Document Title:	**Patient Group Direction for supply of levonorgestrel 1500mcg (Emergency Hormonal Contraception) by Pharmacists**		
PCT Doc Ref.:		**Version No.:**	1
Local Doc Ref.:	PGD		
Author/Owner:	Jacqui Seaton, Head of Medicines Management/Hitesh Patel, Pharmaceutical Adviser, NHS Telford & Wrekin CCG		
File Reference:	C:\MyDocuments\ApprovedPGDs		
Document Overseeing Group:	PGD Working Group		
Placement in Framework:			
Approval Level:	Medicines Management Group		
Date of Approval:	May 2018		
Review Date:	May 2020		

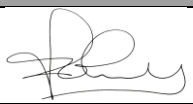
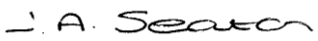
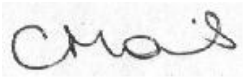
Amendment Dates:	**Page(s)**	**Brief Description**
February 2018		New PGD

NB: Always access the electronic version of this PGD to ensure that you are using the most up to date version.

The practitioner MUST be authorised by name, under the current version of this PGD before working according to it.

Patient Group Direction for: Levonorgestrel 1500mcg

Approved By

NHS Telford and Wrekin Clinical Commissioning Group	Name	Signature
Clinical Chair	**Dr Jo Leahy**	
Head of Medicines Management	**Jacqui Seaton**	
Executive Lead for Quality, Nursing and Safety	**Christine Morris**	

Date of patient group direction approved	May 2018
Date this patient group direction becomes due for review	May 2020 or in response to new local/national guidelines

Specialist Advice	Organisation	Signature	Date
Dr Arabinda Kundu – Consultant in Sexual and Reproductive Health	SSSFT		25/04/2018

STAFF CHARACTERISTICS

- Working for providers of NHS Pharmaceutical Services within NHS Telford and Wrekin CCG
- GPhC registered Pharmacist deemed competent in the administration and supply of post-coital contraception (levonorgestrel) for post-coital contraception purposes. The pharmacist will have due regard for the General Pharmaceutical Council Standards of conduct, ethics and performance.

Specialist competencies or qualifications:

- The healthcare professional must have a good understanding of the NICE Good Practice Guidance on Patient Group Directions
- The clinical manager or service lead has evidence that the registered healthcare professional has undertaken training to carry out clinical assessment of patient leading to confirmation that the patient requires treatment according to the indications listed in the PGD.
- The healthcare professional must provide evidence of training, appropriate annual updates and continued professional development undertaken to support their competence for administration of this treatment.
- Completion of current online EHC CPPE (learning programme and assessment)
- Completion of CPPE safeguarding children and vulnerable adults level 1, Combating CSE and NHS Spotting the signs of child sexual exploitation (e-assessment learning)
- The clinical manager or service lead has proof of training by the healthcare professional on the legal aspects of supply or administration of medicines under a Patient Group Direction
- The clinical manager or service lead has assessed the competency of the healthcare professional to work to a Patient Group Direction at least every 2 years (for pharmacists this will usually be in the form of training and a self-declaration of competency) The NICE competency framework for people authorising PGDs and the NICE competency framework for healthcare professionals using Patient Group Directions should be used to support this assessment.
- Must have access to all relevant sources of information e.g. information issued by the Department of Health (DH), British National Formulary (BNF), Summary of Product Characteristics (SPC), and any clinical guidelines concerning medicine(s) within this Patient Group Direction (PGD).
- All staff operating within the PGD must update their knowledge and skills in this area of practice with particular reference to changes and national directives
- All staff operating within the PGD must be competent to follow and administer patient group direction - showing clear understanding of indications for treatment, exclusions from treatment (and subsequent action to be taken) and the treatment itself.
- All staff operating within the PGD should have a clear understanding of the drug administered including side effects and contraindications
- The registered healthcare practitioner is professionally accountable for supply or administration under the PGD as defined in their own profession's Code of Professional Conduct and Ethics.

