Trafford Clinical Commissioning Group

TRAFFORD COUNCIL

PATIENT GROUP DIRECTION FOR THE SUPPLY OF

Levonorgestrel 1500 microgram Tablet

By registered Pharmacists for Emergency Hormonal Contraception in Community Pharmacy

Version 4.0

Valid from: 13/07/2018

Expires on: 25/01/2019

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 siqned version of the PGD should be used.

LEVONORGESTREL 1500 MICROGRAM TABLET	P.O.M. [Prescription Only Medicine]

DOCUMENT CONTROL- PGD Ready for authorisation

Document Location

Copies of this PGD can be obtained from:

Name:	Trafford Council
Address:	Public Health, Trafford Town Hall, Talbot Road, Stratford, M32 OTH
Telephone:	0161 912 3431

Revision History

The latest and master version of the unsigned PGD is held by Greater Manchester Shared Service.

REVISION DATE	ACTIONED BY	SUMMARY OF CHANGES	VERSION
30/06/2014	S. Woods	Finalise document for signing	2.0
03/05/2016	S Woods	Under 'Characteristics of Staff 'Additional requirements' changed: • Has had training in the use of PGDs • Has had training which enables the pharmacist to make a clinical assessment in order to establish the need and supply the treatment according to this PGD as detailed in the service specification. • Has satisfied the competencies appropriate to this PGD, as detailed in the CPPE and NHS Health Education North West *Declaration of Competence for community pharmacy services- Chlamydia screening and treatment* document (htt!:;!:l/www .CQQe.ac.uk/sQ/sg4 .asg?PID=189&10=203). • Is competent in the assessment of the individuals using Fraser guidelines • Has undergone regular training and updating in safeguarding children and vulnerable adults • Has an understanding of how to deal with a possible anaphylactic reaction. This could include access to a member of staff trained in basic life support. To: • Has undertaken training in the use of PGDs • Has undertaken training which enables the pharmacist to make a clinical assessment in order to establish the need and supply the treatment according to this PGD as detailed in the service specification. • Has satisfied the competencies and completed the self-declaration form appropriate to this PGD, as detailed in the CPPE and NHS Health Education North West *Declaration of Competence for community pharmacy services- Emergency Contraception Service with the use of*	2.1

		a Patient Group Direction document (ht1o://www.cppe.ac.uk/sp/sp4.asp?Pl0=189&1D=203). • Is competent in the assessment of the individuals using Fraser guidelines. Under 'Continued training requirements' changed the bullet point: • Must assess their own competence on the medicines supplied under this PGD at least every 2 years To: • Must assess and maintain their own competence on the medicine supplied under this PGD in line with the requirements contained within the *Declaration of Competence for community pharmacy services – Emergency Contraception Service with the use of a Patient Group Direction* document Under 'Suggested supporting learning corrected: It is essential that pharmacists complete and satisfy the competencies detailed in the CPPE and NHS Health Education North West *Declaration of Competence for community pharmacy services – Chlamydia screening and treatment* document. To: It is essential that pharmacists complete and satisfy the competencies detailed in the CPPE and NHS Health Education North West *Declaration of Competence for community pharmacy services- Emergency Contraception Service with the use of a Patient Group Direction* document. Under 'Clinical condition or situation to which the direction applies.' Added the foot note: Although there is potential for a false negative where fertilisation occurred less than 3 weeks previously, the FSRH CEU recommends that LNG 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 (>120 hours) (outside product licence), as there is no evidence to indicate LNG is not safe in pregnancy. Please note in this PGD use is only allowed within the treatment window of 72 hours. Removed section 'Reference to national/local policies or guidelines' as these are listed at the end. Under 'Cautions (including any relevant action to be taken)' changed the bullet point: • Very small amounts of the active ingredient of	

