Patient Group Direction for the administration and / or supply of for the treatment of : levonorgestrel for treatment of patients requiring emergency contraception	
Title of patient group direction	Patient Group Direction for the administration or supply of : Levonorgestrel (LNG) for treatment of patients requiring emergency contraception
Approved at	NMP/PGD Group
PGD approved / valid from	June 2019
Review date	March 2021
Expiry date	June 2021
Clinical area(s) where PGD applies	YorSexualHealth, HIV and Outreach Services
Identified Lead for monitoring / review and contact details	Wendy Billsborough, YorSexualHealth

CONSULTATION PROCESS ADOPTED IN DEVELOPING THE PATIENT GROUP DIRECTION (PGD)	
New Document	No
Reviewed Document	Yes
If the PGD is revised what revisions were required and for what reasons e.g. change in medical procedures or change in legislation	None
List of persons involved in the consultation process. (The group must include a sponsoring clinician, a pharmacist and a senior representative of the professional group. The job title and level of consultation should also be listed).	Wendy Billsborough, Advanced Nurse Specialist Alison Chorlton, Lead Nurse Sexual Health Dr Ian Fairley, Clinical Director Lead Carol Belt, Principal Pharmacy Technician

CLINICAL CONDITION	
Condition	Postcoital emergency contraception (EC)
Inclusion criteria	• See FSRH Decisional algorithm • When the Cu-IUD is not appropriate or not acceptable • Any woman requesting oral emergency contraception within 72 hours of UPSI (unprotected sexual intercourse) or contraceptive failure • Any woman requesting oral emergency contraception from 72 – 96 hours who is unable to take UPA or chooses LNG (off-label use) • LNG can be used more than once in a cycle. • LNG may be given for UPSI even if there has been an earlier episode outside the treatment window (>96 hours ago) where EC was or wasn't given • A repeat dose may be supplied if the first treatment has been vomited within 3 hours providing the new dose is still within 96 hours of UPSI • When LNG is indicated as the appropriate EC and a woman has a BMI > 26 or weight > 70kg a double dose (3mg) LNG EC should be issued
Exclusion criteria	• Patient 12 years of age or under • Children under 16 years not considered competent under Fraser guidelines • Known pregnancy • More than 96 hours since this episode of unprotected sexual intercourse (N.B. LNG may be used more than once in a cycle or for a recent indication even if there has been an earlier episode of UPSI outside the treatment window more than 96 hours ago) • Known allergy to the active ingredient levonorgestrel or any excipients • Active acute porphyria • Avoid LNG EC in the 5 days after taking UPA EC • Severe malabsorption syndromes where drug absorption may be reduced (e.g. active Crohn's disease) • If further UPSI occurs within 12 hours of a dose of levonorgestrel further EC treatment is not required

Actions for patients excluded	• Discuss/offer an alternative method of emergency contraceptive if appropriate • Refer to a doctor/independent nurse prescriber, or GP if more appropriate in an outreach setting Document all action taken in the patient records
Action for patients not wishing to receive care under the PGD	Record the refusal in the clinical record Refer to clinic doctor/independent nurse prescriber if agreed with the client

<table>
<tr><th colspan="4">DESCRIPTION OF TREATMENT</th></tr>
<tr><td>Name of Medicine</td><td colspan="3">Levonorgestrel</td></tr>
<tr><td>Legal Classification</td><td colspan="3">POM</td></tr>
<tr><td>Licensing information</td><td colspan="3">• Licenced for up to 72 hours
• Use from 72 - 96 hours is outside the product licence but is supported by the faculty guidance. FSRH - Emergency Contraception
• A double dose (3mg) used when taking liver enzyme inducing drugs is outside the product licence but is supported by the FSRH
• A double dose (3mg) of LNG EC is recommended if a woman has a BMI of >26 or weight > 70kg (off-label and supported by the FSRH)</td></tr>
<tr><td></td><td>Is the medicine licensed for the intended use?</td><td>YES</td><td></td></tr>
<tr><td></td><td>Does it have a black triangle status?</td><td></td><td>NO</td></tr>
<tr><td></td><td>Does it have a Risk Minimisation Measures (RMM) recommendation</td><td>YES</td><td></td></tr>
<tr><td>Form</td><td colspan="3">Tablet</td></tr>
<tr><td>Strength</td><td colspan="3">1.5mg</td></tr>
<tr><td>Dose</td><td colspan="3">1.5mg single dose
Or
3mg (2 x 1.5mg tablets as a single dose: outside product licence) if the woman is on liver enzyme inducing drugs (or has stopped taking them within the last 28 days

