

This Patient Group Direction (PGD) must only be used by registered healthcare 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.

# PATIENT GROUP DIRECTION (PGD)

## Administration of lidocaine hydrochloride 1% injection to facilitate insertion and/or removal of subdermal etonogestrel (e.g. Nexplanon®) implant in Sheffield primary care services

Version Number 2.0

Change History	
Version and Date	Change details
Version 1 October 2020	New template
Version 2.0 August 2023	<p><b>Dose and frequency of administration section amended to:</b>  <b>Insertion:</b> Initially 5-20mg (0.5-2ml). A further dose of up to 10mg (1ml) may be used if required to a total maximum dose of 30mg (3ml).  <b>Removal:</b> 5-10mg (0.5-1ml).  <b>Total maximum dose for concurrent removal and insertion is 40mg (4ml).</b></p> <p>Updated exclusions, adverse effects and references. Minor changes to some wording and formatting. Aligned content with other PGDs for same or associated medicine / group. Updated PGD development group members.</p>

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

#### PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	1 <sup>st</sup> September 2023
Review date:	March 2026
Expiry date:	31 <sup>st</sup> August 2026

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in April 2023

#### **This section MUST REMAIN when a PGD is adopted by an organisation.**

Name	Designation
Dr Cindy Farmer	Vice President, General Training 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)
Dr Kathy French	Specialist Nurse
Dr Sarah Pillai	Associate Specialist
Alison Crompton	Community pharmacist
Andrea Smith	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

**The PGD template is not legally valid until it has had the relevant organisational approval - see below.**

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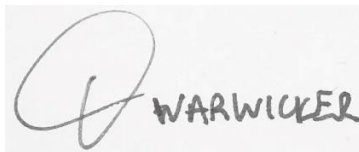

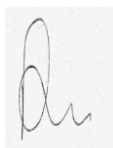

## ORGANISATIONAL AUTHORISATIONS

Authorisation is limited to those registered healthcare professionals listed in Appendix A.

Any practitioner intending to work under the PGD must be individually authorised by their / the designated manager, under the current version of this PGD before working according to it (see Appendix A). Each registered healthcare professional is professionally accountable for ensuring they have undergone appropriate family planning training and are approved as competent in the administration of lidocaine 1% injection in accordance with the following patient group direction.

The registered healthcare professional must act within their code of professional conduct at all times.

The PGD template has been reviewed, adapted to meet local requirements and authorised by:

Name	Job title and organisation	Signature	Date
<b>Dr David Warwicker</b>	Medical Advisor to Medicines Optimisation Team NHS South Yorkshire ICB		2 <sup>nd</sup> August 2023
<b>Emily Parsons</b>	Medicines Governance Pharmacist NHS South Yorkshire ICB		2 <sup>nd</sup> August 2023
<b>Alun Windle</b>	Chief Nurse NHS South Yorkshire ICB		3 <sup>rd</sup> August 2023
<b>Person signing on behalf of NHS Sheffield CCG</b>  <b>Alex Molyneux</b>	  Chief Pharmacy Officer NHS South Yorkshire ICB	  	  8/9/2023

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## 1. Characteristics of staff

<b>Qualifications and professional registration</b>	<p>Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation.</p> <p>Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.</p>
<b>Initial training</b>	<p>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 individuals ensuring safe provision of the medicines listed in accordance with local policy.</p> <p>Recommended requirement for training would be successful completion of a relevant module/course accredited or endorsed by the FSRH, CPPE 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/or removal of the subdermal implant which should also include training and been assessed as competent in the administration of lidocaine.</p> <p>Individual has undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - <a href="#">eLfH PGD elearning programme</a></p> <p>The healthcare professional must keep up to date with current FSRH guidance relevant to the insertion/removal of the contraceptive implant including any relevant MHRA Drug Safety Updates.</p> <p>The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent.</p> <p>The healthcare professional must ensure that they have an up to date certificate for Basic Life Support (BLS) and anaphylaxis as required by the employing Trust/organisation</p>
<b>Competency assessment</b>	<ul style="list-style-type: none"> <li>• Individuals operating under this PGD must be assessed as competent or complete a self-declaration of competence for contraception supply.</li> <li>• Staff operating under this PGD are encouraged to review their competency using the <a href="#">NICE Competency Framework for health professionals using patient group directions</a></li> </ul>
<b>Ongoing training and competency</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Organisational PGD and/or medication training as required by employing Trust/organisation.</li> </ul>
<p>The decision to administer any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.</p>	

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## 1. Clinical condition or situation to which this PGD applies