		levonorgestrel may appear in breast milk. This is not thought to be harmful to the baby. (Limited epidemiological data indicates no adverse effects on the foetus). If the patient is concerned they can take their tablet immediately after a breast-feed and avoid nursing following levonorgestrel administration then drain their milk with a breast pump for 6 hours after taking levonorgestrel and throw away the milk. In this way they can reduce the amount of active ingredient their baby may take in with the breast milk. This would be the only reason that would allow patients to take their treatment away with them. To: • The small amount of levonorgestrel that appears in breast milk should not be harmful to the baby, however, patients should be advised to take levenorgestrel immediately after a breast feed, thus reducing the amount of the drug the baby may take in the next feed. This would be the only circumstance in which a patient may take their treatment away with them. Under 'Details of medicine' 'Drug interactions' changed: • If the patient is taking any concomitant medication or treatment it is the practitioner's responsibility to ensure that treatment with the drug detailed in this Patient Group Direction is appropriate. (For drug interaction see Appendix 1 of BNF or contact the Medicine Information Service at Liverpool- telephone number inside front cover of BNF) In the case of any doubt, further advice must be sought from an appropriate health professional and recorded as having been sought before the drug is given. • If the requirements of this Patient Group Direction cannot be complied with the patient must be referred to a suitable independent prescriber. To: • If the patient is taking any concomitant medication or treatment it is the practitioner's responsibility to ensure that treatment with the drug detailed in this Patient Group Direction is appropriate. (For drug interaction see Appendix 1 of BNF (https://www.medicinescomplete.com/mc/) or the Summary of Product Characteristics (http://www.medicines.org.uk/emc/) or contact the Medicine Information Service at Liverpool – telephone number inside front cover of BNF) • In the case of any doubt, further advice must be sought from an appropriate health professional and recorded as having been sought before the drug is given.	

		• If the requirements of this Patient Group Direction cannot be complied with the patient must be referred to a suitable independent prescriber. Under 'Advice to be given to the patient or carer' changed the bullet point: • Discuss on going contraception including Quick Starting Contraception guidance (recommending starting contraception immediately after oral emergency hormonal contraception with seven days additional protection, if appropriate). To: • Discuss on going contraception including Quick Starting Contraception guidance (recommending starting contraception immediately after oral emergency hormonal contraception with additional protection as appropriate for the method used). Added reference to Centre for Pharmacy Postgraduate Education.	
07/07/2016	S Woods	Final formatting ready for signatures	3.0
11/07/2018	L Lord	Extension of existing PGD ready for agreement and signatures	4.0

LEVONORGESTREL 1500 MICROGRAM TABLET	P.O.M. [Prescription *Only* Medicine]

Approvals

This PGD must be approved by the following before distribution:

NAME	TITLE	DATE OF ISSUE	VERSION
Leigh Lord	Locality Lead Medicines Optimisation Pharmacist, Trafford CCG	11/07/2018	4.0
Dr Mark Jarvis	Medical Director, Trafford CCG	11/07/2018	4.0
Eleanor Roaf	Interim Director of Public Health, Trafford Council	11/07/2018	4.0

Distribution

This PGD has been distributed to during its development:

NAME	TITLE	DATE OF ISSUE	VERSION
Dipesh M Raghwani	Clinical Lead, Greater Manchester LPC	24/5/2016	2.1
Dr Mark Jarvis	Medical Director, Trafford CCG	24/5/2016	2.1
Andrew Martin	Strategic Medicines Optimisation Pharmacist, Greater Manchester Shared Service	6/7/2016	2.1

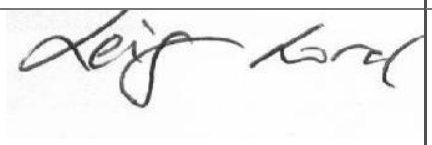
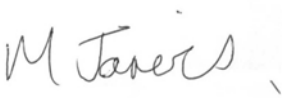
PGD Development

Originally developed / Reviewed by:	Stephen Woods (Author)	Senior Medicines Optimisation Pharmacist, Greater Manchester Shared Service
	Dr. Mark Jarvis	Medical Director, Trafford CCG
	Dipesh M Raghwani	Clinical Lead, GM LPC

Date applicable:	13th July 2018
Review date:	1st December 2018
Expiry date:	25th January 2019

