deficiency o Hereditary problems of galactose intolerance o Glucose-galactose malabsorption Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence • Females should be informed that higher weight or BMI could reduce the effectiveness of oral EC. FRSH concluded that there is no evidence that an increased dose of UPA-EC is more effective than a standard dose and therefore, double dosing is not recommended. Females should be informed that the effectiveness of the Cu-IUD is not known to be affected by weight or BMI, therefore a Cu-IUD is the preferred EC. If the copper IUD is declined or unavailable standard dose Ulipristal Acetate 30mg or levonorgestrel 2x 1500 micrograms (see levonorgestrel PGD) may be offered. • UPA-EC can be offered to a woman if she has had UPSI earlier in the same cycle as well as within the last 5 days, as evidence suggests that UPA-EC does not disrupt an existing pregnancy and is not associated with foetal abnormality. Use of UPA-EC in pregnancy is unlicensed but is supported by FSRH and this should be explained to the patient. • If other episodes of UPSI have occurred earlier in the cycle (>120 hours ago) without using emergency contraception, Cu-IUD fitting up to day 19 (of a 28 day cycle) should be offered. • If a woman requiring oral EC for UPSI in the last 5 days has also had (or may also have had) UPSI more than 21 days ago AND has not had a normal menstrual period since the earlier UPSI, a high-sensitivity urine pregnancy test (able to detect hCG levels around 20mIU/ml) should be done before UPA-EC is taken • If a woman has already taken UPA-EC once or more in a cycle she can be offered UPA-EG again after further UPSI in the same cycle and this is supported by the FSRH as there is no evidence that UPA-EC will disrupt existing pregnancy or increase the risk of foetal abnormality if taken in very early pregnancy. Repeated administration of UPA-EC is well tolerated and can continue to delay ovulation for some time. • The effectiveness of UPA-EC could theoretically be reduced by immediate subsequent use of progestogen-containing contraception or

Cautions and Further Information continued	drug. Therefore, ongoing hormonal contraception or hormone therapy should not be started until 5 days after UPA-EC administration. • The SPC for ellaOne® states that in the absence of safety data Ulipristal should be avoided by women with hepatic impairment. The FSRH have sought expert opinion on the issue and concluded that pregnancy poses a significant risk in women with severe impairment and the use of single dose of Ulipristal Acetate 30mg is therefore acceptable. **Supplied in advance of need** • There may be individual circumstances in which it is considered that advance supply of oral emergency contraception is appropriate. If UPA-EC is requested in advance of need signpost individuals to the appropriate service. **UPSI may have occurred as a result of any of the following;** • No contraception used • Barrier method failure e.g. slipped or split condoms, diaphragm or cap inserted incorrectly or dislodged during intercourse or found to be torn/ damaged or removed less than 6 hours after SI • Complete or partial expulsion of an intrauterine contraceptive device (IUCD) including mid-cycle IUCD removals • Prolonged oral contraceptive pill* or patch* or ring* free interval including vomiting or diarrhoea due to medication and/or illness leading to a prolonged contraceptive pill or patch or ring free interval • Late or missed Depo-Provera® contraceptive injection. i.e. last injection administered more than 14 weeks ago • The risk of pregnancy in the fourth year of use of the implant Nexplanon® and in the sixth year of the intrauterine system Mirena® is low, and levonorgestrel may be considered in this situation • Concomitant use of drugs that induce liver enzyme activity with COCs, contraceptive patches and combined vaginal rings, POPs or progestogen only implant or within 28 days of stopping them The following list of enzyme inducing drugs is derived from the FSRH guideline 'Drug Interactions with Hormonal Contraception' Jan 2017: o Antiepileptics e.g. Carbamazepine, Eslicarbazepine, Oxcarbazepine, Phenobarbital, Phenytoin, Primidone, Rufinamide, Topiramate, Perampanel, Fosphenytoin o Anti-infectives e.g. Rifabutin, Rifampicin, Griseofulvin o Anti-retroviral treatments e.g. Ritonavir, Ritonavir-boosted protease inhibitors, Efavirenz, Nevirapine. o Antidepressants e.g. St John's Wort (Hypericum perforatum) Bosentan, Modafinil, Aprepitant o Refer to the current BNF and FSRH guideline for Drug Interactions (2017) when the presenting female takes other medication.

