Rotherham Doncaster and South Humber NHS Foundation 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 a progestogen only contraceptive pill (POP) in Rotherham, Doncaster and South Humber NHS Foundation Trust (RDaSH)

Version Number 2.0

Change History	
Version and Date	**Change details**
Version 1 April 2020	New template
Version 1.1 November 2020	Minor rewording and highlighting of contents caution section relating to individuals for whom pregnancy presents an unacceptable risk and those on a pregnancy prevention plan. Porphyria added as exclusion criteria.
Version 2.0 April 2023	Updated template – amended references and minor editing and wording changes/clarifications.

Reference Number: 2
Valid from: April 2023
Review date: September 2025
Expiry date: March 2026

PGD DEVELOPMENT GROUP

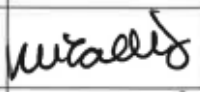
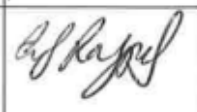
Date PGD template comes into effect:	April 2023
Review date	September 2025
Expiry date:	March 2026

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.

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

Name	Designation
Dr Cindy Farmer	Vice President, General Training Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Vicky Garner	Deputy Chief Midwife British Pregnancy Advisory Service (BPAS)
Gail Rowley	Quality Matron British Pregnancy Advisory Service (BPAS)
Katie Girling	British Pregnancy Advisory Service (BPAS)
Julia Hogan	CASH Nurse Consultant MSI Reproductive Choices
Kate Devonport	National Unplanned Pregnancy Advisory Service (NUPAS)
Chetna Parmar	Pharmacist adviser Umbrella
Helen Donovan	Royal College of Nursing (RCN)
Carmel Lloyd	Royal College of Midwives (RCM)
Clare Livingstone	Royal College of Midwives (RCM)
Kirsty Armstrong	National Pharmacy Integration Lead, NHS England
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Pharmacy Postgraduate Education (CPPE)
Dr Kathy French	Specialist Nurse
Dr Sarah Pillai	Associate Specialist
Alison Crompton	Community pharmacist
Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	NHS Northeast 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

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Dr Graeme Tosh	Medical Director		21/02/23
Stephen Davies	Chief Pharmacist		8/3/23
Kate McCandlish	Interim Director of Nursing		1/3/23
Anil Rajpal	Senior pharmacist		01/3/23
Tina Proctor	Nurse Consultant *Senior representative of professional group using the PGD*		21/3/23

Committee Approval:

NAME	**DATE**
Medicines Management Committee	17/02/2023

Date of Implementation	22/03/2023

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 individuals ensuring safe provision of the medicines listed in accordance with local policy. Suggested requirement for training would be successful completion of a relevant contraception module/course accredited or endorsed by the FSRH, CPPE or a university or as advised in the RCN training directory. The individual must have undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfH PGD elearning programme The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults, or level 2 safeguarding for adults and children, or equivalent
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix A) 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. • Organisational PGD and/or medication training as required by employing Trust/organisation.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Contraception
Criteria for inclusion	• Individual (age from menarche to 55 years) presenting for contraception. • Consent given.
Criteria for exclusion	• Consent not given. • Individuals under 16 years of age and assessed as not competent using Fraser Guidelines. • Individuals 16 years of age and over and assessed as lacking capacity to consent. • Established pregnancy. Note - risk of pregnancy with a negative pregnancy test is not an exclusion • Known hypersensitivity to the active ingredient or to any constituent of the product - see Summary of Product Characteristics • Individuals using enzyme-inducing medicines/herbal products or within 4 weeks of stopping them. • Acute porphyria **Cardiovascular Disease** • 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. **Cancers** • Current or past history of breast cancer. • Malignant liver tumour (hepatocellular carcinoma). **Gastro-intestinal conditions** • Severe decompensated cirrhosis. • Benign liver tumour (hepatocellular adenoma). • Any bariatric or other surgery resulting in malabsorption. **Medicines** Individuals taking any interacting medicines (other than enzyme inducers), including medicines purchased – see current British National Formulary (BNF) www.bnf.org or individual product SPC http://www.medicines.org.uk
Cautions including any relevant action to be taken	• If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. • If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy. • Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain. • 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). • Individuals should be advised that it is possible that medications that induce diarrhoea and/or vomiting (e.g.orlistat, laxatives) could reduce the effectiveness of POP. • **Offer LARC to all individuals in particular those with medical conditions for whom pregnancy presents an unacceptable risk and those on a pregnancy prevention plan.** • **If an individual is known to be taking a medication which is known to be harmful to pregnancy a highly effective form of contraception is recommended. Highly effective methods include the LARC methods: copper IUD, LNG-IUD and implant. If a LARC method is unacceptable/unsuitable and a POP is chosen then an additional barrier method of contraception is advised. See FSRH advice.**
Action to be taken if the individual is excluded or declines treatment	• Explain the reasons for exclusion to the individual and document in the consultation record. • Record reason for declining treatment in the consultation record. • Where appropriate refer the individual to a suitable health service provider and/or provide them with information about further options.

