The Rotherham NHS Foundation Trust

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

Patient Group Direction

for the supply of

Levonorgestrel

By Community Pharmacists in Rotherham that hold a valid contract for supply of

Emergency Hormonal Contraception (EHC)

Version number: 1.0

Change history

Version number	Change details	Date
V1.0	Approved by Rotherham Medicines Optimisation Group	03.06.2020

PGD development

Name	Job title and organisation	Signature	Date
Lead author	Dr Nadi Gupta, Consultant ISHS, TRFT		9/6/2020
Lead doctor	Dr Nadi Gupta, Consultant ISHS, TRFT		9/6/2020
Lead pharmacist	Gabrielle Lawson, Senior Pharmacist, TRFT		5/6/20
Representative of other professional group using PGD	N.Williams / N.Gibbons - Lead Nurses – Integrated Sexual Health Services		9/6/20. 9/6/20

PGD authorisation

Name	Job title and organisation	Signature	Date
Senior doctor (or dentist)	Dr Nadi Gupta, Consultant ISHS, TRFT		9/6/2020
Senior pharmacist	Osman Chohan, Chief Pharmacist, TRFT		03/06/2020

Training and competency of registered health professionals

	Requirements of registered health professionals working under the PGD
Qualifications and professional registration	Registered pharmacists with the GPhC who have completed all the required CPPE modules outlined in the service specification
Initial training	Appropriate training has been undertaken to carry out clinical assessment of patients leading to a diagnosis that requires treatment in accordance with the indications listed in the PGD This includes: • Knowledge of working under Patient Group Directions for the supply and administration of medicines. • The significance of the patient's past medical history and current medication • Knowledge of correct dosage and administration • Recognition and treatment of adverse effects and hypersensitivity reactions
Competency assessment	Pharmacists who have completed training will make a self-declaration of competence on PharmOutcomes
Ongoing training and competency	• The pharmacist will ensure s/he has the relevant training and is competent in all aspects relevant to the PGD • The pharmacist will keep up to date with respect to the medicinal product listed in this PGD and of current developments in the field of emergency hormonal contraception • Attends updates in administration of medicines through the use of Patient Group Directives at appropriate intervals

Clinical condition

Clinical condition or situation to which this PGD applies	• Unprotected Sexual Intercourse (UPSI) within last 72 hours and/or in circumstances where potential failure of regular contraceptive method is recognised or no hormonal contraceptive method is being used • Copper intra uterine device (IUD) should be discussed and offered if suitable and acceptable. If accepted, levonorgestrel should still be given, if suitable, in case IUD cannot be fitted or patient does not attend fitting appointment
Inclusion criteria	Request for emergency contraception up to 72 hours after risk and option of copper intra-uterine device is not suitable for, or not accepted by: • Any female aged 16 years and over • Resident in Rotherham Borough **Unprotected sexual intercourse also includes:** • Missed taking hormonal contraception (See Faculty SRH Clinical Guidance for missed pills, patch or ring, summarised in annex) • Late injectable contraceptive, expired implant or coil (See Faculty of Sexual and Reproductive Health Clinical Guidance: Progestogen-only Injectable Contraception) • Barrier method failure - Male/female condom and diaphragm or cap • Coitus interruptus • Severe diarrhoea and vomiting which may have reduced oral contraceptive efficacy • Complete or partial expulsion of IUD/IUS **Off label inclusions:** • Request for emergency contraception where previous risks have occurred in the same cycle. • Request for emergency contraception more than once in the same cycle. • Request for emergency contraception by patients taking liver enzyme inducing medication, in which case 3mg dose should be supplied (see interactions below) • Request for emergency contraception by patients with BMI more than 26 or weight more than 70kg, levonorgestrel 3mg dose must be supplied. **Off label/unlicensed inclusions are based on Faculty of Sexual and Reproductive Health (FSRH) guidance on emergency hormonal contraception**