	Safeguarding • With all people, but particularly with the young or vulnerable, be satisfied that sexual intercourse has been consensual and is not occurring in an abusive relationship. If non-consensual sex or sexual abuse is suspected, follow local safeguarding policy. • If under 13 years of age, follow local safeguarding policy
Management of excluded patients	• Document reason for exclusion in client's record including any advice given, and suggested referral destination • Refer to a doctor,or the local sexual health services, and highlight the need to seek further medical advice where appropriate. • If it is more than 120 hours since the latest episode of UPSI, discuss insertion of the Cu-IUD. It can be inserted within 5 days of the earliest expected date of ovulation. Refer to the local sexual health clinic or a GP with emergency coil fitting services
Action for patients not wishing to receive care under this PGD	• Refer to local sexual health service or their usual GP • Document treatment declined in client's record including the reason for declining treatment if known, any advice given included suggested referral destination

Drug Details	
Name, form & strength of medicine	Ulipristal Acetate 30mg Tablets
Legal classification	P – Pharmacy Medicine The MHRA have advised that medicines supplied under a PGD would usually be considered to be dispensed medicines and should be labelled accordingly
Route/Method	Oral
Dosage	One tablet (30mg) as a single dose taken as soon as possible up to 120 hours after unprotected intercourse Dose can be repeated if vomiting occurs within 3 hours of first dose
Frequency and duration	A single dose of 30mg
Maximum or minimum treatment period	The treatment is a single dose. Although multiple supplies are possible to the same client within the same cycle, the client should be fully assessed each time a supply is requested. Emergency contraception is not a substitute for ongoing contraception and signposting advice should be given to all clients, regardless of how many times a client presents for emergency contraception.

Quantity to supply/administer	1x 30mg tablet

Side effects	• The patient should be provided with advice about side effects, in particular written and verbal advice about vomited tablets. The manufacturer's patient information leaflet must be supplied
	• Common (not exhaustive):
	  • Nausea or vomiting
	  • Abdominal pain or discomfort
	  • Headache
	  • Dizziness
	  • Muscle pain (myalgia)
	  • Dysmenorrhea
	  • Pelvic pain
	  • Breast tenderness
	  • Fatigue
	  • Uncommon (not exhaustive):
	  • Diarrhoea
	  • Dry mouth
	  • Dyspepsia
	  • Flatulence
	  • Acne pruritus
	  • Menorrhagia
	  • Vaginal discharge
	  • Vaginitis
	  • Hot flushes
	  • Chills
	  • Malaise
	  • Pyrexia
	  • Anxiety
	  • Insomnia
	  • Changes in libido
	• If vomiting occurs within three hours of taking the tablet, a second dose will be required as soon as possible. If however the client is subsequently outside of the 120 hour treatment window, a repeat dose is unlikely to be effective and fitting of an IUD should be considered.
	• For a comprehensive list of possible side effects please see the latest BNF, or Summary of Product Characteristics

