NHS Grampian | NHS Highland | NHS Orkney | NHS Shetland | NHS Tayside | NHS Eileanan Siar Western Isles

Patient Group Direction For The Supply Of Combined Oral Contraception (COC) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Adapted from FSRH/SPS Supply of a combined oral hormonal contraceptive (COC) version 2.1 - Publication date April 2023		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature: 		**Signature:** 
NoS Identifier: NoS/PGD/COC/1448	**Review Date:** September 2025 **Expiry Date:** March 2026	**Date Approved by NoS:** 29th April 2024

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 2.1

Revision History for NoS:

NoS PGD that has been superseded	NoS/PGD/COC/MGPG1169, Version 1	
Date of change	**Summary of Changes**	**Section heading**
June 2023	Statement added in about nurses being registered by the NMC.	Professional registration
June 2023	Removed SPS advised training and added TURAS NoS PGD training link added.	Initial Training
June 2023	Added in statement about capacity under the age of 13 and the legislation statement added.	Criteria for inclusion
June 2023	NICE Competency framework statement removed.	Competency assessment
June 2023	Added clinical systems utilised.	Records
August 2023	Reference to NoS Appendix 1 and 2.	Authorisation
September 2023	Link added for FSRH training.	Initial training
February 2024	Local authority statement removed.	Qualifications and professional registration
April 2024	Additional information about pregnancy testing at 4 weeks after quick starting added.	Dose and frequency of administration

FSRH/SPS most recent changes

Version and Date	**Change details**
Version 1 April 2020	New template.
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 1.2 March 2022	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 2.0 April 2023	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.
Version 2.1 April 2023	Exclusion added relating to Zoely® only.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Authorisation

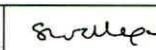
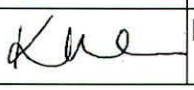
This specimen Patient Group Direction (PGD) template has been produced by SPS/FSRH and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may Supply medicines under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all medicines Supply in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Supply of the medicines has to be by the same practitioner who has assessed the patient under the PGD.

All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines under PGD (Appendix 1).

A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

This PGD has been produced for NoS by:					
Doctor	Dr Sarah Wallage	Signature		Date Signed	27/03/2024
Pharmacist	Joanne Adam	Signature		Date Signed	10/04/2024
Nurse	Kimberley MacInnes	Signature		Date Signed	07/03/2024

Approved for use within NoS by:

NoS Group Chair	**Signature**	**Date Signed**
Lesley Coyle		14/04/2024

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Adam Coldwells – Interim Chief Executive		29/04/2024

Version 2.1 Approved for NoS from 29th April 2024

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 Kathy French	Specialist Nurse
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 (Working Group Co-ordinator)	Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service

1. Characteristics of staff

Qualifications and professional registration	Registered nurses and midwives as recognised by the Nursing and Midwifery Council (NMC).
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. Suggested requirement for training would be successful completion of a relevant contraception module/course accredited or endorsed by the FSRH, CPPE or a university or as advised in the RCN training directory. • Education and Training - Faculty of Sexual and Reproductive Healthcare (fsrh.org) Have undertaken NoS PGD module training on TURAS Learn. 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 1 and Appendix 2) or complete a self-declaration of competence for contraception supply.
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. • Individuals requiring control of problematic bleeding caused by the subdermal implant, IUS or medroxyprogesterone injection for up to three months.
Criteria for inclusion	• Individual (age from menarche to up to 50 years) presenting for contraception. • Individuals requiring control of problematic bleeding caused by the subdermal implant, IUS or medroxyprogesterone injection for up to three months. • Consent given. • Aged 13 years and over*. All individuals under the age of 18 years - follow local young person's risk assessment or equivalent local process. • An individual under 16 years of age may give consent for the supply of COC, provided they understand fully the benefits and risks involved. The individual should be encouraged to involve a parent/guardian, if possible, in this decision. Where there is no parental involvement and the individual indicates that they wish to accept the supply, supply should proceed, if the healthcare professional deems the individual to have the legal capacity to consent. The Age of Legal Capacity (S) Act 1991, s2 (4) states that 'a person under the age of 16 years shall have legal capacity to consent on their own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending them, they are capable of understanding the nature and possible consequences of the procedure or treatment. • 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. • Established pregnancy. Note - risk of pregnancy with a negative pregnancy test is not an exclusion.

