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 insertion of Etonogestrel (e.g. Nexplanon®) 68mg subdermal implant for contraception by Registered Nurses and Midwives in BPAS Clinics.

Version Number 2.1

Change History	
Version and Date	Change Details
Version 1 October 2020	New template
Version 1.1 November 2020	Addition of acute porphyria to exclusion criteria *Version 1.1 not adopted by BPAS as clients with porphyria already excluded from treatment at BPAS.*
Version 1.2 June 2021	Special considerations – addition of the following wording: *Other possible complications of insertion and removal procedures include local reaction, nerve damage, and deep or intramuscular insertion.* *Version 1.2 authorised for use in BPAS 21/12/2022.*
Version 1.2 May 2023	Expiry date extended to full 3 year term from original authorisation of PGD in November 2020.
Version 2.0 May 2023	Updated template (no clinical changes to expired V1). Updated adverse effects and references. Removed statement relating to Covid-19. Minor changes to some wording and formatting. Aligned content with other PGDs for same or associated medicine / group. Updated PGD development group members.
Version 2.0 January 2024	PGD expiry date changed from 31/10/2026 to 31/08/2026 to align with SPS PGD template expiry. No other changes to PGD content. Version number unchanged.
Version 2.1 June 2024	Added note re low risk of breast cancer. Updated references. Updated SLWG.

Valid from: 01/08/2024
Review Date: 01/05/2026
Expiry Date: 31/08/2026

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 Executive Chair

Signature: 

Date: 22/08/2024

Glossary	
BPAS	British Pregnancy Advisory Service
BLS	Basic life support
BNF	British National Formulary
FSRH	Faculty of sexual and reproductive health
IUC	Intrauterine contraception
MHRA	Medicines Health Regulatory Agency
NICE	National Institute for Health and Care Excellence
NMC	Nursing and Midwifery Council
SmPC	Summary of medicinal product characteristics

PGD DEVELOPMENT GROUP

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 February 2023.

Name	Designation
Dr Cindy Farmer	Vice President, General Training FSRH
Michelle Jenkins	Advanced Nurse Practitioner FSRH
Vicky Garner	Consultant Midwife British Pregnancy Advisory Service (BPAS)
Sim Sesane	CASH Nurse Consultant MSI Reproductive Choices
Kate Devonport	National Unplanned Pregnancy Association (NUPAS)
Chetna Parmar	Pharmacist adviser Umbrella
Heather Randle	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 Postgraduate Pharmacy 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	ICB pharmacist
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Jo Jenkins	Lead Pharmacist PGDs and Medicine Mechanisms, Medicines Use and Safety, Specialist Pharmacy Service
Rosie Furner (Working Group Co-ordinator)	Governance Pharmacist, Medicines Use and Safety, Specialist Pharmacy Service

1. Characteristics of staff authorised to use this PGD:	
Qualifications and professional registration	• NMC Registered Nurse • NMC Registered Midwife With a current contract of employment with BPAS Practitioners must also fulfil the additional requirements listed below.
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 as advised in the RCN training directory. In addition, completion of the FSRH Letter of Competence (LOC) in Subdermal implants (LOC SDI-IR/LOC SDI-IO) or locally agreed additional training and been assessed as competent at the insertion and removal, if applicable of the subdermal implant. PGD users should have read thoroughly and be familiar with the FSRH IUC guidance. Individuals working under this PGD will be required to administer local anaesthesia in line with local protocols/PGDs. The healthcare professional must keep up to date with current FSRH guidance on the insertion site, including any relevant MHRA Drug Safety Updates. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent. Pharmacological knowledge relating to the administration and supply of the medicine, its uses, contraindications, dosage and adverse effects Additionally, practitioners: • Must have completed appropriate training for working under a PGD for the supply / administration of medicines (see training requirements in the BPAS PGD policy) • Must be familiar with the medicine and observant to changes in the BNF and Summary of Product Characteristics (SmPC) • Must be competent in the recognition and management of adverse reactions, including anaphylaxis • Must be competent in the administration of adrenaline for anaphylaxis and have up to date Basic Life Support (BLS) skills as a minimum • Must have access to the PGD and associated online resources **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.**

Competency Assessment	Practitioners working under this PGD are required to review their own competency using the NICE Competency Framework for Health Professionals using Patient Group Directions Practitioners working under this PGD must be assessed as competent or complete a self-declaration of competence to use this PGD (see appendix A). **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.**
Ongoing training and competency	• Practitioners must complete 3-yearly PGD Theory Refresher training and competency assessment • 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 • Practitioners must make sure they are aware of any changes to the recommendations for this medication • 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 • Practitioners are responsible for maintaining their competency to work under this PGD
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policy.	

