NHS
Liverpool University Hospitals
NHS Foundation Trust

PATIENT GROUP DIRECTION

The Supply of Progestogen only oral Contraceptive Pill for Contraception

by registered Pharmacists delivering Community Contraceptive and Sexual Health services

Version 3

Date of Introduction: January 2023

(It is intended that this document will be updated in 3 years subject to no amendments in the interim period)

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Version Control:

Version	Date	Author	Status	Comment
1	March 2017	Development group as listed in PGD	Expired	
2	March 2020	Development group as listed in PGD	Expired	Full revision of version 1 with amendments in line with FSRH updated UKMEC 2016 guidance
3	January 2023	Development group as listed in PGD		Full review

Patient Group Direction:	Progestogen only contraceptive pill (POP)
Clinical Department/Service:	Community Pharmacies

1. Clinical Condition

1.1	Define situation/condition	Woman requesting contraception
1.2	Criteria for inclusion	• Women requesting first issue of POP following a full discussion and assessment. • Quick starting contraception method for women following the use of emergency hormonal contraception & a full discussion choose to use POP These situations are included in the Guidance 'Emergency Contraception', March 2017 Faculty of Sexual & Reproductive Healthcare. POP may be started, if it is in the best interest of the patient: A) at the same time as taking Levonorgestrel 1500mcg B) 5 days after taking Ullipristal acetate 30mg • Fraser guideline competent if under 16

1.3	Criteria for exclusion	**ABSOLUTE –** • Pregnancy • Current or past breast cancer or other hormone dependant cancer • Severe liver cirrhosis or hepatic tumour • Porphyria • Hypersensitivity or allergy to any of the constituents of POP • Woman refuses treatment under the PGD (no consent) • Aged under 13 Follow safeguarding guidelines and refer as appropriate. (see Appendix) • Under 16 and not deemed Fraser competent. Follow safeguarding guidelines and refer as appropriate. (see Appendix) • History of recurrent ovarian cyst • Current or history of ischaemic heart disease or cerebrovascular disease/stroke including transient ischemic attack (TIA). • Woman taking liver enzyme inducing medication/on antiretroviral therapy • Taking drugs/medications (including prescription, over the counter preparations, herbal, recreational drugs and dietary supplements) that may interact with the progestogen only pill including: Aprepitant, atazanavir, barbiturates, boceprevir, bosentan, carbamazepine, ciclosporin, crizotinib, dabrafenib, efavirenz, elvitegravir, eslicarbazepine, griseofulvin, lamotrigine, nelfinavir, nevirapine, oral anticoagulants, orlistat, oxcarbazepine, perampanel, phenytoin, primidone, rifabutin and rifampicin (rifamycins), ritonavir, rufinamide, selegiline, St John's Wort (Hypericum perforatum), sugammadex, terbinafine,tizanidine, topiramate, ulipristal, vemurafenib, voriconazole.

		(See section 1.4) • Undiagnosed vaginal bleeding (after exclusion of Chlamydia) • Any condition or situation about which the pharmacist has concerns or is uncertain that it may be relevant be POP use • https://www.fsrh.org/standards-and-guidance/documents/ukmec-2016-summary-sheets/ See Appendix **Exclusion under this PGD does not necessarily mean the medicine is contraindicated, but it would be outside its remit and another form of authorisation will be required.**
1.4	**Cautions/additional information**	• For up-to-date detailed drug information consult BNF/ Summary of Product Characteristics (SPC) at http://emc.medicines.org.uk https://www.bnf.org/products/bnf-online • Drug interactions The possibility of interaction should be borne in mind in patients receiving concurrent treatment with other drugs. A list of medication is in Section 1.3 above but always refer to the BNF or SPC. http://emc.medicines.org.uk https://www.bnf.org/products/bnf-online • Liver enzyme inducing drugs:- may reduce the efficacy of the POP. Those on long term treatment with liver enzyme inducing drugs should be advised to use a method of contraception unaffected by the treatment. Those on short courses of treatment may choose to continue the POP, but should use a barrier method (e.g. condoms) during the time of treatment and for 28 days after its discontinuation. • https://www.fsrh.org/standards-and-guidance/documents/ukmec-2016-summary-sheets/ • Gastrointestinal upsets:- women should continue to take their POP but should use an additional method or abstain during the upset and until pill taking has been resumed for 2 days. • Missed pills: If a pill is taken 3 or more hours late (12 or more hours late for desogestrel 75mcg pills) take the last missed pill as soon as possible and continue with the pack. Use an alternative method of contraception e.g. a condom for the following 48 hours. • Women weighing more than 70kg:- there is no evidence that the efficacy of progestogen only pills are reduced in women weighing more than 70kg

