WESTMORLAND & FURNESS COUNCIL COMMISSIONED SERVICES

Clinical Content of Patient Group Direction for the Supply of Levonorgestrel 1500 Microgram Tablet for Emergency Hormonal Contraception

Version: Levonorgestrel 1500 2021.1

Protocol Details	
Date comes into effect	30th September 2023
Date of expiry + review	30th September 2026 or in the light of significant changes in best legal practice
Staff characteristics	Accredited community pharmacists supplying as part of the EHC scheme commissioned by Cumbria County Council Public Health Department who must: - Understand and accept the principles relating to patient group directions and relevant clinical situations and have undertaken training regarding working under PGDs. - Complete appropriate training in EHC supply, be up to date with and competent to work under the Faculty of Sexual and Reproductive Health Care Emergency Contraception Guidance. - Have made a CPPE Declaration of Competence. **YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING UNDER IT**

Clinical Details	
Indication	• Prevention of pregnancy within 72 hours of unprotected sexual intercourse (UPSI) or failure of a contraceptive method. • Prevention of pregnancy between 72-120 hours (unlicensed use) of unprotected sex or failure of a contraceptive method where Ulipristal Acetate (UPA) is contraindicated and the women declines a Cu-IUD. • Prevention of pregnancy within 120 hours of unprotected sexual intercourse or failure of a contraceptive method when taking liver enzyme inducing drugs (or have taken in the previous 28 days). • Prevention of pregnancy within 120 hours of unprotected sexual intercourse or failure of a contraceptive method when the woman has a BMI of >26 or weighs more than 70kg where Ullipristal Acetate is contraindicated (unlicensed use). • Prevention of pregnancy if patient unwilling to cease hormonal contraception for 5 days after Ulipristal Acetate EC Levonorgestrel EC can be considered following full discussion surrounding efficacy of both oral methods of EC. • If the woman has used any hormonal contraception in the 7 days prior to UPSI.
Inclusion Criteria	Competent women (assess formally if aged under 16 or if competence in doubt) presenting within 72 hours of unprotected sexual intercourse, or between 72hrs and 120 hrs of UPSI if UPA is contraindicated, whether due to: • No contraception used or failed barrier method of contraception. • Missed or incorrectly used combined or progestogen only contraceptive pill/patch/ring. • Contraceptive pill vomited or affected by diarrhoea or medicines. • Late injectable contraception - over 14 weeks since the last injection was given. • Expired contraceptive implant. • Removal or loss of intrauterine device/system in the previous 7 days. • Vomited supplied course of EHC and re-presented within 3 hours of taking it providing UPSI was in the past 120 hours. • Loss of protection following change in contraceptive method. • Women who cannot be reassured that they are not at risk of pregnancy. • Women who could already be pregnant, i.e. other episode of unprotected sexual intercourse in this cycle or women who have irregular periods, where pregnancy cannot be excluded at the time of consultation. Pregnancy >21 days can be ruled out with a negative pregnancy test; ideally with first morning urine. Assessment of competency is satisfactory according to current guidelines e.g. Fraser Guidelines and Mental Capacity Act. All sexually active under 13-year olds must be discussed with the nominated child protection lead in the organisation and there should be a presumption that the case will be referred to children's social care.