YOU MUST BE AUTHORISED BY NAME BY YOUR MANAGER UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

PGDs DO NOT REMOVE INHERANT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

Always ensure that you are using the most up to date version of this PGD.

Patient Group Direction for supply of levonorgestrel 1500mcg (Emergency Hormonal Contraception) by registered Pharmacists	
CLINICAL CONDITION	
Clinical need addressed	Clients requesting emergency contraception within 72 hours of unprotected sexual intercourse (UPSI) for the prevention of unwanted pregnancy where Cu-IUD is declined by the client or where unable to get access for this provision. **NB** Clients should always be advised that the Cu-IUD is the most effective method of emergency contraception. If the client is referred on for a Cu-IUD, oral emergency contraception should be given at the time of the referral in case the Cu-IUD cannot be fitted or the client changes their mind.
Inclusion criteria	• All clients aged 13 years to 25 years of age presenting for emergency contraception within 72 hours of unprotected sexual intercourse, or failure of other method of contraception where the patient has declined Intra-Uterine Contraceptive Device (copper) or where unable to get access for this provision • Clients aged 13 to 25 years of age that have received levonorgestrel 1500mcg under PGD but have vomited within 3 hours of the dose (provided still within 72 hours of sexual intercourse) NB: • **If the patient is aged 16 or under, they must be assessed for competence using the Fraser Guidelines. (Appendix 1)** • **The client must be competent to give informed consent to treatment** • If a client presents within 72 hours of UPSI, and the UPSI is likely to have taken place during the 5 days prior to the estimated day of ovulation (usually days 11-15 of cycle) then a supply of **ulipristal 30mg via PGD is recommended (refer to ulipristal acetate 30mg PGD)** For missed pills see current guidance from Faculty of Family Planning and Reproductive Healthcare Clinical Effectiveness Unit. https://www.fsrh.org/documents/cec-ceu-statement-missed-pills-may-2011/
Exclusion criteria (for full details of interacting medicines refer to current Summary of Product Characteristics (SPC) www.medicines.org.uk & BNF)	• If UPSI occurred more than 72 hours previously (See ulipristal PGD) • If UPSI is likely to have taken place during the 5 days prior to the estimated day of ovulation (see ulipristal PGD) • Pregnancy or suspected pregnancy (if a woman's menstrual period is late or in case of symptoms of pregnancy, pregnancy should be excluded before levonorgestrel is supplied) • Client weighs more than 70kg or has a BMI >26Kg/m^2 (see ulipristal PGD) • Clients less than 13 years of age • Clients aged 26 years and over • Known hypersensitivity to any constituent of the progestogen only emergency contraception (POEC) • Individuals under 16 years of age and assessed as not competent to consent to treatment using Fraser guidelines • Individuals not consenting to treatment or deemed not competent to consent to treatment • Individuals who have had two supplies of levonorgestrel 1.5mg tablets during the current menstrual cycle • Individuals who have taken ulipristal 30mg during the current menstrual cycle • Individuals at risk of ectopic pregnancy (previous history of salpingtis or of ectopic

