PGD5017

South Staffordshire & Shropshire Healthcare NHS
NHS Foundation Trust

PATIENT GROUP DIRECTION
FOR THE SUPPLY OF PROGESTOGEN ONLY PILLS (POPs)
by registered nurses and midwives in Integrated Sexual Health services employed by South Staffordshire and Shropshire NHS Foundation Trust

This Patient Group Direction for use in South Staffordshire & Shropshire Healthcare NHS Foundation Trust and is authorised by:			
Position of Signatory	**Name**	**Signed**	**Date**
Medical Director	Dr Abid Khan		
Chief Pharmacist	Cathy Riley		
Director of Quality & Clinical Performance	Therèsa Moyes		
Director of Nursing	Alison Bussey		

The named below, being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to supply progestogen only pills to patients in Integrated Sexual Health Services under this Patient Group Direction

Name	Job Title	Signed	Date

This Patient Group Direction is operational from: 1st October 2017
Review date: Aug 2019. Expires on 31st Oct 2019
Replaces PGD3916

Professional Responsibility

All registered nurses and non medical prescribers being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to supply progestogen only pills as specified under this Patient Group direction following demonstration of the competencies below;

Professional Responsibility / Competencies

1. The registered nurse will have undertaken appropriate training in order to carry out clinical assessments of patient that requires treatment according to the indication listed in the PGD
2. Qualification in contraception/sexual health (university modules/FSRH): Note: an introduction to contraception is not sufficient
3. Is competent in the assessment of individuals using Fraser guidelines
4. Has undergone regular training and updating in safeguarding children and vulnerable adults
5. The nurse must be familiar with current FSRH clinical guidelines on progestogen only pills
6. All nurses will have received training in the management and treatment of anaphylactic shock on an annual basis
7. Each nurse will keep a record in their professional portfolio of the updates attended during every 12 month period – This information will also form part of the team's annual training plan
8. The nurse will have due regard for the NMC Code of Conduct, Scope of Professional Practice and Standards for Medicines Management (Nursing & Midwifery Council)
9. Undertaken appropriate training and possess the competencies for working under PGDs for the supply and administration of medicines All registered nurses details and signature must be entered onto the PGD
10. Following administration a record of the date, strength, brand and dose of the medication should be recorded in the clients records and documented in the medicine card with PGD number recorded as authorisation

For full product information, always refer to the latest SPC (Summary of Product Characteristics).

If the anaphylaxis is related to a medication, please remember to report to the CSM, via a Yellow Card Report (http://emc.medicines.org.uk)

Supply/Administration of	• Levonorgestrel 30micrograms tablets • Norethisterone 350micrograms tablets • Desogestrel 75micrograms tablets Note: this PGD does not restrict which brand can be supplied. Refer to local CCG formulary for further information.
Legal Classification	Prescription Only Medicine
Black Triangle?	No
Type	Tablets
Storage	Supplies will be available from central stock location, pre-labelled with the correct dose and quantity by the pharmacy department. Details of service user name and date of issue must be completed on the label prior to supplying to the patient. Information leaflets must be given. Any relevant documentation must be completed.
Condition to be treated	Contraception
Inclusion Criteria	Any individual (age from 13 to 50 years) presenting for contraception and who has no contraindications. Individuals with unscheduled bleeding associated with current non oral methods of contraception.
Exclusion Criteria	**Personal Characteristics & Reproductive History** • Known or suspected pregnancy (exclude pregnancy) • Known hypersensitivity to any constituent of the POP • Individuals under 16 years of age and not competent using Fraser guidelines • Individuals aged 16 years of age and over and not competent to consent **Cardiovascular Disease** • Development of ischaemic heart disease, transient ischaemic attack or stroke whilst taking the POP • Severer arterial disease **Cancers** • Current or past history of breast cancer • Benign liver tumour • Malignant liver tumour (hematoma) **Gastro-intestinal conditions** • Severe decompensated cirrhosis

