Brighton and Sussex University Hospitals NHS Trust

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

PATIENT GROUP DIRECTION (PGD)

Supply of combined hormonal contraceptive vaginal ring in Brighton and Sussex University Hospitals NHS Trust Sexual Health & Contraception (SHAC) Service

Version Number 1.0

Change History	
Version and Date	**Change details**
Version 1 April 2020	New template

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

Approved date JUNE 2020 Expiry date 31 MARCH 2023

PGD DEVELOPMENT GROUP

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

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

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

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

Group Co-ordinator)	
Silvia Ceci	Chief Pharmaceutical Officer’s Clinical Fellow Specialist Pharmacy Service

PGD approval - meets local need and guidelines

Name	Job title and organisation	Signature	Date
Lead author: Reproductive Health PGDs Short Life Working Group	As listed on Page 2/3		
Lead Doctor: Dr Juliet Bowie	Associate Specialist, SHAC Service, BSUH	Email approval	02/07/20
Lead pharmacist: Claire Richardson	Lead Pharmacist, HIV & Sexual Health Service, BSUH	Email approval	07/07/20
Lead Clinician for area: Dr Debbie Williams	Consultant (HIV & GUM), SHAC, BSUH	Email approval	02/06/20
Reviewed by: Dr Daniel Richardson	Consultant HIV & SHAC Service, BSUH	Email approval	01/07/20
Representative of other professional group using PGD: Wendy Gardiner	Advanced Nurse Practitioner, SHAC Service, BSUH	Email approval	01/07/20

Organisational authorisations

Brighton & Sussex University Hospitals NHS Trust authorises this PGD for use by the services or providers listed below:
Sexual Health & Contraception (SHAC) Service.
Limitations to authorisation
Only Registered Nurses who work within the SHAC Service, hold a relevant contraception qualification, and are signed to the PGD.

Name	Signature & Name	Date
Chair of PGD Group	Joanne Pendlebury	Email approval 07/07/20
Chief Pharmacist	Mike Cross	Email approval 24/07/20
Medicines Governance Group chair	Mike Okorie	Email approval 27/07/20

Local enquiries regarding the use of this PGD may be directed to Bsuh.pgdgroup@nhs.net or PGD group chair.

Appendix 1 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD.

1. Characteristics of staff

Qualifications and professional registration	Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation. Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
Initial training	The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with local policy. Recommended requirement for training would be successful completion of a relevant contraception module/course accredited or endorsed by the FSRH, CPPE or a university or advised in the RCN training directory. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent. Register and complete PGD training module (certificate can be printed out as evidence) https://portal.e-lfh.org.uk/ (3 yearly) Has undertaken training appropriate to recognise and manage allergic/anaphylactic reactions. Has undertaken appropriate Trust resuscitation training.
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see section 7) or complete a self-declaration of competence for contraception supply. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required. • Organisational PGD and/or medication training as required by employing Trust/organisation, including: ➢ PGD e-learning 3 yearly ➢ Up to date with mandatory training
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
Criteria for inclusion	• Individual (age from menarche to up to 50 years) presenting for contraception. • Consent given. • A recent, accurate blood pressure recording and BMI should be documented for all individuals prior to first CHC supply and repeated for each subsequent supply. In exceptional circumstances, such as the COVID-19 pandemic, where a remote consultation has to take place and it is not possible to obtain a BP or BMI then the 'FSRH clinical advice to support provision of effective contraception during the COVID-19 outbreak' or equivalent should be used for assessing whether a client is suitable to receive treatment under this PGD. See https://www.fsrh.org/documents/fsrh-ceu-clinical-advice-to-support-provision-of-effective/
Criteria for exclusion	• Consent not given. • Individuals under 16 years of age and assessed as not competent using Fraser Guidelines. • Individuals 16 years of age and over and assessed as lacking capacity to consent. • Known or suspected pregnancy. • Known hypersensitivity to the active ingredient or to any constituent of the product - see Summary of Product Characteristics • Less 21 days after childbirth (for deliveries over 24 weeks gestation) • Breastfeeding and less than six weeks postpartum. • Not breastfeeding and 3-6 weeks post-partum with other risk factors for venous thromboembolism (VTE). • Individuals aged 50 years and over. **Cardiovascular disease** • Individuals aged 35 years or more and a smoker or stopped smoking less than one year ago • Body Mass Index (BMI) equal to or greater than 35kg/m^2 • Blood pressure greater than 140/90mmHg or controlled hypertension • Multiple risk factors for cardiovascular disease (CVD) (such as smoking, diabetes, hypertension, obesity and dyslipidaemias) • Current or past history of ischaemic heart disease, vascular disease, stroke or transient ischaemic attack • Current or past history of venous thromboembolism • Complicated valvular or congenital heart disease e.g. pulmonary hypertension, history of subacute bacterial endocarditis • First degree relative with venous thromboembolism under 45 years of age • Known thrombogenic mutations e.g. factor V Leiden, prothrombin mutation, protein S, protein C and antithrombin

