

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 Combined Hormonal Contraceptive (CHC) Vaginal Ring  
by Registered Nurses and Midwives in BPAS clinics

Version Number 2.1

<b>Change History</b>	
<b>Version and Date</b>	<b>Change details</b>
Version 1 April 2020	New template <i>Adapted for use in BPAS 04/11/20.</i>
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. <i>Version not used in BPAS.</i>
Version 1.2 April 2021	Addition of contents of SyreniRing® 11.0mg etonogestrel and 3.474mg ethinylestradiol to Name, strength & formulation of drug section.
Version 1.3 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). <i>Version not used in BPAS.</i>
Version 2.0 April 2023	Updated template – amended references and minor editing and wording changes/clarifications. <i>Adapted for use in BPAS 03/04/23.</i>
Version 2.1 June 2024	Reinstated following review. Documentation section updated. Removed option for off-label dosing regimes.

Valid from: 01 August 2024




Review Date: September 2025

Expiry Date: 31 March 2026

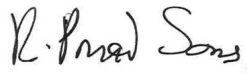
*N.B. Review and update may occur prior to this period if national guidance changes or legal or clinical issues arise*

**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
CHC	Combined hormonal contraceptive
CVD	Cardiovascular disease
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.

<b>Name</b>	<b>Designation</b>
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

<b>1. Characteristics of staff authorised to use this PGD:</b>	
<b>Qualifications and professional registration</b>	<ul style="list-style-type: none"> <li>• NMC Registered Nurse</li> <li>• NMC Registered Midwife</li> </ul> With a current contract of employment with BPAS  Practitioners must also fulfil the additional requirements listed below.
<b>Initial training</b>	Pharmacological knowledge relating to the administration and supply of the medicine, its uses, contraindications, dosage and adverse effects  Additionally, practitioners: <ul style="list-style-type: none"> <li>• 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 - <a href="#">eLfh PGD elearning programme</a></li> <li>• Must be familiar with the medicine and observant to changes in the <a href="#">BNF</a> and <a href="#">Summary of Product Characteristics</a> (SmPC)</li> <li>• Must be competent in the recognition and management of adverse reactions, including anaphylaxis</li> <li>• Must be competent in the administration of adrenaline for anaphylaxis and have up to date Basic Life Support (BLS) skills as a minimum</li> <li>• Must have access to the PGD and associated online resources</li> <li>• Must have completed FSRH 'Essential Contraception for Abortion Care Providers' training or equivalent</li> <li>• Must have completed required BPAS training (including updates) in safeguarding children and vulnerable adults</li> </ul> <p><b>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</b></p>
<b>Competency Assessment</b>	Practitioners working under this PGD are required to review their own competency using the <a href="#">NICE Competency Framework for Health Professionals using Patient Group Directions</a>  Practitioners working under this PGD must be assessed as competent or complete a self-declaration of competence to use this PGD (see appendix A).  <p><b>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.</b></p>
<b>Ongoing training and competency</b>	<ul style="list-style-type: none"> <li>• Practitioners must complete 3-yearly PGD Theory Refresher training and competency assessment</li> <li>• 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</li> <li>• Practitioners must make sure they are aware of any changes to the recommendations for this medication</li> </ul>

	<ul style="list-style-type: none"> <li>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</li> <li>Practitioners are responsible for maintaining their competency to work under this PGD</li> </ul>
<p><i>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policy</i></p>	