		and therefore the licenced use of one per day is recommended. General advice regarding weight reduction should be given. • See situations not covered by the product licence • History of cholasma gravidarum, client should avoid exposure to the sun or ultraviolet radiation whilst taking this preparation. • . The incidence of ectopic pregnancies for progestogen-only oral contraceptive users is 5 per 1000 woman-years, which is higher than for women using other contraceptive methods but similar to the incidence for women not using any contraception. Up to 10% of pregnancies reported in clinical studies of progestogen-only oral contraceptive users are extra-uterine. Although symptoms of ectopic pregnancy should be watched for, a history of ectopic pregnancy need not be considered a contraindication to use of this contraceptive method. Vaginal bleeding and abdominal pain are typical symptoms of an ectopic pregnancy. Women reporting these symptoms should be evaluated.
1.5	Action if patient excluded	Discuss other methods of contraception. Refer to the GP or sexual health services if appropriate or if the woman requests. www.axess.clinic
1.6	Action if patient declines	Refer to the GP or sexual health services if appropriate or if the woman requests www.axess.clinic

2. Characteristics of staff

2.1	Class of Health Professional for whom PGD is applicable (professional qualification and training)	Registered pharmacist with full and valid registration with the General Pharmaceutical Council **You must be authorised by name, under the current version of the PGD before you attempt to work according to it.**
2.2	Additional requirements	• Holds a valid DBS • Satisfactory completion of training to administer /supply in accordance with this patient group direction ** • Have undertaken training that enables them to identify

		potential cases of abuse, neglect and/or exploitation; Holds a current safeguarding level 2 certificate as minimum but need to work towards level 3 safeguarding for both children and adults. Renewal depending upon the advice from the training provider this maybe annual, biannual or tri-annual • Satisfies the competencies set out in the NICE Competency Framework for Healthcare professionals using Patient Group Directions.** The Framework and associated assessment tools are available at https://www.nice.org.uk/guidance/mpg2/resources • Have undertaken service specific training. Providers of EHC and oral contraception will be working under a PGD, however, it is expected that staff delivering the service will have received an appropriate level of training in contraception provision from a recognised body e.g. Faculty of Sexual and Reproductive Healthcare (FSRH), Centre for Pharmaceutical Postgraduate Education /(CPPE) Declaration of competence (DOC) in oral contraception and emergency hormonal contraception
2.3	Continued training requirements	• Commitment to continuing updating and re-validation relevant CPPE modules for each current version of the PGD • Completion of mandatory and statutory training requirements as required to maintain registration • Maintains 2 yearly training updates for **sections in 2.2

3. Description of Treatment

3.1	Generic name of medicine and form	Progestogen only contraceptive pill. The following may be supplied under the terms of the PGD:
		Norethisterone 350mcg e.g Noriday/Micronor Levonorgestrel 30mcg e.g Norgeston Desogestrel 75mcg e.g Cerazette, Cerelle, Aizea, Zelleta, Nacrex, desomono,feanolla, desorex or any other generic version
3.2	Legal status	POM
3.3	Storage	Locked cupboard. Room temperature not above 25°C

