Patient Group Direction For The Insertion Of The Etonogestrel Implant Nexplanon® By Nurses and Midwives Working Within NHS Grampian

<table>
<thead>
<tr>
<th>Lead Author:</th>
<th>Consultation Group:</th>
<th>Approver:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultant in Sexual and Reproductive Health</td>
<td>See relevant page in the PGD</td>
<td>Medicine Guidelines and Policies Group</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Signature:</th>
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<tr>
<td>[Signature]</td>
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<table>
<thead>
<tr>
<th>Identifier:</th>
<th>Review Date:</th>
<th>Date Approved:</th>
</tr>
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<tbody>
<tr>
<td>NHSG/PGD/Nexplanon/MGPG886</td>
<td>June 2019</td>
<td>June 2017</td>
</tr>
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<table>
<thead>
<tr>
<th>Expiry Date:</th>
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<tr>
<td>June 2020</td>
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</table>

A Patient Group Direction is a specific written instruction for the supply or administration of named medicines in an identified clinical situation. It is drawn up locally by Doctors, Pharmacists and other appropriate professionals, approved by the employer and advised by the relevant professional advisory committees. In most cases, appropriate clinical care is provided on an individual basis by a specific prescriber to a specific individual patient. Patient Group Directions should only be considered where they offer a benefit to patient care without compromising patient safety in any way.

Uncontrolled when printed

Version 3
Revision History:

<table>
<thead>
<tr>
<th>Date of change</th>
<th>Approval date of PGD that is being superseded</th>
<th>Summary of Changes</th>
<th>Section heading</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 2017</td>
<td>April 2014</td>
<td>Age range extended 13-54 inclusive.</td>
<td>Inclusions</td>
</tr>
<tr>
<td>June 2017</td>
<td>April 2014</td>
<td>Specify that Nexplanon&lt;sup&gt;®&lt;/sup&gt; does not affect breast feeding.</td>
<td>Precautions</td>
</tr>
<tr>
<td>June 2017</td>
<td>April 2014</td>
<td>Added information about release rate over time.</td>
<td>Form/strength</td>
</tr>
<tr>
<td>June 2017</td>
<td>April 2014</td>
<td>Clearer specification of insertion site. Specify that new device should only be fitted through same incision if removal straightforward. Specify 1% not 2% lidocaine for fit/removal.</td>
<td>Route/ method of administration</td>
</tr>
<tr>
<td>June 2017</td>
<td>April 2014</td>
<td>State that BMI/ weight does not affect duration of effect.</td>
<td>Duration</td>
</tr>
<tr>
<td>June 2017</td>
<td>April 2014</td>
<td>Added information about HIV medication. Added information supporting use with concurrent lamotrigine.</td>
<td>Concurrent medication</td>
</tr>
<tr>
<td>June 2017</td>
<td>April 2014</td>
<td>Section re-written – more information about bleeding pattern, progestogenic side effects, resolution of side effects and chloasma.</td>
<td>Adverse reactions</td>
</tr>
<tr>
<td>June 2017</td>
<td>April 2014</td>
<td>Addition of Etonogestrel Implant.</td>
<td>Definition of situation/condition</td>
</tr>
<tr>
<td>June 2017</td>
<td>April 2014</td>
<td>Clarity around ages, greater than 54 years changed to 55 years or over.</td>
<td>Exclusion Criteria</td>
</tr>
<tr>
<td>June 2017</td>
<td>April 2014</td>
<td>Refer to medical professional added.</td>
<td>Action if Patient Declines Treatment</td>
</tr>
<tr>
<td>June 2017</td>
<td>April 2014</td>
<td>Information regarding release rate removed.</td>
<td>Form/Strength</td>
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</tr>
<tr>
<td>June 2017</td>
<td>April 2014</td>
<td>Lidocaine PGD reference added.</td>
<td>Route/Method of Administration and Facilities and Supplies Required.</td>
</tr>
<tr>
<td>June 2017</td>
<td>April 2014</td>
<td>Change in wording regarding implants to be removed.</td>
<td>Duration of Treatment</td>
</tr>
<tr>
<td>June 2017</td>
<td>April 2014</td>
<td>SRH Abbreviation written in full.</td>
<td>Advice to Patient (Verbal)</td>
</tr>
<tr>
<td>June 2017</td>
<td>April 2014</td>
<td>Nexplanon® user card added.</td>
<td>Advice to Patient (Written)</td>
</tr>
<tr>
<td>June 2017</td>
<td>April 2014</td>
<td>References updated to include FRSH.</td>
<td>References and Definition of situation/condition</td>
</tr>
</tbody>
</table>