PGD Authorisation

This Patient Group Direction has been approved for use in the Trafford Council area by:

Designation	Name	Signature	Date
Senior Pharmacist (Locality Lead Medicines Optimisation Pharmacist, Trafford CCG)	Leigh Lord		11.7.2018
Doctor (Medical Director, Trafford CCG)	Dr. Mark Jarvis		11.7.2018
Community Pharmacist Representative (Clinical Lead, Greater Manchester LPC)	Dipesh M Raghwani		12.7.2018
Trafford Council (Director of Public Health)	Eleanor Roaf		11.7.2018

1. Characteristics of Staff

Qualifications required	• Pharmacist with current General Pharmaceutical Council registration • Work in a Community Pharmacy within Trafford Council area
Additional requirements	• Has undertaken training in the use of PGDs • Has undertaken training which enables the pharmacist to make a clinical assessment in order to establish the need and supply the treatment according to this PGD as detailed in the service specification. • Has satisfied the competencies and completed the self-declaration form appropriate to this PGD, as detailed in the CPPE and NHS Health Education North West *Declaration of Competence for community pharmacy services – Emergency Contraception Service with the use of* a *Patient Group Direction* document (http://www.cppe.ac.uk/sp/sp4.asp?PID=189&1D=203). • Is competent in the assessment of the individuals using Fraser guidelines
Continued training requirements	• The pharmacist should be aware of any change to the recommendations for the medicine listed. • Must be able to show regular update in the field of family planning and reproductive health care including emergency contraception • Must assess and maintain their own competence on the medicine supplied under this PGD in line with the requirements contained within the *Declaration of Competence for community pharmacy services – Emergency Contraception Service with the use of* a *Patient Group Direction* document • It is the responsibility of the pharmacist to keep up-to-date with continuing professional development • It is the responsibility of the pharmacist to maintain their own competency to practice within this PGD. Further training may be necessary when the PGD is reviewed.
Suggested supporting learning	It is essential that pharmacists complete and satisfy the competencies detailed in the CPPE and NHS Health Education North West *Declaration of Competence for community pharmacy services – Emergency Contraception Service with the use of* a *Patient Group Direction* document.

The Pharmacy Contractor is responsible for ensuring that only suitable Pharmacists sign up to this PGD and should maintain a record of the names of individual Pharmacists and evidence of the their self-declaration and sign up to the current PGD.

2. Clinical condition or situation to which the direction applies.

Indication (Clinical condition or situation to which this PGD applies)	• Sexual health services provided by community pharmacies commissioned by Trafford Council • A patient requesting oral emergency contraception who presents within 72 hours of unprotected sexual intercourse (UPSI) or potential contraception failure.
Criteria for inclusion	Women with spontaneous menstrual cycles presenting within 72 hours of UPSI or potential contraception failure (e.g. condom failure, severe vomiting/diarrhoea whilst on oral hormonal contraception), and who: • Have no known contraindications to progestogen in their known medical history • Understand the risks, benefits and side effects • Meet Fraser guidelines, if under 16 years of age. *Note children under 13 years of age must be notified to the local Safeguarding Team; however, this should not prevent treatment if considered necessary under this PGD.* • Are competent to consent to treatment • Have been offered the option of an intrauterine device. If referring for a post-coital intrauterine device, oral emergency hormonal contraception should be administered if within PGD and acceptable to the patient • Has reached the menarche • Has vomited within three hours of administration a previous dose of levonorgesterol
Criteria for exclusion[1] (Continued on next page)	• UPSI more than 72 hours ago • Allergy / known intolerance to progestogen or other product ingredients • Severe Liver disease • Active acute porphyria • Known pregnancy (Suspected pregnancy should be excluded using a pregnancy test) • Unexplained or unusual vaginal bleeding • At risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy) • Patients taking ciclosporin • Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

[1] Exclusion under this Patient Group Direction (PGD) does not necessarily mean the medication is contraindicated but it may be outside the remit of the PGD and another form of authorisation may be suitable.
[2] Although there is potential for a false negative where fertilisation occurred less than 3 weeks previously, the FSRH CEU recommends that LNG 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 (>120 hours) (outside product licence}, as there is no evidence to indicate LNG is not safe in pregnancy. Please note in this PGD use is only allowed within the treatment window of 72 hours.