	• Advise the client to contact their GP or a sexual health clinic if the client experiences any adverse effects to the treatment. • Use the Yellow Card System to report adverse drug reactions directly to the Committee of Safety in Medicines (CSM). Yellow Cards and guidance on their use are available at the back of the BNF as well as on the MHRA website https://yellowcard.mhra.gov.uk/ **Anaphylaxis** • Before administering any medication, the possibility of anaphylaxis must be considered and appropriate medical treatment should be available for immediate use in case of anaphylactic reactions. For further information, please see the resuscitation council guidelines. http://www.resus.org.uk/pages/glalgos.htm http://www.resus.org.uk/pages/reaction.pdf
Interactions	• The effectiveness of UPA-EC could be reduced in women taking enzyme-inducing drugs and for 28 days after use of these drugs. Use of UPA-EC is not recommended • In women who are using enzyme-inducing drugs a referral for Cu-IUD fitting is first line. Where this is declined or while awaiting fitting, a double dose of levonorgestrel may be considered (see levonorgestrel PGD). • The following list of enzyme inducing drugs is derived from the FSRH guideline 'Drug Interactions with Hormonal Contraception' Jan 2017: • Antiepileptics e.g. Carbamazepine, Eslicarbazepine, Oxcarbazepine, Phenobarbital, Phenytoin, Primidone, Rufinamide, Topiramate, Perampanel, Fosphenytoin • Anti-infectives e.g. Rifabutin, Rifampicin, Griseofulvin • Anti-retroviral treatments e.g. Ritonavir, Ritonavir-boosted protease inhibitors, Efavirenz, Nevirapine. • Antidepressants e.g. St John's Wort (Hypericum perforatum) Bosentan, Modafinil, Aprepitant • The effectiveness of UPA-EC may be reduced by progestogen, therefore women who have used a progestogen-containing drug in the 7 days prior to taking UPA-EC should be offered a suitable alternative EC. • Refer to the current BNF and FSRH guideline for Drug Interactions (2017) when the presenting female takes other medication.
Advice to patient	• Inform clients that the Cu-IUD is the preferred first line treatment for all suitable individuals due to its low documented failure rates. (This is a recommendation from the FSRH). Cu-IUD can be inserted up to 120 hours after the first episode of unprotected sexual intercourse (UPSI) or within 5 days of the earliest expected date of ovulation. • The pregnancy risk from a single act of intercourse is highest (between 20-30%) in the days just before and just after ovulation. Counting the

Advice to patient continued	first day of menstrual bleeding as day 1, the pregnancy risk is low before day 7 and after day 17 inclusive in a 28-day cycle • The possible mechanisms of action should be explained to the client as some methods may not be acceptable, depending on individual beliefs about the onset of pregnancy and abortion. (FSRH Emergency Contraception, December 2017) • UPA-EC acts by delaying ovulation for at least 5 days, until sperm from the UPSI for which EC was taken are no longer viable. UPA-EC delays ovulation even after the luteinising hormone (LH) surge whereas LNG-EC is no longer effective after the start of the LH surge. • Neither UPA-EC and LNG-EC are effective post-ovulation • Inform patient that the majority of women will go on to ovulate later in the cycle and are therefore at risk of pregnancy from subsequent UPSI. Women should be made aware of this risk regarding ongoing contraception • Give client a copy of the manufacturer's patient information leaflet and the FPA leaflet on emergency contraception – discuss as required especially any difference in missed pill advice between the manufacturer's PIL and the FPA leaflets (developed in conjunction with FSRH). Note female clients who have taken progestogen-containing drugs in the previous 7 days are excluded. • The patient should be provided with advice about side effects. In particular both written and verbal advice should be given about what to do if vomiting occurs within three hours of treatment • Advise client that she could still become pregnant. Her period may arrive earlier or heavier than normal and stress that this supply only treats this episode of UPSI. If menstrual periods are delayed by more than 7 days or is lighter than usual or she is concerned about changes to her period, the client should be advised to have a pregnancy test and seek medical advice from her GP or local sexual health service • There is no guarantee of a normal outcome to any pregnancy. However there is no evidence of EHC causing birth defects or pregnancy complications if it fails • Advise the use of barrier methods until onset of the next period or the OCP/contraceptive patches are effective again, discuss future contraceptive need and give information pack that contains free condoms • Patient should be advised to make a follow up appointment with her GP or local sexual health service as soon as is practical to ensure that the method has worked and to discuss on-going contraception. Women should be advised that the effectiveness of UPA-EC could be reduced if she takes progestogen in the 5 days after taking UPA-EC • As part of raising awareness around sexually transmitted infections and to increase Chlamydia screening uptake, all clients presenting for UPA-EC should be informed that it does not protect against sexually transmitted infections and should be offered a Chlamydia screening kit and advised how to submit it for testing