Exclusion criteria	• Patient under 16 years of age **All 13 to 16 year olds should be urgently referred directly to Rotherham Integrated Sexual Health by telephone that day (01709 427777) and Integrated Sexual Health will provide the contraception free of charge. (If Integrated Sexual Health is closed, please signpost to the GP Out-of-Hours service or the Urgent and Emergency Care Centre).** • Children aged 12 and under **Complete a Social Services referral and contact the on-call gynaecologist at Rotherham Hospital immediately**. • Patient refusing treatment • Patient has taken ulipristal acetate emergency hormonal contraception within the previous 120 hours • Patient pregnant • Known hypersensitivity to levonorgestrel or any component of the product • Unexplained or unusual vaginal bleeding • Acute severe liver disease • Acute porphyria • Severe intestinal malabsorption syndromes e.g. Crohn's disease • Lactose intolerance, galactose intolerance, Lapp lactase deficiency, glucose- galactose malabsorption • Current Breast Cancer
Cautions (including any relevant action to be taken)	Patients taking, or have taken within the past four weeks, liver enzyme-inducing medication (CYP3A4 inducers) including: • Certain anti-retrovirals (see BNF) • Barbiturates (e.g. primidone and phenobarbital) • Bosentan • Carbamazepine • Eslicarbazepine • Griseofulvin • Modafinil • Oxcarbazepine • Phenytoin • Rifabutin • Rifampicin • Rufinamide • St John's Wort • Topiramate This list is not exhaustive; medication should be checked using the current BNF, SPC and/or http://reference.medscape.com/drug-interactionchecker Liver enzyme inducing drugs have the potential to reduce the contraceptive efficacy of levonorgestrel.

	Patients taking liver enzyme inducing drugs (or who have stopped within the last 4 weeks) should be advised that the copper IUD is the only method of emergency contraception not affected by these drugs Patients taking liver enzyme inducing medications who decline or are not eligible for a copper IUD, should be advised to take a 3mg dose of levonorgestrel (two tablets) as soon as possible within 72 hours of UPSI - **outside product license but recommended in FSRH Emergency Contraception Guidance**
Arrangements for referral for medical advice	Patients who are excluded from treatment under the contraindications identified above must be referred to an appropriate medical practitioner/prescriber
Action to be taken if patient excluded	**Action if excluded:** • Explain the reason for the exclusion and advise them to see their GP, or Rotherham Integrated Sexual Health • Record reason for exclusion in PharmOutcomes • Patient under 16 years of age **All 13 to 16 year olds should be urgently referred directly to Rotherham Integrated Sexual Health by telephone that day (01709 427777) and Integrated Sexual Health will provide the contraception free of charge. (If Integrated Sexual Health is closed, please signpost to the GP Out-of-Hours service or the Urgent and Emergency Care Centre).** • Children aged 12 and under • **Complete a Social Services referral and contact the on-call gynaecologist at Rotherham Hospital immediately**. • Referral for post-coital copper IUD if patient wishes
Action to be taken if patient declines treatment	**Action if patient declines:** • Explain rationale for compliance to those not wishing to receive the medication • Give patient option to be referred to an appropriate agency • Document actions in patient's clinical records • Advise patient to perform a pregnancy test 3 weeks if she has not had a normal menstrual period or if her period is more than 7 days late

Details of the medicine

Name, form and strength of medicine	Levonorgestrel 1.5 mg tablet - POM
Legal category	POM – 3mg dose for use in patients taking enzyme inducing drugs or with BMI above 26 is off-label but supported by FSRH guidance
Route/method of administration	Oral
Dose and frequency	Levonorgestrel 1.5 mg (one tablet) taken as soon as possible (preferably within 72 hours of UPSI) preferably immediately after the consultation **Off-label use** Levonorgestrel 3mg (1.5mg x two tablets, taken as a single dose) • For patients taking, or who have taken within the past four weeks, liver enzyme inducing medication (CYP3A4 inducers) • For patients with BMI more than 26, or weight more than 70kg Dose should be provided orally as soon as possible and preferably immediately after the consultation. If the patient vomits within three hours of taking a dose, a replacement supply should be issued, providing this is still within 72 hours of UPSI and there are no new contraindications
Quantity to be administered and/or supplied	See above
Maximum or minimum treatment period	Some patients may require an additional supply of levonorgestrel if attending with further risk within the same cycle. The Faculty of Sexual and Reproductive Health recommends that levonorgestrel can be used more than once in the same cycle or can be used for a recent episode of UPSI, even if there has been an earlier episode of UPSI outside the treatment window i.e. more than 72 hours. The Faculty of Sexual and Reproductive Health advises that if further UPSI occurs within 12 hours of a dose of levonorgestrel, further emergency contraception treatment is not required.
Adverse effects	This list may not represent all reported side effects of this medicine.