Criteria for exclusion continued	If the patient is receiving any concomitant medication or treatment, it is the responsibility of the healthcare professional identified in 'Characteristics of Staff' to ensure that treatment with the medicines detailed in this PGD is appropriate. In case of any doubt, further advice must be sought from an appropriate healthcare professional (e.g. patient's GP, sexual health clinic doctor) and this must be recorded as having been sought before the medicine is given.
Cautions (including any relevant action to be taken)	• Severe intestinal malabsorption syndromes, e.g. Crohn's disease, might impair the efficacy of levonorgestrel 1500microgram. Advise patient accordingly. • Active trophoblastic disease (until return of normal urine and plasma gonadotrophin concentrations). • Patients receiving warfarin - progestogens may enhance or reduce anticoagulant effect of coumarins, patients should be made aware of this and visit their anticoagulant clinic to have their INR checked within 3 days of consuming treatment. • The small amount of levonorgestrel that appears in breast milk should not be harmful to the baby, however, patients should be advised to take levonorgestrel immediately after a breast feed, thus reducing the amount of the drug the baby may take in the next feed. This would be the only circumstance in which a patient may take their treatment away with them. • The FSRH Clinical Evidence Unit (CEU) advises that if further UPSI occurs within 12 hours of a dose of levonorgestrel, further emergency contraceptive treatment is not required. ***The Cu-IUD can offer a more effective option and it is important that patients understand the risk of emergency contraception failure.***
Action if excluded	• Refer to a doctor or to the nearest available contraceptive clinic as appropriate. • Document action taken.
Action if patient or carer declines treatment	• Inform patient/carer re risks of not receiving treatment compared to the benefits. • Refer to a doctor or to the nearest available contraceptive clinic as appropriate. • Document action taken.

3. Details of medicine

Name, strength & formulation of drug	Levonorgestrel 1500 microgram tablet
Presentation	Oral tablet
Storage	Store in the original package in order to protect from light.
Legal category	POM
Black Triangle ▼	No
Unlicensed / off label use	In the following circumstances levonorgestrel 1500microgram may be used outside the terms of the product licence; such use is justified by current best practice (FSRH guidance): • Enzyme-inducing medication can reduce the efficacy of oral emergency hormonal contraception. If the patient is currently receiving treatment with enzyme-inducing medication or has taken one within the previous 28 days, then they should always be offered the alternative of a copper-bearing intrauterine device which is unaffected by concomitant drug use. If levonorgestrel 1500microgram is preferable to the intrauterine device, then the dose of levonorgestrel 1500microgram must be doubled, i.e. levonorgestrel 3000 micrograms, to be taken immediately as a single dose, in patients prescribed enzyme-inducing medication. • A repeat dose may be given within three hours of vomiting after taking levonorgestrel 1500microgram. This is a good practice point where no evidence exists but where best practice is based on the clinical experience of the multidisciplinary group. • Higher weight or BMI could reduce the effectiveness of levonorgestrel 1500 micrograms. Therefore if woman has a BMI >26 kg/m^2 or weight >70 kg it is recommended that a double dose, 3000 micrograms, of levonorgestrel is given. 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. *If used outside the licensed indication then this must be documented in the consultation record.*
Route / method	Oral
Dose and frequency	One tablet to be taken as a single dose as soon as possible and no later than 72 hours after UPSI. If the patient is taking enzyme-inducing medication, the dosage should be increased to **TWO** tablets, i.e. 3000 micrograms (see 'Unlicensed/off label use'). This should be taken as a single dose as soon as possible and no later than 72 hours after UPSI. Two 1500microgram tablets (3000 micrograms) to be taken as a single dose for women with a BMI >26 kg/m^2 or weight >70 kg. *If patient experiences vomiting within three hours of taking levonorgestrel, a second supply is allowed providing it is taken within 72 hours of UPSI.*

