Gateshead Council
www.gateshead.gov.uk

Patient Group Direction (PGD) for the Administration of

Levonelle® 1500 tablet (Levonorgestrel 1.5mg) by Registered Professionals to Individuals Accessing *Gateshead Council Commissioned Emergency Hormonal Contraception* Service in *Gateshead*

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

Direction Number: - CP 01C
Valid from: 30 09 2016
Review date: 30 03 2018
Expiry date: 31/03/2019

This patient group direction has been developed & produced by: -			
Title	Name	Signature	Date
Pharmacist	*Helena Nettleton, North of England Commissioning Support (NECS)*		30/9/2016
Senior Doctor	*Dr Janet Gallagher, Lead associate specialist for sexual health services.*		30/9/2016
Local Authority Sexual health Programme Lead	*David Brady Gateshead Public Health*		30/9/2016
Local Pharmaceutical Committee representative	*Sami Hanna Communications Officer Gateshead & South Tyneside LPC*		30/9/2016

This PGD has been approved for use in Gateshead by: -			
Title	Name	Signature	Date
Director of Public Health, Gateshead Council	*Alice Wiseman*		30/9/2016

1. Clinical Condition or Situation to Which the Direction Applies

Indication (defines situation or condition)

Request for Emergency Contraception.

Objectives of care

The supply will be made by Pharmacists registered with the General Pharmaceutical Council (GPhC), working in registered community pharmacy premises, who have undertaken additional training and are accredited by the Local Authority within which the pharmacy premises is located.

The supply will be made to women aged 14 years and over, and in their reproductive years, following unprotected sexual intercourse (UPSI) in order to minimise the potential for an unintended pregnancy.

Inclusion criteria

Only use those criteria that are specific to your authorised role & competence.

Women aged 14 years and over, and in their reproductive years, presenting within 72 hours of Unprotected sexual intercourse (UPSI) or potential failure of a contraceptive method.

Women aged less than 16 years must be assessed and considered to be Fraser competent.

All under 18 years must be assessed for Child Sexual Exploitation (CSE) risks. Refer to Appendix 2 of the Specification.

Potential failure of contraception includes [1,2]:

- Women who have severe diarrhoea and/or vomiting which may have reduced the efficacy of oral contraception (see BNF). [2]
- 'Failure to use additional contraceptive precautions when starting hormonal methods of contraception.' [1]
- 'Failure to use additional contraceptive precautions (or barrier failure) to Combined Hormonal Contraception (CHC), Progestogen Only Pill (POP), Progestogen only implant, whilst using liver enzyme-inducing drugs or in the 28 days after use, e.g. concomitant use of enzyme-inducing rifamycins (such as rifabutin and rifampicin) and CHC.

  EHC is not required when using combined hormonal contraception (CHC) with antibiotics that are not enzyme inducers. Please see section entitled 'Precautions' for recommended action.' [1]

- Non-compliance with dosage regime of hormonal contraceptives. i.e. delayed or missed pills, patches or rings.

- 'Late injection (>14 weeks since last injection of depo medroxyprogesterone acetate (DMPA) or >10 weeks since norethisterone enanthate NET-EN) and UPSI during time that extra precautions were required.' [1]
- Having reason to believe that a barrier method has failed.
- Failed to use an additional barrier method of contraception when current methods have failed or been missed.
- Can confirm that their intrauterine contraceptive device (IUCD)/IUS or Subdermal implant has expired, is not present, or displaced. [1] This would indicate that their current method cannot be relied on, and she has not used additional contraception.
- Women who are taking oral contraception who have also taken prescribed, or OTC, medication that is known to interact with their oral contraception (producing a reduced effect).
- Women aged 14 years and over presenting within 72 hours of unprotected sexual intercourse who have vomited within two hours* of initial dose of *Levonelle® 1500 tablet (Levonorgestrel 1.5mg)* [1,3], and decline the offer of a Cu-IUD, but are still within the 72 hour window.

  *Use outside produce license: product license [4] states vomiting within 3 hours, however, this PGD is based on Faculty of Sexual And Reproductive Health (FSRH) [1] and BNF [2] recommendations, and is consistent with good practice recommendations in the UK.