<b>2. Clinical condition or situation to which this PGD applies:</b>	
<b>Clinical condition or situation to which this PGD applies</b>	Contraception
<b>Inclusion criteria</b>	<ul style="list-style-type: none"> <li>Individual (age from menarche to up to 50 years) presenting for contraception</li> <li>Consent given</li> <li>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.</li> </ul>
<b>Exclusion criteria</b>	<ul style="list-style-type: none"> <li>Clients not suitable for treatment at BPAS (<i>N.B. please refer to BPAS <a href="#">suitability criteria</a></i>)</li> <li>Consent not given</li> <li>Individuals under 16 years of age and assessed as not competent using Fraser Guidelines</li> <li>Individuals 16 years of age and over and assessed as lacking capacity to consent</li> <li>Known hypersensitivity to an active ingredient or to any constituent of the product - see <a href="#">Summary of Product Characteristics</a></li> <li>Individuals aged 50 years and over</li> <li>Significant or prolonged immobility</li> </ul> <p><b>Cardiovascular disease</b></p> <ul style="list-style-type: none"> <li>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)</li> <li>BMI equal to or greater than 35kg/m<sup>2</sup></li> <li>Blood pressure greater than 140/90mmHg or controlled hypertension</li> <li>Multiple risk factors for cardiovascular disease (CVD) (such as smoking (includes vaping/use of e-cigarettes), diabetes, hypertension, obesity and dyslipidaemias)</li> <li>Current or past history of ischaemic heart disease, vascular disease, stroke or transient ischaemic attack</li> <li>Current or past history of venous thromboembolism</li> <li>Complicated valvular or congenital heart disease e.g. pulmonary hypertension, history of subacute bacterial endocarditis</li> <li>First degree relative with venous thromboembolism which first occurred when they were under 45 years of age</li> <li>Known thrombogenic mutations e.g. factor V Leiden, prothrombin mutation, protein S, protein C and antithrombin deficiencies</li> <li>Cardiomyopathy with impaired cardiac function</li> <li>Atrial fibrillation</li> </ul>

	<p><b>Neurological Conditions</b></p> <ul style="list-style-type: none"> <li>• Current or past history of migraine with neurological symptoms including aura at any age</li> <li>• Migraine without aura; when first attack occurred on a method of contraception containing an oestrogen</li> </ul> <p><b>Cancers</b></p> <ul style="list-style-type: none"> <li>• Past or current history of breast cancer</li> <li>• Undiagnosed breast mass (for initiation of method only)</li> <li>• Carrier of known gene mutations associated with breast cancer e.g. BRCA1 or 2</li> <li>• Malignant liver tumour (hepatocellular carcinoma)</li> </ul> <p><b>Gastro-intestinal Conditions</b></p> <ul style="list-style-type: none"> <li>• Viral hepatitis, acute or flare (for initiation only)</li> <li>• Benign liver tumour (hepatocellular adenoma)</li> <li>• Severe decompensated cirrhosis</li> <li>• Gallbladder disease; currently symptomatic or medically managed.</li> <li>• Any bariatric or other surgery resulting in malabsorption.</li> <li>• Cholestasis (related to past combined hormonal contraceptive use)</li> </ul> <p><b>Other conditions</b></p> <ul style="list-style-type: none"> <li>• Imminent planned major surgery (CHC should be stopped at least 4 weeks prior to planned major surgery or expected period of limited mobility).</li> <li>• Diabetes with end organ disease (retinopathy, nephropathy, neuropathy)</li> <li>• Positive anti-phospholipid antibodies (with or without systemic lupus erythematosus)</li> <li>• Organ transplant, with complications</li> <li>• Known severe renal impairment or acute renal failure</li> <li>• Acute porphyria (excluded from treatment at BPAS by Suitability Criteria)</li> </ul> <p><b>Medicines</b></p> <ul style="list-style-type: none"> <li>• Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them.</li> <li>• Interacting medicines (other than enzyme inducers), including any medicines purchased – see current British National Formulary (BNF) <a href="http://www.bnf.org">www.bnf.org</a> or individual product SPC <a href="http://www.medicines.org.uk">http://www.medicines.org.uk</a></li> </ul>
<p><b>Cautions/Circumstances in which further advice should be sought (including any relevant action to be taken)</b></p>	<ul style="list-style-type: none"> <li>• If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented</li> <li>• If the individual is less than 13 years of age, the healthcare professional should speak to local safeguarding lead and refer to the <a href="#">BPAS Safeguarding and Management of Clients Aged under 18</a> policy</li> <li>• Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is uncertain</li> <li>• Individuals taking lamotrigine should be advised that COC may interact with lamotrigine; this could result in reduced seizure control or lamotrigine toxicity</li> </ul>