	• Known hypersensitivity to an active ingredient or to any constituent of the product - see Summary of Product Characteristics. • Less than 21 days after childbirth (for deliveries over 24 weeks gestation). • Breastfeeding and less than six weeks postpartum. • Not breastfeeding and less than 6 weeks post-partum with other risk factors for venous thromboembolism (VTE). • Individuals aged 50 years and over. • Significant or prolonged immobility. **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). • 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 (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 estrogen. • **Zoely® only** – individuals with a meningioma or a history of meningioma. **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. • Individuals requiring control of problematic bleeding caused by the subdermal implant, IUS or medroxyprogesterone injection for longer than 3 months (maximum period of supply under this PGD for this condition). **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 *Children under the age of 13 years should not be treated under this PGD. (The child protection team must be contacted for children of 12 years and under who present having had sexual intercourse). For those aged 13 - 16 years consider child protection team referral for these individuals if appropriate and according to local Board protocols.
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 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. • Record reason for declining treatment 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 and 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 30micrograms and desogestrel 150micrograms. • Ethinylestradiol 30micrograms and drospirenone 3mg. • Ethinylestradiol 30micrograms and gestodene 75micrograms. • Ethinylestradiol 30micrograms and levonorgestrel 150micrograms. • Ethinylestradiol 35micrograms and norgestimate 250micrograms. • Ethinylestradiol 35micrograms and norethisterone 500micrograms. • Ethinylestradiol 35micrograms and norethisterone 1mg. • Mestranol 50microgram and norethisterone 1mg tablets. **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 30/40/30micrograms and levonorgestrel 50/75/125micrograms. • Ethinylestradiol 35micrograms and norethisterone 0.5/1mg. **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
Route of administration	Oral

Off label use	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 (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 and Reproductive Healthcare (FSRH). The regimes detailed within this PGD are permitted under this PGD. • Use for the control of problematic bleeding caused by the subdermal implant, IUS or medroxyprogesterone injection. 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.
Dose and frequency of administration	**Contraception** 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. **Monophasic COC products/regimen** • 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:

Type of regimen	Period of COC use	Hormone (pill) free interval
Standard use		
Standard use	21 days (21 active pills)	7 days
Tailored use		
Shortened hormone-free interval	21 days (21 active pills)	4 days
Extended use (tri-cycling)	9 weeks (3x21 active pills)	4 or 7 days
Flexible extended use	Continuous use (≥21 days) of active pills until breakthrough bleeding occurs for 3–4 days	4 days
Continuous use	Continuous use of active pills	None

- 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) to support tailored COC use.

Monophasic everyday, phasic and phasic everyday COC products/regimens

- 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 exceptions to this are:
  - Qlaira®, which should be started on day 1, or if not, additional precautions should be used for 9 days after starting
  - Zoely®, which should be started on day 1, or if not, additional precautions should be used for 7 days after starting
- Thereafter follow manufacturer's instructions for individual product use.

For all COC products/regimens

- 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 4 weeks and 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 appropriate to offer UPA-EC. Discuss with a prescriber in this specific circumstance. • For guidance on changing from one contraceptive method to another, and when to start after an abortion and postpartum, refer to the FSRH guidance. **Control of problematic bleeding caused by the subdermal implant, IUS or medroxyprogesterone injection.** • Can be taken as a 21 day cycle/7 day pill free interval or continuously without a pill free interval.
Duration of treatment	**Contraception** • For as long as the individual requires COC and has no contraindications to its use. **Control of problematic bleeding caused by the subdermal implant, IUS or medroxyprogesterone injection.** • Three months.
Quantity to be supplied	**Contraception** • 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. **Control of problematic bleeding caused by the subdermal implant, IUS or medroxyprogesterone injection.** • Supply of up to three 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	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 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 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.
Management of and reporting procedure for adverse reactions	• Healthcare professionals and individuals/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 individual's clinical record. • Report via organisation incident policy.

Written information and further advice to be given to individual	• 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. • **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 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 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.
Advice / follow up treatment	• 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	**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, smoking status and family history
	• Examination finding including BMI and blood pressure
	• 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 in line with local procedures
	• 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. Depending on the clinical setting where supply is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • NaSH – Sexual Health Electronic Patient Record • BadgerNet – Digital Maternity Notes • HEPMA • Individual's GP records if appropriate • Individual service specific systems.

4. Key references

Key references (accessed September 2022)	• 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/

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 1 - Healthcare Professional Agreement to Supply Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to supply the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Supply Of Combined Oral Contraception (COC) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2.1

I have completed the appropriate training to my professional standards enabling me to supply the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2 - Healthcare Professionals Authorisation to Supply Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to supply the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to supply the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that supply is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
Patient Group Direction For The Supply Of Combined Oral Contraception (COC) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2.1
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Patient Group Direction For The Supply Of Combined Oral Contraception (COC) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2.1					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**