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Quantity to be administered and/or supplied	Single dose of 1500 micrograms or 3000 micrograms to be supplied. Patients should be observed taking the medication unless they are breast feeding, when they can be allowed to take away for later consumption if necessary, but this must occur within the 72 hour window.
Maximum or minimum treatment periods	Single episode of treatment which may be repeated in the same cycle if appropriate.
Disposal	All waste must be disposed of in accordance with the relevant waste regulations.
Drug interactions[3]	• If the patient is taking any concomitant medication or treatment it is the practitioner's responsibility to ensure that treatment with the drug detailed in this Patient Group Direction is appropriate. (For drug interaction see Appendix 1 of BNF (https://www.medicinescomplete.com/mc/) or the Summary of Product Characteristics (http://www.medicines.org.uk/emc/) or contact the Medicine Information Service at Liverpool -telephone number inside front cover of BNF) • In the case of any doubt, further advice must be sought from an appropriate health professional and recorded as having been sought before the drug is given. • If the requirements of this Patient Group Direction cannot be complied with the patient must be referred to a suitable independent prescriber.
Identification & management of adverse reactions[2]	**Very common and common adverse effects**

Very common(10%)	**Common(1/100 to <1/10)**
Headache	Dizziness
Nausea Lower abdominal pain	Diarrhoea Vomiting
Bleeding not related to menses*	Delay of menses more than 7 days ** Irregular menstruation Breast tenderness
Fatigue	

*Bleeding patterns may be temporarily disturbed, but most women will have their next menstrual period within 7 days of the expected time.

** If the next menstrual period is more than 5 days overdue, pregnancy should be excluded.

If pregnancy occurs after treatment with levonorgestrel 1500microgram, the possibility of an ectopic pregnancy should be considered. Severe abdominal pain may be an indication of ectopic pregnancy.

[3] Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list

Identification & management of adverse reactions continued	For a full adverse effects profile, refer to the Summary of Product Characteristics (SPC- www.medicines.org.uk) or the most current edition of the British National Formulary (BNF- www.bnf.org) In the event of any adverse reaction: • Record the adverse reaction in the patient consultation note • Inform the patient's GP if the patient consents to this If appropriate report the adverse reaction under the Yellow Card scheme (forms can be found at the back of the BNF or completed online at http://yellowcard.mhra.gov.uk)

4. Records

Records	The pharmacist must keep a record of the consultation and outcome on the patient proforma for a period of time in line with Records management: NHS code of practice or use any agreed web based solution. The minimum required information to be collected is: • Patient's name • Date of birth • Dose supplied • Batch number • Expiry date • Significant information e.g. if used off licence reason why • Record if the treatment is taken away from the pharmacy • Signature/name of health professional who administered or supplied the medication. Computerised patients medication records can be used where considered appropriate. Where there is no web based solution the pharmacist must complete the agreed audit form and submit to the relevant department in line with the service specification. Clinical records must be kept for at least 8 years following completion of treatment. In patients who are aged under 17 years, clinical records must be kept until the patient's 25th birthday, or for 8 years following a child's death. (Records Management: NHS Code of Practice- https://www.gov.uk/governmenVpublications/records-managemen t-nhs-code-of-practice)

