PGD4517

South Staffordshire & Shropshire Healthcare NHS
NHS Foundation Trust

PATIENT GROUP DIRECTION
FOR THE SUPPLY OF COMBINED ORAL CONTRACEPTIVE (COC) PILLS

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 combined oral contraceptive 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: August 2019. Expires on 31st October 2019.
Replaces PGD 2216

Professional Responsibility

All registered nurses and non medical prescribers being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to supply combined oral contraceptive 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/ sexual health 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 combined hormonal contraception
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	Combined Oral Contraceptive Pills This is a generic list of combined oral contraceptive pills. Alternative brands or generic versions can be used under this PGD. A list of all preparations can be found in the BNF at https://www.medicinescomplete.com/mc/ **Monophasic** • Ethinylestradiol 35 micrograms and norgestimate 250 micrograms • Ethinylestradiol 30 micrograms and gestodene 75 micrograms • Ethinylestradiol 20 micrograms and gestodene 75 micrograms • Ethinylestradiol 30 micrograms and levonorgestrel 150 micrograms • Ethinylestradiol 20 micrograms and norethisterone 1mg • Ethinylestradiol 30 micrograms and desogestrel 150 micrograms • Ethinylestradiol 20 micrograms and desogestrel 150 micrograms • Ethinylestradiol 30 micrograms and norethisterone 1.5mg • Ethinylestradiol 35 micrograms and norethisterone 500 micrograms • Ethinylestradiol 35 micrograms and norethisterone 1mg • Ethinylestradiol 30 micrograms and gestodene 75 micrograms **Monophasis Every Day** • Ethinylestradiol 30 micrograms and gestodene 75 micrograms + 7 inactive • Ethinylestradiol 30 micrograms and levonorgestrel 150 micrograms + 7 inactive **Phasic** • Ethinylestradiol 30/40/30 micrograms and levonorgestrel 50/75/125 micrograms • Ethinylestradiol 30/40/30 micrograms and gestodene 50/70/100 micrograms • Ethinylestradiol 35 micrograms and norethisterone 500/750/1000 micrograms
Legal Classification	Prescription Only Medicine
Black Triangle?	No

Type	Tablet
Storage	Store in the original pack, within a designated medicines cabinet at a temperature between 15°C and 25°C 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 (as per FSRH guidance) https://www.fsrh.org/documents/ceuguidanceproblematicbleedinghormonalcontraception/
Exclusion Criteria	**Personal Characteristics & Reproductive History** • Known or suspected pregnancy • Under 16 years of age and not competent using Fraser Guidelines • Over 16 years of age and over and not competent to consent • Known hypersensitivity to any constituent of the combined oral contraceptive pill • Less than 21 days post-partum • Breastfeeding and less than six months post-partum **Cardiovascular disease** • 35 years of age or more and a smoker or stopped smoking less than one year ago • Body Mass Index (BMI) equal to or greater than 35kg/m^2 • Blood pressure greater than 140/90mmHg or controlled hypertension • Two or more risk factors for cardiovascular disease such as over 35 years of age, smoking, diabetes, hypertension, obesity (BMI 30-34 kg/m^2) • Hyperlipidaemia • Current or past history of ischaemic heart disease, stroke or transient ischaemic attack • Current or past history of venous

	thromboembolism • Complicated valvular or congenital heart disease e.g. with subacute bacterial endocarditis • First degree relative with venous thromboembolism under 45 years of age • Known thrombogenic mutations e.g. factor V Leiden, prothrombin mutation, protein S, protein C and antithrombin deficiencies • Significant or prolonged immobility including planned major surgery **Neurological Conditions** • Current or past history of migraine with neurological symptoms including aura at any age • Migraine without aura, first attack when on oestrogenic method of contraception **Cancers** • Past or current history of breast cancer • Undiagnosed breast mass (for initiation of method only) • Carrier of known gene mutations associated with breast cancer e.g. BRCA1 • Malignant liver tumour (hepatoma) **Gastro-intestinal Conditions** • Viral hepatitis, acute or flare • Severe decompensated cirrhosis • Gall bladder disease, symptomatic, medically treated • Gall bladder disease, currently symptomatic • Cholestasis (past combined hormonal contraceptive related) • Benign liver tumour **Other Conditions** • Diabetes with end organ disease • Raynaud's disease, secondary, with lupus anticoagulant • Systemic Lupus Erythematosus (SLE) with positive or unknown anti-phospholipid antibodies • • Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them • Individual wishes to see a doctor

	Cautions: • Undiagnosed abnormal vaginal bleeding • Discuss with appropriate doctor/independent non-medical prescriber any medical condition or medication of which the nurse is unsure/uncertain • Interacting medicines (not enzyme inducers –see current British National Formulary (BNF)
Action if excluded or patient declines	• Refer to appropriate doctor/independent non-medical prescriber • Discuss /offer alternative contraceptive method • Document all actions taken • Record refusal in the clinical record • Refer to appropriate doctor/independent non-medical prescriber • Discuss /offer alternative contraceptive method • Document all actions taken
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	**Monophasic** **Mercilon; Gedarel 20/150:** Ethinylestradiol 20 micrograms and desogestrel 150 micrograms **Femodette:** Ethinylestradiol 20 micrograms and gestodene 75 micrograms **Loestrin 20:** Ethinylestradiol 20 micrograms and norethisterone 1 milligram **Gedarel 30/150; Marvelon; Maexeni:** Ethinylestradiol 30 micrograms and desogestrel 150 micrograms **Microgynon 30:** Ethinylestradiol 30 micrograms and levonorgestrel 150 micrograms **Loestrin 30:** Ethinylestradiol 30 micrograms and norethisterone 1.5mg **Cilest:** Ethinylestradiol 35 micrograms and norgestimate 250 micrograms **Norimin:** Ethinylestradiol 35 micrograms and