Furthermore, following assessment, discussion and informed choice (including provision of information about efficacy, adverse effects, interactions, medical eligibility and contraindications, and additional contraceptive precautions), request *Levonelle® 1500 tablet (Levonorgestrel 1.5mg)* as the preferred emergency contraception method. [1]

Exclusion criteria (Refer to current SPC [4])

- UPSI more than 72 hours prior to presentation
- Aged under 14 years
- Aged under 16 years and not considered to be Fraser competent
- Individuals aged 16 years and over and assessed as not competent to consent using local safeguarding guidelines unless under 18 and an appropriate adult can consent for them.
- 'Known hypersensitivity to Levonorgestrel or any excipients contained within the product Levonelle® 1500 tablet (Levonorgestrel 1.5mg)'. [4]
- Known or suspected pregnancy.
- Unexplained or unusual vaginal bleeding.
- Young girls not having gone through menarche.
- 'Previous history of ectopic pregnancy or of Salpingitis'. [4]
- Taking drugs prescribed, OTC medication, or herbal remedies containing St John's wort [8] that is known to interact with Levonorgestrel or produce toxicity, e.g. possible inhibition of metabolism of cyclosporin producing toxicity. Refer to current BNF for list.
- Severe hepatic dysfunction (including acute porphyria) [4]
- Severe malabsorption syndromes (e.g. Crohn's disease). [4]
- Trophoblastic disease. [4]
- 'Rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-

galactose malabsorption'. [4]
- Individual wishes to see a doctor.

Precautions

'All eligible women presenting between 0 and 120 hours of UPSI or within 5 days of expected ovulation should be offered a Cu-IUD because of the low documented failure rate'. [1] If client prefers IUCD, after advice about efficacy, then refer to Contraception & Sexual Health service or GP. However, if appropriate, still offer Levonelle® 1500 tablet (Levonorgestrel 1.5mg) to client.

'Women taking liver enzyme-inducing drugs (or who have stopped taking this medication within the last 28 days) should be advised that a Cu-IUD is the only method of EC not affected by these drugs.' [1]

'Women taking liver enzyme-inducing drugs, including post-exposure HIV prophylaxis after sexual exposure (or who have stopped within the last 28 days), and who decline or are not eligible for a Cu-IUD, should be advised to take a dose of 3 mg Levonorgestrel (two Levonelle® 1500 tablet (Levonorgestrel 1.5mg)) as soon as possible within 120 hours of UPSI (outside the product licence). The efficacy of LNG after 96 hours is uncertain'. [1,5]

Consider risks due to ovulation timing.

When there is suspected sexually transmitted infection (STI) refer to Sexual Health Services or their own GP.

Advice on Chlamydia screening service for under 25's.

Provide information on any appropriate local 'condom supply schemes'.

See supporting information file for specific information relating to services available locally.

Action if excluded

Refer to Contraception & Sexual Health service www.gatesheadsexualhealth.co.uk/ or GP. See supporting information file for specific information relating to services available locally. Document all action taken.

Circumstances in which further advice should be sought from doctor and/or specialist

Refer to a GP or the Contraception & Sexual Health service, if medically indicated or at the patient's request.

Action if patient declines treatment

Refer to Contraception & Sexual Health service or GP.

- See supporting information file for specific information relating to services available locally.
- Record the refusal in the clinical record and document all other actions taken.

2. Description of Treatment.

Name, strength & formulation of drug

Levonelle® 1500 (Levonorgestrel 1.5mg tablet).

Legal Status:

POM

Dosage/Dose range:

UPSI: Single tablet (1.5mg) to be taken as soon as possible (provided dose is taken within 72 hours of unprotected sexual intercourse.)

UPSI and taking liver enzyme inducing medication: If the patient does not want an IUCD inserted, recommended dosage is: Two tablets (3mg) to be taken as soon as possible within 72 hours of unprotected sexual intercourse (Unlicensed dosage). [1,5] See 'Precautions' section above for further information.

Route/Method:

Oral

Frequency of Administration:

Single dose (with possibility of second dose if vomiting occurs within 2 hours of first dose, providing that this second dose is still within the 72 hour window).

Repeated episodes of UPSI may be treated within one menstrual cycle:

Levonelle® 1500 '(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 120 hours' [1]).

Quantity to supply:

UPSI: One original pack containing one tablet (1.5mg).

UPSI and taking liver enzyme inducing medication: Two original packs (total of 2 x 1.5mg tablets) See note above; 'Precautions'.