	<ul style="list-style-type: none"> <li>• 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</li> <li>• 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 CHC is chosen then an additional barrier method of contraception is advised. See <a href="#">FSRH advice</a>.</li> </ul>
<b>Action to be taken if the individual is excluded or declines treatment</b>	<ul style="list-style-type: none"> <li>• Explain the reasons for exclusion to the individual and document in the consultation record</li> <li>• Record reason for declining treatment in the consultation record</li> <li>• Where appropriate refer the individual to a suitable health service provider and/or provide them with information about further options</li> </ul>
<b>Arrangements for referral for medical advice</b>	<ul style="list-style-type: none"> <li>• Inform and discuss with the doctor in clinic. If not available, discuss with a regional clinical director</li> <li>• 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</li> <li>• Document findings/action taken in client's record</li> </ul>

<b>3. Description of treatment:</b>	
<b>Name, strength and formulation medicine</b>	<p>Vaginal ring containing (per ring):</p> <p><b>NuvaRing®</b> 11.7 mg etonogestrel and 2.7 mg ethinylestradiol per ring</p> <p><b>SyreniRing®</b> 11.0mg etonogestrel and 3.474mg ethinylestradiol per ring</p>
<b>Legal category</b>	POM
<b>Route / method of administration</b>	Vaginal
<b>Indicate any off-label use (if relevant)</b>	<p>Best practice advice is given by the FSRH and is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC).</p> <p>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. Specifically, use in those under 18 years or over 45 years of age, but their use is supported by the Faculty of Sexual &amp; Reproductive Healthcare (FSRH). The regimes detailed within this PGD are permitted under this PGD</p> <p>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</p>

	<p>for the decision to release the affected medicines for use lies with pharmacy/Medicines Management</p> <p>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</p>									
<p><b>Dose and frequency of administration</b></p>	<ul style="list-style-type: none"> <li>Each vaginal ring releases an average amount of 0.12 mg etonogestrel and 0.015 mg ethinylestradiol respectively per 24 hours, over a period of three weeks.</li> <li>FSRH guidance states that CHC can either be used following a standard or tailored regime. 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</li> </ul> <p><b>Regimes</b></p> <ul style="list-style-type: none"> <li>The regime which can be advised is detailed below:</li> </ul> <table border="1" data-bbox="564 770 1406 969"> <thead> <tr> <th>Type of regimen</th> <th>Period of CHC use</th> <th>Hormone (ring) free interval</th> </tr> </thead> <tbody> <tr> <td colspan="3" style="text-align: center;"><b>Standard use</b></td> </tr> <tr> <td>Standard use</td> <td>21 days (1 ring)</td> <td>7 days</td> </tr> </tbody> </table> <ul style="list-style-type: none"> <li>A single ring is to be inserted every 21 days starting on day 1-5 of the menstrual cycle with no need for additional precautions.</li> <li>The ring can be inserted at any time after day 5 if it is reasonably certain that the individual is not pregnant. Additional contraception is then required for seven days after starting.</li> <li>Thereafter the dosage regime detailed above should be followed. Individuals should have access to clear information (either written or digital).</li> <li>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</li> <li>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 the CHC ring this is for 7 days after re-starting this method</li> </ul> <p>For guidance on changing from one contraceptive method to another, and when to start after an abortion and postpartum, refer to the FSRH guidance. CHC 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</p>	Type of regimen	Period of CHC use	Hormone (ring) free interval	<b>Standard use</b>			Standard use	21 days (1 ring)	7 days
Type of regimen	Period of CHC use	Hormone (ring) free interval								
<b>Standard use</b>										
Standard use	21 days (1 ring)	7 days								
<p><b>Duration of treatment</b></p>	<p><b>Contraception</b></p> <ul style="list-style-type: none"> <li>For as long as the individual requires CHC and has no contraindications to its use</li> </ul>									



