NHS
Sunderland
Clinical Commissioning Group

This Patient Group Direction (PGD) must only be used by registered nurses or registered pharmacists 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

for the supply and administration of

Etonogestrel 68 mg subdermal implant

by registered nurses or pharmacists for

contraception

in GP practices in Sunderland

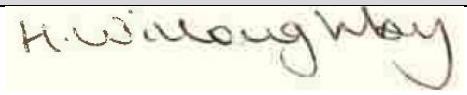
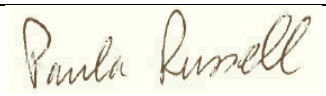
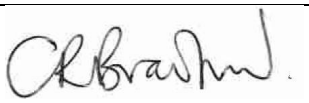
Version number: 1.0

Date PGD comes in to effect:	**March 2016**
Review date:	**January 2018**
Expiry date:	**March 2018**

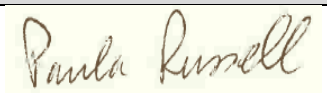
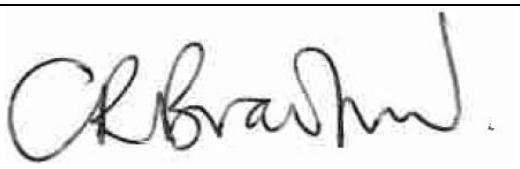
Change history

Version number	Change details	Date
V1.0	Initial approved version	March 2016

PGD development

Name	Job title and organisation	Signature	Date
Medicines optimisation pharmacist Sunderland CCG	**Hannah Willoughby** *(Interface pharmacist)*		March 2016
Medicines optimisation pharmacist Sunderland CCG	**Paula Russell** *(Senior pharmacist)*		March 2016
Practice nurse representative to the executive committee Sunderland CCG	**Florence Gunn** *(Senior nurse)*		March 2016
Medical director Sunderland CCG	**Dr Claire Bradford** *(Senior doctor)*		March 2016
Other members of the PGD working group	Not applicable		

PGD authorisation

Name	Job title and organisation	Signature	Date
Medicines optimisation pharmacist Sunderland CCG	**Paula Russell** *(Senior pharmacist)*		March 2016
Practice nurse representative to the executive committee Sunderland CCG	**Florence Gunn** *(Senior nurse)*		March 2016
Medical director Sunderland CCG	**Dr Claire Bradford** *(Senior doctor)*		March 2016
Person signing on behalf of authorising body			

PGD adoption by the provider

Name	Job title and organisation	Signature	Date
Signatures to be determined locally, if relevant			

Training and competency of registered nurses/pharmacists

	Requirements of registered nurses/pharmacists working under the PGD

Qualifications and professional registration	**Healthcare professionals using this PGD must:**
	• **Have a current contract of employment with a GP practice within Sunderland CCG**
	• **Be currently registered with their relevant professional body**
	  o Nurses: the Nursing & Midwifery Council (NMC)
	  o Pharmacists: General Pharmaceutical Council (GPhC)
	• **Have undergone formalized training to fit etonogestrel 68mg subdermal implant and use lidocaine 1%**
	• **And at least one of the following:**
	  o Holds a recognised post-registration qualification in contraception/sexual health (an introduction to contraception is not sufficient).
	OR
	  o Significant training and experience in contraception and sexual health. This should be confirmed by documentation on individuals personal file.

Initial training	• Has had training in the use of PGDs • Has had training which enables the nurse/pharmacist to make a clinical assessment in order to establish contraceptive need, supply and administer etonogestrel 68 mg subdermal implant according to this PGD. • Has undertaken the competency training appropriate to this PGD • Has been assessed and achieved the required standard deemed necessary by the senior medical representative who deems the healthcare professional competent to practice under the PGD. • Is competent in the assessment of the individuals using Fraser guidelines • Has undergone regular training and updating in safeguarding children and vulnerable adults • Has undergone regular updating in basic life support and anaphylaxis • Insertion of etonogestrel 68 mg subdermal implant should be performed under aseptic conditions and only by a qualified healthcare professional who is familiar with the procedure
Competency assessment	Must have demonstrated an appropriate level of competence to the senior medical representative in the

	practice in contraceptive services
Ongoing training and competency	• The registered nurse/pharmacist should ensure she/he is aware of any changes to the recommendations for this medication. It is the responsibility of the healthcare professional to keep up-to-date with continuing professional development and take part in audit of clinical records on a regular basis. • Continuous professional development completed as per governing body. • Revalidation of professional qualification as dictated by governing body.