3.4	Licensed or unlicensed	Licensed
3.5	Dose(s)	One tablet daily at the same time of day, of one of the following products, or any other brand which contains exactly the same constituents, in the same dosage. Norethisterone 350mcg — Noriday/Micronor Levonorgestrel 30mcg — Norgeston Desogestrel 75mcg — Cerezette, Cerelle, Aizea, Nacrez, Zelleta For a woman under age 40 starting or restarting the POP, the preferred preparation would be a desogestrel 75mcg pill (unless previously used a different formulation and prefers to restart the same). Desogestrel 75mcg was shown in clinical trials to prevent ovulation in 97% of cycles as opposed to 60% of cycles for the older POPs. This may confer higher effectiveness and is the reason for the 12-hour window for daily pill taking versus the 3- hour window for other POPs. Overall, there is no significant difference in bleeding pattern or other side effects between the different formulations. There is no difference in efficacy with any formulation in breastfeeding women or women over the age of 40.
3.6	Route/Method of Administration	Oral
3.7	Frequency of administration	One tablet daily at the same time each day. Start initially on:- **Normal cycles** Up to day 5 of the menstrual cycle. **Postpartum and post-abortum use** Within first 21 days after delivery or within 5 days of first

		trimester abortion or miscarriage. No additional contraception is required. If POP is commenced later than above, risk of pregnancy should first be excluded and additional precautions advised for the first 2 days. **Changing from a COC** **Changing from a 21 day combined pill:** The first tablet of POP should be taken after the last tablet of the current pack. No additional precautions are required. If the normal 7 day break has already been taken then additional precautions are needed for 2 days **Changing from Every Day (ED) combined preparations:** POP should be started after taking the last active tablet from the ED pill pack. The first new POP tablet is taken the next day. Additional contraceptive precautions are not then required. If the 7 inactive pills have already been taken then additional precautions are needed for 2 days. **Changing from a different progestogen-only pill (POP)** Commence on first day of menstrual cycle, or, if periods are absent or irregular, at any time, provided that POP taking has been consistent and there is no risk of pregnancy. **Changing from contraceptive injection or implant:** At any time up until the next injection is due or implant removed, with no need for additional precautions. **Changing from IUD / IUS** **Either:** Start POP and remove IUD / IUS within the first 5 days of a normal cycle. **Or:** Start POP 2 days before IUD / IUS removal, avoiding unprotected sexual intercourse for 7 days before removal. **Or:** At the same time as IUD / S removal, avoiding unprotected sexual intercourse for 7 days before and 2 days after removal. **COMMENCEMENT OUTSIDE THE TERMS OF THE PRODUCT LICENCE** The following situations are not covered by the product licence but are included in the FSRH Guidance documents:- Emergency Contraception Aug 2011 updated Jan 2012 Problematic Bleeding with Hormonal Contraception (July 2015) **Later than day 5 of the menstrual cycle** Later than day 5, or the woman is oligo- or amenorrhoeic: exclude risk of pregnancy and advise additional contraception for the first 2 days **Commencement with emergency contraception** This situation is included in the Guidance 'Emergency

Contraception', April 2006 Faculty of Sexual & Reproductive Healthcare.
Best practice is to wait for the next normal menses before commencing POP. However POP may be started

A) at the same time if the woman has taken Levonorgestrel 1500mcg with extra precautions for 2 days and

B) after 5 days if the woman has taken Ullipristal acetate with extra precautions for 9 days following the ullipristal acetate.

if these options are in the best interest of the woman.
Pregnancy test **must** be advised 3 weeks later, regardless of whether or not the woman has had a bleed.

NHS Executive Health Service Circular 2000/026 states that medicines used outside the terms of the product licence may be included in PGDs, provided that such use is exceptional and justified by current best clinical practice. Any clinician doing so should comply with the following:

1. Explain the risks/benefits to the woman
2. Explain that it is being used out of licence
3. Obtain verbal consent

Accurately document that these issues have been discussed and that the woman has given verbal consent.

