This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

PATIENT GROUP DIRECTION (PGD)

Supply of a combined oral hormonal contraceptive (COC) by Community Pharmacists in England registered to deliver the National Contraception Management Service Pilot

Version 1.0

Change History	
Version and Date	**Change details**

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	1st April 2020
Review date	October 2022
Expiry date:	31st March 2023

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in March 2020.

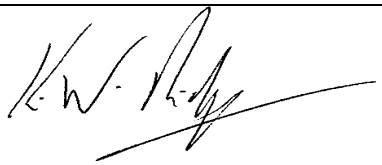
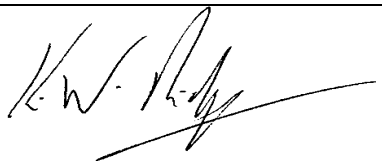
This section MUST REMAIN when a PGD is adopted by an organisation.

Name	**Designation**

Valid from: 28 September 2021
Review date: September 2022
Expiry date: 31 March 2023

Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michael Nevill	Director of Nursing British Pregnancy Advisory Service (BPAS)
Katie Girling	British Pregnancy Advisory Service (BPAS)
Julia Hogan	CASH Nurse Consultant Marie Stopes UK
Kate Devonport	National Unplanned Pregnancy Association (NUPAS)
Chetna Parmar	Pharmacist adviser Umbrella
Helen Donovan	Royal College of Nursing (RCN)
Carmel Lloyd	Royal College of Midwives (RCM)
Clare Livingstone	Royal College of Midwives (RCM)
Leanne Bobb	English HIV and Sexual Health Commissioners Group (EHSHCG)
Deborah Redknapp	English HIV and Sexual Health Commissioners Group (EHSHCG)
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Postgraduate Pharmacy Education (CPPE)
Dr Kathy French	Pan London PGD working group
Dr Sarah Pillai	Pan London PGD working group
Alison Crompton	Community pharmacist
Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	Clinical Commissioning Group pharmacist
Tracy Rogers	Associate Director Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Amanda Cooper	Specialist Pharmacy Service
Jo Jenkins (Woking Group Co-ordinator)	Specialist Pharmacist PGDs Specialist Pharmacy Service
Silvia Ceci	Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor	National Medical Director, NHS England and NHS Improvement		23/09/2021
Senior pharmacist	Chief Pharmaceutical Officer, NHS England and NHS Improvement		28/09/2021
Person signing on behalf of authorising body	Chief Pharmaceutical Officer, NHS England and NHS Improvement		28/09/2021

1. Characteristics of staff

Qualifications and professional registration	Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation. Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
Initial training	The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with local policy. Recommended requirement for training would be successful completion of a relevant contraception module/course accredited or endorsed by the FSRH, CPPE or a university or advised in the RCN training directory. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent.
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for contraception supply. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required. • Organisational PGD and/or medication training as required by employing Trust/organisation.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	• Contraception • Patients requiring control of problematic bleeding caused by the subdermal implant, IUS or medroxyprogesterone injection.
Criteria for inclusion	• Individual (age from menarche to up to 50 years) presenting for contraception. • Consent given. • A recent, accurate blood pressure recording and BMI should be documented for all individuals prior to first COC supply and repeated for each subsequent supply. In exceptional circumstances, such as the COVID-19 pandemic, where a remote consultation has to take place and it is not possible to obtain a BP or BMI then the 'FSRH clinical advice to support provision of effective contraception during the COVID-19 outbreak' or equivalent should be used for assessing whether a client is suitable to receive treatment under this PGD. See https://www.fsrh.org/documents/fsrh-ceu-clinical-advice-to-support-provision-of-effective/
Criteria for exclusion	• Consent not given. • Individuals under 16 years of age and assessed as not competent using Fraser Guidelines. • Individuals 16 years of age and over and assessed as lacking capacity to consent. • Known or suspected pregnancy. • Known hypersensitivity to the active ingredient or to any constituent of the product - see Summary of Product Characteristics • Less 21 days after childbirth (for deliveries over 24 weeks gestation) • Breastfeeding and less than six weeks postpartum. • Not breastfeeding and 3-6 weeks post-partum with other risk factors for venous thromboembolism (VTE). • Individuals aged 50 years and over. **Cardiovascular disease** • Individuals aged 35 years or more and smoking 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 • Multiple risk factors for cardiovascular disease (CVD) (such as smoking, diabetes, hypertension, obesity and dyslipidaemias) • Current or past history of ischaemic heart disease, vascular disease, stroke or transient ischaemic attack • Current or past history of venous thromboembolism • Complicated valvular or congenital heart disease e.g. pulmonary hypertension, history of 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 • Cardiomyopathy with impaired cardiac function

