

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

<p>Lead Author: Adapted from the SPS/FSRH National PGD Template by the Medicines Management Specialist Nurse NHSG</p>	<p>Consultation Group: See relevant page in the PGD</p>	<p>Approver: NoS PGD Group</p> <p>Authorisation: NHS Grampian</p>
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<p>Signature:</p> 		<p>Signature:</p> 
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<p>NoS Identifier: NoS/PGD/COC/MGPG1169</p>	<p>Review Date: June 2023</p> <p>Expiry Date: June 2024</p>	<p>Date Approved: June 2021</p>
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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 1

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	New PGD adapted from FRSH/SPS National PGD and supersedes NHSG/PGD/CHC_PillPatch/MGPG913, NESH 07_34_v7, NESH 07_35_v7, NHST Patient Group Direction for the initial supply of Oral Combined Hormonal Contraception.	
Date of change	Summary of Changes	Section heading
April 2021	New NoS PGD adapted from FRSH/SPS National PGD	

NoS Identifier:

NoS/PGD/COC/MGPG1169

Keyword(s):

PGD Patient Group Direction combined hormonal contraception oral pill

Policy Statement: It is the responsibility of the individual healthcare professionals and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

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.

Document:

Drafted: April 2021
 Completed: June 2021
 Approved: June 2021 (published – August 2021)
 Amended:


Organisational Authorisations

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


PGD Developed/Reviewed by;

<p>Medical practitioner</p>	<p>Name: Dr Sarah Wallage Health Board: NHSG Title: Consultant in Reproductive and Sexual Health Contact email: sarah.wallage@nhs.scot Signature: </p>
<p>Senior representative of the professional group who will provide care under the direction</p>	<p>Name: Deborah Syme Health Board: NHST Title: Team Leader The Corner Contact email: deborah.syme@nhs.scot Signature: </p>
<p>Lead author</p>	<p>Name: Frances Adamson Health Board: NHSG Title : Medicines Management Specialist Nurse Contact email: frances.adamson@nhs.scot Signature: </p>
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Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		August 2021

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		August 2021

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	Title:
Frances Adamson	Lead Author: Medicines Management Specialist Nurse NHSG
Claire O'Brien	Pharmacist: Lead Clinical Pharmacist Women, Children & Families NHST
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Clinical indication to which this PGD applies

<p>Definition of situation/ Condition</p>	<p>This Patient Group Direction (PGD) will authorise approved healthcare professionals to supply the combined oral contraceptive (COC) to individuals from 13 years with established menstrual cycles up to 50 years of age.</p> <p>This PGD should be used in conjunction with the individual Board protocols and the recommendations in the current Faculty of Sexual & Reproductive Healthcare (FSRH) guidelines, the British National Formulary (BNF) and the individual Summary of Product Characteristics (SmPC).</p>
<p>Inclusion criteria</p>	<ul style="list-style-type: none"> • Are aged 13 years and over from menarche up to 50 years of age. • 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. <p>Note: 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.</p> <p>Prior to the supply of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.</p>
<p>Exclusion criteria</p>	<ul style="list-style-type: none"> • Pre-menarche • Under 13 years of age* • Post-menopausal or age 50 years and over • Under 16 years of age and judged to be incapable of understanding the nature and possible consequences of procedures or treatment as per Age of Legal Capacity (Scotland) Act 1991 (commonly referred to as Fraser competency) • 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 SmPC

