Patient Group Direction for the administration of : etonorgestrel (Nexplanon®) subdermal contraceptive implant	
Title of patient group direction	Patient Group Direction for the administration of etonorgestrel subdermal Implant for contraception
Approved at	NMP/PGD Group
PGD approved / valid from	July 2018
Review date	February 2021
Expiry date	July 2021
Clinical area(s) where PGD applies	Sexual heath and HIV outreach services within contractive and sexual health clinics, and in sexual health outreach services/locations
Identified Lead for monitoring / review and contact details	Wendy Billsborough
CONSULTATION PROCESS ADOPTED IN DEVELOPING THE PATIENT GROUP DIRECTION (PGD)	
New Document	No
Reviewed Document	Yes
If the PGD is revised what revisions were required and for what reasons e.g. change in medical procedures or change in legislation	Changes to exclusions in line with updated UKMEC 2016
List of persons involved in the consultation process. (The group must include a sponsoring clinician, a pharmacist and a senior	Wendy Billsborough – Advanced Nurse Specialist . Dr Frances Baker Alison Chorlton – Lead Nurse Sexual Health Dr Ian Fairley, Clinical Director Lead

representative of the professional group. The job title and level of consultation should also be listed).	Carol Belt, Principal Pharmacy Technician Medicines Information Jill McEnaney, Directorate Pharmacist

CLINICAL CONDITION	
Condition	Contraception
Inclusion criteria	• Any eligible woman (menarche to under 55 years of age) presenting for long acting reversible contraception and who has consented to treatment • Women who accept the possibility of unpredictable bleeding patterns • The inclusion criteria for the lidocaine 1% PGD should also be met
Exclusion criteria	**Personal Characteristics and Reproductive History:** • Child aged 12 years or under • Child under 16 years and **NOT** Fraser competent • Known or suspected pregnancy • Allergy to any constituent of the contraceptive implant • Allergy or contraindication to local anaesthetic (see lidocaine PGD) **Cardiovascular Disease:** • Development of ischaemic heart disease, stroke or transient ischaemic attack whilst using the implant **Cancers**: • Breast cancer- current or past history • Liver tumour – benign (hepatocellular adenoma) or malignant (hepatocellular carcinoma) **Gastro-intestinal conditions**: Severe decompensated Cirrhosis

	Other conditions: ▪ Interacting medicines including the use of liver enzyme inducing drugs/herbal products or within 4 weeks of stopping them ▪ Acute porphyria ▪ Unexplained vaginal bleeding
Action if excluded	▪ Discuss/offer an alternative contraceptive method ▪ If implant preferred choice refer to clinic doctor/independent nurse prescriber or GP if more appropriate in an outreach setting ▪ Document all action taken in the patient records
Action for patients not wishing to receive care under the PGD	▪ Record the refusal in the clinical record ▪ Refer to appropriate doctor/independent nurse prescriber if agreed with the client

<table>
<tr><th colspan="4">DESCRIPTION OF TREATMENT</th></tr>
<tr><td>Name of Medicine</td><td colspan="3">Etonogestrel 68mg subdermal implant</td></tr>
<tr><td>Legal Classification</td><td colspan="3">Prescription Only Medicine (POM)</td></tr>
<tr><td>Licensing information</td><td colspan="3">▪ Best practice advice given by the Faculty of Sexual and Reproductive Healthcare is used for guidance in this PGD and may vary from the summary of product characteristics.
This PGD includes off-label use:
▪ Quick starting after day 5 of the menstrual cycle or after hormonal emergency contraception and when switching methods
▪ Use in women under the age of 18 and over 40 years of age
▪ Use in women with current VTE or history of</td></tr>
<tr><td></td><td>Is the medicine licensed for the intended use?</td><td>YES</td><td></td></tr>
<tr><td></td><td>Does it have a black triangle status?</td><td></td><td>NO</td></tr>
<tr><td></td><td>Does it have a Risk Minimisation Measures (RMM) recommendation</td><td></td><td>NO</td></tr>
<tr><td>Form</td><td colspan="3">Implant</td></tr>
<tr><td>Strength</td><td colspan="3">68mg</td></tr>
<tr><td>Dose</td><td colspan="3">Single implant</td></tr>
<tr><td>Frequency</td><td colspan="3">• Insert between day 1-5 of the menstrual cycle with no need for additional protection
• The implant may be inserted or reinserted at any time (off label) 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 quick starting after the use of levonorgestrel emergency contraception, additional contraception is required for 7 days</td></tr>
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	• If quick starting after ulipristal acetate emergency contraception it is recommended that hormonal contraception should not be used for five days. Extra precautions should then be used for a further 7 days • A pregnancy test is advised 3 weeks after any oral emergency contraception • Replace every 3 years for as long as the individual requires and has no contraindications (if replaced immediately and no longer than 3 years since insertion, additional contraceptive precautions are not needed after replacement) • For guidance on changing from one contraceptive method to another, and when to start after an abortion and post-partum refer to FSRH guidelines, 'Switching or starting methods of contraception' and 'Contraception after pregnancy'
Route	▪ Subdermal (as per manufacturer's instruction) preferably into the inner side of the non-dominant arm ▪ Appropriate local anaesthetic should be administered prior to insertion and removal of implant ▪ Confirm insertion by palpation
Total Treatment Quantity	▪ One subdermal implant ▪ Can be exchanged every 3 years for as long as the client requires an implant and has no contraindications ▪ The Implant can be exchanged earlier or later depending on patient attendance. Flexibility may be required to ensure patient has adequate contraceptive cover. If however a replacement is after 3 years, an assessment should be made regarding emergency contraception requirements, a pregnancy test may be required, and the woman may have immediate insertion if quick starting is appropriate, or be required to return no sooner than 3 weeks later for a repeat pregnancy test and insertion ▪ Earlier replacement can be considered in heavier