Clinical condition

Clinical condition or situation to which this PGD applies	Contraception
Inclusion criteria	• Any individual from 18 to 40 years presenting for contraception and who has no contradictions • 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) • Patients must be fully consented, counselled and provided with a patient information leaflet prior to anaesthetic administration/insertion of the implant.
Exclusion criteria	**Personal characteristics & reproductive history** • Individuals under the age of 18 must be excluded due to the product license • Known or suspected pregnancy • If individual assessed as not competent to consent • Known hypersensitivity to any constituent of the contraceptive implant **Cardiovascular disease** • Development of ischaemic heart disease, sustained elevated blood pressure, transient ischaemic attack or stroke whilst using the implant • Active venous thromboembolic disorder • Current or past history of thrombosis or thromboembolic disorders. • Severe arterial disease **Cancers** • Current or past history of breast cancer • Current or past progestin-sensitive cancer • Malignant liver tumour (hepatoma) **Gastro-intestinal conditions** • Benign liver tumour • Severe decompensated cirrhosis • Severe hepatic disease **Other conditions** • Acute porphyria

	• 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
Cautions (including any relevant action to be taken)	• Diabetic women • History during pregnancy of pruritus or of deterioration of otosclerosis • Malabsorption syndromes • Disturbances of lipid metabolism • History of chloasma gravidarum • Interacting medicines –check drug history and refer to current BNF for more detail and potential drug interactions and ask for advice on management if necessary. • If on anticoagulant therapy, an experienced clinician should perform the procedure due to the risk of bleeding • Women with an increased BMI • Discuss with appropriate doctor/independent nurse prescriber any medical condition or medication for which the nurse/pharmacist is unsure/uncertain
Arrangements for referral for medical advice	NA
Action to be taken if patient excluded	• Refer to appropriate doctor/independent nurse presciber • Discuss/offer alternative contraceptive method • Document all actions taken
Action to be taken if patient declines treatment	• 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.

Details of the medicine

Name, form and strength of medicine *Include ▼for black triangle medicines*	Etonogestrel 68 mg subdermal implant
Legal category	Prescription only medicine
Indicate any off-label use (if relevant)	Not applicable
Route/method of administration	Implant inserted subdermally, preferably into non-dominant arm under aseptic conditions, using pre-loaded applicator, following administration of local anaesthetic (see PGD for lidocaine 1% injection).
Dose and frequency	• In patients not currently taking hormonal contraceptives, insert between day 1-5 of the menstrual cycle with no need for additional precautions • Insert at any time if the women is amenorrhoeic, so long as it is reasonably certain she is not pregnant. • The implant may be inserted or reinserted at any time as quick start if certain that the individual is not pregnant. Additional contraception is then required for 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 (including hormonal contraception), and when to start after an abortion /miscarriage or postpartum, refer to FSRH guidance.
Quantity to be administered and/or supplied	One subdermal implant
Maximum or minimum treatment period	Remove implant no later than three years after insertion. Consider earlier replacement in heavier women (nurse/pharmacist to refer patient if unsure). Patients can receive subsequent implants for as long as the individual requires the implant and has no contraindications to its use.
Adverse effects	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: • Vaginal infection • Amenorrhoea, frequent or prolonged bleeding • Headache • Dizziness • Hot flushes • Abdonminal pain • Flatulence • Alopecia • Ovarian cyst • Implant site pain • Implant site reaction • Fatigue • Flu like illness • Pain • Acne • Breast tenderness and pain • 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.
Records to be kept	The authorised registered nurse/pharmacist 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 • 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 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/pharmacist supplying and administering the medicine • "Supplied and administered under PGD"

Patient information

Written information to be given to patient or carer	• Provide manufacturer's patient information leaflet (PIL) and user record card.
Follow-up advice to be given to patient or carer	• 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 or if she has any concerns • Follow up at individual's request • Consider early replacement in individuals with a high BMI • Ensure individual has the contact details of the clinic/GP practice • Individual to return to clinic/GP practice if she has any concerns • Advise individual what to do if has concerns out of hours

Appendices

Appendix A Key references

1) LONDON CONTRACEPTION AND SEXUAL HEALTH PATIENT GROUP DIRECTION PGD FOR THE SUPPLY AND ADMINISTRATION of ETONOGESTREL (SUBDERMAL IMPLANT)
2) Nexplanon prescribing information accessible at: http://www.merck.com/product/usa/pi_circulars/n/nexplanon/nexplanon_pi.pdf (16/02/2016)
3) Faculty of Sexual and Reproductive Healthcare (2014) Progestogen only implants http://www.fsrh.org/pdfs/CEUGuidanceProgestogenOnlyImplants.pdf

Appendix B Health professionals' agreement to practise

I have read and understood the Patient Group Direction and agree to supply and/or administer this medicine only in accordance with this PGD.

Name of registered nurse/pharmacist	Signature	Senior representative authorising nurse/pharmacist	Date