	<ul style="list-style-type: none">• Less than 6 weeks postpartum with or without risk factors for venous thromboembolism (VTE)• Where there is no valid consent. <p>Cardiovascular disease</p> <ul style="list-style-type: none">• Individuals aged 35 years or more and smoking/vaping or stopped smoking/vaping less than one year ago• Body Mass Index (BMI) equal to or greater than 35kg/m²• Blood pressure greater than 140/90mmHg• Current treatment for hypertension (even if BP is less than 140/90mmHg)• 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 VTE• Complicated valvular or congenital heart disease, e.g. pulmonary hypertension, history of subacute bacterial endocarditis• First degree relative with VTE 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 or recent major surgery (COC should be stopped at least 4 weeks prior to scheduled major surgery or expected period of limited mobility and not be restarted until 6 weeks after the procedure and when fully mobile). <p>Neurological Conditions</p> <ul style="list-style-type: none">• Current or past history of migraine with neurological symptoms including aura at any age• Previous first attack of migraine without aura when taking a method of contraception containing an estrogen. <p>Cancers</p> <ul style="list-style-type: none">• Past or current history of breast cancer• Undiagnosed breast mass (for initiation of method only)• Carrier of known gene mutations associated with breast cancer, e.g. BRCA1 or 2• Malignant liver tumour (hepatocellular carcinoma).
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	<p>Gastro-intestinal Conditions</p> <ul style="list-style-type: none"> • 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). <p>Other conditions</p> <ul style="list-style-type: none"> • Diabetes with end organ disease (retinopathy, nephropathy, neuropathy) • Positive anti-phospholipid antibodies (with or without systemic lupus erythematosus) • Severe dyslipoproteinaemia • Organ transplant, with complications • Acute porphyria <p>Medications</p> <ul style="list-style-type: none"> • Individual is taking interacting medicines. Check Appendix 1 of current edition of the British National Formulary (BNF) for full list of interacting medicines for individual COC pills which includes but is not limited to; <ul style="list-style-type: none"> ○ Liver enzyme inducers, e.g. rifampicin, rifabutin, St John's Wort (Hypericum) or griseofulvin ○ Certain anticonvulsants (e.g. phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine) ○ Antiretrovirals • A detailed list of drug interactions is available in the individual product SmPC, 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/ <p>*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.</p>
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<p>Precautions and special warnings</p>	<ul style="list-style-type: none"> • 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.
<p>Action if excluded from treatment</p>	<p>Medical advice must be sought – refer to relevant medical practitioner.</p> <p>Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.</p>
<p>Action if treatment is declined</p>	<p>Inform/refer to the relevant medical practitioner if individual declines treatment.</p> <p>Document that the supply was declined, the reason and advice given in appropriate clinical records.</p>

Description of treatment available under the PGD

<p>Name form and strength of medicine</p>	<ul style="list-style-type: none"> • Below 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.
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	<ul style="list-style-type: none"> • COC containing ≤30micrograms ethinylestradiol in combination with levonorgestrel or norethisterone is a reasonable first-line choice of CHC to minimise cardiovascular risk. <p>Monophasic</p> <ul style="list-style-type: none"> • Ethinylestradiol 20micrograms and desogestrel 150micrograms • Ethinylestradiol 20micrograms and gestodene 75micrograms • Ethinylestradiol 30micrograms and desogestrel 150micrograms • 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 <p>Monophasic every day</p> <ul style="list-style-type: none"> • Ethinylestradiol 30micrograms and gestodene 75micrograms + 7 inactive • Ethinylestradiol 30micrograms and levonorgestrel 150micrograms + 7 inactive <p>Phasic</p> <ul style="list-style-type: none"> • Ethinylestradiol 30/40/30micrograms and gestodene 50/70/100 micrograms • Ethinylestradiol 30/40/30micrograms and levonorgestrel 50/75/125micrograms • Ethinylestradiol 35micrograms and norethisterone 0.5/1/0.5mg <p>Phasic every day</p> <ul style="list-style-type: none"> • Ethinylestradiol 30/40/30micrograms and levonorgestrel 50/75/125micrograms + 7 inactive.
<p>Legal status</p>	<p>All COC pills are Prescription-only Medicines (POM).</p> <p>In accordance with the MHRA all medicines supplied under a PGD must either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply.</p>

	<p>This PGD includes inclusion criteria and dosage regimes 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 FSRH. The regimen detailed within this PGD are permitted under this PGD. However, this use is outside the terms of the marketing authorisation and constitutes an off-label use of the vaccine. The individual should be informed prior to the administration that the use is off-label.</p>																								
<p>Dosage/Maximum total dose</p>	<p>FSRH guidance states that COC can either be taken following a standard or tailored regimen.</p> <p>Individuals should be given information about both standard and tailored COC regimen to broaden contraceptive choice.</p> <p>Monophasic COC products/regimen</p> <ul style="list-style-type: none"> • Monophasic COC can either be taken as a standard regimen or in a tailored regimen depending on the choice of the individual. <p>The regimens which can be advised are detailed below:</p> <table border="1" data-bbox="523 1081 1426 1680"> <thead> <tr> <th>Type of regimen</th> <th>Period of COC use</th> <th>Hormone (pill) free interval</th> </tr> </thead> <tbody> <tr> <td colspan="3" style="text-align: center;">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" style="text-align: center;">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> </tbody> </table> <ul style="list-style-type: 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. • 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. 	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
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	<p>Monophasic everyday, phasic and phasic everyday COC products/regimens</p> <ul style="list-style-type: none"> 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. Thereafter follow manufacturer's instructions for individual product use. <p>For all COC products/regimens</p> <ul style="list-style-type: none"> 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 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. See FSRH Quick Starting Contraception guideline In line with FSRH guidance individuals using hormonal contraception should delay restarting their regular hormonal contraception for 5 days following ulipristal acetate use. Additional contraception is required for 7 days and a pregnancy test should be performed 21 days after the last unprotected sexual intercourse. For guidance on changing from one contraceptive method to another, and when to start after an abortion and postpartum, refer to the FSRH guidance.
<p>Frequency of dose/Duration of treatment</p>	<p>For as long as individual requires COC and has no contraindications to the use of COC.</p>
<p>Maximum or minimum treatment period</p>	<p>See Frequency of dose/Duration of treatment section above.</p>
<p>Route/Method of administration</p>	<p>Oral.</p>
<p>Quantity to be supplied</p>	<p>Initial supply – Provide a 3 month supply (x1 box) in appropriately labelled original packs.</p> <p>Repeat supply – Provide a 12 month supply (x4 boxes) in appropriately labelled original packs.</p>
<p>Storage requirements</p>	<p>Storage requirements vary slightly between COC products, however in general they should not be stored above 30°C and in the original packaging.</p>

