Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Patient Group Direction (PGD) must only be used by registered health professionals 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. Health professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version

Patient Group Direction

for the insertion of

Etonogestrel 68mg Subdermal Implant (e.g. Nexplanon®)

as contraception

by Registered Nurses or Midwives

in Sexual Health Clinics in Powys Teaching Health Board or postnatally via PTHB Maternity Services

Version number: PGD 0177B

Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys
Powys Teaching Health Board is the operational name of Powys Teaching Health Board

Reference Number: PGD 0177B
Valid from: 07/05/2024
Review date: 31/03/2026
Expiry date: 31/08/2026

Change history

Version number	Change details	Date
PGD 0177	Initial issue, use of national PGD template	04/06/2021
PGD 0177A	Review in line with SPS template version 2.0: 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. 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.*	01/09/2023
PGD 0177B	Review in line with SPS template version 2.1: Added note re low risk of breast cancer. Updated references. Updated SLWG. Minor updates to PTHB PGD template	07/05/2024

This Powys Teaching Health Board (PTHB) PGD is based on a template developed on behalf of the Specialist Pharmacy Service, which had been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It had been approved by the Faculty for Sexual and Reproductive Health (FSRH) in April 2023. Acknowledgements:

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

PGD authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Kate Wright**	Lead doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	5/13/2024
Chief Pharmacist **Jacqui Seaton**	Chief Pharmacist for PTHB	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	5/3/2024
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB- Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	5/22/2024
Senior representative of professional group using the PGD **Claire Roche**	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: Claire Roche F07413E114E04B1...	5/20/2024

Appendix A provides a staff accreditation sheet. Individual practitioners must be authorised by name to work to this PGD.

Those using this PGD must ensure that it is organisationally authorised and signed by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**
The final authorised copy of this PGD should be kept by PTHB for 25 years after the PGD expires.

[1] This includes any relevant amendments to legislation.

1. Characteristics of staff

Qualifications and professional registration	Current contract of employment with PTHB. Practitioners must only work under this PGD where they are competent to do so. Practitioners working under this PGD must also be a registered professional with the following body: • nurse or midwife currently registered with the Nursing and Midwifery Council (NMC) and providing Sexual Health Services or postnatal care The practitioners must also fulfil the training and additional requirements detailed below. Check Appendix A: Staff accredited to use the Patient Group Direction to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
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 (including the insertion of etonogestrel 68 mg subdermal implant and knowledge of its uses, contraindications and adverse effects; be alert to changes in the BNF and Summary of Product Characteristics; and be competent to assess an individual's capacity to understand the nature and purpose of the treatment and capacity to give or refuse consent to treatment). Recommended requirement for training would be successful completion of a relevant general contraception module/course accredited or endorsed by the FSRH (sign in with your Athens account, then search for Contraception), HEIW 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.

	Individual has undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfH PGD elearning programme, PTHB staff to access via ESR at https://my.esr.nhs.uk. 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 a minimum of 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, and be competent in the administration of adrenaline. Additionally, practitioners: • must be competent in the recognition, management and reporting of adverse drug reactions • must have access to the Patient Group Direction and associated online resources **THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix A). The individual must complete a self-declaration of competence for contraception supply, in their Personal Appraisal and Development Review (PADR) – the **personal development plan** (yellow) section of the PADR booklet should be used to record completion of Statutory and Mandatory training, including annual PGD e-learning. • Staff operating under this PGD are encouraged to review their competency using the NICE

	Competency Framework for health professionals using patient group directions. • A minimum of Level 2 safeguarding passport • Evidence of ongoing PGD training to be submitted to Line Manager annually- this should include an annual completion certificate of PGD e-learning or a dated screenshot of the PGD e-learning assessment results as proof of completion. • Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly. • Evidence of training in BLS and anaphylaxis.
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. • Annual PGD training. • Recertification on implant insertion to be undertaken every 5 years to ensure competence maintained as per FSRH requirements. • Practitioners must ensure they are up to date with relevant issues and clinical skills and management of anaphylaxis, Life Support Skills, with evidence of appropriate Continued Professional Development (CPD). • Updating at least every 2 years on the use of PGDs and etonogestrel implant. • Compliance with all mandatory NHS training including a minimum of safeguarding level 2. **It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.**
The decision to insert 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 **It is the responsibility of the inserting healthcare professional to ensure that the individual is within the inclusion criteria, and**