<b>Total quantity to be administered or quantity to be supplied as TTO</b>	Up to three months' supply in appropriately labelled TTO pack(s)
<b>Storage</b>	<p>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: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p> <p><b>NuvaRing®</b></p> <ul style="list-style-type: none"> <li>• The vaginal ring must be stored between 2-8°C prior to supplying to the individual</li> <li>• Advise the individual that the ring should be stored at 2-8°C until use. However, the rings are stable at room temperature for up to 4 months after removal from storage at 2-8°C but must then be discarded if not used</li> </ul> <p><b>SyreniRing®</b></p> <p>This medicinal product does not require any special temperature storage conditions. Store in the original package to protect from light</p>
<b>Drug interactions</b>	<p>All concurrent medications, including those purchased should be considered for interactions.</p> <p>A detailed list of drug interactions is available in the individual product SPC, which is available from the electronic Medicines Compendium website <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> the BNF <a href="http://www.bnf.org">www.bnf.org</a> and FSRH CEU Guidance: Drug Interactions with Hormonal Contraception <a href="https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/">https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/</a></p>
<b>Identification and management of adverse reactions</b>	<p>A detailed list of adverse reactions is available in the individual product SmPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> and BNF <a href="http://www.bnf.org">www.bnf.org</a></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"> <li>• Nausea</li> <li>• Breast tenderness</li> <li>• Headache and migraine</li> <li>• Temporary disturbances of bleeding patterns</li> <li>• Change in mood including depression</li> <li>• Fluid retention</li> <li>• Change in libido</li> <li>• Skin changes including acne</li> </ul> <p>Serious adverse effects - these are less common but the risks should be discussed with the individual:</p> <ul style="list-style-type: none"> <li>• Venous thromboembolic events</li> <li>• Arterial thromboembolic disorders (including ischaemic heart disease)</li> <li>• Strokes (e.g. transient ischaemic attack, ischaemic stroke, haemorrhagic stroke)</li> <li>• Hypertension</li> </ul> <p>This list may not represent all reported side-effects of this medicine. Refer to the most current SmPC for more information</p>

	If necessary, seek appropriate emergency medical advice and assistance
<b>Management and reporting procedure for adverse reactions</b>	<p>Document any adverse effects in the client's clinical records. If necessary, seek appropriate emergency medical advice and assistance as clinically indicated.</p> <p>Serious adverse drug reactions should be reported to the MHRA via <a href="https://yellowcard.mhra.gov.uk/">https://yellowcard.mhra.gov.uk/</a></p> <p>Adverse drug reactions must also be reported via Datix, including drug name, strength, formulation, batch numbers and expiry dates.</p>
<b>Written information and further advice to be given to the individual or carer</b>	<ul style="list-style-type: none"> <li>• Provide manufacturer's information leaflet (PIL) provided with the original pack</li> <li>• Individuals should be informed about the superior effectiveness of LARC</li> <li>• Individuals should be provided with written information or a link to a trusted online resource to support safe, effective CHC use</li> <li>• Explain mode of action, side effects, and benefits of the medicine</li> <li>• Where CHC vaginal ring(s) are 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 CHC and a decision to continue the pregnancy is made, it should be stopped. The BPAS unit should be informed and any unused CHC should be returned to a BPAS unit or pharmacy for disposal</li> <li>• Advise individual on insertion and removal of the vaginal ring and action to be taken if the ring becomes damaged or is accidentally expelled</li> <li>• Advise on correct storage for supplied product (see Storage section above)</li> <li>• 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 CHC could outweigh the benefits. <b>Serious symptoms:</b> the individual should stop using the CHC 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 develops aura with existing migraine</li> <li>• Individuals should be advised that current use of CHC is associated with a small increased risk of breast cancer which reduces with time after stopping CHC</li> <li>• Individuals should be advised that current use of CHC for more than 5 years is associated with a small increased risk of cervical cancer the risk of which reduces over time after stopping CHC and is no longer increased by about 10 years after stopping</li> <li>• Individuals should be advised that current use of CHC is associated with an increased risk of VTE/ATE</li> <li>• Individuals using CHC should be advised about reducing periods of immobility during travel</li> <li>• Individuals trekking to high altitudes (above 4500 m or 14 500 feet) for periods of more than 1 week may be advised to consider switching to a safer alternative contraceptive method</li> <li>• Individuals should be advised to stop CHC and to switch to an alternative contraceptive method at least 4 weeks prior to planned major surgery or expected period of limited mobility</li> </ul>