POM pack should be supplied.
OTC pack should not be supplied.

Follow up treatment:

- Refer to Contraception & Sexual Health service or GP if client experiences a missed or abnormal period.
- When there is suspected sexually transmitted infection (STI) refer to Sexual Health services.
- Advise on dual STI screening service for under 25's.
- Advise any person who has had unprotected sexual intercourse to attend Sexual Health services for a full sexual health screen (testing for chlamydia, GC ,HIV and STS) or see their GP.
- Provide information on any appropriate local "condom supply schemes". See www.gatesheadsexualhealth.co.uk/
- Provide contraception leaflet
- Signpost to local contraceptive services.
- Inform client that if there is an abnormal period and/or abdominal pain then they should contact their local sexual health services or see their GP.

See supporting information file for specific information relating to services available locally.

3. Further Aspects of Treatment:

Relevant Warnings & Potential Adverse Effects

Relevant Warnings:

- Failure rate and efficacy.
- Possible effects on menstrual cycle. Discuss what to do if period does not arrive/or is unusual (see management of adverse drug reactions (ADRs) below.
- Seeking medical advice promptly if any lower abdominal pain occurs.
- If taken more than once in a cycle that each subsequent dose would be less effective than the time before and would increase the effect on the menstrual cycle.

Then explain/discuss the potential side effects, and the likelihood of them occurring (see below; adverse effects/reactions.

Potential Adverse Effects/ Reactions:

- Well tolerated, however common side effects include:
  - Nausea and vomiting
  - Diarrhoea, lower abdominal pain
  - Breast tenderness
  - Headache, Dizziness
  - Menstrual irregularities
  - Fatigue.

Refer to Manufacturers SPC [4] for complete list of side effects and additional details (a copy of the most recent SPC, at the time of development of the PGD is included in the supporting information pack. Be aware that this may have been superseded. Current SPCs can be accessed via the electronic Medicine Compendium: http:///www.medicines.org.uk/emc.

Identification and Management of Adverse Reactions

Bleeding patterns may be temporarily disturbed, but most women will have their next menstrual period within 7 days of the expected date. If the next menstrual period is more than 5 days overdue, pregnancy should be excluded. [4]

In the event of untoward or unexpected adverse reactions:

- If necessary seek appropriate emergency advice and assistance.
- Document in the Patient Medication Record (PMR) and inform GP.
- Complete local organisational incident procedure if appropriate.

Reporting Procedure of Adverse Effects

See manufacturers Summary of Product Characteristics for details of all potential adverse reactions.

Client to report any suspected ADRs believed to be associated with Levonelle® 1500 tablet (Levonorgestrel 1.5mg) to a Healthcare Professional or directly using the Yellow Card system.

Clients and Healthcare Professionals can log ADRs directly via the MHRA website (http://yellowcard.mhra.gov.uk/) or call freephone 0808 100 3352 (10am to 2pm Monday-Friday only).

Advice to Patient / Carer (verbal or written)

- Give patient information leaflet (PIL) and discuss as required.
- Reason treatment required.
- Mode of action.
- Treatment administration.
- Side effects and failure rates (as above).
- When a pregnancy test is required.

- What to do if vomiting occurs within 2 hours. (Advice may differ depending on timing of presentation with respect to 72 hour window).
- Effective contraception.
- 'After using emergency contraception it is recommended to use a barrier method (e.g. condom, diaphragm or cap) or abstain until the next menstrual period starts. The use of Levonelle® 1500 tablet (Levonorgestrel 1.5mg) does not contraindicate the continuation of their regular hormonal contraception.' [4] However this may take some time to be effective if missing pills have created the need for emergency contraception
- 'Women should be advised that oral EC methods do not provide contraceptive cover for subsequent UPSI and that they will need to use contraception or refrain from sex to avoid further risk of pregnancy.' [1]

Arrangements for Referral to Medical Advice

Contraception & Sexual Health Service or GP
See supporting information file for specific information relating to services available locally.

Records

Records should be kept that will demonstrate;

- Details of all drugs supplied for audit purposes.
- Fraser guidance fulfilled for under 16.
- If individual is under 14 years, record of action taken.
- If individual is 16 years or over and not competent, action taken.
- Evidence of counselling and future contraception needs explored.
- Documentation of referral onward or advice sought.

Records will be made on standard documentation.

