

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 a progestogen only contraceptive pill (POP) in Brighton and Sussex University Hospitals NHS Trust Sexual Health & Contraception (SHAC) Service**

Version Number 1.0

<b>Change History</b>	
<b>Version and Date</b>	<b>Change details</b>
Version 1 April 2020	New template

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## PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	1 <sup>st</sup> April 2020
Review date	October 2022
Expiry date:	31 <sup>st</sup> 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

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

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## PGD approval - meets local need and guidelines

Name	Job title and organisation	Signature	Date
<b>Lead author:</b> Reproductive Health PGDs Short Life Working Group	As listed on Page 2/3		
<b>Lead Doctor:</b> Dr Juliet Bowie	Associate Specialist, SHAC Service, BSUH	Email approval	02/07/20
<b>Lead pharmacist:</b> Claire Richardson	Lead Pharmacist, HIV & Sexual Health Service, BSUH	Email approval	07/07/20
<b>Lead Clinician for area:</b> Dr Debbie Williams	Consultant (HIV & GUM), SHAC, BSUH	Email approval	02/06/20
<b>Reviewed by:</b> Dr Daniel Richardson	Consultant HIV & SHAC Service, BSUH	Email approval	01/07/20
<b>Representative of other professional group using PGD:</b> 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
<b>Chair of PGD Group</b>	Joanne Pendlebury	Email approval 07/07/20
<b>Chief Pharmacist</b>	Mike Cross	Email approval 24/07/20
<b>Medicines Governance Group chair</b>	Mike Okorie	Email approval 27/07/20

Local enquiries regarding the use of this PGD may be directed to [Bsuh.pgdgroup@nhs.net](mailto: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.

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## 1. Characteristics of staff

<b>Qualifications and professional registration</b>	<p>Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation.</p> <p>Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.</p>
<b>Initial training</b>	<p>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.</p> <p>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.</p> <p>The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent.</p> <p>Register and complete PGD training module (certificate can be printed out as evidence) <a href="https://portal.e-lfh.org.uk/">https://portal.e-lfh.org.uk/</a> (3 yearly)</p> <p>Has undertaken training appropriate to recognise and manage allergic/anaphylactic reactions.</p> <p>Has undertaken appropriate Trust resuscitation training.</p>
<b>Competency assessment</b>	<ul style="list-style-type: none"> <li>• Individuals operating under this PGD must be assessed as competent (see section 7) or complete a self-declaration of competence for contraception supply.</li> <li>• Staff operating under this PGD are encouraged to review their competency using the <a href="#">NICE Competency Framework for health professionals using patient group directions</a></li> </ul>
<b>Ongoing training and competency</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Organisational PGD and/or medication training as required by employing Trust/organisation, including:             <ul style="list-style-type: none"> <li>➤ PGD e-learning 3 yearly</li> <li>➤ Up to date with mandatory training</li> </ul> </li> </ul>
<p>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.</p>	

## 2. Clinical condition or situation to which this PGD applies

<b>Clinical condition or situation to which this PGD applies</b>	Contraception
<b>Criteria for inclusion</b>	<ul style="list-style-type: none"> <li>• Individual (age from menarche to 55 years) presenting for contraception.</li> <li>• Consent given.</li> </ul>
<b>Criteria for exclusion</b>	<ul style="list-style-type: none"> <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 the active ingredient or to any constituent of the product - see <a href="#">Summary of Product Characteristics</a></li> <li>• Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them.</li> </ul> <p><b>Cardiovascular Disease</b></p> <ul style="list-style-type: none"> <li>• Current or past history of ischaemic heart disease, vascular disease, stroke or transient ischaemic first attack only if taking the method when the event occurred.</li> </ul> <p><b>Cancers</b></p> <ul style="list-style-type: none"> <li>• Current or past history of breast cancer.</li> <li>• Benign liver tumour (hepatocellular adenoma).</li> <li>• Malignant liver tumour (hepatocellular carcinoma).</li> </ul> <p><b>Gastro-intestinal conditions</b></p> <ul style="list-style-type: none"> <li>• Severe decompensated cirrhosis.</li> <li>• Any bariatric or other surgery resulting in malabsorption.</li> </ul> <p>Interacting medicines (other than enzyme inducers) – 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></p>
<b>Cautions including any relevant action to be taken</b>	<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 follow the local safeguarding policy.</li> <li>• Some brands of progestogen only contraceptive pills contain soya or soya lecithin and are therefore contraindicated in individuals with an allergy to soya or peanuts. If individual is allergic, check manufacturer's information for brand being used and if necessary, exclude from PGD or select an alternative suitable brand if available.</li> <li>• Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain.</li> <li>• Offer Long Acting Reversible Contraception (LARC) to all individuals in particular those with medical conditions for</li> </ul>