<b>Clinical condition or situation to which this PGD applies</b>	Local anaesthetic for insertion and/or removal of subdermal etonogestrel subdermal contraceptive implant.
<b>Criteria for inclusion</b>	<ul style="list-style-type: none"> <li>Any individual requiring the insertion and/or removal of etonogestrel subdermal contraceptive implant where this has been prescribed by an appropriate medical or non-medical prescriber.</li> <li>Consent given.</li> </ul>
<b>Criteria for exclusion</b>	<ul style="list-style-type: none"> <li>Consent not given.</li> <li>Individuals under 16 years of age and assessed as not competent using Fraser Guidelines.</li> <li>Individuals 16 years of age and over and assessed as lacking capacity to consent.</li> <li>Known hypersensitivity to the active ingredient or to any constituent of the product - see <a href="#">Summary of Product Characteristics</a> or other amide type anaesthetics</li> <li>Individual who had received a previous maximum infiltration of local anaesthetic within 4 hours (200mg)</li> </ul> <p><b>Cardiovascular Disease</b></p> <ul style="list-style-type: none"> <li>Complete heart block</li> <li>Hypovolaemia</li> </ul> <p><b>Other conditions</b></p> <ul style="list-style-type: none"> <li>Porphyria</li> </ul>
<b>Cautions including any relevant action to be taken</b>	<ul style="list-style-type: none"> <li>If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented.</li> <li>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.</li> <li><b>Individuals who are breastfeeding.</b> The individual should be informed that small amounts of lidocaine may be excreted into the breast milk. The possibility of an allergic reaction in the infant, albeit remote, should be borne in mind when receiving lidocaine when breastfeeding.</li> <li>The SmPC recommends use with caution in the following patient groups. Given the dose and route used, they are not excluded under this PGD. No additional monitoring is required. This is in line with FSRH feedback. <ul style="list-style-type: none"> <li>Bradycardia</li> <li>Congestive heart failure</li> <li>Known acute porphyria</li> <li>Known epilepsy</li> <li>Known myasthenia gravis</li> <li>Impaired respiratory function</li> <li>Severe renal impairment (eGFR &lt;10ml/min/Stage 5)</li> </ul> </li> </ul>
<b>Action to be taken if the individual is excluded or declines treatment</b>	<ul style="list-style-type: none"> <li>Explain the reasons for exclusion to the individual and document in the consultation record.</li> <li>Record reason for decline in the consultation record.</li> <li>Where required refer the individual to the prescriber or a suitable health service provider if appropriate and/or provide them with information about further options.</li> </ul>

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## 2. Description of treatment

<b>Name, strength &amp; formulation of drug</b>	Lidocaine 1% w/v (10 mg in 1 mL) solution for injection in 2mL, 5 mL or 10 mL ampoules
<b>Legal category</b>	POM
<b>Route of administration</b>	Subcutaneous or intradermal surface infiltration only
<b>Off label use</b>	<p>Medicines should be stored according to the conditions detailed in the Storage section below. However, 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.</p> <p>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.</p>
<b>Dose and frequency of administration</b>	<p><b>Insertion:</b> Initially 5-20mg (0.5-2ml). A further dose of up to 10mg (1ml) may be used if required to a total maximum dose of 30mg (3ml).</p> <p><b>Removal:</b> 5-10mg (0.5-1ml).</p> <p><b>Total maximum dose for concurrent removal and insertion is 40mg (4ml).</b></p>
<b>Duration of treatment</b>	Single episode of care permitted under this PGD (i.e. insertion or removal only or concurrent removal and insertion).
<b>Storage</b>	Medicines must be stored securely according to national guidelines and in accordance with the product SPC. If only part of an ampoule is used, the remainder should be discarded.
<b>Drug interactions</b>	<p>All concurrent medications, including those purchased should be considered for interactions.</p> <p>A detailed list of drug interactions is available in the individual product SPC, which is available from the electronic Medicines Compendium website <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> the BNF <a href="http://www.bnf.org">www.bnf.org</a> and, as this PGD supports the administration of hormonal contraception, FSRH CEU Guidance: Drug Interactions with Hormonal Contraception <a href="https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/">https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/</a></p> <p>Refer to a prescriber if any concern of a clinically significant drug interaction.</p>
<b>Identification &amp; management of adverse reactions</b>	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium

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	<p>website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> and BNF <a href="http://www.bnf.org">www.bnf.org</a></p> <p>Note when used for surface anaesthesia rapid and extensive absorption may result in systemic side effects.</p> <p>Hypersensitivity reactions (allergic or anaphylactoid reactions, anaphylactic shock)</p> <p>Adverse effects are rare and usually a sign of accidental intravascular injection, excessive dosage or rapid absorption from highly vascular areas, or may result from a hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. Systemic toxicity mainly involves the central nervous system and/or the cardiovascular system.</p> <p>Monitor individual for signs of:</p> <ul style="list-style-type: none"> <li>• Confusion</li> <li>• Respiratory depression</li> <li>• Convulsions</li> <li>• Hypotension</li> <li>• Bradycardia</li> <li>• Dizziness</li> </ul> <p>If overdose or severe adverse reaction suspected manage following local policy.</p>
<b>Additional facilities and supplies</b>	<ul style="list-style-type: none"> <li>• Access to working telephone</li> <li>• Suitable waste disposal facilities</li> <li>• Immediate access to in-date anaphylaxis kit (IM adrenaline 1:1000)</li> </ul>
<b>Management of and reporting procedure for adverse reactions</b>	<ul style="list-style-type: none"> <li>• 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: <a href="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a></li> <li>• Record all adverse drug reactions (ADRs) in the individual's medical record.</li> <li>• Report via organisation incident policy.</li> </ul>
<b>Written information and further advice to be given to individual</b>	<ul style="list-style-type: none"> <li>• Offer Manufacturer's Patient Information Leaflet (PIL).</li> <li>• Explain mode of action, side effects, and benefits of the medicine.</li> </ul>
<b>Advice/follow up treatment</b>	<p>Advise individual:</p> <ul style="list-style-type: none"> <li>• How to care for the injection site and advise to return if concerns about the injection site.</li> <li>• Give information on who to contact in the event of an adverse reaction or concerns.</li> </ul>
<b>Records</b>	<p><b>Record the following, unless already recorded in patient record:</b></p> <ul style="list-style-type: none"> <li>• The consent of the individual and: <ul style="list-style-type: none"> <li>○ If individual is under 13 years of age record action taken</li> <li>○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.</li> <li>○ If individual over 16 years of age and not competent, record action taken</li> </ul> </li> </ul>

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	<ul style="list-style-type: none"> <li>• Individual's name, address and date of birth</li> <li>• GP contact details where appropriate</li> <li>• Attendance date</li> <li>• Reason for attendance</li> <li>• Relevant past and present medical and family history, including drug history</li> <li>• Any known allergy</li> <li>• Relevant examination findings</li> <li>• Inclusion or exclusion from PGD</li> <li>• Name/brand and dose of the medication administered</li> <li>• Site of injection</li> <li>• Batch number and expiry date of product in line with local procedure</li> <li>• A statement that administration is for insertion of subdermal implant and is by using a PGD <ul style="list-style-type: none"> <li>○ SNOMED code: <i>Administration of medication under patient group direction</i></li> </ul> </li> <li>• Advice given about the medication including side effects, benefits, and when and what to do if any concerns</li> <li>• Details of any adverse drug reactions and what action taken</li> <li>• Any referral arrangements</li> <li>• Any administration outside the marketing authorisation</li> <li>• Record the</li> <li>• Any follow up and/or signposting arrangements</li> <li>• Any other relevant information that was provided to the individual</li> <li>• Name and signature (which may be an electronic signature) of the clinician supplying and administering the medicine</li> </ul> <p>Records should be signed and dated (or a password-controlled e-records) and securely kept for a defined period in line with local policy.</p> <p>All records should be clear, legible and contemporaneous.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>
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### 3. Key references

<b>Key references (accessed January 2023)</b>	<ul style="list-style-type: none"> <li>• Electronic Medicines Compendium <a href="http://www.medicines.org.uk/">http://www.medicines.org.uk/</a></li> <li>• Electronic BNF <a href="https://bnf.nice.org.uk/">https://bnf.nice.org.uk/</a></li> <li>• NICE Medicines practice guideline "Patient Group Directions" <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li> <li>• Resuscitation Council (UK) Emergency Treatment of anaphylactic reactions: Guidelines for health care providers Resuscitation Council, 2021 <a href="http://www.resus.org.uk">www.resus.org.uk</a></li> </ul>
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	<ul style="list-style-type: none"> <li>FSRH Clinical Guideline: FSRH Clinical Guideline: Progestogen-only Implant (February 2021)  <a href="https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-implants-feb-2014/">https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-implants-feb-2014/</a></li> </ul>
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## Appendix A – Registered health professional authorisation sheet

**Lidocaine hydrochloride 1% injection to facilitate insertion and/or removal of subdermal etonogestrel (e.g. Nexplanon®) implant - PGD Version 2.0**

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Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

### Registered health professional

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions 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.

<b>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.</b>			
<b>Name</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>

### Authorising manager

<b>I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of</b>			
<b>(Name of organisation) _____</b>			
<b>for the above named health care professionals who have signed the PGD to work under it.</b>			
<b>Name</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>

### Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

You must give this signed PGD to each authorised practitioner as it shows their authorisation to use the PGD. You do not need to return signed forms to the SY ICB but GP practices must ensure that appropriate organisational records are kept of the healthcare professionals authorised to work under the PGD. You may wish to retain a copy in the individual's personal file.

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