2. Clinical condition or situation to which this PGD applies:	
Clinical condition or situation to which this PGD applies	Contraception
Inclusion criteria	• Any individual from menarche to 55 years presenting for contraception and who has no contraindications • Where appropriate individuals requiring insertion of this subdermal contraceptive implant should also meet the inclusion criteria of the lidocaine 1% PGD template (see PGD for lidocaine) • Consent given

Exclusion criteria	• Clients not suitable for treatment at BPAS *(N.B. please refer to BPAS suitability criteria)*
	• 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 hypersensitivity to the active ingredient or to any constituent of the product - see Summary of Product Characteristics (SmPC)
	• Established pregnancy. Note:
	  ○ Risk of pregnancy with a negative pregnancy test is not an absolute exclusion.
	  ○ A pregnancy test may be positive in the immediate post-abortion period even if the abortion is complete

	• Unexplained vaginal bleeding (suspicious of serious condition) before evaluation • Acute porphyria *(clients with this condition are already excluded from treatment at BPAS)* **Cardiovascular Disease** • Current or past history of ischaemic heart disease, vascular disease, stroke or transient ischaemic first attack only if these events first occurred during use of the etonogestrel implant. **Cancers** • Current or past history of breast cancer. • Benign liver tumour (hepatocellular adenoma). **Gastro-intestinal conditions** • Severe decompensated cirrhosis. • Malignant liver tumour (hepatocellular carcinoma). **Interacting medicines** • Individuals using enzyme-inducing drugs/herbal products or within 28 days of stopping them. See Interactions section.
Cautions/Circumstances in which further advice should be sought (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 refer to the BPAS Safeguarding and Management of Clients Aged under 18 policy • If the individual is taking any anticoagulant therapy, an experienced clinician should perform the procedure due to the risk of bleeding and a pressure bandage should be applied after insertion. See Management of women taking anticoagulants or antiplatelet medications who request intrauterine contraception or subdermal implants for information about timing the insertion in relation to the anticoagulant dose • Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain.
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.
Arrangements for referral for medical advice	• Inform and discuss with the doctor in clinic. If not available, discuss with a regional clinical director • 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 • Document findings/action taken in client's record

3. Description of treatment:	
Name, strength and formulation medicine	Etonogestrel 68 mg subdermal implant
Legal category	POM

Route / method of administration	Superficial subdermal implant inserted, preferably into non-dominant arm, under aseptic conditions following administration of local anaesthetic, where appropriate (see PGD for lidocaine 1% injection). Manufacturer (SmPC) and current MHRA guidance must be followed.
Indicate any off-label use (if relevant)	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 (SmPC). This PGD includes the following unlicensed use(s): • Insertion in individuals over 40 years of age • Insertion in individuals under 18 years of age • Active venous thromboembolic disorder • The implant may be inserted or reinserted at any time as a quick start method if it is reasonably certain that the individual is not pregnant. Additional contraception is then required for 7 days after insertion. • The implant may be inserted immediately post-partum and after 2nd trimester abortion or miscarriage. • The implant may be inserted at any time after mifepristone administration at medical abortion or at any stage in a surgical abortion process. Medicines should be stored according to the conditions detailed in the Storage section below. 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 that the medicine is being offered in accordance with national guidance but that this is outside the product licence.
Dose and frequency of administration	• Insert or change implant every 3 years. Implants should be removed once expired and/ or prior to inserting a new implant. • Insert between day 1-5 of the menstrual cycle with no need for additional precautions • The implant may be inserted or reinserted at any time as quick start if it is reasonably certain that the individual is not pregnant. Additional contraception is then required for 7 days after insertion • If the individual has an implant in situ which has been in place for under 3 years the implant can be removed and replaced immediately. • If the individual has an implant in situ which has been in place for over 3 but less than 4 years the implant can be removed and replaced immediately. A pregnancy test should be performed and if negative* replace the implant and advise additional contraception for 7 days after insertion with a repeat pregnancy test after 3 weeks. • If the individual has an implant in situ which has been in place for over 4 years the implant can be removed and replaced immediately. A pregnancy test should be performed and if negative* replace the implant and advise additional contraception for 7 days after insertion with a repeat pregnancy test after 3 weeks. • If inserting the implant after levonorgestrel emergency contraception, a barrier contraception is required for 7 days.