	women but no direct evidence is available	
Interactions with other medicines (This must include all potentially serious interactions listed in the BNF)	▪ Check any medicines in Appendix 1 of the British National Formulary (BNF) and CEU drug interactions guidelines under progestogens or UpToDate – Drug interactions via staff room ▪ The efficacy of etonorgestrel may be affected by enzyme inducing drugs or herbal preparations concomitant and within the previous 4 weeks. **If in doubt contact Medicines Information for advice ext 5960**	
Adverse Reactions (This should include all the common and potentially serious adverse reactions. It is acceptable to state that the BNF should be referred to for further information)	This list may not represent all reported side effects of this medicine. See Summary of Product Characteristics (SPC)for further information. The implant is generally well tolerated **Most commonly reported**: ▪ Amenorrhoea, infrequent, frequent or prolonged bleeding ▪ Breast tenderness ▪ Acne ▪ Headache ▪ Vaginal infection **Less common**: ▪ Weight changes ▪ Mood changes ▪ Reduced libido ▪ Local pain/bruising/infection or scarring ▪ Possible migration of the implant ▪ Possible deep implant	**Treatment of adverse reactions** ▪ If necessary seek appropriate emergency advice and assistance ▪ Document any adverse reaction in the client's records. Inform the GP with client consent ▪ Any serious adverse drug reactions should be reported to the MHRA by the yellow card scheme. Guidance on its use is available in the BNF or can be accessed via www.mhra.gov.uk/yellowcard Women should be advised to return if: they cannot feel their implant or it appears to have changed shape; they notice any skin changes or pain around the site of the implant; they

	insertion ▪ Possible accidental intravascular insertion ▪ Allergy	become pregnant If on anticoagulant therapy, an experienced clinician should perform the procedure due to the risk of bleeding and a pressure bandage should be applied after insertion
Advice to Patients: Written and Oral advice (This should include the provision of a patient information leaflet)	• Refer to web based FPA implant patient information. Offer the patient information leaflet (PIL) • Explain the mode of action, duration of use, efficacy, possible side effects, risks and benefits and how the implant is inserted/removed • Advice regarding interacting medicines • Give after care instructions for the insertion site • Advise to return if there are any concerns regarding the implant, if they cannot feel it, it appears to have changed shape, they have any skin changes, pain around the site or any new medical condition that would contraindicate use. If they become pregnant. • Advice regarding the need for additional contraception	

	when starting and if after emergency contraception as appropriate • Advise to return for a pregnancy test in 3 weeks after quick starting if pregnancy could not be excluded at the time of administration • Diabetic women should be carefully monitored during the first months of Nexplanon use as it may have an effect on peripheral insulin resistance and glucose tolerance • Offer condoms and advice on safer sex
Follow up action	• Provide the written date when renewal/removal is needed • Provide contact details for the service and advise to return if any problems. Routine follow up not required
Storage	• Locked medicines cupboard or briefcase for outreach use – store below 25 °C
Records to be Kept	• Assessment of client request in relation to insertion of the implant • Any reason for exclusion and action taken • Any known allergies • Relevant past and present medical and family history, including drug history • Consent of the individual • Date • Completion of implant proforma • On the prescription, record drug name and quantity supplied and administered • Batch number and expiry date • That the implant was administered under a PGD • Route of administration • Site of implant • Advice given and any follow up • Details of any adverse drug reactions and what action taken • Any communication with other health care professionals • Name of health professional supplying the medicine (may be electronic)

