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

PATIENT GROUP DIRECTION (PGD)

For the supply of a combined oral hormonal contraceptive (COC) by registered nurses and midwives in BPAS clinics.

Version Number 2.3

Change History	
Version and Date	Change Details
Version 1 April 2020	New template. *Approved for use in BPAS November 2020.*
Version 1.1 November 2020	Minor rewording and highlighting of contents cautions section relating to individuals for whom pregnancy presents an unacceptable risk and those on a pregnancy prevention plan. Acute porphyria added to exclusion criteria. *Version not adopted by BPAS.*
Version 1.2	Addition of vaping/use of e-cigarettes where reference to smoking within PGD. Following exclusion criteria updated from 3-6 weeks to less than 6 weeks: 'Not breastfeeding and less than 6 weeks post-partum with other risk factors for venous thromboembolism (VTE). Clarification of advice for Zoely® *Version not adopted by BPAS.*
Version 2.0	Updated template – amended references and minor editing and wording changes/clarifications. Strengthened detail on use in individuals requiring control of problematic bleeding caused by the subdermal implant, IUS or medroxyprogesterone injection for up to three months. Addition by BPAS of information to provide to client in the event COC supplied ahead of abortion treatment and client chooses to continue with pregnancy. Inclusion criteria and associated points with reference to individuals requiring control of problematic bleeding caused by subdermal implant, IUS or medroxyprogesterone removed as not applicable to BPAS. *Version adopted by BPAS 01/04/23.*
Version 2.1 April 2023	SPS update: exclusion added relating to Zoely® (not applicable to BPAS) *For version control, approved for use in BPAS 09/05/23.*
Version 2.2 October 2023	Updated PGD development group members Statement added in exclusion criteria regarding consideration of lactose/sucrose content in individual products.
Version 2.3 May 2024	Added information re: starting after EHC or abortion Removed option for off-label dosing regimes.

Valid from: 01/08/2024
Review Date: September 2025
Expiry Date: 31/03/2026

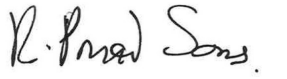
N.B. Review and update may occur prior to this period if national guidance changes or legal or clinical issues arise.

BPAS PGD Organisational Authorisations:

This PGD is not legally valid until it has had the relevant organisational authorisations below.

Name	Job title and organisation	Signature	Date
Mary Sexton	BPAS Clinical Director		19/08/2024
Dr Julie Miller	BPAS Deputy Medical Director		16/08/2024
Kalpesh Thakrar	BPAS Lead Pharmacist		30/07/2024

Authorising Body:

Cheshire and Merseyside ICB	*Rowan Pritchard-Jones*		*07/11/2024*

Responsible person who has approved this PGD on behalf of BPAS	Name: Heidi Stewart Position: BPAS Chief Executive Signature:  Date: 22/08/2024

Glossary	
BPAS	British Pregnancy Advisory Service
BMI	Body Mass Index
BLS	Basic life support
BNF	British National Formulary
COC	Combined oral contraceptive
CVD	Cardiovascular disease
EHC	Emergency hormonal contraception
FSRH	Faculty of sexual and reproductive health
IUD	Intrauterine device
LARC	Long-acting reversible contraception
LNG-IUD	Levonorgestrel intrauterine device
MHRA	Medicines Health Regulatory Agency
NICE	National Institute for Health and Care Excellence
NMC	Nursing and Midwifery Council
SmPC	Summary of medicinal product characteristics
STI	Sexually transmitted infection
TTO	To take out
VTE	Venous thromboembolism

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	April 2023
Review date:	September 2025
Expiry date:	March 2026

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 November 2022.

Name	Designation
Dr Cindy Farmer	Vice President, General Training Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Vicky Garner	Deputy Chief Midwife British Pregnancy Advisory Service (BPAS)
Gail Rowley	Quality Matron British Pregnancy Advisory Service (BPAS)
Katie Girling	British Pregnancy Advisory Service (BPAS)
Julia Hogan	CASH Nurse Consultant MSI Reproductive Choices
Kate Devonport	National Unplanned Pregnancy Advisory Service (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)
Kirsty Armstrong	National Pharmacy Integration Lead, NHS England
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Pharmacy Postgraduate Education (CPPE)
Dr Sarah Pillai	Associate Specialist
Alison Crompton	Community pharmacist
Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	NHS North East London ICB pharmacist
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Jo Jenkins	Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service
Rosie Further (Working Group Co-ordinator)	Specialist Pharmacists PGDs and Medicine Mechanisms Specialist Pharmacy Service