**Subject:** Patient Group Direction  
**Identifier:** NHSG/PGD/Nexplanon/MGPG886  
**Replaces:** NHSG/PGD/Nexp/MGPG555, Version 2  
**Keyword(s):** PGD patient group direction nurses midwives contraception implant etonogestrel nexplanon

**Policy Statement:** It is the responsibility of individual nurse or midwife and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect patient, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

**Review date:** The review date for a PGD needs to be decided on a case-by-case basis in the interest of patient safety. The expiry date should not be more than 3 years from the date the PGD was authorised.

**Document:**  
Drafted: April 2017  
Completed: June 2017  
Approved: July 2017 (published – August 2017)
Patient Group Direction For The Insertion Of The Etonogestrel Implant Nexplanon® By Nurses and Midwives Working Within NHS Grampian

Clinical indication to which this PGD applies

<table>
<thead>
<tr>
<th>Definition of situation/condition</th>
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<tbody>
<tr>
<td>This Patient Group Direction (PGD) will authorise nurses and midwives to insert Etonogestrel Implant Nexplanon®, a progestogen implant for contraception.</td>
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</table>

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
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</thead>
<tbody>
<tr>
<td>Women from age 13 with established menstrual cycles to age 54 years inclusive who choose the Nexplanon® implant as their method of contraception after full discussion.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>This PGD is not suitable for women with conditions in UKMEC categories 3 and 4. See <a href="http://www.fsrh.org/">http://www.fsrh.org/</a> for UKMEC guidance.</td>
</tr>
</tbody>
</table>

Under this PGD, the contraceptive implant Nexplanon® should not be used in patients with the following conditions or characteristics:

- known sensitivity to any excipients
- premenarche or post menopause or age less than 13 years or 55 years or over
- current or past breast cancer
- current or past ischaemic heart disease
- current or past cerebrovascular disease

This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), the individual Summary of Product Characteristics (SPC), and the Faculty of Sexual and Reproductive Healthcare (FSRH) UKMEC guidance (April 2016)
- uninvestigated abnormal vaginal bleeding
- severe cirrhosis
- liver tumours past or current benign or malignant
- women taking ciclosporin
- women taking liver enzyme inducing drugs such as phenytoin, phenobarbital, primidone, carbamazepine, rifampicin and derivatives, oxcarbazepine, topiramate, felbamate, ritonavir, nelfinavir, nevirapine, griseofulvin, St. John’s Wort or modafinil
- women with contraindications to local anaesthetic
- current coagulation/bleeding disorder with increased risk of haemorrhage
- women on therapeutic doses of anticoagulant drugs such as heparin, warfarin or direct oral anticoagulants
- personal or family history of conditions which are of unknown relevance to the nurse or midwife
- patient queries or anxieties that cannot be answered or addressed by the nurse or midwife.

### Precautions and special warnings

The use of progestogen-containing contraceptives may have an effect on peripheral insulin resistance and glucose tolerance. Therefore, diabetic women should be carefully monitored during the first months of Nexplanon® use.

Nexplanon® does not affect breast feeding.

### Referral criteria

Patients who fall into the categories detailed in the exclusion criteria.

### Action if excluded from treatment

Medical advice should be sought – refer to General Practitioner/Consultant (relevant medical practitioner).

The reason why the patient was excluded under the PGD will be documented in the patient’s medical notes.

### Action if patient declines treatment

Patient should be advised of the risks and consequences of not receiving treatment.

Refer to General Practitioner/Consultant (relevant medical practitioner).

Record outcome in Patient Medication Record if appropriate and refer the patient to their General Practitioner/Consultant (relevant medical practitioner).
| Consent | Prior to the administration of the drug, valid consent must be obtained. Consent must be in line with current NHSG “Staff Policy for Obtaining Consent for Clinical Procedures and Healthcare Interventions”. See link below.  