	pregnancy) • severe hepatic dysfunction • Severe malabsorption syndrome such as Crohn's disease • Unexplained vaginal bleeding • Current breast cancer • Active acute Porphyria
Supply to young persons	• If a young person (aged <16 years) requests emergency contraception, then they must be assessed for competency. If they are deemed as being 'Fraser Competent' then a supply can be made, but this must be documented in the records. • Pharmacists must use their professional judgement when considering 'safeguarding' issues related to sexual activity in young persons**. If there are any concerns about a child being abused pharmacists must contact Family Connect (01952 385385 / after 5pm and on weekends contact the emergency duty team 01952 676500) – records details of the referral including the names of all individuals you spoke to.** • If a child under 13 years requests emergency contraception, and there is a reasonable concern that sexual activity has taken place, the pharmacist should always contact the local child protection lead, and there must always be a presumption that the case will be referred to the Children's Social Care Services in the area where the child lives
Management of excluded patients	• Explain reason for exclusion and document all actions taken within clients Pharmoutcomes record • Refer all clients to their GP or the Sexual Health Clinic (Tel 0300 123 0994) for further consultation. • If more than 72 hours have elapsed, IUD or ulipristal 30mg (if within 120 hours) will need to be considered. If an IUD is considered the most appropriate intervention, clients should be referred to the sexual health clinic as soon as possible (Tel 0300 123 0994 details of service opening times can be found on their website openclinic.org.uk) • If a client presents within 72 hours of UPSI, and the UPSI is likely to have taken place during the 5 days prior to the estimated day of ovulation (usually days 11-15 of cycle) and Cu-IUD is not acceptable then a supply of ulipristal 30mg via PGD is recommended (refer to ulipristal PGD) • If a client weighs more than 70kg or has a BMI >26kg/m^2 ulipristal Acetate is recommended. (Refer to ulipristal PGD) • If the client is aged under 13 years, the Pharmacist should contact the local safeguarding team – Family Connect 01952 385385. With the clients consent contact Sexual Health services (Tel 0300 123 0994) to inform them of the client's attendance such that the consultation can be prioritised • Clients aged 26 years and over should be advised that they can purchase EHC or refer them to the sexual health services/their GP
Action for patients not wishing to receive care under this PGD	• The patient should be advised of the risks of not receiving the supply of **levonorgestrel 1500mcg** • Refer client to the GP or sexual health service doctor • If the client requests an emergency Cu-IUD refer to Sexual Health Clinic (Tel 0300 123 0994 details of service opening times can be found on their website openclinic.org.uk). Oral emergency contraception, if appropriate, should still be given at the time of the referral in case the Cu-IUD cannot be fitted or the

	client changes their mind • Client should receive advice regarding future contraception • Details of consultation and referral must be recorded within Pharmoutcomes client record. Notes should clearly document noncompliance with the PGD
Treatment and Drug details	
Name form and strength of medicine	**levonorgestrel 1500 micrograms (LNG)**
Legal classification	POM – Prescription only medicine.
Black triangle warning Suspected adverse reactions. Should be reported using the Yellow Card reporting scheme (www.yellowcard.gov.uk).	• None
Method of obtaining supply	• From licensed and authorised supplier • From community pharmacies
Site for treatment	Designated clinic sites/Community pharmacies
Route / method	• Oral route only
Dose	• One tablet (1500 micrograms levonorgestrel) to be taken preferably within 12 hours, and no later than 72 hours of unprotected sexual intercourse or contraceptive failure. • Women who request oral EHC while taking enzyme-inducing drugs (see drug interactions below) or within 28 days of stopping them, should be advised to take a total of 3 mg levonorgestrel (two 1.5 mg tablets) as a single dose as soon as possible and within 72 hours of unprotected sexual intercourse. Women should be informed that the effectiveness of this regimen is unknown • If vomiting occurs within 3 hours of the dose, the efficacy of the treatment may be reduced and the dose should therefore be repeated. Under these circumstances repeat supply
Number of times treatment may be administered or supplied	One single dose per episode (see notes above regarding vomiting) Repeat supply within the same menstrual cycle: **<u>This is outside of the product licence</u>**. However current best practice justifies the use of repeat doses of levonorgestrel 1500 following unprotected sexual intercourse. A second supply of levonorgestrel 1500 within the same cycle may be given, provided the pharmacist is satisfied that supply is within the clients best interests, and its use is clinically indicated. A client should not be given more than 2 supplies of levonorgestrel 1500 within the same cycle. The pharmacist should refer the client to a doctor on a third request within the same cycle. Any patient being issued a repeat supply in the same cycle should be referred to the sexual health clinic or their own GP for appropriate contraceptive advice.
Quantity to be supplied or administered	**One tablet -** 1500 micrograms levonorgestrel Two tablets if taking enzyme inducing drugs **Medication should be issued directly to client to be taken immediately**