1. Characteristics of staff authorised to use this PGD:	
Qualifications and professional registration	• NMC Registered Nurse • NMC Registered Midwife With a current contract of employment with BPAS Practitioners must also fulfil the additional requirements listed below.
Initial training	Pharmacological knowledge relating to the administration and supply of the medicine, its uses, contraindications, dosage and adverse effects. Additionally, practitioners: • Must have completed appropriate training for working under a PGD for the supply / administration of medicines (see training requirements in the BPAS PGD policy). Recommended training - eLfH PGD elearning programme • Must be familiar with the medicine and observant to changes in the BNF and Summary of Product Characteristics (SmPC) • Must be competent in the recognition and management of adverse reactions, including anaphylaxis • Must be competent in the administration of adrenaline for anaphylaxis and have up to date Basic Life Support (BLS) skills as a minimum • Must have access to the PGD and associated online resources • Must have completed FSRH 'Essential Contraception for Abortion Care Providers' training or equivalent • Must have completed required BPAS training (including updates) in safeguarding children and vulnerable adults **The practitioner must be authorised by name, under the current version and terms of this PGD in the Approved Practitioner List before working to it.**
Competency Assessment	Practitioners working under this PGD are required to review their own competency using the NICE Competency Framework for Health Professionals using Patient Group Directions Practitioners working under this PGD must be assessed as competent or complete a self-declaration of competence to use this PGD (see appendix A). **Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.**
Ongoing training and competency	• Practitioners must complete 3-yearly PGD Theory Refresher training and competency assessment • Practitioners working under this PGD are responsible for ensuring they remain up to date with the use of the medicines and guidance included in the PGD, ensuring any training needs identified are addressed with further training • Practitioners must make sure they are aware of any changes to the recommendations for this medication

	• Practitioners must ensure they remain up to date with relevant clinical skills, management of anaphylaxis, BLS (as a minimum), with evidence of continued professional development Practitioners are responsible for maintaining their competency to work under this PGD
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policy.	

2. Clinical condition or situation to which this PGD applies:	
Clinical condition or situation to which this PGD applies	• Contraception
Inclusion criteria	• Individual (age from menarche to up to 50 years) presenting for contraception. • Consent given. • A recent, accurate blood pressure recording, and Body Mass Index (BMI) should be documented for all individuals prior to first COC supply and repeated for each subsequent supply.
Exclusion criteria	• Clients not suitable for treatment at BPAS *(N.B. please refer to BPAS suitability criteria)* • Consent not given • BMI equal to or greater than 35 kg/m^2 • 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 hypersensitivity to an active ingredient or to any constituent of the product - see Summary of Product Characteristics • Some COC products contain lactose/sucrose – individuals with rare hereditary problems of galactose intolerance, total lactase deficiency, fructose intolerance or glucose-galactose malabsorption or sucrase-isomaltase should not take these medicines. Where applicable, check product excipients before supplying. • Individuals aged 50 years and over • Significant or prolonged immobility (wheelchair use, debilitating illness) **Cardiovascular disease** • Individuals aged 35 years or more who currently smoke or stopped smoking less than one year ago (this includes vaping and the use of e-cigarettes) • Blood pressure greater than 140/90 mmHg or controlled hypertension • Multiple risk factors for cardiovascular disease (CVD) (such as smoking (includes vaping/use of e-cigarettes), 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 which first occurred when they were 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 **Neurological Conditions** • Current or past history of migraine with neurological symptoms including aura at any age • Migraine without aura; when first attack occurred on a method of contraception containing an oestrogen **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) • Benign liver tumour (hepatocellular adenoma) • Severe decompensated cirrhosis • Gallbladder disease; currently symptomatic or medically managed. • Any bariatric or other surgery resulting in malabsorption. • Cholestasis (related to past combined hormonal contraceptive use) **Other conditions** • Imminent planned major surgery (COC should be stopped at least 4 weeks prior to planned major surgery or expected period of limited mobility). • Diabetes with end organ disease (retinopathy, nephropathy, neuropathy) • Positive anti-phospholipid antibodies (with or without systemic lupus erythematosus) • Organ transplant, with complications • Known severe renal impairment or acute renal failure • Acute porphyria **Medicines** • Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them • Interacting medicines (other than enzyme inducers), including any medicines purchased – see current British National Formulary (BNF) www.bnf.org or individual product SPC http://www.medicines.org.uk
Cautions/Circumstances in which further advice should be sought (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 refer to the BPAS Safeguarding and Management of Clients Aged under 18 policy • Discuss with an appropriate prescriber any medical condition or medication of which the healthcare professional is 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

	oral contraception is not contra-indicated it may be less effective and so these individuals should be advised to consider long-acting reversible contraception (LARC). • Individuals should be advised that it is possible that medications that induce diarrhoea and/or vomiting (e.g. orlistat, laxatives) could reduce the effectiveness of COC. • Offer 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: copper IUD, LNG-IUD 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 • If excluded due to high VTE risk, consider alternative contraceptive methods • Record reason for declining treatment in the consultation record • Where appropriate refer the individual to a suitable health service provider and/or provide them with information about further options
Arrangements for referral for medical advice	• Inform and discuss with the doctor in clinic. If not available, discuss with either a regional clinical director • In the event of a medical emergency, e.g. anaphylaxis, provide immediate care in line with UK Resuscitation Council guidance, dial 999 to summon a paramedic response and initiate emergency transfer to NHS care • Document findings/action taken in client's record

