NHS Grampian | NHS Highland | NHS Orkney | NHS Shetland | NHS Tayside | NHS Eileanan Siar Western Isles

Patient Group Direction For The Insertion Of The 68mg Etonogestrel Implant (Nexplanon®) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Lead Author: Adapted from FSRH/SPS and Patient Group Direction (PGD) Insertion of etonogestrel (e.g. Nexplanon®) 68mg subdermal implant for contraception, Version 2.1 – Date Published April 2024		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/Nexplanon/1282	**Review Date:** March 2026 **Expiry Date:** August 2026	**Date Approved by NoS:** 28th January 2025

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 2.1

Revision History for NoS:

NoS PGD that has been superseded	Supersedes PGD NoS/PGD/Nexplanon/MGPG1282, Version 2	
Date of change	**Summary of Changes**	**Section heading**
December 2024	Transferred onto SPS template format for updated version.	
December 2024	Safeguarding training added.	Initial training
December 2024	Removed SPS advised training and TURAS NoS PGD training link added.	Initial Training
December 2024	Reference to NoS Appendix 1 and 2.	Authorisation
December 2024	Added in statement about capacity under the age of 13 and the legislation statement added.	Criteria for inclusion
December 2024	Link added to NoS PGD for Insertion/removal of Nexplanon® implant under local.	Criteria for inclusion
December 2024	NICE Competency framework statement removed.	Competency assessment
December 2024	DATIX reporting added.	Management of and reporting procedure for adverse reactions
December 2024	Added clinical systems utilised.	Records
December 2024	HEPMA added.	Records

FSRH/SPS Most Recent Changes

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: *Other possible complications of insertion and removal procedures include local reaction, nerve damage, and deep or intramuscular insertion.*
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 2.1 April 2024	Added note regarding low risk of breast cancer. Updated references. Updated SLWG.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Authorisation

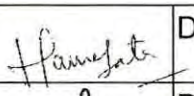
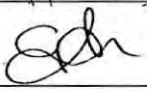
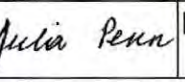
This specimen Patient Group Direction (PGD) template has been produced by Specialist Pharmacy Service (SPS)/ Faculty of Sexual & Reproductive Healthcare (FSRH) and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer medicines under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all medicines administered in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the medicines has to be by the same practitioner who has assessed the patient under the PGD.

All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1).

A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

This PGD has been produced for NoS by:					
Doctor	Dr Hame Lata	Signature		Date Signed	17/12/2024
Pharmacist	Gayle Anderson	Signature		Date Signed	08/01/2025
Nurse	Julia Penn	Signature		Date Signed	16/12/2024

Approved for use within NoS by:

NoS Group Chair	**Signature**	**Date Signed**
Lesley Coyle		20/01/2025

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Adam Coldwells – Interim Chief Executive		28/01/2025

Version 2.1 – Approved for NoS from 28th January 2025

PGD DEVELOPMENT GROUP	
Date PGD template comes into effect:	September 2023
Review date:	March 2026
Expiry date:	August 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 April 2023. Note the working group and approving organisation(s) agreement to the content only applies to the national template and does not extend to any local adaptations made to any of the content which are solely the responsibility of the organisation authorising the PGD. The most up to date version of the template is available here: https://www.sps.nhs.uk/home/guidance/patient-group-directions/templates/

This section must remain when a PGD is adopted by an organisation.

Name	Designation
Dr Cindy Farmer	Vice President, Professional Learning and Development 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)
Alison Crompton	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

Qualifications and professional registration	Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
Initial training	The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with local policy. Have undertaken NoS PGD module training on TURAS Learn. 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-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. 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. 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.
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix 1 and Appendix 2) or complete a self-declaration of competence for contraception supply.

Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required. • Organisational PGD and/or medication training as required by employing Trust/organisation.
The decision to administer 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	• Any individual from menarche to 55 years presenting for contraception and who has no contraindications. • Individual under 16 years of age may give consent for the Insertion Of The 68mg Etonogestrel Implant (Nexplanon®) provided they understand fully the benefits and risks involved. The individual should be encouraged to involve a parent/guardian, if possible, in this decision. Where there is no parental involvement and the individual indicates that they wish to accept the supply, supply should proceed, if the healthcare professional deems the individual to have the legal capacity to consent. The Age of Legal Capacity (S) Act 1991, s2 (4) states that 'a person under the age of 16 years shall have legal capacity to consent on their own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending them, they are capable of understanding the nature and possible consequences of the procedure or treatment. • Individuals requiring insertion of Nexplanon® should also meet the inclusion criteria of the PGD for the Administration of Lidocaine 1% Injection for the Insertion/Removal of 68mg Etonogestrel Implant (Nexplanon®) by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles. The PGD for lidocaine 1% must be used in conjunction with this PGD. • 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. • Known hypersensitivity to the active ingredient or to any constituent of the product - see Summary of Product Characteristics (SPC) • Established pregnancy. Note - risk of pregnancy with a negative pregnancy test is not an absolute exclusion. • Unexplained vaginal bleeding (suspicious of serious condition) before evaluation. • Acute porphyria. **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 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.

	• 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.

3. Description Of Treatment

Name, strength & formulation of drug	Etonogestrel 68mg subdermal implant.
Legal category	POM
Route 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 (SPC) and current MHRA guidance must be followed.
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 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.
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	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
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 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/

	Refer to a prescriber if any concern of a clinically significant drug interaction.
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SPC, 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.
Additional facilities and supplies	• 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	• Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme • Record all adverse drug reactions (ADRs) in the individual's medical record. • Report via DATIX incident policy.

Written information and further advice to be given to individual	• 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.
Advice/follow up treatment	**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	**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 supply 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. All records should be clear, legible and contemporaneous. Depending on the clinical setting where insertion is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • NaSH – Sexual Health Electronic Patient Record • BadgerNet – Digital Maternity Notes • HEPMA • Individual's GP records if appropriate • Individual service specific systems. 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 February 2024)	• 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 revised July 2019 https://www.nice.org.uk/guidance/cg30 • FSRH Clinical Guideline: Progestogen-only Implant (February 2021) Progestogen-only Implants | FSRH • Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception – May 2022 FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (May 2022) | FSRH • Faculty of Sexual and Reproductive Healthcare (2016) UK Medical Eligibility Criteria for Contraceptive Use. UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) | FSRH • Faculty of Sexual and Reproductive Healthcare Clinical Guideline: Quick Starting Contraception (April 2017) FSRH Clinical Guideline: Quick Starting Contraception (April 2017) | FSRH • FSRH Clinical Guideline: Problematic Bleeding with Hormonal Contraception (July 2015) FSRH Clinical Guideline: Problematic Bleeding with Hormonal Contraception (July 2015) | FSRH • Faculty of Sexual and Reproductive Healthcare (2014) Contraceptive choices for women with cardiac disease FSRH Clinical Guideline: Contraceptive Choices for Women with Cardiac Disease (June 2014) | FSRH • Faculty of Sexual and Reproductive Healthcare (2017) Amended October 2020 Contraception After Pregnancy Contraception After Pregnancy | FSRH • 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) | FSRH • 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)

Appendix 1 - Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Insertion Of The 68mg Etonogestrel Implant (Nexplanon®) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles, Version 2.1

I have completed the appropriate training to my professional standards enabling me to administer the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2 - Healthcare Professionals Authorisation to Administer Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administer the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to administer the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
Patient Group Direction For The Insertion Of The 68mg Etonogestrel Implant (Nexplanon®) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles, Version 2.1
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date