See supporting information pack for copies of documentation.

Additional Facilities

Special Considerations / Additional Information

References

[1] FSRH (2012). Emergency Contraception. https://www.fsrh.org/documents/ceu-emergency-contraception-jan-2012/. *Accessed 15/9/16.*

[2] BMA, RPS (2016). British National Formulary. https://www.medicinescomplete.com/mc/bnflegacy/current/PHP4869-combined-hormonal-contraceptives.htm. *Accessed 15/9/16*

[3] BMA, RPS (2016). British National Formulary. https://www.medicinescomplete.com/mc/bnflegacy/current/PHP5027-levonelle-1500.htm?q=levonelle&t=search&ss=text&tot=2&p=2#PHP5027-levonelle-1500. *Accessed 15/9/16.*

[4] Bayer (2014). SPC. Levonelle 1500 microgram tablet. https://www.medicines.org.uk/emc/medicine/16887. *Accessed 19/9/16.*

[5] CEU (2016). CEU Statement: Use of double dose (3mg) levonorgestrel emergency contraception by women taking enzyme-inducing medications. https://www.fsrh.org/news/ceu-statement-use-of-double-dose-3mg-levonorgestrel-emergency/. *Accessed 6/9/16.*

[6] DOH (2011). Quality criteria for young people friendly health services. https://www.gov.uk/government/publications/quality-criteria-for-young-people-friendly-health-services. *Accessed 21/9/16.*

[7] CPPE (2016). Specimen Declaration of Competence for Pharmacy Emergency Contraception Service. https://www.cppe.ac.uk/services/docs/ec_wgll.pdf. *Accessed 21/9/16*.

[8] MHRA (2016). Levonorgestrel-containing emergency hormonal contraception: advice on interactions with hepatic enzyme inducers and contraceptive efficacy. https://www.gov.uk/drug-safety-update/levonorgestrel-containing-emergency-hormonal-contraception-advice-on-interactions-with-hepatic-enzyme-inducers-and-contraceptive-efficacy. *Accessed 27/09/16*.

4. Characteristics of Healthcare Professional Staff

Only those healthcare professionals that have been specifically authorised by their clinical lead/supervisor/manager may use this PGD for the indications defined within it.

Under current legislation, only the following currently registered healthcare professionals may work under Patient Group Directions (PGDs). These professionals may only supply or administer medicines under a PGD as named individuals. These professionals include -

Pharmacists	Nurses	Chiropodists/Podiatrists
Health Visitors	Physiotherapists	Midwives
Dieticians	Optometrists	Registered Orthoptists
Prosthetists and Orthotists	Radiographers	Occupational Therapists
Speech and Language Therapists	Dental Hygienists	Dental Therapists
State registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by the Secretary of State, or issued with his approval.		

Qualifications required (professional registration applies to specific professions**)**

Professionals using this PGD must be currently registered with their relevant professional body, e.g.

- For Pharmacists: - General Pharmaceutical Council (GPhC)

Additional requirements (applies to all staff)

Pharmacists currently accredited and delivering the service (as per 2014-16 PGD Number CP01B, Gateshead Council Levonelle 1500), their training requirements remain valid up to February 1st 2017. New pharmacists wanting to deliver this service will be required to adhere to the new Accreditation requirements below:

Accreditation of pharmacists is conditional on successful completion of assessment (every 3 years) of the following Centre for Pharmacy Postgraduate Education (CPPE) e-learning and assessment packages:

- Emergency Contraception
- Contraception
- Safeguarding Children and Vulnerable Adults.

- Completion of a CPPE self-assessment and signed and dated Declaration of Competence (DoC) for community pharmacy emergency contraception services (hosted on www.cppe.ac.uk). This should indicate dates of successful completion of assessment of the above CPPE packages and a copy sent to the Council annually.

The signed DoC must also confirm:

- 'Pharmacist must have met or be **actively** working towards the Consultation Skills for Pharmacy Practice: Practice Standards for England, as determined by Health Education England.' [7]
- Appropriate training for working under PGDs for supply/administration of medicines has been undertaken.
- Competency in the use of PGDs (see NICE competency framework for health professionals using patient group directions). https://www.nice.org.uk/guidance/mpg2/resources
- Current registration with the GPhC and date of annual registration.
- Date of attendance (at least every 2 years) of a local workshop training session, which will cover local safeguarding arrangements and relevant Integrated Sexual Health Service pathways.