	• Atrial fibrillation • Significant or prolonged immobility. • Imminent planned major surgery (COC should be stopped at least 4 weeks prior to planned major surgery or expected period of limited mobility). **Neurological Conditions** • Current or past history of migraine with neurological symptoms including aura at any age • Migraine without aura, first attack when on method of contraception containing an estrogen **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. BRCA1or 2 • Malignant liver tumour (hepatocellular carcinoma) **Gastro-intestinal Conditions** • Viral hepatitis, acute or flare (for initiation only) • Severe decompensated cirrhosis • Gall bladder disease, symptomatic, medically treated • Gall bladder disease, currently symptomatic • Any bariatric or other surgery resulting in malabsorption. • Cholestasis (related to past combined hormonal contraceptive use) • Benign liver tumour (hepatocellular adenoma) **Other conditions** • Diabetes with end organ disease (retinopathy, nephropathy, neuropathy) • Positive anti-phospholipid antibodies (with or without systemic lupus erythematosus) • Organ transplant, with complications • Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them. • Known severe renal impairment or acute renal failure • Acute porphyria Interacting medicines (other than enzyme inducers) – see current British National Formulary (BNF) www.bnf.org or individual product SPC http://www.medicines.org.uk
Cautions including any relevant action to be taken	• If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. • If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy. • Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain. • Individuals taking lamotrigine should be advised that COC may interact with lamotrigine; this could result in reduced seizure

	control or lamotrigine toxicity. • Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn's disease. Although the use of COC is not contra-indicated it may be less effective and so these individuals should be advised offered Long Acting Reversible Contraception (LARC). • Women should be advised that it is possible that medications that induce diarrhoea and/or vomiting (e.g. orlistat, laxatives) could reduce the effectiveness COC. • **Offer Long Acting Reversible Contraception (LARC) to all individuals in particular those with medical conditions for whom pregnancy presents an unacceptable risk and those on a pregnancy prevention plan.** • **If an individual is known to be taking a medication which is known to be harmful to pregnancy a highly effective form of contraception is recommended. Highly effective methods include the LARC methods: IUD, IUS and implant. If a LARC method is unacceptable/unsuitable and a COC is chosen then an additional barrier method of contraception is advised. See FSRH advice.**
Action to be taken if the individual is excluded or declines treatment	• Explain the reasons for exclusion to the individual and document in the consultation record. • Record reason for decline in the consultation record. • Where required refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options.

3. Description of treatment

Name, strength & formulation of drug	• This is a list of generic combined oral contraceptive pills. • This PGD does not restrict which brands can be supplied – local formularies/restrictions should be referred to. • See http://www.mhra.gov.uk/spc-pil/ or http://www.medicines.org.uk for further information and further brand information including full details of adverse effects and interactions. • COC containing ≤30micrograms ethinylestradiol in combination with levonorgestrel or norethisterone is a reasonable first-line choice of CHC to minimise cardiovascular risk. **Monophasic** • Ethinylestradiol 20micrograms and desogestrel 150micrograms • Ethinylestradiol 20micrograms and drospirenone 3mg • Ethinylestradiol 20micrograms and gestodene 75micrograms • Ethinylestradiol 20micrograms and norethisterone 1mg • Ethinylestradiol 30micrograms and desogestrel 150micrograms • Ethinylestradiol 30micrograms and drospirenone 3mg • Ethinylestradiol 30micrograms and gestodene 75micrograms • Ethinylestradiol 30micrograms and levonorgestrel 150micrograms • Ethinylestradiol 30micrograms and norethisterone 1.5mg • Ethinylestradiol 35micrograms and norgestimate 250micrograms