<p>Follow-up (if applicable)</p>	<ul style="list-style-type: none"> • 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. <p>For repeat supply – See after the first 3 months of use and then annually. Update medical/medicine/smoking history and check for contraindications to ongoing supply. Specifically enquire about migraines and bleeding pattern. Record blood pressure and BMI. Refer to doctor if any concerns and do not provide repeat supply.</p>
<p>Advice (Verbal)</p>	<ul style="list-style-type: none"> • Advise individual what to expect and what to do for minor and major reactions. • Individuals should be informed about the superior effectiveness of LARC. • 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 (see Identifying and managing possible adverse reactions section below). • 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 and arterial thrombolism (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 estimate data pre-dates the introduction of the HPV vaccine); risk reduces over time after stopping COC and is no longer increased by about 10 years after stopping. • 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 scheduled major surgery or expected period of limited mobility. It should not be restarted until 6 weeks after procedure and only when returned to full mobility. • Advise on action if vomiting or severe diarrhoea occurs and missed pill advice - see FSRH guidance.

	<ul style="list-style-type: none"> • 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. • If serious adverse or persistent effects occur, the individual should be advised to contact their GP/Accident and Emergency department/NHS24.
<p>Advice (Written)</p>	<p>The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.</p> <p>Individuals should be provided with written information or a link to a trusted online resource to support safe, effective COC use.</p> <p>Ensure the individual has contact details of local service/sexual health services.</p>
<p>Identifying and managing possible adverse reactions</p>	<p>The following possible adverse effects are commonly reported with COC (but may not reflect all reported adverse effects):</p> <ul style="list-style-type: none"> • Nausea • Breast tenderness • Headache • Temporary disturbances of bleeding patterns • Change in mood • Fluid retention. <p>Serious adverse effects - these are less common but the risks should be discussed with the individual:</p> <ul style="list-style-type: none"> • VTE • Arterial thromboembolic events (ATE) including transient ischaemic attack, ischaemic stroke, heart attack and ischaemic heart disease • Hypertension. <p>Note: the individual should stop taking the COC and seek urgently medical help 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 worsening or more frequent migraine or develop migraine with aura.</p>

	<p>This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.</p> <p>BNF/BNFC: https://www.bnf.org/products/bnf-online/</p> <p>SmPC/PIL/Risk Minimisation Material: https://www.medicines.org.uk/emc/ http://www.mhra.gov.uk/spc-pil/index.htm https://www.medicines.org.uk/emc/rmm-directory</p> <p>If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.</p> <p>Report any severe reactions using the Yellow Card System. https://yellowcard.mhra.gov.uk/</p>
<p>Facilities and supplies required</p>	<p>The following are to be available at sites where the medicine is to be supplied:</p> <ul style="list-style-type: none"> • Appropriate storage facilities • An acceptable level of privacy to respect individual’s right to confidentiality and safety • Access to a working telephone • Access to medical support (this may be via the telephone) • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this current PGD in print or electronically.

Characteristics of staff authorised to supply medicine(s) under PGD

<p>Professional qualifications</p>	<p>Registered nurses and midwives as recognised by the Nursing and Midwifery Council (NMC).</p>
<p>Specialist competencies</p>	<p>Approved by the organisation as:</p> <ul style="list-style-type: none"> • Competent to assess the individual’s capacity to understand the nature and purpose of the medicine supply in order to give or refuse consent • Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual • Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD • Competent to undertake supply of the medicine • Competent to work under this PGD.