### Description of treatment available under the PGD

<table>
<thead>
<tr>
<th>Name of medicine</th>
<th>Etonogestrel Implant Nexplanon®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal status</td>
<td>Nexplanon® is a Prescription-only Medicine (POM).</td>
</tr>
<tr>
<td>Form/Strength</td>
<td>Nexplanon® is a radiopaque, non-biodegradable, progestogen-only, flexible implant for subdermal use.</td>
</tr>
</tbody>
</table>
| Route/Method of administration | The implant is for subdermal use. The flexible rod is in an applicator which is designed to be operated with one hand to facilitate subdermal insertion of the implant. The insertion of Nexplanon® should only be performed under aseptic conditions by a nurse or midwife who has undergone specific training.  
Nexplanon® should be inserted at the inner side of the non-dominant arm about 8-10cm above the medical epicondyle of the humerus. It should be inserted parallel to the humerus just radial to the bicipital groove. Subsequent implants can be inserted immediately after the old implant is removed using the same incision if the removal was straightforward. The new device should be inserted in the opposite arm if removal was not straightforward or was not completed.  
Nexplanon® insertion requires subcutaneous local anaesthetic injection. Refer to separate PGD For The Administration Of Lidocaine 1% Injection For The Insertion/Removal Of The 68mg Etonogestrel Contraceptive Implant By Nurses And Midwives Working Within NHS Grampian. |
| Dosage/Total Dose | Single dose application in a pre-loaded sterile disposable applicator. |
The implant may be fitted within 5 days of a first or second trimester miscarriage or termination with immediate contraceptive effect.

The implant may be inserted within 21 days of a third trimester delivery with immediate contraceptive effect.

The Nexplanon® implant may also be inserted out with these times if the woman is reasonably certain she is not pregnant. In this situation, additional contraceptive protection is required for the first 7 days and a pregnancy test should be carried out after 4 weeks. Emergency contraception should be considered if unprotected intercourse occurs during the first 7 days.

**Duration of treatment**

For as long as the individual requires the implant and has no contraindications to the use of the implant. Weight/BMI does not affect duration of use.

Each individual implant should be removed no later than three years after the date of insertion.

**Storage requirements**

This medicinal product does not require any special storage conditions.

Store in the original blister package.

**Follow-up (if applicable)**

Women using implants should be advised that no routine follow-up is required, but that they can return at any time to discuss problems or if they want to change their contraceptive method.

The health professional will ensure the patient has the contact number for the clinic and will give the patient the manufacturer’s card showing date and site of Nexplanon® implant insertion and the date after which it can no longer be relied on for contraception.

**Advice to patient (Verbal)**

Advice should be given as per NHS Grampian checklist about Nexplanon® implant and wound care and action needed if problems.

Checklist available from Sexual and Reproductive Health clinic, Health Village Aberdeen.
### Advice to patient (Written)

- The FPA leaflet on The Contraceptive Implant should be made available.
- The Nexplanon® user card which is included in the packaging should be given to the patient.
- The Patient Information Leaflet (PIL) contained in the medicine(s) should be made accessible to the patient, parent, guardian, or person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.

Copies of PIL and SPCs for all medicines can be found at [http://www.medicines.org.uk](http://www.medicines.org.uk) or [http://www.mhra.gov.uk/spc-pil/index.htm](http://www.mhra.gov.uk/spc-pil/index.htm)

### Concurrent Medications/Drug Interactions

- Liver enzyme inducing drugs reduce the contraceptive effects of etonogestrel and women on these drugs should not use Nexplanon® for contraception. These drugs include: barbiturates, bosentan, carbamazepine, phenytoin, primidone, rifampicin and derivatives, ritonavir, efavirenz, boceprevir, nevirapine, felbamate, griseofulvin, oxcarbazepine, topiramate, modafinil and St. John's Wort.

**See current BNF for full information.**

Many combinations of HIV protease inhibitors and non-nucleoside reverse transcriptase inhibitors, including combinations with HCV inhibitors, can increase or decrease plasma concentrations of progestogens, including etonogestrel. The net effect of these changes may be clinically relevant in some cases. Seek advice from HIV physician.

- Etonogestrel can increase ciclosporin concentrations to toxic levels. Women taking ciclosporin are not eligible for Nexplanon® supply under this PGD.

- Etonogestrel may alter lamotrigine levels but the FSRH advises that women on lamotrigine can use the contraceptive implant.