	• After the use of ulipristal acetate emergency contraception the implant should not be inserted for five days. A barrier contraceptive should then be used for a further 7 days. • A pregnancy test is advised three weeks after any oral emergency contraception - see FSRH guidance • For guidance on changing from one contraceptive method to another, and when to start after an abortion, miscarriage and post-partum refer to FSRH guidelines. * Note: a pregnancy test may be positive in the immediate post-abortion period even if the abortion is complete
Duration of treatment	• Each implant is effective for three years. • Repeat implants can be inserted for as long as the individual requires the implant and has no contraindications to its use.
Special considerations	There have been rare reports of local and distant intravascular migration of Nexplanon® implants. An implant that cannot be palpated at the insertion site should be located as soon as possible; if unable to locate implant within the arm, the MHRA recommends using chest imaging. Refer individual with suspected migration as required. Correct subdermal insertion reduces the risk of these events. Insertion or removal of the implant may cause some bruising, including haematoma in some cases, slight local irritation, pain or itching. Other possible complications include nerve damage, and deep or intramuscular insertion. Insertion of the implant may cause vasovagal reactions (such as hypotension, dizziness, or syncope).
Storage	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: www.medicines.org.uk
Drug interactions	Individuals using enzyme-inducing drugs/herbal products or within 28 days of stopping them are excluded from this PGD. Refer to FSRH CEU Guidance: Drug Interactions with Hormonal Contraception for further detail. All concurrent medications, including those purchased should be considered for interactions. A detailed list of drug interactions is available in the individual product SmPC, which is available from the electronic Medicines Compendium website www.medicines.org.uk the BNF www.bnf.org and FSRH CEU Guidance: Drug Interactions with Hormonal Contraception https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ Refer to a prescriber if any concern of a clinically significant drug interaction.
Identification and management of adverse reactions	A detailed list of adverse reactions is available in the SmPC, which is available from the electronic Medicines Compendium and BNF The implant is generally well tolerated. The main reported side effects include: **Common** • Irregular, unpredictable bleeding which includes amenorrhoea, frequent or prolonged bleeding • Headache

	• Acne • Breast tenderness and pain **Less common** • Mood changes • Reduced libido • Nausea • Fluid retention • Some local scarring If overdose or severe adverse reaction suspected manage following local policy. If necessary, seek appropriate emergency medical advice and assistance.
Additional facilities and supplies	• Access to working telephone • Suitable waste disposal facilities • Immediate access to in-date anaphylaxis kit (IM adrenaline 1:1000)
Management and reporting procedure for adverse reactions	Document any adverse effects in the client's clinical records. If necessary, seek appropriate emergency medical advice and assistance as clinically indicated. Serious adverse drug reactions should be reported to the MHRA via https://yellowcard.mhra.gov.uk/ Adverse drug reactions must also be reported via Datix, including drug name, strength, formulation, batch numbers and expiry dates.
Written information and further advice to be given to the individual or carer	• Ensure access to product information prior to insertion or supply of the medicine and especially discuss the side effects and how to report. • Provide Manufacturer's Patient Information Leaflet (PIL). • Explain mode of action, side effects, and benefits of the medicine. • Advise that limited evidence suggests no increased risk of venous or arterial thromboembolic events associated with use of the implant. • Advise on need for additional barrier method and pregnancy test as appropriate. • How to care for the insertion site and advise to return (or where to seek advice) if concerns about insertion site • Advise that a change in bleeding pattern is likely and provide clear, accessible information about possible bleeding patterns and advise how to access support for management of problematic bleeding and advise to return (or where to seek advice) if they are concerned or if irregular bleeding persists. • Individuals should be advised that intravascular insertion and distant migration are rare complications of the implant insertion procedure. Advise individual to return (or where to seek advice) if unable to palpate implant, it changes shape or individual develops pain around the site. • Individuals should be advised that current use of progestogen-only contraceptives is associated with a small increased risk of breast cancer which reduces with time after stopping • Give information on who to contact in the event of an adverse reaction or concerns. • Provide verbal and written information on the implant.
Follow-up advice to be given to the individual or carer	Advise individual: • How long the implant lasts for – when they need to arrange for removal and replacement. • To return to clinic (or where to seek advice) if they have any concerns.

