



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)

Insertion of etonogestrel (e.g. Nexplanon®) 68mg subdermal implant for contraception in York and North Yorkshire Sexual health services including specialist clinical outreach services

Version Number 1.2

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 1.2 June 2021	Special considerations – addition of the following wording: <i>Other possible complications of insertion and removal procedures include local reaction, nerve damage, and deep or intramuscular insertion.</i>

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.

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	1st October 2020
Review date	March 2023

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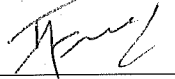




This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in September 2020.

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 (EHSCHG)
Deborah Redknapp	English HIV and Sexual Health Commissioners Group (EHSCHG)
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
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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 (Working Group Co-ordinator)	Specialist Pharmacist PGDs Specialist Pharmacy Service
Silvia Ceci	Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service

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ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor	Ian Fairley, Lead Consultant		07/04/22
Senior pharmacist	Jill McEnaney ^{KATE NORTH}		11/8/22
Senior representative of professional group using the PGD	Simone Layton, Advanced Nurse Specialist		9/6/22
Person signing on behalf of <u>authorising body</u>	Jennie Booth, Lead Nurse Medicines Management		4.8.2022
	Stuart Parkes, Chief Pharmacist		15/8/22

PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct. Individual practitioners must declare that they have read and understood the Patient Group Direction and agree to supply/administer medication(s) listed only in accordance with the PGD.

- Trust PGD policy is available via on Staff Room
- An audit must be completed at renewal- see Trust PGD Policy for audit requirements

1. Characteristics of Staff

The practitioner should be aware of any change to the recommendations for Nexplanon and current guidance from national authorities e.g. the BNF and NICE.

It is the responsibility of the individual to keep up to date with continued professional development and to work within the limitations of their individual scope of practice

Qualifications and professional registration	<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>
Initial training	<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 general 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/LOC SDI-IO) or locally agreed additional training and been assessed as competent at the insertion and removal of the subdermal implant.</p> <p>Individuals working under this PGD will be required to administer local anaesthesia in line with local PGD –Administration of lidocaine hydrochloride 1% injection to facilitate insertion and/or removal of subdermal etonogestrel.</p> <p>The healthcare professional must keep up to date with current FSRH guidance on the insertion site, including any relevant MHRA Drug Safety Updates.</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>The healthcare professional must ensure that they have an up to date certificate for Basic Life Support (BLS) and anaphylaxis as required by the employing Trust/organisation</p>
Competency assessment	<ul style="list-style-type: none"> • 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 <u>NICE Competency Framework for health professionals using patient group directions</u>
Ongoing training and competency	<ul style="list-style-type: none"> • 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. • Completion of Trust PGD HUB e-learning
<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

Clinical condition or situation to which this PGD applies	Long-acting reversible contraception (LARC)
Criteria for inclusion	<ul style="list-style-type: none"> 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)
Criteria for exclusion	<ul style="list-style-type: none"> 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 <u>Summary of Product Characteristics (SPC)</u> Unexplained vaginal bleeding (suspicious of serious condition) before evaluation Acute porphyria <p>Cardiovascular Disease</p> <ul style="list-style-type: none"> 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. <p>Cancers</p> <ul style="list-style-type: none"> Current or past history of breast cancer. <p>Gastro-intestinal conditions</p> <ul style="list-style-type: none"> Severe decompensated cirrhosis. Benign liver tumour (hepatocellular adenoma). Malignant liver tumour (hepatocellular carcinoma). <p>Interacting medicines</p> <ul style="list-style-type: none"> Individuals using enzyme-inducing drugs/herbal products or within 28 days of stopping them. Interacting medicines other than enzyme inducers – see current British National Formulary (<u>BNF</u>) or individual product <u>SPC</u>
Cautions including any relevant action to be taken	<ul style="list-style-type: none"> 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. 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 <u>Management of women taking anticoagulants or antiplatelet medications who request</u>