- Concomitant administration of strong (e.g. ketoconazole, itraconazole, clarithromycin) or moderate (e.g. fluconazole, diltiazem, erythromycin) CYP3A4 inhibitors may increase the serum concentrations of progestogens, including etonogestrel. This is of unknown clinical relevance.
## Identifying and managing possible adverse reactions

Local complications at the insertion site include discomfort, bruising (common), infection (rare) or implant site reaction (rare) in the first two weeks after fitting.

Removal is usually a straightforward clinic procedure with local anaesthetic. However women should be aware that removal may be complicated if insertion was deeper than usual or if they have significant weight gain. Rarely (<1:1000) ultrasound localisation and removal in theatre by the plastic surgery team is needed.

Both insertion and removal leave small <5mm scars. A complicated removal may leave a larger scar.

Side effects include an altered bleeding pattern for most women. This often stabilises after the first 3-6 months but can vary throughout the 3 year duration. Women may have light, infrequent or absent bleeding (approx. 50%) or frequent prolonged bleeding (approx. 20-30%). Women should seek advice if their bleeding pattern is troublesome.

Other progestogenic side effects include headache, acne, breast tenderness, low libido, altered mood and nausea. There is no causal association with weight change.

There is considerable individual variation in side effects and they may resolve within 3-6 months as circulating etonogestrel levels fall to a lower steady state.

Systemic progestogenic side effects are expected to resolve within 2-3 weeks of implant removal.

Epidemiological studies suggest increased breast and cervical and reduced ovarian and endometrial cancer risks with combined oral contraception. Less evidence is available for Nexplanon®.

Chloasma may occur, especially in women with a history of chloasma in pregnancy. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation whilst using Nexplanon®.

This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SPC for details of all potential adverse reactions.

**BNF:**
https://www.medicinescomplete.com/mc/bnf/current/
https://www.medicinescomplete.com/mc/bnfc/current/
SPCs/PILs:
https://www.medicines.org.uk/emc/
http://www.mhra.gov.uk/spc-pil/index.htm

If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.

Report the reaction to the MHRA using the Yellow Card System. https://yellowcard.mhra.gov.uk/

Medical advice in cases of anaphylaxis

Injections of IM adrenaline/epinephrine 1:1000 must be available to treat an anaphylactic reaction should this occur. Medical advice must be sought as soon as possible from a doctor if any patient develops any signs of hypersensitivity. If there is a delay in medical support arriving and the condition of the patient is deteriorating then an emergency ambulance must be called on 999 or direct via ambulance control or dial 2222 (hospital internal) according to local procedure, or seek urgent medical advice. (Refer to Patient Group Direction for the administration of adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals)


Facilities and supplies required

The following should be available at sites where the medication is to be administered:

- Appropriate storage facilities.
- An acceptable level of privacy to respect patient’s right to confidentiality and safety.
- Resuscitation equipment.
- Access to medical support (this may be via the telephone).
- Approved equipment for the disposal of used materials.
- Clean and tidy work areas, including access to hand washing facilities.
- Copies of the current PGD for the medicine specified in the PGD.
- PGD for the administration of Adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals.
- PGD For the administration of lidocaine 1% injection for the insertion/removal of the 68mg etonogestrel contraceptive implant by nurses and midwives working within NHS Grampian.
### Characteristics of staff authorised to administer medicine under PGD

<table>
<thead>
<tr>
<th>Professional qualifications</th>
<th>Registered Nurses and Midwives as recognised by the Nursing and Midwifery Council (NMC).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialist competencies</td>
<td>Be competent to assess the patient’s capacity to understand the nature and purpose of the administration in order for the patient to give or refuse consent.</td>
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<tr>
<td></td>
<td>Has undertaken appropriate training to carry out clinical assessment of patients leading to a diagnosis that requires treatment according to the indications listed in the PGD.</td>
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<td></td>
<td>Be aware of current treatment recommendations and be competent to discuss issues about the drug with the patient.</td>
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<td></td>
<td>Has current FSRH letter of competence or NHSG local certificate of competence in implant insertion.</td>
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<tr>
<td>Ongoing training and competency</td>
<td>Have attended basic life support training which is required to be updated annually.</td>
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<tr>
<td></td>
<td>Have undertaken the NHS e-anaphylaxis training session (and annual updates) which covers all aspects of the identification and management of anaphylaxis. This can be accessed via eKSF, or the AT Learning® tool.</td>
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<tr>
<td></td>
<td>Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct.</td>
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<tr>
<td></td>
<td>The practitioner must be familiar with the SPC for all medicines supplied in accordance with this PGD.</td>
</tr>
<tr>
<td>Professional managers/Lead Nurses will be responsible for:</td>
<td>Ensuring that the current PGD is available to staff providing care under this direction.</td>
</tr>
<tr>
<td></td>
<td>Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.</td>
</tr>
<tr>
<td></td>
<td>Maintain up to date record of all staff authorised to administer drug specified in PGD.</td>
</tr>
</tbody>
</table>
### Documentation