	• Ethinylestradiol 35micrograms and norethisterone 500micrograms • Ethinylestradiol 35micrograms and norethisterone 1mg **Monophasic every day** • Ethinylestradiol 20micrograms and drospirenone 3mg + 7 inactive • Ethinylestradiol 30micrograms and gestodene 75micrograms + 7 inactive • Ethinylestradiol 30micrograms and levonorgestrel 150micrograms + 7 inactive • Estradiol (as hemihydrate) 1.5mg and nomegestrol acetate 2.5mg + 4 inactive ▼ **Phasic** • Ethinylestradiol 30/40/30 micrograms and gestodene 50/70/100 micrograms • Ethinylestradiol 30/40/30micrograms and levonorgestrel 50/75/125micrograms • Ethinylestradiol 35micrograms and norethisterone 0.5/1mg • Ethinylestradiol 35micrograms and norethisterone 0.5/1/0.5mg • Ethinylestradiol 35micrograms and norethisterone 0.5/0.75/1mg **Phasic every day** • Estradiol valerate 3/2/2/1mg + dienogest 0/2/3/0mg + 2 inactive • Ethinylestradiol 30/40/30 micrograms and levonorgestrel 50/75/125micrograms + 7 inactive
Legal category	POM
Black triangle ▼	Estradiol (as hemihydrate) 1.5mg and nomegestrol acetate 2.5mg + 4 inactive is a black triangle▼
Route of administration	Oral
Off label use	Best practice advice is given by the FSRH and is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC). This PGD includes inclusion criteria, exclusion criteria and dosage regimen which are outside the market authorisation for many of the available products but which are included within FSRH guidance. Specifically the use of tailored COC regimen is outside the manufacturer's licence but is supported by the Faculty of Sexual & Reproductive Healthcare (FSRH). The regimen detailed within this PGD are permitted under this PGD. Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where medicines have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected medicines for use lies with pharmacy/Medicines Management. Where a medicine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the

<table>
<tr><td></td><td>medicine is being offered in accordance with national guidance but that this is outside the product licence.</td></tr>
<tr><td>Dose and frequency of administration</td><td>FSRH guidance states that COC can either be taken following a standard or tailored regimen.

Individuals should be given information about both standard and tailored COC regimen to broaden contraceptive choice.

<u>Monophasic COC products/regimen</u>
• Monophasic COC can either be taken as a standard regimen or in a tailored regimen depending on the choice of the individual.
• The regimens which can be advised are detailed below:
<table>
<tr><th>Type of regimenn</th><th>Period of COC use</th><th>Hormone (pill) free interval</th></tr>
<tr><td colspan="3">Standard use</td></tr>
<tr><td>Standard use</td><td>21 days (21 active pills)</td><td>7 days</td></tr>
<tr><td colspan="3">Tailored use</td></tr>
<tr><td>Shortened hormone-free interval</td><td>21 days (21 active pills)</td><td>4 days</td></tr>
<tr><td>Extended use (tri-cycling)</td><td>9 weeks (3x21 active pills)</td><td>4 or 7 days</td></tr>
<tr><td>Flexible extended use</td><td>Continuous use (≥21 days) of active pills until breakthrough bleeding occurs for 3–4 days</td><td>4 days</td></tr>
<tr><td>Continuous use</td><td>Continuous use of active pills</td><td>None</td></tr>
</table>
• For the monophasic regimen detailed above a single tablet is to be taken at the same time each day starting on day 1-5 of the menstrual cycle with no need for additional precautions. The exception to this is Qlaira®, which should be started on day 1, or if not, additional precautions should be used for 9 days after starting.
• Thereafter the dosage regimen detailed above should be followed. Individuals should have access to clear information (either written or digital) to support tailored COC use.

<u>Monophasic everyday, phasic and phasic everyday COC products/regimens</u>
• For monophasic everyday, phasic and phasic everyday regimens a single tablet is to be taken at the same time each day starting on day 1-5 of the menstrual cycle with no need for additional precautions. The exception to this is Qlaira®, which should be started on day 1, or if not, additional precautions should be used for 9 days after starting.
• Thereafter follow manufacturer’s instructions for individual product use.

<u>For all COC products/regimens</u>
• COC can be started at any time after day 5 of the menstrual cycle if it is reasonably certain that the individual is not pregnant. Additional precautions are then required for 7 days after starting (9 days for Qlaira®)
• When starting or restarting the CHC as quick start after levonorgestrel emergency contraception, additional contraception is required for 7 days and a pregnancy test should be performed</td></tr>
</table>