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	<p><u>intrauterine contraception or subdermal implants for information about timing the insertion in relation to the anticoagulant dose</u></p> <ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	Etonogestrel 68 mg subdermal implant
Legal category	POM
Route of administration	<p>Superficial subdermal implant inserted, preferably into non-dominant arm, under aseptic conditions following administration of local anaesthetic (see PGD for lidocaine 1% injection).</p> <p>Manufacturer (SPC) and current MHRA guidance must be followed.</p>
Off label use	<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 the following unlicensed use(s):</p> <ul style="list-style-type: none"> • 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. <p>Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where medicines have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release</p>

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	<p>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 that the medicine is being offered in accordance with national guidance but that this is outside the product licence.</p>
Dose and frequency of administration	<ul style="list-style-type: none"> • Insert once every three years. • 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 over 3 but less than 4 years the implant can be removed and replaced. A pregnancy test should be performed and if negative replace the implant and advise additional contraception is then required 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.
Duration of treatment	<ul style="list-style-type: none"> • 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. • Note: In exceptional circumstances such as during the Covid-19 pandemic when there may be significant health risk associated with implant removal/replacement procedures, extended use of an etonogestrel implant may be considered. See FSRH guidance
Special considerations	<p>There have been rare reports of local and distant intravascular migration of Nexplanon® implants. An implant that cannot be palpated at its insertion site should be located and removed 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.</p> <p>Correct subdermal insertion reduces the risk of these events.</p> <p>Other possible complications of insertion and removal procedures include local reaction, nerve damage, and deep or intramuscular insertion.</p>
Storage	<p>Medicines must be stored securely according to national guidelines.</p>

Drug interactions	A detailed list of drug interactions is available in the individual product SPC, which is available from the <u>electronic Medicines Compendium</u> , the <u>BNF</u> and FSRH CEU Guidance: <u>Drug Interactions with Hormonal Contraception</u>
Identification & management of adverse reactions	<p>A detailed list of adverse reactions is available in the SPC, which is available from the <u>electronic Medicines Compendium</u> and <u>BNF</u></p> <p>The implant is generally well tolerated. The main reported side effects include:</p> <p>Common</p> <ul style="list-style-type: none"> • Irregular, unpredictable bleeding which includes: amenorrhoea, frequent or prolonged bleeding • Headache • Acne • Breast tenderness and pain <p>Less common</p> <ul style="list-style-type: none"> • Mood changes • Reduced libido • Nausea • Fluid retention • Some local scarring
Additional facilities and supplies	<ul style="list-style-type: none"> • Access to working telephone • Suitable waste disposal facilities • Immediate access to in-date anaphylaxis kit (IM adrenaline 1:1000)
Management of and reporting procedure for adverse reactions	<ul style="list-style-type: none"> • Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the <u>Yellow Card reporting scheme</u> • Record all adverse drug reactions (ADRs) in the individual's medical record. • Report via organisation incident policy.
Written information and further advice to be given to individual	<ul style="list-style-type: none"> • 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

	<p>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.</p> <ul style="list-style-type: none"> • Give information on who to contact in the event of an adverse reaction or concerns. • Provide verbal and written information on the implant.
Advice/follow up treatment	<p>Advise individual:</p> <ul style="list-style-type: none"> • 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	<p>Record:</p> <ul style="list-style-type: none"> • The consent of the individual and <ul style="list-style-type: none"> ○ 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 • Record batch number and expiry date according to local policy or national guidelines • Record any referral, follow up and/or signposting arrangements • Any other relevant information that was provided to the individual • A statement that supply and insertion is by using a PGD • Name and signature (which may be an electronic signature) of the nurse supplying and administering the medicine <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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4. Key references

<p>Key references (accessed March 2020)</p>	<ul style="list-style-type: none"> • 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/
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Appendix A - Registered health professional authorisation sheet

PGD - Insertion of etonogestrel (e.g. Nexplanon®) 68mg subdermal implant for contraception v1 Valid from: March 2022 Expiry: 31st August 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 York & Scarborough Teaching Hospitals 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.

When the expiry date is exceeded, this PGD ceases to be a legal document. Staff authorisation records must be maintained for 8 years if the PGD relates to adults only, 10 years for implants and 25 years after the expiry date if the PGD relates to children