Exclusion Criteria	• Hypersensitivity - previous severe adverse reaction to levonorgestrel or any ingredient. • Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption. Patients with less severe intolerance should be advised that some abdominal discomfort may accompany the dose and that they must decide if this is acceptable in the interest of preventing unwanted pregnancy. • UPSI > 72hours (qualified exclusion - see special circumstances, below) • Previous experience of any severe clinical problems with hormonal contraception, apart from nausea. • Acute porphyria.
Special Circumstances Levonorgestrel MAY be supplied to clients presenting with these characteristics if they are managed as indicated	• Unexplained or unusual vaginal bleeding - EXCLUDE PREGNANCY before making supply. If unable to exclude pregnancy, FSRH state that there would be no harm to the foetus if Levonorgestrel is taken, however you may wish to discuss with your senior. *In the following cases efficacy of levonorgestrel may be reduced; supply should be made if in the best interests of the client, but strongly advise that the copper IUD is more reliable, preferred option* • Prior use of Ullipristal acetate (EllaOne®) in the previous 7 days. Supply can be made up to 120 hours after UPSI. • Acute porphyria. • Severe intestinal malabsorption conditions e.g. active Crohn's disease. *In the following case a dose of TWO levonorgestrel 1500mcg tablets can be given if in the client's best interests, but they must be advised that the copper IUD is more reliable. (Unlicensed use).* • Prevention of pregnancy within 120 hours of unprotected sexual intercourse or failure of a contraceptive method when taking, or have taken in the previous 28 days, liver enzyme inducing drugs, e.g. carbamazepine, nevirapine, oxcarbazepine, phenytoin, primidone and other barbiturates, rifabutin, rifampacin, ritonavir, modafinil, eslicarbazepine, rufinamide, efavirenz, bosentan and aprepitant, St Johns Wort or topiramate. • Unlicensed use: refer to FSRH Guidance 2017.
Management of Excluded Patients	• Refer for emergency IUD. A copper coil can be fitted up to 5 days after a single episode of UPSI in a cycle or up to 5 days after the earliest ovulation date expected within a regular cycle. • If >72 (or 120 hours if unable to tolerate Ulipristal acetate) since episode of unprotected sexual intercourse, refer urgently to the nearest specialist sexual health service, GP or other suitable facility for assessment. • Refer other **excluded patients for urgent** medical or sexual health review.
Action for patients not wishing to receive care under this PGD	• Make patient aware of alternative sources of treatment. (GP or Specialist Sexual Health Service or Young Person's Service). • Document if the patient declines EC. • Refer for emergency IUD. A copper coil can be fitted up to 5 days after a single episode of unprotected sexual intercourse in a cycle or up to 5 days after the earliest ovulation date expected within a cycle.

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Description of Treatment	
Name of medicine	Levonorgestrel 1500 Microgram Tablet.
Formulation and route	Oral tablet.
Dosage	• One tablet (1.5mg) to be taken as soon as possible after unprotected sexual intercourse preferably within 12 hours but no later than 72 hours (or 120 hours if unable to tolerate Ulipristal acetate - Unlicensed Use). • 2 tablets (3mgs) to be taken as soon as possible after unprotected sexual intercourse up to 120 hours when the patient ls taking, or has taken in the last 28 days, liver enzyme inducing drugs following FSRH Guidance 2017 (Unlicensed Use). • 2 tablets (3mg) to be taken as soon as possible after unprotected sexual intercourse up to 120 hours when the woman has a BMI >26 or weighs greater than 70 kg (unlicensed use) following FSRH Guidance 2017 (when Ulipristal is unsuitable). **Dose is to be taken during the consultation; supplies are not to be given to take away.**
Repeated dosage instructions	• **NOTE:** Supply of a subsequent course during the same menstrual cycle is more likely to disrupt the normal menstrual pattern. • Where a patient returns having vomited the first dose within 2 hours of taking it, a replacement dose should be administered, as long as the replacement dose is also taken within 72 hours (and up to 120 hours if appropriate - unlicensed use) of the episode of unprotected sexual intercourse.
Quantity to supply	Single dose as above. **Dose is to be taken during the consultation; supplies are not to be given to take away.**
Legal Status	Prescription Only Medicine (POM).