	deficiencies • Cardiomyopathy with impaired cardiac function • Atrial fibrillation • Significant or prolonged immobility. • Imminent planned major surgery (CHC should be stopped at least 4 weeks prior to planned major surgery or expected period of limited mobility). **Neurological Conditions** • Current or past history of migraine with neurological symptoms including aura at any age • Migraine without aura, first attack when on method of contraception containing an estrogen **Cancers** • Past or current history of breast cancer • Undiagnosed breast mass (for initiation of method only) • Carrier of known gene mutations associated with breast cancer e.g. BRCA1or 2 • Malignant liver tumour (hepatocellular carcinoma) **Gastro-intestinal Conditions** • Viral hepatitis, acute or flare (for initiation only) • Severe decompensated cirrhosis • Gall bladder disease, symptomatic, medically treated • Gall bladder disease, currently symptomatic • Cholestasis (related to past combined hormonal contraceptive use) • Benign liver tumour (hepatocellular adenoma) **Other conditions** • Diabetes with end organ disease (retinopathy, nephropathy, neuropathy) • Positive anti-phospholipid antibodies (with or without systemic lupus erythematosus) • Organ transplant, with complications • Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them. • Known severe renal impairment or acute renal failure Interacting medicines (other than enzyme inducers) – see current British National Formulary (BNF) www.bnf.org or individual product SPC http://www.medicines.org.uk In particular consider an alternative method or, if this is not desired by the patient, referral to a prescriber for review when individuals are taking lamotrigine. Those users should be advised that CHC may interact with lamotrigine, resulting in either reduced seizure control or lamotrigine toxicity.
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 doctor/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain. • 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 IUD/LARC. If an IUD/LARC is unacceptable/unsuitable and a CHC is chosen then an additional barrier method of contraception is advised. See FSRH advice.
Action to be taken if the individual is excluded or declines treatment	• Explain the reasons for exclusion to the individual and document in the consultation record. • Record reason for decline in the consultation record. • Where required refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options.

3. Description of treatment

Name, strength & formulation of drug	Vaginal ring containing 11.7 mg etonogestrel and 2.7 mg ethinylestradiol per ring
Legal category	POM
Route of administration	Vaginal
Off label use	Best practice advice is given by the FSRH and is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC). This PGD includes inclusion criteria, exclusion criteria and dosage 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 CHC regimens is outside the manufacturer's licence, as is use in those under 18 years of age/over 40 years of age but is supported by the Faculty of Sexual & Reproductive Healthcare (FSRH). The regimes detailed within this PGD are permitted under this PGD. Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where medicines have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected medicines for use lies with pharmacy/Medicines Management.

	Where a medicine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the medicine is being offered in accordance with national guidance but that this is outside the product licence.
Dose and frequency of administration	• The 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. • FSRH guidance states that CHC can either be used following a standard or tailored regime. • Individuals should be given information about both standard and tailored CHC regimens to broaden contraceptive choice. **Regimes** • The vaginal ring can either be used as a standard regime or in a tailored regime depending on the choice of the individual. • The regimes which can be advised are detailed below:

Type of regimen	Period of CHC use	Hormone (ring) free interval
Standard use		
Standard use	21 days (1 ring)	7 days
Tailored use		
Shortened hormone-free interval	21 days (1 ring)	4 days
Extended use (tri-cycling)	9 weeks (3 rings)	4 or 7 days
Flexible extended use	Continuous use (≥21 days) of active rings until breakthrough bleeding occurs for 3–4 days	4 days
Continuous use	Continuous use of active rings	None

- For the regimes detailed above 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.
- 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.
- Thereafter the dosage regime detailed above should be followed. Individuals should have access to clear information (either written or digital) to support tailored CHC use.
- When starting or restarting the CHC as quick start after levonorgestrel emergency contraception, additional contraception is required for 7 days and a pregnancy test should be performed 21 days after the last unprotected sexual intercourse.
- In line with FSRH guidance individuals using hormonal contraception should delay restarting their regular hormonal contraception for 5 days following ulipristal acetate use. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective.
- For guidance on changing from one contraceptive method to another, and when to start after an abortion and postpartum,

	refer to the FSRH guidance.
Duration of treatment	• For as long as individual requires CHC and has no contraindications to the use of CHC.
Quantity to be supplied	**Nuvaring®** • A maximum supply of up to four months (maximum 6 rings) in appropriately labelled original packs. **Syreniring®** • A maximum supply of up to twelve months (maximum 18 rings) in appropriately labelled original packs.
Storage	**Nuvaring®** • The vaginal ring must be stored between 2-8°C prior to supplying to the individual. • 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. **Syreniring®** • This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from light. Medicines must be stored securely according to national guidelines.
Drug interactions	A detailed list of drug interactions is available in the individual product SPC, which is available from the electronic Medicines Compendium website www.medicines.org.uk the BNF www.bnf.org and FSRH CEU Guidance: Drug Interactions with Hormonal Contraception https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the individual product SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org The following possible adverse effects are commonly reported with CHC (but may not reflect all reported adverse effects): • Nausea • Breast tenderness • Headache • Temporary disturbances of bleeding patterns • Change in mood • Fluid retention Serious adverse effects - these are less common but the risks should be discussed with the individual: • Venous thromboembolic events (VTE) • Arterial thromboembolic events (ATE) including transient ischaemic attack, ischaemic stroke, heart attack and ischaemic heart disease • Hypertension

Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report via organisation incident policy.
Written information and 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 CHC use. • Explain mode of action, side effects, and benefits of the medicine. • Advise individual on insertion and removal of the vaginal ring and action to be taken if the ring becomes damaged or is accidently expelled. • Advise on correct storage (see Storage section above) and need to keep refrigerated at the correct temperature. • 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. **Serious symptoms:** the individual should stop taking the CHC 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 CHC is associated with a small increased risk of breast cancer which reduces with time after stopping CHC. • Individuals should be advised that current use of CHC is associated with an increased risk of VTE/ATE. • Individuals should be advised that current use of CHC for more than 5 years is associated with a small increased risk of cervical cancer; risk which reduces over time after stopping CHC and is no longer increased by about 10 years after stopping. • Individuals using CHC should be advised about reducing periods of immobility during travel. • Individuals trekking to high altitudes (above 4500m or 14500 feet) for periods of more than 1 week may be advised to consider switching to a safer alternative contraceptive method. • Individuals should be advised to stop CHC and to switch to an alternative contraceptive method at least 4 weeks prior to planned major surgery or expected period of limited mobility. • Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs)

	• Ensure the individual has contact details of local service/sexual health services.
Advice / follow up treatment	• The individual should be advised to seek medical advice in the event of an adverse reaction. • Individual should be encouraged to tell all clinicians that they are taking the supplied medication in the event of other medication/s being prescribed. • Individual to seek further advice if they has any concerns • Review annually.
Records	**Record:** • The consent of the individual and if individual over 16 years of age and not competent, record action taken • Name of individual, address, date of birth • GP contact details where appropriate • Relevant past and present medical history, including medication and family history. • Examination finding where relevant e.g. BMI, blood pressure. • Any known allergies • Name of registered health professional • Name of medication supplied • Date of supply • Dose supplied • Quantity supplied • Advice given, including advice given if excluded or declines treatment • Details of any adverse drug reactions and actions taken • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Any follow up and/or referral arrangements made • Any supply outside the terms of the product marketing authorisation • Recorded that supply is via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy. All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

Audit

Plan for audit, It is essential for PGD renewal that audits have occurred**.**	Service audit to be completed using the recommended BSUH PGD audit template. N. B. Individual PGD users should keep records to audit their own use of PGDs / procedures.
Frequency	Minimum of once in lifetime of PGD 2 years after start date of PGD to inform PGD review.
Nominated lead to manage audit	Advanced Nurse Practitioner, SHAC Service will manage Service PGD audit process and support / guide those completing the audit. SHAC Nurse(s) who use the PGD will complete the service audit.

4. Key references

Key references	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2 • Faculty of Sexual and Reproductive Health CEU Guidance: Drug Interactions with Hormonal Contraception (January 2017, last reviewed 2019) https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/ Faculty of Sexual and Reproductive Healthcare (2019) Combined Hormonal Contraception https://www.fsrh.org/standards-and-guidance/documents/combined-hormonal-contraception/ • Faculty of Sexual and Reproductive Healthcare (2016) UK Medical Eligibility Criteria for Contraceptive Use. https://www.fsrh.org/documents/ukmec-2016/ • Faculty of Sexual and Reproductive Healthcare (2016 Clinical Guideline: Quick Starting Contraception (April 2017) https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/ • Learning for Health https://portal.e-lfh.org.uk/ • BSUH policies and procedures: ➢ C085 – Policy for Patient Group Directions: accessed on BSUH intranet https://nww.bsuh.nhs.uk/search/?q=c085+policy+for+patient+group+directions ➢ SHAC Service Standard Operating Procedure for supply of medicines following telephone / video consultations.

Appendix A - Registered health professional authorisation sheet

PGD Name/Version: ***Supply of combined hormonal contraceptive vaginal ring / Version 1***

Valid from: June 2020 **Expiry: 31 March 2023**

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

Registered health professional

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

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

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

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

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Brighton and Sussex University Hospitals NHS Trust for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

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

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

SHAC SERVICE RETENTION OF PGD AUTHORISATION RECORDS

Records of the authorisation of nurses for the use of this PGD are stored as follows:

- **HARD COPY:**

  A paper copy of the signature sheet will be kept with the PGD in the PGD Master Copy File in the SHAC Nurse Management Office.

- **ELECTRONIC RECORD:**

  - A scanned copy of each authorisation sheet to be saved.
  - An electronic record of SHAC Nurse authorisation for this PGD will be stored on the SHAC Service PGD Assessment Record database.
  - The scanned authorisation sheets and the database are stored in the shared Integrated Sexual Health file (within the specific PGD file).

- **INDIVIDUALS:**

  Individual nurses are provided with the PGD assessment sheet which details the assessment process for PGD approval for their own records. A copy of this document is stored in the individual nurses' Personal File.