3mg (2 x 1.5mg tablets as a single dose: outside product licence) if the woman has a BMI of >26 or weight of >70kg</td></tr>
<tr><td>Frequency</td><td colspan="3">Single treatment dose</td></tr>
<tr><td>Route</td><td colspan="3">Oral</td></tr>
</table>

<table>
<tr><td>Total Treatment Quantity</td><td colspan="2">Single treatment</td></tr>
<tr><td>Interactions with other medicines
(This must include all potentially serious interactions listed in the BNF)</td><td colspan="2">• Check any medicines in appendix 1 of the British National Formulary (BNF) and CEU drug interactions guideline under progestogens or UpToDate – Drug Interactions via Staff Room
• The efficacy of levonorgestrel may be affected by enzyme-inducing drugs – concomitant and within the previous 4 weeks. See Dose and frequency section.
• Avoid use with liver enzyme-inducing drugs and within 28 days of stopping them. These include:

Anti-epileptics- carbamazepine, eslicarbazepine, oxcarbazepine, phenobarbital, phenytoin, primidone, rufinamide and topiramate

Anti-bacterials-rifampicin, rifabutin

Anti-retrovirals-ritonavir, nevirapine, efavirinez

Anti-fungal-griseofulvin

Others: St John's Wort, modafinil, bosentan, aprepitant

• NB: Offer a Cu-IUD as the most effective method of EC
• Anti-retroviral-Always use the HIV Drug Interaction Checker (www.hiv-druginteractions.org) to identify potential interactions
• If in doubt contact Medicines Information for advice - Ext 5960</td></tr>
<tr><td>Adverse Reactions
(This should include all the common and potentially serious adverse reactions. It is acceptable to state that the BNF should be referred to for further information)</td><td>Mostly well tolerated but some clients may experience:
• Temporary menstrual disturbances: spotting/bleeding/delayed or early next period
• Nausea
• Vomiting
• Low abdominal pain
• Headache
• Dizziness</td><td>Treatment of adverse reactions

• If necessary seek appropriate emergency advice and assistance
• Document the adverse reaction in the patient's medical records. The GP should also be informed with client consent
• Use the yellow card system</td></tr>
</table>

	• Breast tenderness • See Summary of Product Characteristics for the product for full list of adverse reactions	to report any suspected adverse reactions to the MHRA. Guidance on use is available at the back of the BNF or can be accessed via *(http://www.yellowcard.gov.uk)*
Advice to Patients: Written and Oral advice (This should include the provision of a patient information leaflet)	• Explain options including the use of an IUD as the most effective form of EC • Provide a copy of the leaflet or refer to web based FPA Emergency contraception patient information. Provide the product patient information leaflet (PIL) • Discuss mode of action, how to take and warn of possible side effects • Explain that the Cu-IUD is considered a more effective method of emergency contraception and refer to an appropriate healthcare provider after supply of UPA-EC, where appropriate and acceptable • Advise that oral EC may be less effective if the individual has a higher weight or BMI • Advise that oral EC is ineffective if given after ovulation • Advise that the use of levonorgestrel beyond 72 hours is outside the product license and may have reduced efficacy • Advise on action to take if vomiting occurs within 3 hours of taking levonorgestrel • Explain there is no known effect on a fetus if treatment fails • Advise that emergency contraception with levonorgestrel only gives protection for the current risk • Discuss and offer on-going contraception • Advise that when starting or continuing a hormonal method immediately after taking levonorgestrel a reliable barrier method is used for: 7 days for CHC, and progestogen-only implant/ injectable 2 days for POP 9 days for Qlaira	