3. Description of treatment

Name, strength & formulation of drug	• Desogestrel 75micrograms tablets • Levonorgestrel 30micrograms tablets • Norethisterone 350micrograms tablets Note: • The above names the generic component of available progestogen only contraceptive pills. • This PGD does not restrict which brands can be supplied – local formularies/restrictions should be referred to. • Some desogestrel products contain excipients containing soya/nut – awareness of allergy may be required depending on product offered. • 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. **NOTE** this PGD template does not include drospirenone only oral contraception, as detailed in the FSRH POP guideline, as, at the time of this template's publication, there were no UK licensed formations available. This template will be reviewed as/when this position changes.

Legal category	POM
Route of administration	Oral
Off label use	Best practice advice is given by the FSRH and is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC). 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. 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	• Single tablet taken at the same time each day starting on day 1-5 of the menstrual cycle with no need for additional protection. • 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. • When starting or restarting the POP as quick start after levonorgestrel emergency contraception, additional contraception is required for 48 hours. • In line with FSRH guidance individuals using hormonal contraception should delay restarting their regular 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 Faculty of Sexual and Reproductive Healthcare (FSRH) guidelines
Duration of treatment	• For as long as the individual requires POP and has no contraindications to the use of POP.
Quantity to be supplied	• Supply up to twelve months in appropriately labelled original packs.

Storage	Medicines must be stored securely according to national guidelines.
Drug interactions	All concurrent medications, including those purchased should be considered for interactions. A detailed list of drug interactions is available in the individual product SPC, which is available from the electronic Medicines Compendium website www.medicines.org.uk the BNF www.bnf.org and FSRH CEU Guidance: Drug Interactions with Hormonal Contraception https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the 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 POP (but may not reflect all reported adverse effects): • Acne • Breast tenderness • Headache • Disturbance of bleeding patterns • Changes in mood/libido • Weight change
Management of and reporting procedure for adverse reactions	• Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the individual's clinical record. • Report via organisation incident policy.
Written information and further advice to be given to individual	• Provide manufacturer's information leaflet (PIL) provided within the original pack. • Individuals should be informed about the superior effectiveness of LARC. • Explain mode of action, side effects, and benefits of the medicine. • Advise on action if the individual vomits within two hours of taking the pill or in cases of prolonged vomiting or severe diarrhoea. See FSRH guidance. • Advise on missed pills (missed pills; twelve hours after normal administration time for desogestrel; three hours after normal administration time for all other POPs). See FSRH guidance. • Advise on risks of the medication including failure rates, serious side effects and the actions to be taken. • 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. • A follow up review should be undertaken annually. • Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs)

	• Ensure the individual has the contact details of local sexual health services. • Advise the individual to seek advice from a pharmacist, doctor or other prescriber before starting any new medications, including those purchased.
Advice / follow up treatment	• The individual should be advised to seek medical advice in the event of an adverse reaction. • The individual should seek further advice if they have any concerns. • Review annually.

Records	**Record:**
	• The consent of the individual and
	  ○ If individual is under 13 years of age record action taken
	  ○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.
	  ○ If individual over 16 years of age and not competent, record action taken
	• Name of individual, address, date of birth
	• GP contact details where appropriate
	• Relevant past and present medical history, including medication and family history.
	• Examination finding where relevant
	• Any known allergies
	• Name of registered health professional
	• Name of medication supplied
	• Date of supply
	• Dose supplied
	• Quantity supplied including batch number and expiry date in line with local procedures.
	• Advice given, including advice given if excluded or declines treatment
	• Details of any adverse drug reactions and actions taken
	• Advice given about the medication including side effects, benefits, and when and what to do if any concerns
	• Any 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.

4. Key references

Key references (accessed September 2022)	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2 • Faculty of Sexual and Reproductive Health Clinical Guideline: Progestogen-only Pills August 2022 https://www.fsrh.org/standards-and-guidance/documents/cec-guideline-pop/ • FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (May 2022) FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (May 2022) - Faculty of Sexual and Reproductive Healthcare • Faculty of Sexual and Reproductive Healthcare (2019, amended November 2020) Combined Hormonal Contraception https://www.fsrh.org/standards-and-guidance/documents/combined-hormonal-contraception/ • Faculty of Sexual and Reproductive Healthcare (2016, amended 2019) UK Medical Eligibility Criteria for Contraceptive Use. https://www.fsrh.org/documents/ukmec-2016/ • Faculty of Sexual and Reproductive Healthcare Clinical Guideline: Quick Starting Contraception (April 2017) https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/

Appendix A – example registered health professional authorisation sheet

PGD Name/Version: Progestogen only contraceptive pill (POP)
Valid from: 1st April 2023 Expiry: 31st March 2026

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 RDaSH NHS Foundation 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.

This information will be retained by the Chief Pharmacist of RDASH NHS Foundation

Trust.