	• Any administration made outside the product licence
Audit Arrangements	As per current Trust PGD Policy
References	▪ Faculty of Sexual and Reproductive Healthcare (2014) Progestogen-only Implants ▪ Faculty of Sexual and Reproductive healthcare (2015) Problematic bleeding with hormonal contraception ▪ Faculty of Sexual and Reproductive Healthcare UK Medical Eligibility Criteria for Contraceptive Use (2016) ▪ British National Formulary (BNF) www.bnf.org.uk ▪ NICE Guideline on Long Acting Reversible Contraception October 2005 ▪ Nexplanon 68mg implant for subdermal use Manufacturer's Summary of Product Characteristics – 2014 ▪ Faculty of Sexual and Reproductive Healthcare (2017) Drug interactions with hormonal contraception ▪ Faculty of Sexual and Reproductive Healthcare (2017) Quick Starting Contraception ▪ Faculty of Sexual and Reproductive Healthcare e-lfh/SHR Module 17 ▪ Faculty of Sexual and Reproductive Healthcare (2016) Switching or starting methods of contraception ▪ Policy and Procedure for the supply and/or administration of medicines under a patient group direction (2015) York Teaching Hospital ▪ Statement from the Clinical Effectiveness Unit Intravascular insertion of Nexplanon® June 2016
Competency Requirements (attach any competency frameworks / documents)	The Nurse must be authorised by name under the current version of this PGD before working to it <u>Education, training, qualifications and competencies</u>: • Sexual health Nurse

	• Clinical competence in sexual history taking. • Completion of the Trust PGD awareness session or Trust HUB e-learning. • Knowledge of the current FSRH Progestogen Only implant guidance and completion of the e-SRH module 17 theory training for etonorgestrel subdermal implant – (assessed via e-lfh) • Model arm and local anaesthetic training • Assessment as competent by a faculty registered trainer in the insertion/removal of subdermal contraceptive implants to achieve the required competency level for the FSRH letter of competence (LoC SDI) • Knowledge base of the interaction of etonorgestrel with other drugs, and other exclusions and contraindications to the implant • Competence in the above will be demonstrated by the undertaking of a local clinical competency based training and assessment programme, evidenced by completion of theoretical study including e-learning and clinical experience within sexual health. • Assessment will be undertaken by the Lead Nurse/ANS or designated PGD assessor, who will be practising as an independent prescriber. • Maintain professional accountability with the NMC and ensure continual professional development • Receive clinical supervision and/or audit of case notes on an ongoing basis • Evidence of relevant continuing professional development identified through clinical supervision and appraisal • Regular attendance and participation in educational clinical governance sessions and nurse updates • Ensure keeps up to date with any changes to FSRH/manufacturers guidance relevant to this PGD

AUTHORISATION OF THE PATIENT GROUP DIRECTION (PGD) FOR ADMINISTRATION OF the etonorgestrel subdermal contraceptive implant			
PGD Development / Review Team – responsible for PGD content			
Title	**Name**	**Signature**	**Date**
Lead Author	Wendy Billsborough	WBillsborough	2/7/2018
Clinical Director Lead Approval	Dr Ian Fairley		28/06/18.
Directorate Pharmacy Lead Approval	Jill McEnaney	Jill McEnaney	10.8.18
PGD Approved by the NMP/PGD Group			
Title	**Name**	**Signature**	**Date**
NMP Lead / Lead Nurse Medicines Management	Jennie Booth		
Chief Pharmacist / Deputy Chief Pharmacist	Stuart Parkes		16/8/18.

Authorisation to work within the PGD

This patient group direction must be agreed to and signed by all health care professionals involved in its use.

The PGD must be easily accessible in the clinical setting.

Notes to the NMP/PGD Authorising staff

- Do not proceed unless this document carries the signatures of the development / review team (Lead Author, Lead Clinical Director and Directorate Lead Pharmacy)
- You are responsible for fulfilling the legal requirement that a senior person from the profession ensures that only fully competent, qualified and trained professionals operate under this PGD
- Using a PGD is not a form of prescribing

Staff authorised to work under this PGD	
Ward / Department	Sexual Health and Sexual Health Outreach Clinics
Professionals to whom this Patient Group Direction applies	Qualified nurses who work within sexual health and have completed the agreed training programme

I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct when working for this Trust:

Name (Capitals)	Sign	Job Title	Authorising Manager	Date
This is to be completed when the PGD has been approved	This is to be completed when the PGD has been approved	This is to be completed when the PGD has been approved	This is to be completed when the PGD has been approved	This is to be completed when the PGD has been approved

When the review date is exceeded, this PGD ceases to be a legal document	
TEMPLATE DOCUMENTATION CONTROL	
The template documentation control refers to the PGD template not the completed PGD. **Do not alter this section.**	
Author:	Jennie Booth, Lead Nurse Medicines Management Carol Belt, Principal Pharmacy Technician Stuart Parkes, Deputy Chief Pharmacist
Owner:	NMP/PGD Group
Date of issue:	February 2018
Version:	3
Approved by	NMP/PGD Group
Review date:	February 2021