Prior to administration the pharmacist should:

- Take or update history to exclude contraindications and drug interactions
- Discuss safer sex, cervical cytology and smoking status as appropriate
- Assess Fraser Competency if under 16. Be aware of current guidance from the department of health and the local Safeguarding Children's Board
- Offer a Chlamydia test if the woman is aged under 25 and to all age groups if there has been unusual bleeding or change of partner.
- Offer a pregnancy test if there has been sudden or unusual oligo- or amenorrhoea. If negative and no other contra-indications, continue to supply. If positive or test declined do not supply.
- Teach / reinforce pill taking method and action in the event of missed pills, vomiting and diarrhoea or interacting drug use
- Advise on efficacy, benefits and risks / side effects
- Provide the relevant fpa leaflet

3.8	Total dose and number of times treatment can be administered over what time	**First issue** - Three months' supply. Once only supply
3.9	Side effects of drugs (including potential Adverse Drug Reaction)	Minor adverse events Menstrual irregularities; amenorrhoea, irregular or regular bleeds may occur. There is no evidence that POPs cause weight or mood change, headache, cardiovascular disease or breast cancer. For less frequent undesirable effects affecting < 1% of patients see *Patient Information Leaflet and Summary of Product Characteristics on www.medicines.org.uk* Major adverse events – seek medical advice immediately Although the absolute incidence of ectopic pregnancy is reduced the POP may offer less protection against ectopic pregnancy than against intrauterine pregnancy. If there is sudden severe abdominal pain; possibilities related to POP include ectopic pregnancy and rupture of ovarian cyst
3.10	Advice/management of adverse reactions/events	Inform patient to seek advice from GP practice. Healthcare Professional: Report serious adverse drug reactions (or all suspected ADRs if the medicine is black triangle) to the Medicines and Healthcare Products Regulatory Agency using either yellow cards of via www.yellowcard.gov.uk Record any adverse drug reaction in the patient's notes Inform LUHFT (Axess clinical service) of any adverse events related to PGD use.
3.11	Procedure for reporting Adverse Drug Reactions (ADR's)	• Report serious suspected adverse drug reactions (or all suspected ADR's if the medicine is black triangle) to the Medicines and Healthcare products Regulatory Agency using either the yellow cards or via www.yellowcard.gov.uk • Record any adverse drug reaction in the patient's record.
3.12	Information on follow up treatment	• Inform client that further supplies of progestogen only pills will be required from her GP or alternatively provide information about the local contraceptive and sexual health service.
3.13	Written/verbal advice for patient/carer	• Thorough discussion of contraceptive options • Full counseling on risks and benefits of the method

	before/after treatment.	• Provision of a written patient information leaflet • Teach / reinforce correct pill taking method and action in the event of missed pills, vomiting and diarrhoea or interacting drug use. • Additional contraceptive precautions are not required during or after courses of antibiotics that do not induce liver enzymes. Although women should be advised about the importance of correct contraceptive practices during periods of illness. However if the antibiotics (and/or the illness) cause vomiting or diarrhoea then the usual additional precautions relating to these conditions should be observed • Health promotion advice such as condom use to protect against sexually transmitted infection
3.14	Specify method of recording supply/ administration, names of health professional, patient identifiers, sufficient to enable audit trail.	The following will be recorded in the woman's record: • Name of patient, address, date of birth, current contact number and GP • Past and present medical history including medication and any allergies • Fraser competency and Safeguarding assessment if under 16 • All advice given to woman both verbal and written concerning taking the progestogen only pill corrrectly. • The name and quantity of progestogen only contraceptive pill supplied • The batch number and expiry date. • The date of administration or supply. • The name of the person supplying the medicine.

Development of the PGD and authorisation

Multidisciplinary Group:

The group who have been involved in the review and update of this PGD included the following people:

Name	Designation
Dr Sue Walsh	Associate Specialist Contraception + Sexual Health
Dr Jo Dennis	Associate Specialist Contraception + Sexual Health
Dr Charlotte Simpson	Consultant in Public Health East Cheshire Council
Debbie Ritchie	Advanced Nurse Practitioner Reproductive + Sexual Health

Fiona Leon	Lead Pharmacist for Medicine and Medicines Management, East Cheshire NHS Trust
Suzanne Austin	Pharmacist Advisor, Public Health East Cheshire
Michelle Bocarro	Senior Nurse Manager

PGD Approval

Name	Designation	Signature	Date
Dr Martyn Wood	Regional Clinical Director Axess Liverpool LUHFT	Martyn Wood	27/01/2023
Mr Paul Skipper	Associate Clinical Director of Pharmacy, LUHFT		24/1/23.
Mr Colin Hont	Deputy Chief Nurse, LUHFT	C Hont	11/1/2023
Dr J Naisbitt	Trust Medical Director, Deputy LUHFT	J Naisbitt	12/1/23