Cautions/need for further advice	Emergency contraception does not prevent a pregnancy in every instance. If there is uncertainty about the timing of the unprotected intercourse or if the woman has had unprotected intercourse more than 72 hours earlier in the same menstrual cycle, conception may have occurred. Treatment with levonorgestrel 1500 following the second act of intercourse may therefore be ineffective in preventing pregnancy. If menstrual periods are delayed by more than 5 days or abnormal bleeding occurs at the expected date of menstrual periods or pregnancy is suspected for any other reason, pregnancy should be excluded **Client weighs more than 70kg or has a BMI >26kg/m^2** Women should be informed that a weight >70kg or BMI **>26kg/m^2** could reduce the effectiveness of oral emergency contraception, particularly levonorgestrel. If oral emergency contraception is requested ulipristal Acetate is recommended. (Refer to ulipristal PGD) **Clients for whom ovulation has already occurred within the current cycle** Women should be advised that oral emergency contraception administered after ovulation is **unlikely to be effective**. If the client's ovulation date cannot be determined, or if there is any likelihood that ovulation has already occurred supply of oral emergency hormonal contraception can only be made if the pharmacist deems that it is in the best interests of the client to receive a supply, and the client is specifically advised that post ovulation, oral emergency hormonal contraception may not be effective **Breast Feeding** Women who breastfeed should be informed that available limited evidence indicates that LNG-EHC has no adverse effects on breastfeeding or on their infants The SPC for Levonelle advises that LNG is secreted into breast milk and that potential exposure of the infant to levonorgestrel can be reduced if the woman takes the tablet immediately after feeding and avoids nursing for at least 8 hours
Side effects *Full details of side effects are available in the SPC.* *www.medicines.org.uk* *And* ***Current BNF http://bnf.org/bnf*** *Suspected adverse reactions to drugs including vaccines should be reported on the yellow card available at the back of the BNF. Also at www.yellowcard.gov.uk*	Very common side effects(>1/10) include; • Nausea • Low abdominal pain • Fatigue • Bleeding not related to menses Other commonly reported side effects (>1/100) include; • Delayed menses • Vomiting • Diarrhoea • Headache • Breast tenderness • Irregular bleeding and spotting - Bleeding patterns may be temporarily disturbed and spotting may occur, but most women will have their next menstrual period within seven days of the expected time. Use the Yellow Card System to report adverse drug reactions directly to the MHRA. Yellow Cards and guidance are available at the back of the BNF. **http://yellowcard.mhra.gov.uk/**
Drug Interactions	**Women taking enzyme inducing drugs** Women who request oral EHC while using enzyme-inducing drugs or within 28 days of stopping them should be advised to take a total of 3 mg levonorgestrel (two 1.5 mg tablets) as a single dose as soon as possible and within 72 hours of unprotected sexual intercourse (UPSI) (use of levonorgestrel >72 hours after UPSI and double dose are outside the product licence)