5. Patient Information

Written information to be given to the patient or carer	The patient/carer should be given the following written information if appropriate: • The product specific patient information sheet supplied with the medicine. • Provide a copy of the Family Planning Association (FPA) leaflet 'Your guide to emergency contraception' (available at http://www.fpa.org .uklresources/down loads) to patients.
Advice to be given to the patient or carer	The patient/carer should be given the following information verbally if appropriate and requested: • Effectiveness of method, dependent on length of time from UPSI / potential contraceptive failure to treatment. • Beneficial effects, side effect and risks should be discussed. • How to take the pill correctly, preferably as an immediate dose in the pharmacy. Breast feeding mothers may be allowed to take away with them to allow them to feed their child before taking. This should only occur if it fits within the allowed time limits. • If vomiting occurs within three hours of taking, a repeat dose is required (see 'Use outside the terms of the product licence'). • When to seek further medical advice e.g. INR check if on warfarin. • To refer to Sexual Health Clinic or GP if no / light period up to three weeks after treatment. • Discuss on going contraception including Quick Starting Contraception guidance (recommending starting contraception immediately after oral emergency hormonal contraception with additional protection as appropriate for the method used). • Discuss long-acting reversible contraception and give written information that is in line with NICE guidance, CG 30, October 2005. • Encourage use of condoms and reinforce the safer sex message. • Recommend sexually transmitted infections screening. • Supply or recommend condoms as detailed in the service specification. • Use of the product outside the terms of its licence should be discussed with the patient, including the reasons why this may be necessary. • Advise where the patient will continue to use a hormonal method of contraception that they should use an additional contraceptive method for 7 days (2 days for Progestogen Only Pill; 9 days for *Qlaira®).* ***To patients taking enzyme-inducing medication or patients with a BMI > 26kgm^2 or weight >70kg:*** • Advise on necessity for increased dose of levonorgestrel to 3000microgram (two tablets) (Off licence recommendation).

6. References used to develop this PGD

1. Faculty of Sexual and Reproductive Healthcare, Clinical Effectiveness Unit:
   - Emergency Contraception. Clinical Guidance, August 2011 (Updated January 2012). Accessed on 3rd May 2016 via http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraceplion11.pdf
   - Contraceptive Choices for Young People. Clinical Guidance, March 2010. Accessed on 3rd May 2016 via http://www.fsrh.org/pdfs/ceuGuidance_Young People2010.pdf
2. Manufacturer's Summaries of Product Characteristics (SPC)
   - Levonelle® 1500microgram tablet, Bayer pic. Date of last revision of the text 20/10/2014 http://www.medicines.org.uk/emc/medicine/16887/SPC/Levonelle+1500+microgram+tablet/. Accessed 3ra May 2016.
3. General Pharmaceutical Council.
   - Standards of conduct ethics and performance, July 2012. https://www.pharmacyregulation.org/standards/conduct-ethics-and-performance Accessed 2th April2016.
   - Standards for Continuing professional development, September 2010. https://www.pharmacyregulation.or/standards/continuing-professional-development. Accessed 27[1] April 2016.
   - Guidance on maintaining clear sexual boundaries, February 2012. https://www.pharmacyregulation.org/standards/guidance. Accessed 27th April 2016
   - Guidance on patient confidentiality, April 2012. htlps://www.pharmacyregulation.org/standards/guidanee. Accessed 27th April 2016.
4. Centre for Pharmacy Postgraduate Education
   - Declaration of competence for community pharmacy services; Emergency Contraception Service with the use of a Patient Group Direction. Version 14 (23rd April 2015) https://www.cppe.ac.uklservices/commissioners. Accessed 3rd May 2016.

LEVONORGESTREL 1500 MICROGRAM TABLET	P.O.M. [Prescription Only Medicine]

The Patient Group Direction is to be read, agreed to and signed by the healthcare professional and their employer. The healthcare professional retains a copy of the PGD. The employer retains a record of all PGDs held by healthcare professionals employed or contracted by them.

Individual Authorisation

By signing this PGD you are agreeing that:

- You have read and understood the content;
- To the best of your knowledge, the content of the PGD is correct and supports best practice;
- You will act within the parameters of the PGD;
- You take responsibility for maintaining your competence and on-going training requirements to continue to use the PGD safely

Named Healthcare Professional : _____

Designation : _____

The above named healthcare professional is authorised to work within the confines of this Patient Group Direction

Name of Employer: _____
/ Contractor

Address of Employer: _____
/ Contractor

_____

_____

_____

Signature of Employer : _____
/ Contractor

I, the undersigned, have read and understood this PGD and agree to work within its confines

Signature of Named

Healthcare Professional : _____

Date: _____

One copy to be retained by the named healthcare professional
One copy to be retained by the employer / contractor
The healthcare professional's details must be recorded on a register of PGDs held by their employer/contractor.