Records to be kept	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:
	
	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
	• GP contact details where appropriate
	• Attendance date
	• Reason for attendance
	• Relevant past and present medical and family history, including drug history
	• Any known allergy
	• Relevant examination findings
	• Inclusion or exclusion from PGD
	• Advice given about the implant including side effects, benefits, and when and what to do if any concerns
	• Details of any adverse drug reactions and what action taken
	• Any administration outside the marketing authorisation
	• Record the name/brand, dose of the medication, site of insertion (including which arm and exact location), and palpation of implant following procedure by both the nurse and the individual
	• Batch number and expiry date of product in line with local procedure
	• Record any referral, follow up and/or signposting arrangements
	• Any other relevant information that was provided to the individual
	• A statement that supplies and insertion is by using a PGD
	• Name and signature (which may be an electronic signature) of the clinician supplying and administering the medicine
	
	Records should be signed and dated (or a password-controlled e-records) and securely kept for a defined period in line with local policy.
	
	A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.
	
	All records should be clear, legible and contemporaneous.

4. References and other source material:

- 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
- National Institute of Health and Clinical Excellence; Long-Acting Reversible Contraception CG30 (2005) Last updated September 2014 https://www.nice.org.uk/guidance/cg30
- FSRH Clinical Guideline: Progestogen-only Implant (February 2021) https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-implants-feb-2014/
- Faculty of Sexual and Reproductive Healthcare (2016) UK Medical Eligibility Criteria for Contraceptive Use https://www.fsrh.org/standards-and-guidance/documents/ukmec-2016/
- CEU Clinical Guidance: Drug Interactions with Hormonal Contraception - November 2017 https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/

- FSRH Clinical Guidance: Quick Starting Contraception - April 2017
- https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/
- Faculty of Sexual and Reproductive Healthcare (2015) Problematic bleeding with hormonal contraception https://www.fsrh.org/documents/ceuguidanceproblematicbleedinghormonalcontraception/
- Faculty of Sexual and Reproductive Healthcare (2014) Contraceptive choices for women with cardiac disease https://www.fsrh.org/documents/ceu-guidance-contraceptive-choices-for-women-with-cardiac/
- Faculty of Sexual and Reproductive Healthcare (2017) Contraception After Pregnancy https://www.fsrh.org/news/new-fsrh-guideline--contraception-after-pregnancy/

- Faculty of Sexual and Reproductive Healthcare (2023)

Response to new study on use of combined and progestogen-only hormonal contraception and breast cancer risk.
FSRH Response to new study on use of CHC and POC and breast cancer risk (March 2023) - Faculty of Sexual and Reproductive Healthcare

- Medicines and Healthcare Regulatory Agency (2016)

Nexplanon (etonogestrel) contraceptive implants: reports of device in vasculature and lung

- Nexplanon (etonogestrel) contraceptive implants: reports of device in vasculature and lung - GOV.UK (www.gov.uk)
- UK Resuscitation Council, 2021. Adult basic life support Guidelines | Resuscitation Council UK

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).

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

Patient Group Direction (PGD) name:	Insertion of etonogestrel (e.g. Nexplanon®) 68mg subdermal implant for contraception v2.1	
	Valid from: 01/08/2024	**Expiry: 31/08/2026**

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 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.				
Name (print)	**Designation**	**NMC PIN**	**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 for the above named health care professionals who have signed the PGD to work under it.				
Name	**Position**	**BPAS Treatment Unit**	**Signature**	**Date:**

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.