<p>Ongoing training and competency</p>	<p>All professionals working under this PGD must:</p> <ul style="list-style-type: none"> • Have undertaken PGD training as required/set out by each individual Health Board • Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct • Have knowledge and familiarity of the following; <ul style="list-style-type: none"> ○ SmPC for the medicine(s) to be supplied in accordance with this PGD.
<p>Responsibilities of professional manager(s)</p>	<p>Professional manager(s) will be responsible for;</p> <p>Ensuring that the current PGD is available to all staff providing care under this direction.</p> <p>Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.</p> <p>Maintain up to date record of all staff authorised to supply the medicine(s) specified in this direction.</p>

Documentation

<p>Authorisation of supply</p>	<p>Nurses and midwives working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to supply the medicine(s) specified in this PGD by their Professional Line Manager/Consultant/Practice GPs.</p> <p>All authorised staff are required to read the PGD and sign the Agreement to Supply Medicines Under PGD (Appendix 1).</p> <p>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.</p>
<p>Record of supply</p>	<p>An electronic or paper record for recording the screening of individuals and the subsequent supply, or not of the medicine(s) specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum:</p> <ul style="list-style-type: none"> • Date and time of supply • Individuals name and CHI • Exclusion criteria, record why the medicine was not supplied (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, dose, form, route of the medicine supplied

	<ul style="list-style-type: none"> • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who supplied the medicine • Record of any adverse effects (advise individuals GP/relevant medical practitioner). <p>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:</p> <ul style="list-style-type: none"> • NaSH – Sexual Health Electronic Patient Record • BadgerNet – Digital Maternity Notes • Individual’s GP records if appropriate • Individual service specific systems. 																		
Audit	<p>All records of the medicine(s) specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines supplied under a PGD.</p>																		
References	<p>Electronic Medicines Compendium http://www.medicines.org.uk Date Accessed 28/04/21.</p> <table border="1" data-bbox="523 1077 1423 1966"> <thead> <tr> <th>Brand name</th> <th>Content</th> <th>SmPC Revision</th> </tr> </thead> <tbody> <tr> <td>Mercilon[®] Organon Pharma (pack size 3 x 21)</td> <td>Ethinylestradiol 20micrograms and desogestrel 150micrograms</td> <td>26/02/21</td> </tr> <tr> <td>Akizza[®] (Morningside Healthcare pack size 3 x 21)</td> <td>Ethinylestradiol 20micrograms and gestodene 75micrograms</td> <td>03/03/20</td> </tr> <tr> <td>Lizinna[®] Morningside Healthcare (pack size 3 x 21)</td> <td>Ethinylestradiol 35micrograms and norgestimate 250micrograms</td> <td>29/07/19</td> </tr> <tr> <td>Brevinor[®] Pfizer (pack size 3 x 21)</td> <td>Ethinylestradiol 35micrograms and norethisterone 500micrograms</td> <td>August 2019</td> </tr> <tr> <td>Norimin[®] Pfizer (pack size 3 x 21)</td> <td>Ethinylestradiol 35micrograms and norethisterone 1mg</td> <td>August 2019</td> </tr> </tbody> </table>	Brand name	Content	SmPC Revision	Mercilon [®] Organon Pharma (pack size 3 x 21)	Ethinylestradiol 20micrograms and desogestrel 150micrograms	26/02/21	Akizza [®] (Morningside Healthcare pack size 3 x 21)	Ethinylestradiol 20micrograms and gestodene 75micrograms	03/03/20	Lizinna [®] Morningside Healthcare (pack size 3 x 21)	Ethinylestradiol 35micrograms and norgestimate 250micrograms	29/07/19	Brevinor [®] Pfizer (pack size 3 x 21)	Ethinylestradiol 35micrograms and norethisterone 500micrograms	August 2019	Norimin [®] Pfizer (pack size 3 x 21)	Ethinylestradiol 35micrograms and norethisterone 1mg	August 2019
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Akizza [®] (Morningside Healthcare pack size 3 x 21)	Ethinylestradiol 20micrograms and gestodene 75micrograms	03/03/20																	
Lizinna [®] Morningside Healthcare (pack size 3 x 21)	Ethinylestradiol 35micrograms and norgestimate 250micrograms	29/07/19																	
Brevinor [®] Pfizer (pack size 3 x 21)	Ethinylestradiol 35micrograms and norethisterone 500micrograms	August 2019																	
Norimin [®] Pfizer (pack size 3 x 21)	Ethinylestradiol 35micrograms and norethisterone 1mg	August 2019																	

Brand name	Content	SmPC Revision
Femodene® ED Bayer (pack size 3 x 21 + 7 placebo)	Ethinylestradiol 30micrograms and gestodene 75micrograms	03/04/20
Microgynon® 30 ED Bayer (pack size 3 x 21 + 7 placebo)	Ethinylestradiol 30micrograms and levonorgestrel 150micrograms + 7 inactive	01/6/20
Logynon® Bayer (pack size 3 x 21)	Ethinylestradiol 30/40/30micrograms and levonorgestrel 50/75/125micrograms	15/01/21

British National Formulary <https://www.bnf.org/products/bnf-online/> accessed 28/04/21.

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 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

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: _____

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 he or she is 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 he or she understands and is 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 his or her 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

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**

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date