PATIENT GROUP DIRECTION FOR LEVONORGESTREL 1500 mcg TABLETS

Version:EC 2019.1
Start Date: 1st April 2019
Expiry Date: 31st March 2022

THIS PATIENT GROUP DIRECTION HAS BEEN AGREED BY THE FOLLOWING ORGANISATIONS:
Lancashire County Council
Blackburn with Darwen Council

CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR LEVONORGESTREL 1500 mcg TABLETS

Version PHEC- 2019.1

Protocol Details	
Date comes into effect	1st April 2019
Date of expiry + review	31st March 2022 or earlier in the light of significant changes in best practice

Staff characteristics	▪ An accredited community pharmacist with current GPhC registration supplying as part of the EHC scheme, who has undertaken training relating to the provision of emergency contraception. ▪ Commissioned by :Lancashire County Council and/or Blackburn with Darwen Borough Council Public Health Departments ▪ Understands and accepts the principles relating to PGDs and relevant clinical situations. ▪ Have evidence of Continuous Personal Development (CPD). ▪ Sign the approved Patient Group Direction (PGD) for the supply of emergency hormonal contraception by a community pharmacist from a community pharmacy, and agree to work in accordance with the PGD. ▪ Provide the CPPE (or equivalent) EHC 'Declaration of Competence' (DoC) documentation. Records of assessment for all the programmes must be retained by the pharmacy contractor, together with the EHC PGD ▪ Have appropriate indemnity insurance to provide this service. ▪ Undertake reassessment of competence to deliver the EHC service is recommended at least every 3 years ▪ Undertake Disclosure and Barring https://www.gov.uk/disclosure-barring-service-check/tracking-application-getting-certificate All must have undertaken training regarding working under patient group directions **>> YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION <<** **>> OF THIS PGD BEFORE WORKING UNDER IT <<**

Clinical Details

indication	• Women who are unable/unwilling to have an IUD inserted at the time of requesting EC • Prevention of pregnancy within 72 hours of unprotected sexual intercourse or failure of a Contraceptive method. • Prevention of pregnancy within 72 - 96 hours (unlicensed use) of unprotected sex or failure of a contraceptive method where Ulipristal Acetate (UPA) is contraindicated or unable to be provided free of charge at the time of requesting EC • Have been given information regarding the other methods available for EC and provided with information on the services that provide them, but decides not to access them. • Prevention of pregnancy within 96 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_eg: carbamazepine,,nevirapine, oxcarbazepine, phenytoin, primidone and other barbiturates, rifabutin, rifampicin, ritonavir, modafinil, esclicarbazepine, rufinamide, efavirnez, bosentan and aprepitant, St Johns Wort or topirimate • 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 day prior to UPSI • If a women is referred for a copper intrauterine device (CU-IUD) levonorgestrel EC should be given at the time of referral in case the Cu-IUD cannot be fitted or the women changes her mind,
Inclusion criteria	**Competent woman (assess formally if aged under 16 or if competence in doubt) presenting within 72 hours of unprotected sexual intercourse or between 72 and 96 hours of unprotected sexual intercourse 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 *method* affected by diarrhoea or medicines. • Late contraceptive injection. • Expired or impalpable contraceptive implant. • Removal of IUC and failure of immediate replacement or partial/complete expulsion and the woman has had UPSI in the previous 96 hours • Vomited supplied course of EC and represented within 3 hours of taking it providing the UPSI is within the previous 96 hours • Loss of protection following commencement or change in contraceptive method. • Women who cannot be reassured that they are not at risk of pregnancy. 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. How-ever this should not prevent treatment if considered necessary under this PGD.
Exclusion criteria	• Hypersensitivity / previous severe adverse reaction to levonorgestrel or any ingredient. • Hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption • Patient who decide to access ulipristal acetate from an alternative provider • If the woman has taken UPA in the previous 5 days
Management of Excluded Patients	• Refer for emergency IUD. A copper IUD 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 more than 72 hours or 96 hours if unable to have UPA, since episode of unprotected intercourse, refer to the next Sexual health Clinic or other suitable facility for assessment. • Refer other excluded women for urgent medical review

Action for patients not wishing to receive care under this PGD	• Make women aware of alternative sources of treatment. (GP, Sexual Health services or Young person's Services) Document refusal.