	• Roux-en-Y gastric bypass or biliopancreatic diversion • Severe liver disease and recurrent cholestatic jaundice **Other conditions** • Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them • Systemic Lupus Erythematosus (SLE) with positive or unknown anti-phospholipid antibodies • • Individual wishes to see a doctor • Severer diabetes with vascular changes <u>Cautions:</u> • Undiagnosed abnormal vaginal bleeding • Interacting medicines (not enzyme inducers) –see current BNF • If individual is under 13 years of age, follow local safeguarding policy • Discuss with appropriate doctor/independent nurse prescriber any medical condition or medication of which the nurse is unsure/uncertain
Action if excluded or patient declines	• Refer to appropriate doctor/independent nurse prescriber • Discuss/offer alternative contraceptive method • Document all actions taken • Record the refusal in the clinical record • Refer to an appropriate doctor/independent nurse prescriber where required
Reasons for seeking further advice from doctor	• Discuss with appropriate doctor/independent nurse prescriber any medical condition or medication of which the nurse is unsure • Should the patient meet any of the exclusion criteria
Administration Route	Oral
Dose	• Desogestrel 75 micrograms tablets • Levonorgestrel 30 micrograms tablets • Norethisterone 350 micrograms tablets <u>Quantity:</u> • Initial supply three months (3 x 28/35) or up to 12 months (12 x 28/35) tablets, (according to local agreement) • Subsequent supply up to twelve (12) months (12 x

	28/35) tablets (according to local agreement)
Administration Schedule	• Single tablet taken at the same time each day starting on day 1-5 of the menstrual cycle with no need for additional protection. • The POP can be started as a quick start at any time after day 5 if it is reasonably certain that the individual is not pregnant. Additional contraception is then required for 48 hours after starting. For guidance on changing from one contraceptive method to another, and when to start after an abortion and post-partum, refer to FSRH guidelines. <u>Duration of Treatment:</u> For as long as the individual requires the POP and for as long as the individual has no contraindications to use of the POP Minimum three months and a maximum of twelve months
Warnings/Adverse Reactions	Refer to current Summary of Product Characteristics (SPC) of relevant product and current British National Formulary (BNF) for further information. This list may not represent all reported side effects of this medicine. Most POPs are well tolerated. Some of the common side effects are: • Acne • Breast tenderness • Headache • Disturbance of bleeding patterns • Changes in mood/libido • Weight change In the event of untoward or unexpected adverse drug reactions: • If necessary seek appropriate emergency advice and assistance • Document in the individual's clinical record and inform appropriate doctor/independent nurse prescriber • Complete incident procedure if adverse reaction is severe (refer to local organisational policy)

	Use yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF or obtained via Freephone 0808 100 3352 or online at www.yellowcard.mhra.gov.uk. The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so.
Advice/Management of Adverse Reactions & Follow-up Action	• Provide Manufacturer's Patient Information Leaflet (PIL) and discuss, including that subsequent doses must be taken at the same time each day (within 3 hours) • Explain mode of action, side effects, and benefits of the medicine • Advise of possible risk of ectopic pregnancy should the POP fail • Advise about the risks of the medication including failure rates and serious side effects and the actions to be taken • Advise on what to do if vomits within two (2) hours of taking the pill or in cases of prolonged vomiting or severe diarrhoea. See FPA leaflet/FSRH guidance • Advise on what to do if forgets to take it (missed pills; >three hours late for all POPs except desogestrel which is 12 hours). See FPA leaflet/FSRH guidance • Provide a copy of the FPA leaflet on the POP • Offer condoms and advise on safer sex practices and possible need for screening for sexually transmitted infections (STIs) • Ensure individual knows what to do if her medical condition changes in the future • Ensure individual has the contact details of the service <u>Follow Up:</u> • Individual to return to clinic if she has any concerns • Review in three or twelve months after initial supply, then annually as appropriate or by local agreement
Use in pregnancy and lactation	Pregnancy: Not appropriate for PGD Lactation: Appropriate, only if benefits outweigh risks

Records	The authorised registered nurse must ensure the following is documented in the clinical record: • Individual's name, address and date of birth • GP contact details where appropriate • Attendance date • Reason for attendance • Relevant past and present medical and family history, including drug history • Any known allergy • Relevant examination findings (where appropriate) • Inclusion or exclusion from PGD • A statement that supply is by using a PGD with the PGD number recorded • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Details of any adverse drug reactions and what action taken • Any referral arrangements • Any supply outside the terms of the product marketing authorisation • The consent of the individual • If individual is under 13 years of age record action taken • If individual is under 16 years of age document competency using Fraser guidelines • If individual is over 16 years of age and unable to consent, record action taken • Record the name/brand, dose of the medication and quantity supplied • Record batch number and expiry date according to local policy or national guidelines • Record follow up and/or signposting arrangements • Any other relevant information that was provided to the individual • Name and signature (which may be an electronic signature) of the nurse supplying the medicine