Special Precautions	• Pregnancy >21 days can be excluded with a negative test, ideally using first morning urine. Note that this will not necessarily show positive for earlier pregnancies. • Patients taking ciclosporin should be advised that Levonorgestrel 1500 microgram may increase the risk of ciclosporin toxicity. • Aprepitant can reduce the efficacy of hormonal contraception for the time of administration and the following 28 days. • Bosentan can reduce the efficacy of hormonal contraception.
Adverse effects	Levonorgestrel 1500 microgram is generally well tolerated. Very common adverse effects (>1/10) may include headaches, nausea, lower abdominal pain and fatigue. Common adverse effects (>1/100, <1/10) may include temporary breast tenderness, vomiting and diarrhoea and dizziness. Refer to BNF and SPC for complete list. https://www.bnf.org/bnf/
	http://emc.medicines.erg.uk/ Adverse effects should be reported using the Yellow Card system if appropriate- see CSM guidelines for use printed on cards in the back of the BNF or www.yellowcard.gov.uk
	Nurses and patients may now report independently.
Advice to Patients	• Refer to patient assessment forms (either paper or IT records) while the patient is present. • If under 21 days post-partum discuss negligible risk of pregnancy. • Advice that EHC is not 100% effective - pregnancy can still occur. • Discuss increased efficacy of IUD especially if mid-cycle. • Advise that menstrual cycle timing may be disrupted. Disruption is more likely if more than one course is taken during a menstrual cycle. • Give advice regarding action to take if tablets are vomited within 3 hours. • Advise woman to seek medical advice if there is any lower abdominal pain, as ectopic pregnancies may occur following use, particularly at risk are women with a history of ectopic pregnancy, fallopian tube surgery or pelvic inflammatory disease. Women who become pregnant after EC use should seek medical follow up to exclude this. • Discuss sexually transmitted infections, especially chlamydia, and refer to GUM where appropriate. • If under 25 years old to be offered chlamydia screening as part of the national screening programme. • If patient is taking ciclosporin, advise that Levonorgestrel 1500 microgram may increase risk of ciclosporin toxicity. • Give the woman the information leaflet (PIL) from the medication packet • Referral to appropriate provider for ongoing contraception if not available at time of EC. • Give woman a supply of condoms in addition to EC and stress need to consistently use a reliable method of barrier contraception, or abstain from intercourse, until the next period or until contraceptive method becomes effective. • FSRH guidance states that provider should advise women that EHC does not provide contraceptive cover for subsequent UPSI and that they will need to use contraception or abstain from sex to avoid further risk of pregnancy.

Records and Follow Up	
Referral arrangements	Refer all excluded patients for urgent GP/Sexual Health Services on non-medical prescriber assessment. All contacts with <13-year olds must be discussed with child protection, but this should not prevent EHC being given again.
Records to be kept	As per service documentation requirements, ensure: • Full history is recorded. • Fraser guidelines completed for all patients under 16 or where competence is in doubt. • Items or leaflets supplied to the patient. • Document any adverse reaction. • Patient Assessment form (can be electronic) to be completed for all cases and retained for 10 years OR Comprehensive record made in sexual health notes / medical records.
Follow up	Ensure patient is aware of local arrangements, e.g. Sexual Health Services and Clinics and is asked to return if any problems occur. Advise patient attends an appropriate service with an Early Morning Urine (EMU) sample for a pregnancy test if no normal bleed within the next three weeks, or if the next bleed is unusual in any way (light, heavy or painful etc.)

Protocol, organisation and individual authorisation signatures can be found on the managerial content sheet along with other non-clinical details relating to this patient group direction.

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Protocol Authorisation	
Lead Doctor	**Name: Matt Phillips** **Position: Consultant in GU Medicine, North Cumbria Integrated Care NHS Foundation Trust** Signature:  Date: 8th September 2023
Lead Pharmacist	**Name: Mark Stakim** Signature:  Date: 13th September 2023
Organisational Authorisation by Westmorland and Furness Council	**Name: Katrina Stephens** **Position: Director of Public Health, Westmorland & Furness Council** Signature:  Date: 13th September 2023

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Individual Authorisation

BY SIGNING THIS PATIENT GROUP DIRECTION YOU ARE INDICATING THAT YOU AGREE TO ITS CONTENTS AND THAT YOU WILL WORK WITHIN IT
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

ENSURE THAT ALL OLDER PGD VERSIONS ARE WITHDRAWN FROM USE WITH IMMEDIATE EFFECT IT IS YOUR REPONSIBILITY TO MAKE SURE YOU ARE USING THE CURRENT VERSION

NOTE TO AUTHORISING MANAGERS: AUTHORISED STAFF SHOULD BE PROVIDED WITH AN INDIVIDUAL COPY OF THE CLINICAL CONTENT OF THE PGD AND A PHOTOCOPY OF THE AUTHORISATION SHEET SHOWING THEIR AUTHORISATION

Name of Professional	Signature	Authorising Manager	Date