	21 days after the last unprotected sexual intercourse. • In line with FSRH guidance individuals using hormonal contraception should delay restarting their regular hormonal contraception for 5 days following ulipristal acetate use. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective. • For guidance on changing from one contraceptive method to another, and when to start after an abortion and postpartum, refer to the FSRH guidance.
Duration of treatment	• For as long as individual requires COC and has no contraindications to the use of COC.
Quantity to be supplied	• Supply of up to twelve months in appropriately labelled original packs. • For all supplies be aware that the regimen to be taken may not be reflected in the dosage information printed on the product packaging or within the supplied PIL – ensure full details of regimen to be followed are supplied.
Storage	Medicines must be stored securely according to national guidelines.
Drug interactions	A detailed list of drug interactions is available in the individual product SPC, which is available from the electronic Medicines Compendium website www.medicines.org.uk the BNF www.bnf.org and FSRH CEU Guidance: Drug Interactions with Hormonal Contraception https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the individual product SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org The following possible adverse effects are commonly reported with COC (but may not reflect all reported adverse effects): • 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 events (VTE) • Arterial thromboembolic events (ATE) including transient ischaemic attack, ischaemic stroke, heart attack and ischaemic heart disease • Hypertension
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report via organisation incident policy.
Written information and	• Provide patient information leaflet (PIL) provided with the

further advice to be given to individual	original pack. • Individuals should be informed about the superior effectiveness of LARC. • Individuals should be provided with written information or a link to a trusted online resource to support safe, effective COC use. • 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 noting that the risks of using COC could outweigh the benefits. **Serious symptoms:** the individual should stop taking the COC and seek medical help urgently if they experience calf swelling, heat or pain in the calf, shortness of breath, chest pain or haemoptysis. The individual should seek advice if they experience their first ever migraine or develops aura with existing migraine. • Individuals should be advised that current use of COC is associated with a small increased risk of breast cancer which reduces with time after stopping COC • Individuals should be advised that current use of COC is associated with an increased risk of VTE/ATE. • Individuals should be advised that current use of COC for more than 5 years is associated with a small increased risk of cervical cancer; risk which reduces over time after stopping COC and is no longer increased by about 10 years after stopping. • Individuals using CHC should be advised about reducing periods of immobility during travel. • Individuals trekking to high altitudes (above 4500m or 14500 feet) for periods of more than 1 week may be advised to consider switching to a safer alternative contraceptive method. • Individuals should be advised to stop CHC and to switch to an alternative contraceptive method at least 4 weeks prior to planned major surgery or expected period of limited mobility. • Ensure the individual has contact details of local service/sexual health services. • Advise on action if vomiting or severe diarrhoea occurs and missed pill advice - see FSRH guidance. • Advise that non enzyme inducing antibiotics do not interact with COC and if these are prescribed COC should be continued as normal with no additional precautions required. • 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 local service/sexual health services.
Advice / follow up treatment	• The individual should be advised to seek medical advice in the event of an adverse reaction. • Individual should be encouraged to tell all clinicians that they are taking the supplied medication in the event of other medication/s being prescribed. • Individual to seek further advice if they have any concerns • Review annually.

Records	**Record:**
	• The consent of the individual and
	  ○ If individual is under 13 years of age record action taken
	  ○ If individual is under 16 years of age document capacity

	using Fraser guidelines. If not competent record action taken. ○ If individual over 16 years of age and not competent, record action taken • Name of individual, address, date of birth • GP contact details where appropriate • Relevant past and present medical history, including medication and family history. • Examination finding where relevant e.g. BMI, blood pressure. • Any known allergies • Name of registered health professional • Name of medication supplied • Date of supply • Dose supplied • Quantity supplied • Advice given, including advice given if excluded or declines treatment • Details of any adverse drug reactions and actions taken • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Any follow up and/or referral arrangements made • Any supply outside the terms of the product marketing authorisation • Recorded that supply is via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy. All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

4. Key references

Key references	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2 • Faculty of Sexual and Reproductive Health CEU Guidance: Drug Interactions with Hormonal Contraception (January 2017, last reviewed 2019) https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/ Faculty of Sexual and Reproductive Healthcare (2019) Combined Hormonal Contraception https://www.fsrh.org/standards-and-guidance/documents/combined-hormonal-contraception/ • Faculty of Sexual and Reproductive Healthcare (2016) UK Medical Eligibility Criteria for Contraceptive Use. https://www.fsrh.org/documents/ukmec-2016/

	• Faculty of Sexual and Reproductive Healthcare (2016 Clinical Guideline: Quick Starting Contraception (April 2017) https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/

Appendix A - Registered health professional authorisation sheet

PGD combined oral contraceptive pill (COC) Version 1.0
Valid from: 28 September 2021 Expiry: 31 March 2023

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered health professional

By signing this patient group direction, you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of insert name of organisation for the above-named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.