| Authorisation of administration | Nurses and Midwives working within NHS Grampian can be authorised to administer the drug specified in this PGD by their Nurse/Midwifery Manager/Consultant/Practice GPs. 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 doctor/manager should be supplied. This should be held in the individual practitioners records, or as agreed locally. |
| Record of administration/supply | An electronic or paper record for recording the screening of patients and the subsequent administration of the drug specified in this PGD must be completed in order to allow audit of practice. This should include:  
- Name and address of patient  
- Patient CHI No and date of birth  
- Details of parent/guardian, or person with parental responsibility where applicable  
- Consultant/General Practitioner details  
- Risk group, if appropriate  
- Findings of physical examination, if appropriate  
- Exclusion criteria, record why the drug was not administered  
- Reason for giving  
- Consent to the administration (if not obtained elsewhere)  
- Signature and name in capital letters of practitioner who administered the drug  
- Date drug given  
- Record of any adverse effects (advise patient’s doctor).  
These records should be retained:  
**For children and young people,** retain until the patient's 25th birthday or 26th if the young person was 17 at the conclusion of treatment.  
**For 17 years and over** retain for 6 years after last date of entry, for 3 years after death, or in accordance with local policy, where this is greater than above. |
### Audit

All records of the drug specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each H&SCP/practice/service will be responsible for auditing completion of drug forms and collation of data.

### References

- Electronic Medicines Compendium

- British National Formulary


### Management and Monitoring of Patient Group Direction

#### PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frances Adamson</td>
<td>Medicines Management Specialist Nurse</td>
</tr>
<tr>
<td>Fiona Doney</td>
<td>Pharmacist: NHSG Formulary Pharmacist</td>
</tr>
<tr>
<td>Amanda Mackie</td>
<td>SRH Nurse</td>
</tr>
<tr>
<td>Dr Linda Sandilands</td>
<td>Medical Professional: SRH Specialty Doctor</td>
</tr>
<tr>
<td>Dr Sarah Wallage</td>
<td>Lead Author: Consultant in Sexual and Reproductive Health</td>
</tr>
</tbody>
</table>
Authorising Managers

Dr Nick Fluck
Medical Director, NHS Grampian

Mr David Pfleger
Director of Pharmacy and Medicines Management, NHS Grampian

Professor Amanda Croft
Director of Nursing, Midwifery and AHPs, NHS Grampian
Health Care Professional Agreement to Administer Medicines Under Patient Group Direction

I:  

____________________________________ (Insert name)

Working within:  

____________________________________  e.g. H&SCP, Practice

Agree to administer medicines under the direction contained within the following Patient Group Direction

Patient Group Direction For The Insertion Of The Etonogestrel Implant Nexplanon® By Nurses and Midwives Working Within NHS Grampian

I have completed the appropriate training to my professional standards enabling me to administer medicines under the above Patient Group Direction. I agree not to act beyond my professional competence nor outwith the recommendations of the Patient Group Direction.

Signed:

____________________________________

Print Name:

____________________________________

Date:

____________________________________

Professional Registration No:

____________________________________
Appendix 2

Certificate Of Authorisation To Administer Medicines Under Patient Group Direction

This authorises: ________________________________________

Working within: ______________________________ e.g. H&SCP, Practice

To administer medicines under the following Patient Group Direction

**Patient Group Direction For The Insertion Of The Etonogestrel Implant Nexplanon® By Nurses and Midwives Working Within NHS Grampian**

The above named person has satisfied the training requirements and is authorised to administer medicines under the above Patient Group Direction. The above named person has agreed not to act beyond their professional competence nor outwith the recommendations of the Patient Group Direction

Signed: ____________________________ Authorising Manager/Doctor

Print Name: ____________________________

Date: ________________________________