Further requirements include:

- Each practitioner must sign and date the current PGD . Locums should sign the PGD for each shop they work in.

Gateshead Council Public Health, via Pharmoutcomes, will verify accreditation using the dates specified within the signed DoC statement – Emergency contraception.

Pharmacists must enable Pharmoutcomes to access their CPPE record.

CPPE assessments must be reviewed at least every three years. If any of the CPPE assessment dates are older than 3 years, they will be considered expired and payment will not be made by the Council until an updated CPPE assessment and Declaration of Competence is evidenced.

Providers must retain copies of their own or employees' certificates of accreditation and training at the premises where they offer the Service.

The Provider will be required to comply with General Pharmaceutical Council Standards of Conduct, Ethics and Performance and demonstrate maintenance of knowledge, skills and competencies, with evidence of Continuing Professional Development, ideally via CPD entries on to the General Pharmaceutical Council Website www.uptodate.org.uk/home/welcome.shtml.

The Provider shall ensure that each practitioner ensures their skills and knowledge are kept up to date prior to supplying under the PGD.

Each pharmacy must have a Standard Operating Procedure in place which covers the supply of Levonelle® 1500 tablet (Levonorgestrel 1.5mg via this PGD.

The Provider must ensure that supporting pharmacy staff are trained in dealing with patients in a patient-centred, user-friendly, confidential and non-judgmental manner when requesting EHC. Providers are expected to work towards implementing the Department of Health paper 'You're Welcome' Quality Standards. [6]

Continued training requirements (applies to all staff)

Maintenance of knowledge, skills and competencies by engaging in continuing professional development.
Each practitioner is accountable for ensuring their skills and knowledge is kept up to date prior to supplying under PGD.

'Pharmacists are responsible for reassessing their competence to provide this service on an ongoing basis by responding to new guidance, standards and any relevant new learning programmes and assessment. In addition, you should complete the DoC system at least once every **3 years**. This should involve revisiting the self-assessment of competencies, reflecting on each competency and identifying personal learning needs to assure self-declaration again at this point. Where changes are introduced to the service, pharmacists will need to update themselves as part of their usual CPD.' [7]

Management & Monitoring of Patient Group Direction *PGD Number*

Levonelle® 1500 (Levonorgestrel 1.5mg) tablets

Individual Healthcare Professional Authorisation

This form can to be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professional.

- **This page is to be retained by the individual healthcare professional/practitioner.**
- This PGD is to be read, agreed to and signed by all registered Healthcare Professionals it applies to. Healthcare Professionals must be authorised by the person(s) named below before using the PGD.
- By signing this document, the healthcare professional confirms that they understand the PGD, that they are competent to work under this PGD, that they will practice in accordance with the parameters of the PGD and accept full clinical responsibility for any decisions made with using this PGD).
- Patient Group Directions should be used in conjunction with reference to national or local policies, guidelines or standard text (e.g. manufacturers Summary of Product Characteristics) and DO NOT replace the need to refer to such sources.

Name of Healthcare Professional:-_____

is authorised to administer

Combined *Name of Medication*

……under this Patient Group Direction (*PGD Number*)

Signature of Healthcare Professional: - _____

Date signed: - _____

State profession: - _____

Authorisation to use this PGD by: -

This above named healthcare professional has been authorised to work under this PGD by:

Name of Manager/Clinical Lead: - _____

Signature of Manager/Clinical Lead: - _____

Date signed: - _____

PGD Valid from:	Review Date:	**Expiry Date:**

Management & Monitoring of Patient Group Direction *PGD Number*

Levonelle® 1500 (Levonorgestrel 1.5mg) tablets

Healthcare Professional Authorisation (service/practice list)

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professionals.

- This page should be signed by all healthcare professionals authorised to use this PGD and retained and kept on file by the service/practice manager and on the premise or clinical area where the PGD is used as a record of all practitioners authorised to use this PGD

The following healthcare professionals are authorised to administer

Name of Medication under the Patient Group Direction (*PGD number*)

PGD Valid from date: **PGD Expiry Date:**

Healthcare Professional			**Authorised by:**		
Name	**Signature**	**Date**	**Name**	**Signature**	**Date**

PGD Valid from:	Review Date:	**Expiry Date:**