	• If the patient is breast-feeding advise that the drug does pass into breast milk but is not thought to be harmful. The patient may express and discard for the next 8 hours if they wish. • Advise to seek medical advice if acute lower abdominal pain occurs as for all pregnancies the possibility of an ectopic should be considered • Advise to return for a pregnancy test in 3 weeks if the next period is more than 7 days delayed or lighter/shorter than normal and after quick starting a hormonal method of contraception
Follow up action	Advise to return for a pregnancy test in 3 weeks if the next period is more than 7 days delayed or lighter/shorter than normal, and after quick starting a hormonal method of contraception
Storage	Locked drugs cupboard or locked case for outreach use
Records to be Kept	• Assessment of client need in relation to the supply of levonorgestrel • Relevant past and present medical history including drug history • Any reason for exclusion • Any known allergies • Date and time • Completion of the emergency contraception checklist including consent to the method • On the prescription record document drug name and strength • Route of administration • Advice given • Follow up required • PGD used • Any supply made outside the product licence • Any other relevant information that was provided to the patient • Any communication with other health care professionals • Record of name of health professional supplying the

	medicine (may be electronic)
Audit Arrangements	As per current Trust PGD Policy
References	• Faculty of Sexual and Reproductive Healthcare. Emergency Contraception Guidance (2017). • British National Formulary www.bnf.org.uk • The Electronic Medicines compendium http://www.medicines.org.uk/emc/ • Policy and Procedure for the supply and/or administration of medicines under a patient group direction (2015). York Teaching Hospital. • The UK Medical Eligibility Criteria for Contraceptive Use (2016) • Faculty of Sexual and Reproductive Healthcare Quick Starting Contraception (2017) • Faculty of Sexual and Reproductive Healthcare (2017) Drug interactions with hormonal contraception
Competency Requirements (attach any competency frameworks / documents)	The Nurse must be authorised by name under the current version of this PGD before working to it <u>Education, training, qualifications and competencies:</u> • Registered nurse • Sexual health nurse • Clinical competence in sexual history taking. • Completion of the Trust PGD awareness session or Trust HUB e-learning. • Knowledge of the 3 available methods of emergency contraception as in the FSRH Guidance (2017) • Indications for emergency contraception and use of the FSRH algorithm to inform choice • Knowledge base of the contraindications to and restrictions for issuing LNG as well as interactions of LNG with other drugs • Competence in the above will be demonstrated by the undertaking of a local clinical competency based training and assessment programme, evidenced by completion of theoretical study including e-learning

	and clinical experience within sexual health. • Assessment will be undertaken by the Lead Nurse/ANS or designated PGD assessor, who will be practising as an independent prescriber. • Receiving clinical supervision and/or audit of case notes on an ongoing basis • Evidence of Commitment to continuing professional development in sexual health as identified through clinical supervision and appraisal • Regular attendance and participation in educational clinical governance sessions and nurse updates • Maintain professional accountability with the NMC and ensure continual professional development • Has undergone regular updating in basic life support and anaphylaxis • It is the responsibility of the individual to keep up to date with continued professional development and to work within the limitations of their individual scope of practice

AUTHORISATION OF THE PATIENT GROUP DIRECTION (PGD) FOR ADMINISTRATION OF: levonorgestrel			
PGD Development / Review Team – responsible for PGD content			
Title	**Name**	**Signature**	**Date**
Lead Author	Wendy Billsborough	Wendy Billsborough	11/6/2019.
Clinical Director Lead Approval	Dr Ian Fairley		13/06/2019.
Directorate Pharmacy Lead Approval	Jill McEnaney	Jill McEnaney	18.6.2019
PGD Approved by the NMP/PGD Group			
Title	**Name**	**Signature**	**Date**
NMP Lead / Lead Nurse Medicines Management	Jennie Booth		17.06.2019
Chief Pharmacist / Deputy Chief Pharmacist	Stuart Parkes	Stuart Parkes	17/06/2019

Authorisation to work within the PGD

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

The PGD must be easily accessible in the clinical setting.

Notes to the NMP/PGD Authorising staff

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

Staff authorised to work under this PGD	
Ward / Department	Sexual Health
Professionals to whom this Patient Group Direction applies	Qualified nurses working within the YorSexualHealth service and have completed the agreed competency training

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

Name (Capitals)	Sign	Job Title	Authorising Manager	Date

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