	The metabolism of levonorgestrel is enhanced by concomitant use of liver enzyme inducers. Drugs suspected of having the capacity to reduce the efficacy of levonorgestrel containing medication include barbiturates (including primidone), phenytoin, carbamazepine, herbal medicines containing Hypericum perforatum (St. John's Wort), rifampicin, ritonavir, rifabutin, griseofulvin For a full list of drugs that affect the efficacy of Levonogestral 1500mg see current BNF and Faculty guidance below: https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/
Additional Information	• Check to ensure patient is not currently taking medicine, which duplicates or interacts with patient group direction medicine.
Advice to Patient	**The pharmacist should ensure the patient gives consent before issuing levonorgestrel 1500 emergency contraception.** Patient Information Leaflets should be highlighted and given to all women supplied with levonorgestrel emergency contraception. Advise the client: • How the medication works, benefits of treatment and how it should be taken • Possible adverse effects • Advise about failure rate Emergency contraception does not prevent a pregnancy in every instance. If there is uncertainty about the timing of the unprotected intercourse or if the woman has had unprotected intercourse more than 72 hours earlier in the same menstrual cycle, conception may have occurred. Treatment with levonorgestrel following the second act of intercourse may therefore be ineffective in preventing pregnancy. If menstrual periods are delayed by more than 5 days or abnormal bleeding occurs at the expected date of menstrual periods or pregnancy is suspected for any other reason, pregnancy should be excluded Women should be advised that oral emergency contraception administered after ovulation is unlikely to be effective • Advise on what to do if individual vomits within three hours of taking the pill(s) • Provide information regarding all methods of ongoing contraception and how to access these • Advice on safer sex and raising awareness of sexually transmitted infections • It is important to advise the client to return for a pregnancy test if the next menses is missed/lighter or more than 7 days late. (The next period may occur within 3 days of the expected date (57%). It may come early (15%), up to seven days late (15%) or over 7 days late (13%). If period is >7 days late- patients should be advised to return for a pregnancy test) • **After using emergency contraception, advise that treatment only provides protection for that episode of UPSI. It is recommended that subsequent acts of intercourse be protected by a reliable barrier method until the next menstrual period starts.** See Appendix 2 for counselling requirements
Follow up	Vomiting within 3 hours of taking dose (see Dosage Guidance) It is important to advise the client to return for a pregnancy test if the next menses is missed/lighter or more than 7 days late.

	If pregnancy occurs after treatment with levonorgestrel, the possibility of an ectopic pregnancy should be considered. The absolute risk of ectopic pregnancy is likely to be low, as levonorgestrel prevents ovulation and fertilisation. Ectopic pregnancy may continue, despite the occurrence of uterine bleeding.
Suspected Adverse reactions	• Patient presenting with suspected adverse drug reaction should be referred to a doctor for further investigations • All adverse reactions should be reported to the MHRA • Use yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF or obtained via Freephone 0808 100 3352 or online at www.yellowcard.mhra.gov.uk
Error reporting	• Any incidents or near miss issues must be reported via the organisation's internal reporting system

RECORD KEEPING	
Documentation needed / treatment records to be kept for audit purposes *A computer or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes.*	In discussion with the client enter consultation details onto the relevant module within PharmOutcomes or complete the paper proforma if unable to access PharmOutcomes at the time of the consultation • Patient's name, address, date of birth • Record of informed consent (record Fraser Competency Assessment where applicable) • Inclusion or exclusion from PGD • Date of supply • Reason for attendance • Relevant past and present medical history, including drug history • Any known allergy • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Details of any adverse drug reactions and what action taken • Any referral arrangements • Any administration outside the terms of the marketing authorisation • If individual is under 13 years of age record action taken • Record Name (brand)/Manufacturer/batch number/expiry date • Quantity supplied • Any other relevant information that was provided to the individual • Details of staff who supplied (sign and print name) • Details of any adverse drug reactions and action taken • Reconciliation – stock balances should be reconcilable with receipts, administration, records and disposal on a patient by patient basis. When the pharmacist has confirmed supply is appropriate the client must sign the treatment consent form before taking levonorgestrel. If the client is excluded, a record of the reason for exclusion must be documented within PharmOutcomes, and any specific advice that has been given.

REFERENCES	
	Current Edition BNF 74
	Product SPC – Levonelle 1500 www.medicines.org.uk (last accessed 25.1.2017)
	Faculty of Sexual and Reproductive Healthcare Emergency Contraception (March 2017 updated Dec 17) https://www.fsrh.org/documents/ceu-clinical-guidance-emergency-contraception-march-2017/
	Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit CEU Statement (May 2011) Missed Pill Recommendations http://www.fsrh.org/pdfs/CEUStatementMissedPills.pdf
	Faculty of Sexual and Reproductive Healthcare (2017) Drug interactions with hormonal contraception https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/

Register of practitioners qualified to administer and/or supply **levonorgestrel 1500mcg** **under this Patient Group Direction**	
Name of clinical manager / Lead	
Signature of clinical manager / Lead	Date:
A copy of this page should be retained by the authorising manager for 2 years for audit purposes	
Please state clinical area where this PGD is in use	

Healthcare professional individual declaration

I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD

- **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.
- All practitioners operating in accordance with this PGD should have a current, signed copy of it readily available for reference.
- If a practitioner is asked to supply, or administer a medicine not covered by this or any other PGD then a patient specific direction is required from a doctor, dentist or independent prescriber.