	Refer to current Summary of Product Characteristics (SPC) of relevant product and current British National Formulary (BNF) for full list and further information. Adverse effects include: Nausea, abdominal pain, vomiting, diarrhoea, breast tenderness, headache, dizziness, fatigue, temporary disturbance of bleeding patterns If pregnancy occurs after treatment, the possibility of an ectopic pregnancy should be considered. In the event of untoward or unexpected adverse reactions: • Advise patients to contact A&E if they develop severe, persistent adverse reactions • Document in PharmOutcomes and report according to pharmacy policy • Complete Yellow Card report for adverse drug reaction if appropriate http://yellowcard.mhra.gov.uk/ Use yellow card system to report all adverse drug reactions for a ▼ medicine, or all serious adverse drug reactions for other medicines 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. The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so.
Records to be kept	**Complete oral emergency contraception documentation on PharmOutcomes:** Record • patient's name, address and date of birth • Menstrual history, including date of last normal menstrual period. If period is late, advise a pregnancy test. • Date and time of unprotected intercourse (UPSI) for which emergency contraception is requested. • Any previous unprotected sexual intercourse since last menstrual period. • Usual cycle length and the day of cycle on which UPSI occurred. • Medication and allergies • BMI, unless previously recorded and patient reports no change in weight (Document use of 3mg dose if BMI more than 26 or weight more than 70kg) • Discussion of side effects • Dose, form • Advice given to patient • Details of any adverse drug reaction and actions taken including documentation in the patient's clinical record • Referral arrangements • Verbal consent given

Patient information

Written information to be given to patient or carer	Give the patient a copy of the manufacturer's patient information leaflet if available and discuss as required
Follow-up advice to be given to patient or carer	• Advise the patient that copper coil is 10 times more effective than oral emergency contraception and ask them to contact Integrated Sexual Health ASAP (01709 427777) if they want to proceed with an emergency copper coil in addition. (Always provide oral emergency contraception in these cases in case the patient decides not to proceed with copper coil). • If vomiting occurs within three hours of taking levonorgestrel the patient should contact the pharmacy where the supply was obtained, or their own GP for advice. Another dose will be required OR consideration may be given to having a copper IUD fitted. • The patient should be advised to undertake a pregnancy test if the next menstrual period is shorter, lighter than usual or more than 7 days late. • Levonorgestrel does not protect against HIV/Sexually Transmitted Infection (STIs) therefore, discuss the need for protection against HIV/STIs and offer STI screening including HIV test and document that incubation periods have been discussed. • Levonorgestrel does not provide any ongoing contraception and patients should be advised to contact their own GP or Integrated Sexual Health to discuss their options and to start a regular contraceptive method as soon as possible. • Give the patient a copy of the TRFT emergency contraception patient information leaflet – this can be printed from PharmOutcomes. • Explain that oral emergency contraception is unlikely to work if she has already ovulated. • All eligible patients presenting between 0 – 120 hours of UPSI, or, within 5 days of the earliest predicted date of ovulation, should be offered a copper IUD. • Advise breastfeeding patients that no restriction on breastfeeding is required. • Discuss the need for on-going contraception. • Patients should be made aware that they are only covered for their recent episode of unprotected sexual intercourse by taking levonorgestrel and NOT for any events that may occur in the future. Document that the need to use a reliable method of contraception has been advised.

The original signed copy of this Patient Group Direction is held in the Pharmacy department.
A copy of the signed document is held on file by the Lead Author.
A copy of the document is also available on the Trust Intranet Site.

Appendices

Appendix A Key references

- HSC 2000/026 (9/8/00) Patient Group Directions
- Faculty of Sexual & Reproductive Healthcare Clinical Guidance. Emergency Contraception. Clinical Effectiveness Unit. 2017
- Faculty of Sexual & Reproductive Healthcare Clinical Guidance. Drug interactions with hormonal Contraception. Clinical Effectiveness Unit. 2017
- Faculty of Sexual & Reproductive Healthcare Clinical Guidance. UK Medical Eligibility Criteria for Contraceptive Use (2016)
- Levonorgestrel - Summary of Product Characteristics (SPC) - (eMC). Retrieved from: http://www.medicines.org.uk/emc
- Joint Formulary Committee. British National Formulary (online) London: BMJ Group and Pharmaceutical Press <http://www.medicinescomplete.com>
- Medscape Drug Interaction Checker http://reference.medscape.com/drug-interactionchecker

Appendix B

List of staff who have agreed to supply or administer medicines in accordance with this Patient Group Direction

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.

Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

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

Medicine: Levonorgestrel		**Version:** 1.0	
Valid from: 03/06/2020		**Expires:** 31/05/2023	
Name	Signature	Designation	Date