	<p>whom pregnancy presents an unacceptable risk and those on a pregnancy prevention plan.</p> <ul style="list-style-type: none"> <li>• 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 POP is not contra-indicated it may be less effective and so these individuals should be advised offered Long Acting Reversible Contraception (LARC).</li> <li>• If an individual is known to be taking a medication which is known to be harmful to pregnancy an additional barrier method of contraception is advised.</li> <li>• Women should be advised that it is possible that medications that induce diarrhoea and/or vomiting (e.g. orlistat, laxatives) could reduce the effectiveness of POP.</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 decline in the consultation record.</li> <li>• Where required refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options.</li> </ul>

### 3. Description of treatment

<b>Name, strength &amp; formulation of drug</b>	<ul style="list-style-type: none"> <li>• Desogestrel 75micrograms tablets</li> <li>• Levonorgestrel 30micrograms tablets</li> <li>• Norethisterone 350micrograms tablets</li> </ul> <p>Note:</p> <ul style="list-style-type: none"> <li>• The above names the generic component of available progestogen only contraceptive pills.</li> <li>• This PGD does not restrict which brands can be supplied – local formularies/restrictions should be referred to.</li> <li>• See <a href="http://www.mhra.gov.uk/spc-pil/">http://www.mhra.gov.uk/spc-pil/</a> or <a href="http://www.medicines.org.uk">http://www.medicines.org.uk</a> for further information and further brand information including full details of adverse effects and interactions.</li> </ul>
<b>Legal category</b>	POM
<b>Route of administration</b>	Oral
<b>Off label use</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, exclusion criteria and dosage regimens which are outside the market authorisation for many of the available products but which are included within FSRH guidance.</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</p>

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	<p>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.</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>
<b>Dose and frequency of administration</b>	<ul style="list-style-type: none"> <li>• Single tablet taken at the same time each day starting on day 1-5 of the menstrual cycle with no need for additional protection.</li> <li>• The POP can be started at any time after day 5 if it is reasonably certain that the individual is not pregnant. Additional precautions are then required for 48 hours after starting and advise to have follow up pregnancy test at 21 days.</li> <li>• When starting or restarting the POP as quick start after levonorgestrel emergency contraception, additional contraception is required for 48 hours.</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.</li> <li>• For guidance on changing from one contraceptive method to another, and when to start after an abortion and postpartum, refer to the Faculty of Sexual and Reproductive Healthcare (FSRH) guidelines</li> </ul>
<b>Duration of treatment</b>	<ul style="list-style-type: none"> <li>• For as long as individual requires POP and has no contraindications to the use of POP.</li> </ul>
<b>Quantity to be supplied</b>	<ul style="list-style-type: none"> <li>• Supply up to twelve months in appropriately labelled original packs.</li> </ul>
<b>Storage</b>	Medicines must be stored securely according to national guidelines.
<b>Drug interactions</b>	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>
<b>Identification &amp; management of adverse reactions</b>	<p>A detailed list of adverse reactions is available in the SPC, 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 POP (but may not reflect all reported adverse effects):</p> <ul style="list-style-type: none"> <li>• Acne</li> <li>• Breast tenderness</li> </ul>