3. Description of treatment:	
Name, strength and formulation medicine	• 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 20 micrograms and desogestrel 150micrograms • Ethinylestradiol 30 micrograms and drospirenone 3mg • Ethinylestradiol 30 micrograms and levonorgestrel 150micrograms • Ethinylestradiol 35 micrograms and norgestimate 250micrograms • Ethinylestradiol 35 micrograms and norethisterone 500micrograms
Legal category	POM
Route / method of administration	Oral
Indicate any off-label use (if relevant)	Best practice advice is given by the FSRH and is used for guidance in this PGD, and this may vary from the Summary of Product Characteristics (SmPC).

<table>
<tr><td></td><td>This PGD includes inclusion criteria and exclusion criteria which are outside the market authorisation for many of the available products, but which are included within FSRH guidance.

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 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><u>Contraception</u>

FSRH guidance states that COC can either be taken following a standard or tailored regimen. However, given that at BPAS, an in depth discussion regarding the benefits and risks of each regime cannot be offered, standard CHC regimens can be offered only. If an individual requests a tailored regime, they should be referred to their GP or sexual health clinic.

<u>Monophasic COC products/regimen</u>
• The regimen which can be advised is detailed below:

<table>
<tr><th>Type of regimen</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>
</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.
• Individuals should have access to clear information (either written or digital).
• Thereafter follow manufacturer’s instructions for individual product use.

<u>For all COC products/regimens</u>
• 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 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 COC this is 7 days after re-starting this method. If, in a current user, two pills are missed in the first week of pill taking, it may be</td></tr>
</table>

	appropriate to offer UPA-EC. Discuss with a prescriber in this specific circumstance. • For guidance on when to start after an abortion, refer to the FSRH guidance. COC can be safely started immediately at any time after abortion. If started within 5 days after abortion, no additional contraceptive precautions are required. If started 5 or more days after abortion, 7 days of additional contraceptive precautions are required.
Duration of treatment	**Contraception** • For as long as the individual requires COC and has no contraindications to its use.
Total quantity to be administered or quantity to be supplied as TTO	Up to three months' supply in pre-labelled TTO pack(s)
Storage	Stock must be securely stored in accordance with the BPAS Medicines Management policy and in conditions in line with the SmPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Drug interactions	Individuals concurrently prescribed enzyme inducing medicines/herbal products or within 4 weeks of stopping them are excluded from treatment under this PGD and must be referred to an appropriate prescriber: All concurrent medications, including those purchased should be considered for 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 and management of adverse reactions	A detailed list of adverse reactions is available in the individual product SmPC, 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 and migraine • Temporary disturbances of bleeding patterns • Change in mood including depression • Fluid retention • Change in libido • Skin changes including acne Serious adverse effects - these are less common, but the risks should be discussed with the individual: • Venous thromboembolic events • Arterial thromboembolic disorders (including ischaemic heart disease) • Strokes (e.g. transient ischaemic attack, ischaemic stroke, haemorrhagic stroke) • Hypertension This list may not represent all reported side-effects of this medicine. Refer to the most current SmPC for more information.

	If necessary, seek appropriate emergency medical advice and assistance.
Management and reporting procedure for adverse reactions	Document any adverse drug reactions (ADRs) in the individual's clinical records. If necessary, seek appropriate emergency medical advice and assistance as clinically indicated. Suspected ADRs are encouraged to be reported to the MHRA via https://yellowcard.mhra.gov.uk/ Adverse drug reactions must also be reported via Datix, including drug name, strength, formulation, batch numbers and expiry dates.
Written information and further advice to be given to the individual or carer	• Provide patient information leaflet (PIL) provided with the 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. • Where COC is supplied ahead of abortion treatment, advise client that if they choose to continue with their pregnancy, the contraception should not be started. If abortion treatment failure occurs after starting the COC and a decision to continue the pregnancy is made, it should be stopped. The BPAS unit should be informed, and any unused COC should be returned to a BPAS unit or pharmacy for disposal • **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 for more than 5 years is associated with a small increased risk of cervical cancer; the risk of which reduces over time after stopping COC and is no longer increased by about 10 years after stopping. • Individuals should be advised that current use of COC is associated with an increased risk of VTE/ATE. • Individuals using COC should be advised about reducing periods of immobility during travel. • Individuals trekking to high altitudes (above 4500 m 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 COC and to switch to an alternative contraceptive method at least 4 weeks prior to planned major surgery or expected periods of limited mobility. • 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 services/sexual health

	services. • Advise individual to seek advice from a pharmacist, doctor or other prescriber before starting any new medications including those purchased. • Offer relevant BPAS client information booklet relevant to their treatment, including Aftercare information
Follow-up advice to be given to the individual or carer	• The individual should be advised to seek medical advice in the event of an adverse reaction. • The individual should be encouraged to tell all clinicians that they are taking the supplied medication in the event of other medication/s being prescribed. • The individual should seek further advice if they have any concerns. • Review annually