Name of professional (please print)	Signature	Authorising Manager (Must sign against each entry)	Date of authorisation

Healthcare professionals working under a PGD must have received appropriate training and been assessed as competent to administer/supply the medicine referred to in the PGD. The clinical lead should review competency of authorised practitioner/s at least annually. Training certificates must be available for inspection.

Authorisation to use this PGD does not remove inherent professional responsibility and accountability.

A copy of this authorisation form must be printed off, signed and dated by the healthcare professional authorised to use this PGD. This should be retained by the service provider and readily available for inspection).

Appendix 1

The Fraser Guidelines

Please use this as a checklist for all clients aged 16 and under.

- The young person understands the advice and has sufficient maturity to understand what is involved.
- That the doctor/nurse could not persuade the young person to inform their parents, nor allow the doctor/nurse to inform them.
- That the young person would be very likely to begin or continue having sexual intercourse with or without contraceptive treatment.
- That without contraceptive advice or treatment, the young person's physical or mental health would suffer.
- That it would be in the young person's best interest to give such advice or treatment without parental consent.
- Under 16s have a right to confidentiality whether asking for contraceptive advice or any medical treatment.

(Family Planning Association Fact-sheet No 12, 1997)

Counselling

All requests for post-coital contraception should be handled in a sensitive and non-judgemental manner.

Before issuing Emergency Hormonal Contraception (EHC) discuss:

1) **Mode of Action-**contains the hormone progestogen thought to make the lining of the womb unsuitable for a pregnancy or by delaying the release of an egg from the ovary.

2) **Efficacy-**It has been estimated that Levonogestrel prevents 85% of expected pregnancies if used within 48 hours. Women should be advised that oral emergency contraception administered after ovulation is unlikely to be effective

3) **Foetal effects-** no evidence to date that this method of EHC has any teratogenic effects on the foetus. However a normal outcome to any pregnancy cannot be guaranteed (every women has a 1/50 chance of foetal abnormality)

4) **Other possible effects-** e.g. nausea or vomiting (in clinical trials 23% had nausea and 5-6% actually vomited), advise take treatment with food. If vomiting occurs within 3 hours of taking either of the two tablets contact nurse, GP, Sexual Health clinic, Pharmacist or 'Shrop Doc' for further advice. Breast tenderness, dizziness and fatigue may also occur.

5) Inform the client that their next period may be early, on time or late.

6) Discuss **future contraception**. Emphasise that Levonogestrel 1500 tablets are for emergency use only and not as a regular method of contraception because it is not effective as regular contraception.

7) Give FPA Emergency Contraception leaflet and ensure manufacturers leaflet is in the box. Print patient's name and date of supply on label if medication is taken away.

8) **Follow up-** Advise the client to return for a pregnancy test if the next menses is missed/lighter or more than 7 days late.

9) **Contact Tel No-** give telephone number of GP surgery and Sexual Health Clinic.

10) **Documentation-** Complete the documentation as required on Pharmoutcomes - record name and dosage of administered drugs date and time given. During discussion of above, complete the **Emergency Hormonal Contraception (EHC) PGD Client Record Form**, which should be signed by the pharmacist issuing under the PGD. (An electronic record of the consultation must be made on Pharmoutcomes.
11) The pharmacist must establish **Fraser Competence** for clients who are aged under 160 yeats and encourage them to discuss the situation with a parent/carer if possible