	<ul style="list-style-type: none"> <li>• Headache</li> <li>• Disturbance of bleeding patterns</li> <li>• Changes in mood/libido</li> <li>• Weight change</li> </ul>
<b>Management of and reporting procedure for adverse reactions</b>	<ul style="list-style-type: none"> <li>• 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: <a href="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a></li> <li>• Record all adverse drug reactions (ADRs) in the patient's medical record.</li> <li>• Report via organisation incident policy.</li> </ul>
<b>Written information and further advice to be given to individual</b>	<ul style="list-style-type: none"> <li>• Provide patient information leaflet (PIL) provided with the original pack.</li> <li>• Individuals should be informed about the superior effectiveness of LARC.</li> <li>• Explain mode of action, side effects, and benefits of the medicine</li> <li>• Advise on action if vomits within two hours of taking the pill or in cases of prolonged vomiting or severe diarrhoea. See <a href="#">FSRH guidance</a>.</li> <li>• Advise on missed pill advice (missed pills; twelve hours after normal administration time for desogestrel; three hours after normal administration time for all other POPs). See <a href="#">FSRH guidance</a>.</li> <li>• Advise on risks of the medication including failure rates and serious side effects and the actions to be taken.</li> <li>• Advise that risk of any pregnancy is low during use of effective contraception. Of pregnancies that occur during use of the traditional POP, 1 in 10 may be ectopic</li> <li>• A follow up review should be undertaken annually.</li> <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> </ul>
<b>Advice / follow up treatment</b>	<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>• Individual to seek further advice if she has any concerns</li> <li>• Review annually.</li> </ul>
<b>Records</b>	<p><b>Record:</b></p> <ul style="list-style-type: none"> <li>• The consent of the individual and if individual over 16 years of age and not competent, record action taken</li> <li>• Name of individual, address, date of birth</li> <li>• GP contact details where appropriate</li> <li>• Relevant past and present medical history, including medication and family history.</li> <li>• Examination finding where relevant</li> <li>• Any known allergies</li> <li>• Name of registered health professional</li> <li>• Name of medication supplied</li> <li>• Date of supply</li> </ul>

	<ul style="list-style-type: none"> <li>• Dose supplied</li> <li>• Quantity supplied</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 referral arrangements made</li> <li>• Any supply outside the terms of the product marketing authorisation</li> <li>• Recorded that supply is via Patient Group Direction (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>
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## Audit

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

## 4. Key references

<b>Key references (accessed March 2020)</b>	<ul style="list-style-type: none"> <li>• Electronic Medicines Compendium <a href="http://www.medicines.org.uk/">http://www.medicines.org.uk/</a></li> <li>• Electronic BNF <a href="https://bnf.nice.org.uk/">https://bnf.nice.org.uk/</a></li> <li>• NICE Medicines practice guideline “Patient Group Directions” <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li> <li>• Faculty of Sexual and Reproductive Health Clinical Guideline: Progestogen-only Pills (March 2015, Amended April 2019) <a href="https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-pop-mar-2015/">https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-pop-mar-2015/</a></li> <li>• Faculty of Sexual and Reproductive Health CEU Guidance: Drug Interactions with Hormonal Contraception (January</li> </ul>
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	<p>2017, last reviewed 2019) <a href="https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/">https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/</a></p> <ul style="list-style-type: none"> <li>• Faculty of Sexual and Reproductive Healthcare (2019) Combined Hormonal Contraception <a href="https://www.fsrh.org/standards-and-guidance/documents/combined-hormonal-contraception/">https://www.fsrh.org/standards-and-guidance/documents/combined-hormonal-contraception/</a></li> <li>• Faculty of Sexual and Reproductive Healthcare (2016) UK Medical Eligibility Criteria for Contraceptive Use. <a href="https://www.fsrh.org/documents/ukmec-2016/">https://www.fsrh.org/documents/ukmec-2016/</a></li> <li>• Faculty of Sexual and Reproductive Healthcare (2016) Clinical Guideline: Quick Starting Contraception (April 2017) <a href="https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/">https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/</a></li> <li>• Learning for Health <a href="https://portal.e-lfh.org.uk/">https://portal.e-lfh.org.uk/</a></li> <li>• BSUH policies and procedures: <ul style="list-style-type: none"> <li>➤ C085 – Policy for Patient Group Directions: accessed on BSUH intranet <a href="https://nww.bsuh.nhs.uk/search/?q=c085+policy+for+patient+group+directions">https://nww.bsuh.nhs.uk/search/?q=c085+policy+for+patient+group+directions</a></li> <li>➤ SHAC Service Standard Operating Procedure for supply of medicines following telephone / video consultations</li> </ul> </li> </ul>
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## Appendix A - Registered health professional authorisation sheet

PGD Name/Version: **Supply of progestogen only pill (POP) / 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.

<b>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.</b>			
<b>Name</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>

### Authorising manager

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

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

Approved date **JUNE 2020**

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## **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.