Records to be kept	The following must be recorded in the client records in line with the NMC Code and BPAS' Record Keeping policy, using black ink if written:
	• 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
	• Any known allergies
	• Name of registered health professional
	• Name of medication supplied
	• Date of supply
	• Dose supplied
	• Quantity supplied, including batch number and expiry date
	• 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 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 password-controlled e-records) and securely kept for the defined period as specified in the BPAS PGD 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 the BPAS PGD policy.

4. References and other source material:

- 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 Healthcare (2019, amended 2020) Combined Hormonal Contraception https://www.fsrh.org/standards-and-guidance/documents/combined-hormonal-contraception/
- FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (May 2022) FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (May 2022) - Faculty of Sexual and Reproductive Healthcare
- Faculty of Sexual and Reproductive Healthcare (2019, amended November 2020) Combined Hormonal Contraception https://www.fsrh.org/standards-and-guidance/documents/combined-hormonal-contraception/
- Faculty of Sexual and Reproductive Healthcare (2016, amended 2019) UK Medical Eligibility Criteria for Contraceptive Use. https://www.fsrh.org/documents/ukmec-2016/
- Faculty of Sexual and Reproductive Healthcare Clinical Guideline: Quick Starting Contraception (April 2017) https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/
- FSRH Clinical Guideline: Problematic Bleeding with Hormonal Contraception (July 2015) https://www.fsrh.org/standards-and-guidance/documents/ceuguidanceproblematicbleedinghormonalcontraception/ NICE, 2017. Medicines practice guideline Patient Group Directions www.nice.org.uk/guidance/mpg2
- UK Resuscitation Council, 2021. Adult basic life support Guidelines | Resuscitation Council UK

5. Audit and ongoing monitoring of this PGD.

Please refer to the 'Audit' section of the BPAS Patient Group Direction policy for additional guidance in relation to PGD audit.

The PGD audit tool is available here: British Pregnancy Advisory Service - Audit Tools - All Documents (sharepoint.com).

Units must retain a local copy of the completed audit tool as evidence.

The PGD audit criteria include:

1. Staff member has named, dated and signed the relevant PGD document.
2. Client is documented as being referred to a medical practitioner if they are excluded from treatment under the PGD and there is no suitable alternative.
3. Date and time of supply / administration is on the prescription record / CAS2.
4. Client details – name, date of birth, allergies and any previous adverse effects are on the prescription record / CAS2.
5. Details of the medicine – name, strength, dose frequency, quantity, route and site (if by injection) of administration are on the prescription record / CAS2.
6. A statement that supplies or administration is by using a PGD is on the prescription record / CAS2.
7. Name and signature (which may be electronic for CAS2 records) of the health professional supplying or administering the medicine is on the prescription record / CAS2.
8. Relevant information was provided to the client or their carer.
9. Client not documented to be allergic to the drug.
10. Paper documentation in related to PGDs are in black ink only.
11. Where appropriate for the medication, correct scheduling has been discussed.
12. Client does not meet any exclusions or contraindications listed in the most up to date PGD.

Appendix A: Approved Practitioner List

Patient Group Direction (PGD) name:	Supply of a combined oral hormonal contraceptive (COC) by registered nurses and midwives in BPAS clinics v2.3.	
	Valid from: 01/08/2024	**Expiry: 31/03/2026**

Registered health professional

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove 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. The practitioner MUST sign this document before they can work under this PGD.

I confirm that I have read and understood the contents of this PGD. I confirm that I am willing and competent to work to this PGD within my professional code of conduct.				
Name (print)	**Designation**	**NMC PIN**	**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 for the above-named health care professionals who have signed the PGD to work under it.				
Name	**Position**	**BPAS Treatment Unit**	**Signature**	**Date:**

Note to authorising manager.

- Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.
- If registered health professional signatures need to be added at a later date, e.g. due to staffing changes, a separate Approved Practitioner List must be signed, ensuring the correct PGD name and version is detailed.
- This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD for the period specified in the BPAS PGD policy.
- This list must be stored by the Treatment Unit in a designated folder and be available for immediate inspection, alongside any training / competency records. If a registered professional works across multiple sites, they must sign the Approved Practitioner List for each PGD at each BPAS site where they will use the PGD.