	that there are no reasons for exclusion before proceeding with the treatment. If there is any reason for concern, seek medical advice.
Criteria for inclusion	• Any individual from menarche (and age 13 years or over) to 55 years presenting for contraception and who has no contraindications • Where appropriate individuals requiring insertion of this subdermal contraceptive implant should also meet the inclusion criteria of the lidocaine 1% PGD 0178 • Informed consent given. Refer to PTHB Consent to Treatment and Examination Policy. In case of any doubt, contact medical team or gynaecologist. The individual should be informed they are being treated using a PGD. Additionally, see Appendix B: PTHB Checklist for Counselling/Consent • Medical and drug history taken, no reason for exclusion • Eligible following risk assessment - departmental UKMEC checklist and history taking proformas (Appendix B: Powys Teaching Health Board Implant Checklist). UKMEC must be determined and documented before issuing contraception. For all clients aged 13 to 17 years, a CSERQ 4/15 questionnaire must be completed. For adults, if safe to do so, client responses to the targeted enquiry (Ask and Act) may highlight risk factors, which will indicate that the practitioner should complete the Safe Lives Risk Identification Checklist (DASH RIC). This will subsequently aid decision making regarding safeguarding and MARAC referrals. Any vulnerable adult or child protection safeguarding concerns or significant risk factors identified should be referred to the local PTHB Safeguarding team and Powys Children Services and PTHB safeguarding policies followed. NB. **Special consideration:** Consultation areas must respect an individuals' right to confidentiality and safety and provide an acceptable level of privacy. **It is the responsibility of the inserting nurse or midwife to ensure that the individual is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the treatment. If there is any reason for concern, seek medical advice.**

Criteria for exclusion	• Consent not given. Individuals for whom valid consent, or 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained or received. Refer to sections "Action to be taken if the individual is excluded or declines treatment". • Individuals over 55 years of age. • Individuals under 13 years of age. 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. Any individual under 13 years of age, known to have engaged in sexual activity must be referred to Powys Children Service or CEOP Safety Centre. See Action to be taken if individual is excluded for further information. • Individuals 13 to 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 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. Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed. Consider discussing with GP. Where there are safeguarding concerns (Child Protection or Protection of Vulnerable Adults, POVA) advice from the local Safeguarding team should be sought from the Safeguarding Hub: • To generic email address: PowysTHB.Safeguarding@wales.nhs.uk And • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 Advice can also be sought from local Safeguarding leads
Arrangements for referral for medical advice	Contact GP via the surgery or the emergency on-call service, document advice given. Where required, refer the individual to gynaecologist/ GUM consultant /level 3 Sexual Health services for advice, if applicable. Call medical cover for advice and document advice given.

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. • If a child under 13 years of age is known to have engaged in sexual activity this must be referred to Powys Children Service and the PTHB Safeguarding Team notified.

3. Description of treatment

Name, strength & formulation of drug	Etonogestrel 68 mg 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 PGD0178 Administration of 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 postpartum, 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 https://bnf.nice.org.uk 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. In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone. In the case of anaphylaxis: • Refer to adrenaline (epinephrine) PGD 0017 and anaphylaxis policy • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in individual's notes

	• Ensure all individual's records are marked **ALLERGIC TO Etonogestrel 68mg Subdermal Implant**. • The individual may be advised to wear a MedicAlert or similar device to alert other healthcare providers Report via Datix Once for Wales Reporting system
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 on: http://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. For established medicines, serious adverse events in adults or all suspected adverse reactions in children that may be attributable to the medication should be reported. Guidance on the yellow card system is available at the back of the BNF or using the above link. • Record all adverse drug reactions (ADRs) in the individual's medical record and inform their GP. • All significant adverse drug reactions and any administration/insertion errors must be recorded. Report via Datix Once for Wales Reporting system.
Written information and further advice to be given to individual	• Ensure access to product information prior to insertion 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. See NHS 111 for services in Wales http://www.111.wales.nhs.uk/