Records and Follow Up	
Referral arrangements	• If clients cannot be treated under this PGD, or wish to have an emergency IUD fitted, they can be referred to Unity Sexual Health (referral proforma can be accessed via PharmOutcomes)

Records/audit trail	• Record the supply in the patient's medication records, and the below information onto PharmOutcomes in line with the service protocol. Following the PharmOutcomes template will result in all of the required information being recorded
	• Records should include;
	  • Client's name
	  • Address
	  • Date of birth (where possible)
	  • Consent given
	  • Up to date drug/medication history (prescribed, non-prescribed & complementary)
	  • Date and time of administration
	  • Dose supplied
	  • Batch number, expiry date and quantity of ulipristal supplied
	  • Name and pharmacist supplying and administering medicine
	  • Referral arrangements (including self-care) and any advice given
	  • Any exclusions or client refusals.
	  • Information or leaflets supplied to the client
	  • Document details of any adverse drug reactions and actions taken
	• Fraser guidelines followed and additional information record sheet completed for all clients under 16 or where competence is in doubt.
	• Note: It is strongly recommended that the client takes the dose of UPA-EC at the time of the consultation. If this is not the case, the reason why should be recorded in the clients record.

Follow up	• Advise a follow up with their GP or local sexual health service in 3 to 4 weeks to ensure that the method has been successful. • If the patient does not have a period within 3 to 4 weeks of taking emergency contraception, or if the period is unusually light, short or painful, or if they have abdominal pain, they should take an early morning sample of urine with them to that appointment. • Patients should be advised to contact their GP or local sexual health service to discuss ongoing contraception.

	• All clients presenting for emergency contraception should be supplied with a screening kit for chlamydia. If sexually transmitted infection is suspected, refer the patient to their GP or local sexual health service.

References

- Department of Health (DH), Review of Prescribing, Supply and Administration of Medicines. Final Report 1999 www.dh.gov.uk
- Department of Health (DH), Patient Group Directions (England only) (HSC) 2000/026 www.dh.gov.uk
- Royal College of Nursing Patient Group Directions Guidance and information for nurses (publication code 001370)
- NMC Code of Professional Conduct (2008) www.nmc-uk.org
- NMC Guidelines for Standards for Medicines Management (April 2010) www.nmc-uk.org
- https://www.bashh.org/guidelines
- Department of Health 2004, Best practice guidance for doctors and other health professionals on the provision of advice and treatment to young people under 16 on contraception, sexual and reproductive health. Gateway reference number 3382 29 July 2004
- Electronic Medicines Compendium accessed at www.emc.medicines.org.uk
- NMC Guidelines for record keeping - guidance for nurses and midwives (2010) www.nmc-uk.org
- Family Planning Association Leaflet on Chlamydia http://www.fpa.org.uk/Information/Readourinformationbooklets/chlamydia
- Faculty of Sexual and Reproductive Healthcare Clinical Guidance, Drug Interactions with Hormonal Contraception, November 2017 https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/
- Faculty of Sexual and Reproductive (2017) CEU Clinical Guidance: Emergency Contraception https://www.fsrh.org/documents/ceu-clinical-guidance-emergency-contraception-march-2017/

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	
Organisations	Bristol City Council North Somerset Council South Gloucestershire Council
Contact details for Sexual Health services	Unity Sexual Health Tel: 0117 342 6900 www.unitysexualhealth.co.uk Unity Chlamydia Screening Office Tel: 0117 3429299
Safeguarding issues (including clients not deemed Fraser competent)	All areas' safeguarding contact details and procedures are available from the following website: www.proceduresonline.com/swcpp/

Individual Authorisation

I have read and understood the Patient Group Directions and agree to supply these medicines only in accordance with these PGDs.

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 their own code of professional conduct.

Name of Pharmacist	Signature	Date