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Description of Treatment	
Name of medicine	Levonorgestrel 1500 microgram tablets
Formulation and route	Oral tablet
Strength	1500 microgram per tablet
Dosage	• 1 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 96 hours where Ulipristal Acetate (UPA) is contraindicated or unable to be provided free of charge at the time of requesting EC • 2 tablets (3mg) to be taken as soon as possible after unprotected sexual intercourse up to 96 hours when the woman is taking or has taken in the last 28 days liver enzyme inducing drugs (unlicensed use)following FSRH Guidance 2017 • 2 tablets (3mg) to be taken as soon as possible after unprotected sexual intercourse up to 96 hours when the woman has a BMI >26 or weighs greater than 70 kg.(unlicensed use) following FSRH Guidance 2017 **Dose is to be taken at the consultation, supplies are not to be given to take away unless issued as an advanced supply**
Repeated dose instructions	• **NOTE:** Supply of a subsequent course in the same menstrual cycle is more likely to disrupt the normal menstrual pattern. • Where a woman returns having vomited the first dose within 3 hours of taking it, a replacement dose should be given (and taken), as long as the replacement dose is also taken within 72 hours (and up to 96 hours if appropriate)of the episode of UPSI (unlicensed use) • Giving repeated doses of LNG may be effective and further UPSI may be an indication for repeat LNG use. As there is no evidence to indicate LNG is not safe in pregnancy, the 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 (> 96hours) (outside product licence) No data were identified regarding a minimum time interval between successive LNG treatments. However, the CEU advises that if further UPSI occurs within 12 hours of a dose of LNG, further EC treatment is not required."
Duration of treatment	**Duration of treatment** Single dose
Quantity to supply	**Dose is to be taken at the consultation, supplies are not to be given to take away unless issued as an advanced supply**
Legal status	Prescription Only Medicine (POM)
Special Precautions	• Pregnancy greater than 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 • Women taking ciclosporin should be advised that Levonorgestrel 1500 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	Very Common adverse effects (more than1/10) may include headaches, nausea, lower abdominal pain and fatigue. Bleeding not related to menses. Common adverse effects (more than 1/100, less than1/10) may include temporary breast tenderness, vomiting and diarrhoea and dizziness. Irregular menstruation Refer to BNF and SPC for complete list. http://www.bnf.org/bnf/ http://emc.medicines.org.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 necessary	• Refer to Womens assessment forms (either paper or IT records) while the woman is present • Advise that EC is not 100% effective – pregnancy can still occur • Advise if less than 21 days post partum the risk of pregnancy is negligible • Advise that menstrual cycle timing may be disrupted. Disruption is more likely if more than one course is taken in 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 to be offered chlamydia screening as part of the national screening programme • Women suffering from severe malabsorption syndromes, such as Crohn's disease, should be strongly recommended to attend the next clinic for an emergency IUD • 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 • FPA leaflet to be emailed or link texted to patient http://www.fpa.org.uk/sites/default/files/emergency-contraception-your-guide.pdf • 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

Records and Follow Up	
Referral arrangements	Refer all excluded patients for urgent GP/ Sexual Health Services assessment
Records to be kept	As per service documentation requirements, ensure: • Full history recorded • Fraser assessments to be completed for all women under 16 and a safeguarding assessment for all under 18 year olds (in line with local policies) or where competence is in doubt • Items or leaflets supplied to the woman • Document any adverse reaction • Comprehensive record made in sexual health notes / medical records
Follow up	Ensure woman aware of local arrangements, eg Sexual Health Services and Clinics and is advised to return if any problems occur. Advise woman attends an appropriate service with an Early Morning Urine (EMU) sample for a pregnancy test if no normal bleed within the next four weeks or if the next bleed is unusual in any way (light or heavy, 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.

MANAGERIAL CONTENT OF PATIENT GROUP DIRECTION FOR LEVONORGESTREL 1500 mcg TABLETS

Version PHEC- 2019.1

Protocol Owner	
Details of protocol owner	Name: Dr A Greenwood Position: Clinical Director Sexual Health, Blackpool Teaching Hospitals NHS Foundation Trust Contact Address: Ashton Community Care Centre, Pointer Court, Lancaster, LA1 4JT Contact Telephone:0300 1234 154 Contact Email:anne.greenwood1@nhs.net

Protocol Authorisation	
Lead Doctor	Name: Dr A Greenwood Position: Clinical Director Sexual Health Blackpool Teaching Hospitals NHS Foundation Trust Signature: AN Greenwood Date: 08 03 19
Lead Pharmacist	Name: Julie Hollingworth Position: Lead Pharmacist – Community Health Services Blackpool Teaching Hospitals NHS Foundation Trust Signature: JK Hollingworth Date: 14/3/19
Lead Nurse	Name: Cath Shelley Position: Nurse Consultant – Sexual Health Blackpool Blackpool Teaching Hospitals NHS Foundation Trust Signature: Date: 5/3/19
Organisational Authorisation by	Name: Dr. Sakthi Karunanithi Position: Director of Public Health Signature: Date: 22/5/19
Organisational Authorisation by	Name: Dominic Harrison Position: Director of Public Health & Wellbeing Signature: Dominic P. Harrison Date: 25.3.19

Patient Group Direction Peer Reviewed By	

Blackpool Teaching Hospitals NHS Foundation Trust

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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

IF THIS IS AN UPDATED OR REPLACEMENT PGD ENSURE THAT ALL OLDER 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

Practices and team leaders must maintain up to date lists of these health professionals

Name of Professional	Signature	Authorising Manager	Date