Records	Record consultation details as required by local procedures. In addition, 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
	• Name of individual, address, 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 allergies and previous adverse events
	• 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/midwife and the individual • Batch number and expiry date 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 (include version number) • Name and signature (which may be an electronic signature) of the healthcare professional inserting 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. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

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) https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-implants-feb-2014/ • Faculty of Sexual and Reproductive Healthcare (2016) Amended September 2019 UK Medical Eligibility Criteria for Contraceptive Use https://www.fsrh.org/standards-and-guidance/documents/ukmec-2016/ • Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception – May 2022 https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ • FSRH Clinical Guidance: Quick Starting Contraception - April 2017 https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/ • Faculty of Sexual and Reproductive Healthcare (2015) Problematic bleeding with hormonal contraception https://www.fsrh.org/documents/ceuguidanceproblematicbleedinghormonalcontraception/ • Faculty of Sexual and Reproductive Healthcare (2014) Contraceptive choices for women with cardiac disease https://www.fsrh.org/documents/ceu-guidance-contraceptive-choices-for-women-with-cardiac/ • Faculty of Sexual and Reproductive Healthcare (2017) Amended October 2020 Contraception After Pregnancy https://www.fsrh.org/news/new-fsrh-guideline--contraception-after-pregnancy/ • 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) - Faculty of Sexual and Reproductive Healthcare • Medicines and Healthcare Regulatory Agency (2016) Nexplanon (etonogestrel) contraceptive implants: reports of device in vasculature and lung https://www.gov.uk/drug-safety-update/nexplanon-etonogestrel-contraceptive-implants-reports-of-device-in-vasculature-and-lung

Appendix A- Staff accredited to use this Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board for the named healthcare professionals below who have signed the PGD to work under it.
The authorising manager must use the competency checklist (below).

Practitioner: By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

Printed name of registered health professional	Signature of registered health professional	Printed name of senior representative authorising health professional (Authorising manager)	Signature of senior representative authorising health professional (Authorising manager)	Date

The authorising manager should retain the original signed copy, which will be required for audit purposes. This list should be kept by PTHB for 25 years after the PGD expires.

The healthcare professional should retain a copy of the document after signing.

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

Name: **Role:**		Sign / Initial	Further training identified (Y/N)	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) _____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to individual's line manager, and to the staff member, in conjunction with the PGD Appendix A authorisation sheet.

A copy of this form should also be kept by service lead in the training file.

Appendix B **POWYS TEACHING HEALTH BOARD**

SEXUAL HEALTH SERVICE: IMPLANT CHECK LIST

Last reviewed July 2023

Name:				**Date of Birth:**	
Address:				**GP contact details:**	
Height:		**Weight:**		**BMI** (Body Mass Index)	

Risk Factors

UK MEC 4/ WHO 4: Absolute Contraindications.

The presence of **ONE** or more risk factors contraindicates the usage of the implant.

CONDITION	PRESENT	ABSENT
Current breast cancer		

NB Also contra-indicated if hypersensitivity to any component, or in established pregnancy

UK MEC 3/ WHO 3: Relative contraindications

Conditions requiring careful consideration where risks generally outweigh advantages & where **Etonogestrel 68mg subdermal Implant** should not generally be used. **THESE CONDITIONS ARE PGD 0177B EXCLUSIONS.**

CONDITION	PRESENT	ABSENT
Severe (decompensated) liver cirrhosis. Malignant liver tumour (hepatocellular carcinoma) or benign Hepatocellular adenoma.		
Current & history of ischaemic heart disease or stroke (**developed while on Etonogestrel 68mg subdermal Implant**)		
Unexplained vaginal bleeding (suspicious for serious condition) before evaluation		
Past history of breast cancer		

NB CHECK DRUG INTERACTIONS – some will be PGD exclusions – check relevant PGD for details

NB If working to PGD 0177B, acute porphyria is a PGD exclusion

Condition	PRESENT	ABSENT
Acute porphyria		

UK MEC 2/WHO 2: Conditions requiring caution but where the advantages generally outweigh the theoretical or proven risks.