	norethisterone 1mg 1 tablet for 21 days with 7 days break **<u>Monophasic every day</u>** **Femodene ED:** Ethinylestradiol 30 micrograms and gestodene 70 micrograms + 7 inactive **Microgynon 30 ED:** Ethinylestradiol 30 micrograms and levonorgestrel 150 micrograms + 7 inactive One tablet every day Alternative brands or generic versions of the above can be used under this PGD see Appendix 1.
Administration Schedule	• A single tablet taken at the same time each day starting on day 1-5 of the menstrual cycle with no need for additional precautions. • Thereafter follow manufacturer's instructions for individual product use • COC can be started at any time after day 5 if it is reasonably certain that the individual is not pregnant. Additional precautions (barrier methods) are then required for 7 days after starting • Starting the COC as quick start after levonorgestrel emergency contraception, additional contraception (barrier) is required for 7 days. • After the use of ulipristal acetate, it is recommended that hormonal contraception should not be used for five days, then restarted. A barrier contraceptive should then be used for a further 14 days • A pregnancy test is advised 21 days after any oral emergency contraception- See FSRH guidance March 2017. For guidance on changing from one contraceptive method to another, and when to start after an abortion and post-partum, refer to the Faculty of Sexual and Reproductive Healthcare (FSRH) guidelines – switching or starting guide (June 2016) <u>Duration of Treatment:</u> For as long as individual requires COC and has no contraindications to the use of COC

	Minimum 3 months supply, maximum 12 months supply.
Warnings/Adverse Reactions	Refer to current Summary of Product Characteristics (SPC) of relevant product and current British National Formulary (BNF) for full list and further information. This list may not represent all reported side effects of this medicine. **Side effects may include:** • Nausea • Breast tenderness • Headache • Temporary disturbances of bleeding patterns • Change in mood • Fluid retention **Serious adverse effects** These are less common but the risks should be discussed with the individual • Venous thromboembolic disorders • Arterial thromoembolic disorders • Strokes (e.g. transient ischaemic attack, ischaemic stroke, haemorrhagic stroke) • Hypertension • Liver tumours (benign and malignant) **In the event of untoward or unexpected adverse 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. For black triangle medicines : report ALL suspected adverse reactions, however minor to Medicines and Healthcare Products Regulatory Agency (MHRA) via the

	Yellow Card Scheme.
Advice/Management of Adverse Reactions & Follow-up Action	• Provide Manufacturer's Patient Information Leaflet (PIL) and discuss • Explain mode of action, side effects, and benefits of the medicine • 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 diarrhoea or vomiting occurs, or if the individual misses any pills-see FPA leaflet/FSRH guidance • Provide a copy of the FPA leaflet on the COC http://www.fpa.org.uk/contraception-help/combined-pill • Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs) • Ensure the individual has contact details of the service /sexual health services • Advise to speak to doctor or pharmacist before taking other medicines since they may reduce the effectiveness of the contraceptive pill **Serious Symptoms** • The individual should stop taking the COC and see a doctor urgently if she experiences calf swelling, heat or pain in the calf, shortness of breath, chest pain or haemoptysis • The individual should seek advice if she experiences her first ever migraine or develops aura with existing migraine <u>Follow Up:</u> • Individual to return to clinic if she has any concerns • Review in 3 months after initial supply, then annually as appropriate or according to 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) • Initial examination to include body mass index (BMI) and blood pressure recording and thereafter according to local policy • Inclusion or exclusion from PGD • A statement that supply is by using a PGD and record the PGD number • 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 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 16 years of age and over and not competent, 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 • Any referral arrangements • 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 or administering the medicine

Appendix 1 - Combined Oral Contraceptive Pills

Monophasic

Ethinylestradiol 35 micrograms/norgestimate 250 micrograms	Cilest®
Ethinylestradiol 30 micrograms/gestodene 75 micrograms	Aidulan® Femodene® Milinette® 30/75 Femodette® Katya®
Ethinylestradiol 30 micrograms/levonorgestrel 150 micrograms	Levest® Microgynon® 30 Rigevidon® Maexeni® Sunya®
Ethinylestradiol 20 micrograms/norethisterone 1mg	Loestrin® 20
Ethinylestradiol 20 micrograms/desogestrel 150 micrograms	Gedarel® 20/150 Munalea® 20/150 Mercilon®
Ethinylestradiol 30 micrograms/desogestrel 150 micrograms	Gedarel® 30/150 Marvelon® Munalea® 30/150 Ovranette®
Ethinylestradiol 30 micrograms/norethisterone 1.5mg	Loestrin® 30
Ethinylestradiol 35 micrograms/norethisterone 500 micrograms	Brevinor® Ovysmen®
Ethinylestradiol 35 micrograms norethisterone 1mg	Norimin®

Monophasic Every Day

Ethinylestradiol 30 micrograms/gestodene 75 micrograms + 7 inactive	Femodene ED®
Ethinylestradiol 30 micrograms/levonorgestrel 150 micrograms + 7 inactive	Microgynon 30 ED®

Phasic

Ethinylestradiol 30/40/30 micrograms/levonorgestrel 50/75/125 micrograms	Logynon® TriRegol®
Ethinylestradiol 30/40/30 micrograms/gestodene 50/70/100 micrograms	Triadene®
Ethinylestradiol 35 micrograms/norethisterone 500/750/1000 micrograms	Trinovum®