South Staffordshire & Shropshire Healthcare NHS
NHS Foundation Trust

PATIENT GROUP DIRECTION
FOR THE SUPPLY AND ADMINISTRATION OF ETONOGESTREL SUBDERMAL IMPLANT

by registered nurses and midwives in Integrated Sexual Health services employed by South Staffordshire and Shropshire NHS Foundation Trust

This Patient Group Direction for use in South Staffordshire & Shropshire Healthcare NHS Foundation Trust and is authorised by:			
Position of Signatory	**Name**	**Signed**	**Date**
Medical Director	Dr Abid Khan		
Chief Pharmacist	Cathy Riley		
Director of Quality & Clinical Performance	Therèsa Moyes		
Director of Nursing	Alison Bussey		

The named below, being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to supply and administer Etonogestrel Subdermal Implant to patients in Integrated Sexual Health Services under this Patient Group Direction

Name	Job Title	Signed	Date

This Patient Group Direction is operational from: 1st October 2017
Review date: Aug 2019. Expires on 31st Oct 2019
Replaces PGD3816

Professional Responsibility

All registered nurses and non medical prescribers being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to supply and administer Etonogestrel Subdermal Implant as specified under this Patient Group direction following demonstration of the competencies below;

Professional Responsibility / Competencies

1. The registered nurse will have undertaken appropriate training in order to carry out clinical assessments of patient that requires treatment according to the indication listed in the PGD
2. Qualification in contraception/sexual health (university modules/FSRH training), an introduction to contraception is not sufficient)
3. Has undertaken appropriate theory training for etonogestrel sub-dermal implant and has achieved the required competency level. E.g. a Letter of Competence (LoCSDI) from the FSRH (RCN accreditation)
4. Has been assessed and achieved the required standard for the insertion and removal of subdermal implants for contraception
5. Is competent in the assessment of individuals using Fraser guidelines
6. Has undergone regular training and updating in safeguarding children and vulnerable adults
7. Reaccreditation of Letter of Competence (LoCSDI) from the FSRH (RCN accreditation)
8. Insert sufficient implants annually to maintain competence as per FSRH guidance
9. The nurse should be familiar with current FSRH guidelines on progesterone-only implants
10. All nurses will have received training in the management and treatment of anaphylactic shock on an annual basis
11. Each nurse will keep a record in their professional portfolio of the updates attended during every 12 month period – This information will also form part of the team's annual training plan
12. The nurse will have due regard for the NMC Code of Conduct, Scope of Professional Practice and Standards for Medicines Management (Nursing & Midwifery Council)
13. Undertaken appropriate training and possess the competencies for working under PGDs for the supply and administration of medicines
14. All registered nurses details and signature must be entered onto the PGD
15. Following administration a record of the date, strength, brand and dose of the medication should be recorded in the clients records and documented in the medicine card with PGD number recorded as authorisation

For full product information, always refer to the latest SPC (Summary of Product Characteristics).

If the anaphylaxis is related to a medication, please remember to report to the CSM, via a Yellow Card Report (http://emc.medicines.org.uk)

Supply/Administration of	Etonogestrel 68 mg subdermal implant
Legal Classification	Prescription Only Medicine
Black Triangle?	No
Type	Implant
Storage	Supplies will be available from central stock location. Information leaflets must be given. Any relevant documentation must be completed
Condition to be treated	Contraception
Inclusion Criteria	• Any individual from 13 to 55 years presenting for contraception and who has no contra-indications. For women aged over 40 years please follow the FSRH guidelines, https://www.fsrh.org/documents/cec-ceu-guidance-womenover40-jul-2010/ Individuals requiring insertion and /or removal of subdermal contraceptive implant should also meet the inclusion criteria of the lidocaine 1% PGD (See separate PGD for lidocaine)
Exclusion Criteria	**Personal Characteristics & Reproductive history** • Known or suspected pregnancy • If individual under 16 years of age and assessed as not competent using Fraser guideline • If individual over 16 years of age and over and assessed as not competent to consent • Known hypersensitivity to any constituent of the contraceptive implant **Cardiovascular Disease** • Development of ischaemic heart disease, transient ischaemic attack or stroke whilst using the implant • Active venous thromboembolic disorder **Cancers** • Current or past history of breast cancer • Benign liver tumour • Malignant liver tumour (hepatoma) – present or past history **Gastro-intestinal conditions** • Severe decompensated cirrhosis • Present or history of severe hepatic disease as long as liver function values have not returned