CONDITION	PRESENT	ABSENT
Multiple risk factors for cardiovascular disease (such as smoking, diabetes, hypertension, obesity, dyslipidaemias)		
Past history of VTE		
Major surgery with prolonged immobilisation		
Current VTE on anticoagulants		
Known thombogenic mutation (e.g. Factor V Leiden, prothrombin mutation, protein S, protein C and antithrombin deficiencies)		
Current & history of ischaemic heart disease or stroke (**before starting Etonogestrel 68mg subdermal Implant**)		
Dyslipidaemia		
Hypertension with vascular disease (includes coronary heart disease presenting with angina, peripheral vascular disease presenting with intermittent claudication, hypertensive retinopathy and TIA)		
Rheumatoid arthritis, SLE with or without Antibodies, or positive antiphospholipid antibodies		
Migraine with or without aura, or History (≥5 years ago) of migraine with aura, any age		
Diabetes (excluding history of gestational diabetes)		
Heavy, prolonged vaginal bleeding or irregular pattern without heavy bleeding		
Cervical cancer (awaiting treatment) or after radical trachelectomy		
Breast conditions – undiagnosed mass/ breast symptoms, carrier of known gene mutation associated with breast cancer (e.g. BRCA1/BRCA2)		
Cardiomyopathy with impaired cardiac function		
Atrial fibrillation		
Symptomatic (treated by cholecystectomy, medically treated or current) or asymptomatic gall bladder disease, history of cholestasis (past COC-related)		
Organ transplant		
Benign Focal nodular hyperplasia		

Any reason/s for exclusion from implant or lidocaine PGDs:	
If individual is under 13 years of age record action taken:	
If under 16 years of age document capacity using Fraser guidelines. If not competent, record action taken	
If over 16 years of age and not competent, record action taken	
Signature:	
Name in full (block Capitals):	
Date of 1st counselling:	
LMP:	
Contraception:	

CHECKLIST FOR COUNSELLING/CONSENT

Mode of action		Option to discontinue	
Safer Sex		After 6 months	

Advantages of Etonogestrel		**Disadvantages of Etonogestrel**	
Effectiveness		**Common or very common side effects may include:** Abdominal pain; alopecia; anxiety; appetite increased; breast abnormalities; depressed mood; dizziness; emotional lability; fatigue; flatulence; headaches; hot flush; increased risk of infection; influenza like illness; libido decreased; menstrual cycle irregularities; nausea; ovarian cyst; pain; skin reactions; weight changes	
Non user dependent			
3 year lifespan			
Easily reversible /Return of pre-existing fertility			
Decrease in painful periods			

INSERTION & REMOVAL TECHNIQUE EXPLAINED			
Site		Due date for removal	
Equipment / Local anaesthesia		Possible problems: - pain, itching, bruising, tenderness at site, possible infection at site, scarring.	
Advised who to contact if any concerns		Advised of the benefits and side effects of lidocaine (if used)	

INSERTION TIME			
Non hormonal contraception: Day 1-5		Currently taking COC : anytime if compliant	
Currently on POP: anytime if compliant		Abortion: up to day 5 post procedure	
Currently on Depo-Provera: and not less than 13 weeks since previous administration		Post delivery up to Day 21	
Implant in situ within license period		Outside these times – exclude pregnancy, advise condoms for 7/7	

PATIENT DECLARATION	
I confirm that I have been counselled prior to the insertion of the Etonogestrel 68mg subdermal Implant contraceptive implant and consent to the procedure and to the administration of local anaesthesia if needed.	
Patient signature:	
Date:	
Fitted by: (Name in block capitals)	
If administered via PGD, version number:	
If local anaesthesia administered via PGD, record version number:	
Practitioner Signature:	
Date:	

Etonogestrel 68mg subdermal Implant BATCH STICKER

Credit Card Issued

Date Inserted:

Site of insertion (including which arm and exact location):

Due date for removal

Record anaesthetic used:

Site of injection:

Dose of anaesthetic:

Batch of anaesthetic:

Expiry date of anaesthetic:

Relevant examination findings:

Any adverse reactions and actions taken:

Implant felt in arm after insertion Practitioner Yes/ No Patient Yes /No