4. References

- SPC for contraindications and cautions (http://emc.medicines.org.uk/)
- BNF 72 Sept 2016
- Faculty of Sexual & Reproductive Healthcare guidance 'Emergency Contraception', March 2017
- Faculty of Sexual & Reproductive Healthcare clinical guidance 'Progestogen only pill' march 2015
- Faculty of Sexual & Reproductive Healthcare clinical guidance 'Drug Interactions with Hormonal contraception' January 2017
- NHS Executive: Health Service Circular: Patient Group Directions. August 2000. (series number: HSC 2000/026).
- UK Medical Eligibility Criteria for Contraceptive Use 2016
- Faculty of Sexual + Reproductive Healthcare Emergency Contraception guidance 2017
- Faculty of Sexual & Reproductive Healthcare Faculty of Sexual and Reproductive Health Care Clinical effectiveness Unit. Best practice guidance for doctors and other health professionals on the provision of advice and treatment to young people under 16 on contraception, sexual and reproductive health. Department of Health. Gateway Reference number 3383. 29 July 2004

Appendix: Drug Interactions

The FSRH guidance 'Drug Interactions with Hormonal Contraception' January 2017. The full guidance can be found at https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/

Further information can be found in the latest copy of a BNF or in the at http://www.medicines.org.uk/emc/

For information on HIV medications, use the online University of Liverpool 'HIV Drug Interactions' Checker http://www.hiv-druginteractions.org/

The UK MECC summary sheets can be found at :-

https://www.fsrh.org/standards-and-guidance/documents/ukmec-2016-summary-sheets/

Appendix: Safeguarding contact details – Liverpool Local Authority

Safeguarding Procedures
Children and Young People (under 18)

Anyone who has concerns for the immediate safety of a **child or young person** must phone:

- Anyone who has concerns for the immediate safety of a child or young person must phone:
- Careline Adults 0151 233 3800 open 7 days a week, 24 hours a day
- Careline Childrens 0151 233 3700 open 7 days a week, 24 hours a day

Do not hesitate. Seek support and advice immediately.

Please refer to the link below for more information about safeguarding children and young people:

Website: https://liverpool.gov.uk this is a one stop shop web address with a search bar for easy location of desired service

Safeguarding Vulnerable Adults

A vulnerable adult is any person 18 or over who is or may be in need of community care services by reason of:

•Mental or other disability, age or illness and;

•Who is or may be unable to take care of him/herself; or

•Unable to protect him/herself from significant harm or serious exploitation

To report concerns about vulnerable adults:

Liverpool:

- 9-5 Referral phone number: 0151 907 8306
- 9-5 Referral Online https://Liverpool.me/safeguarding-adults-alert-form/
- Changing Lives– 0300 11 11 247 (Domestic Abuse Support Service)
- Liverpool Rape and Sexual Assault Support Centre & Liverpool Independent Sexual Violence Advocate: 01925 221 546
- Liverpool City Council main number: 0303 333 4300.

If you have safeguarding concerns do not hesitate to seek support and advice immediately.

Patient Group Direction for the supply of Progestogen only oral Contraceptive Pill for Contraception

Record of authorised staff

Address /location where supply and/or administration of Progestogen only oral contraceptive pill under this PGD will take place:

Pharmacies by pharmacists delivering community contraceptive and sexual health services for Liverpool University Hospitals NHS Foundation Trust

The undersigned nurses / health professionals

- Have read and understood the PGD
- Fulfil the required staff characteristics
- Are willing to accept delegated responsibility
- Will be professionally accountable

Staff Name	Signature of staff member	Date

Authorised to practice by Superintendent (or person acting on behalf of Superintendent)*

Full name	
GPhC number	
Signature	
Date	

*Has responsibility to ensure that only fully competent, qualified and trained professionals implement this PGD.
Agrees to maintain a current list of the names of individuals who may implement this PGD and to keep this with a pharmacy master copy of the PGD.

"Person acting on behalf of Superintendent" is usually the pharmacist Area or Branch manager.