	to normal **Other Conditions** • Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them • Systemic Lupus Erythematosus (SLE) with positive or unknown anti-phospholipid antibodies • Undiagnosed abnormal vaginal bleeding • Individual wishes to see a doctor <u>Cautions:</u> • Interacting medicines (not enzyme inducers) – see current BNF • If on anticoagulant therapy, an experienced clinician should perform the procedure due to the risk of bleeding • A pressure bandage should be applied after insertion • Discuss with appropriate doctor/independent nurse prescriber any medical condition or medication for which the nurse is unsure/uncertain
Action if excluded or patient declines	• Refer to appropriate doctor/independent nurse prescriber • Discuss/offer alternative contraceptive method • Document all actions taken
Reasons for seeking further advice from doctor	• Record the refusal in the clinical record and document all other actions taken • Discuss/offer alternative contraceptive method • Refer to appropriate doctor/independent nurse prescriber where required
Administration Route	Sub-dermal implant
Dose	Etonogestrel 68 mg
Administration Schedule	Subdermal implant inserted preferably into non-dominant arm under aseptic conditions following administration of local anaesthetic (see PGD for lidocaine 1% injection) • 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 barrier contraception is then required for seven (7) days after insertion • If inserting the implant after levonorgestrel emergency contraception, additional contraception is required for 7 days • If inserted after ulipristal acetate emergency contraception, 14 days of additional precautions are required • Replace every three years For guidance on changing from one contraceptive method to another, and when to start after an abortion /miscarriage or postpartum, refer to FSRH guidance. <u>Duration of Treatment:</u> This is a single dose for supply and administration Three years for each implant and for as long as the individual requires the implant and has no contraindications to its use.
Warnings/Adverse Reactions	This list may not represent all reported side effects of this medicine. Refer to current Summary of Product Characteristics (SPC) of relevant product and current British National Formulary (BNF) for full list and further information. The implant is generally well tolerated. The main reported side effects include: **Common** • Amenorrhoea, frequent or prolonged bleeding • Headache • Acne • Breast tenderness and pain **Less common** • Weight changes • Mood changes • Reduced libido • Nausea • Fluid retention • Some local scarring and bruising • Possible migration of implant

	• Possible deep implant insertion In the event of untoward or unexpected adverse reactions: • If necessary seek appropriate emergency advice and assistance • Document in the individual's clinical record and inform appropriate doctor/independent nurse prescriber • Complete incident report if adverse reaction is severe (refer to local organisational policy) • Use yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF or obtained via Freephone 0808 100 3352 or online at www.yellowcard.mhra.gov.uk. The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so.
Advice/Management of Adverse Reactions & Follow-up Action	• Provide Manufacturer's Patient Information Leaflet (PIL) and user record card • Explain mode of action, side effects, and benefits of the medicine • Use of condoms as appropriate • How to care for the insertion site • To return if irregular bleeding persists Follow Up: • Individual to return to clinic if she has any concerns • Follow up at individual's request • Consider early replacement in individuals with a high BMI
Use in pregnancy and lactation	Not appropriate for PGD
Records	The authorised registered nurse must ensure the following is documented in the clinical record: • Individual's name, address and date of birth • 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 • A statement that supply or administration is by using a PGD and the PGD number is recorded • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Details of any adverse drug reactions and what action taken • Any referral arrangements • Any administration outside the marketing authorisation • The consent of the individual • If individual is under 13 years of age record action taken • Individual is under 16 years of age document competency using Fraser guidelines • If individual over 16 years of age and not competent, record action taken • Any referral arrangements • Record the name/brand, dose of the medication, site of insertion, and palpation of implant following procedure • Record batch number and expiry date according to local policy or national guidelines • Record follow up and/or signposting arrangements • Any other relevant information that was provided to the individual • Name and signature (which may be an electronic signature) of the nurse supplying and administering the medicine