	<ul style="list-style-type: none"> <li>• Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs)</li> <li>• Ensure the individual has contact details of local service/sexual health services</li> <li>• Advise individual to seek advice from a pharmacist, doctor or other prescriber before starting any new medications including those purchased</li> <li>• Relevant BPAS client information booklet relevant to their treatment, including Aftercare information</li> </ul>
<p><b>Follow-up advice to be given to the individual or carer</b></p>	<ul style="list-style-type: none"> <li>• The individual should be advised to seek medical advice in the event of an adverse reaction.</li> <li>• 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.</li> <li>• The individual should seek further advice if they have any concerns.</li> <li>• Review annually by GP or sexual and reproductive health services</li> </ul>
<p><b>Records to be kept</b></p>	<p>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:</p> <ul style="list-style-type: none"> <li>• The consent of the individual and             <ul style="list-style-type: none"> <li>○ If individual is under 13 years of age record action taken</li> <li>○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.</li> <li>○ If individual over 16 years of age and not competent, record action taken</li> </ul> </li> <li>• Patient name, date of birth, any known allergies</li> <li>• Relevant past and present medical history, including medication, smoking status and family history.</li> <li>• Examination finding including BMI and blood pressure.</li> <li>• Dose supplied</li> <li>• Quantity supplied including batch number and expiry date</li> <li>• Indications for use, patient inclusion or exclusion from PGD</li> <li>• Date and time of supply</li> <li>• Advice given, including advice given if excluded or declines treatment</li> <li>• Details of any adverse drug reactions and actions taken</li> <li>• Advice given about the medication including side effects, benefits, and when and what to do if any concerns</li> <li>• Any follow up and/or referral arrangements made</li> <li>• Any supply outside the terms of the product marketing authorisation</li> <li>• Any actions taken following supply/administration</li> <li>• Signature, printed name and designation of registered health professional supplying / administering and detail of double checking, if required</li> <li>• Detail that medicine supplied using a PGD</li> </ul> <p>Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy.</p> <p>All records should be clear, legible and contemporaneous.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>

**4. References and other source material:**

- Electronic Medicines Compendium (last updated 20/09/22) [NuvaRing - Summary of Product Characteristics \(SmPC\) - \(emc\) \(medicines.org.uk\)](https://www.medicines.org.uk/SmPC/NuvaRing)
- Electronic BNF <https://bnf.nice.org.uk/drugs/ethinylestradiol-with-etonogestrel/>
- 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](https://www.fsrh.org/standards-and-guidance/documents/ceu-guidance-drug-interactions-with-hormonal-contraception-may-2022/)
- 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/ceu-guidance-problematic-bleeding-hormonal-contraception/>
- NICE, 2017. Medicines practice guideline Patient Group Directions [www.nice.org.uk/guidance/mpg2](https://www.nice.org.uk/guidance/mpg2)
- UK Resuscitation Council, 2021. [Adult basic life support Guidelines | Resuscitation Council UK](https://www.resus.org.uk/guidelines/adult-basic-life-support)

## 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 \(sharepoint.com\)](https://www.sharepoint.com/~/sites/bpas/BPAS%20Patient%20Group%20Directions/Pages/PGD%20Audit%20Tool.aspx).

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 supply 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**

<b>Patient Group Direction (PGD) name:</b>	Supply of combined hormonal contraceptive (CHC) vaginal rings by Registered Nurses and Midwives in BPAS clinics v2.1	
	<b>Valid from: 01/08/2024</b>	<b>Expiry: 31/03/2026</b>

**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><b>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.</b></i>				
<b>Name (print)</b>	<b>Designation</b>	<b>NMC PIN</b>	<b>Signature</b>	<b>Date</b>

**Authorising manager**

<i><b>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.</b></i>				
<b>Name</b>	<b>Position</b>	<b>BPAS Treatment Unit</b>	<b>Signature</b>	<b>Date:</b>

**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.