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| **Patient Group Direction for the administration of:**lidocaine hydrochloride 1% prior to the insertion or removal of the etonogestrel subdermal contraceptive implant |
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| **Title of patient group direction** | Patient Group Direction for the administration of lidocaine 1% injection for the insertion and removal of etonogestrel subdermal contraceptive implant |
| **Approved at**  | NMP/PGD Group |
| **PGD approved / valid from** |  |
| **Review date** |  |
| **Expiry date** |  |
| **Clinical area(s) where PGD applies** | Sexual heath and HIV outreach services within contraceptive and sexual health clinics, and in sexual health outreach services/locations |
| **Identified Lead for monitoring / review and contact details** | Wendy Billsborough |
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| **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** | Due for renewal –wording amended in line with the National PGDTotal treatment quantity amended to 4mls |
| **List of persons involved in the consultation process.**(The group must include a sponsoring clinician, a pharmacist and a senior representative of the professional group. The job title and level of consultation should also be listed). | Wendy Billsborough – Advanced Nurse Specialist .Alison Chorlton – Lead Nurse Sexual HealthDr Ian Fairley, Clinical Director LeadJill McEnaney – Directorate Pharmacist |

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| **CLINICAL CONDITION** |
| **Condition** | Local anaesthetic for insertion and/or removal of the etonogestrel sub-dermal contraceptive implant |
| **Inclusion criteria** | * Individuals requiring local anaesthetic prior to the insertion or removal of the etonogestrel subdermal contraceptive implant
* The etonogestrel contraceptive implant PGD inclusion criteria should also be met.
* Consent given
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| **Exclusion criteria** | * Child aged 12 years or under
* Children under 16 years not considered competent under Fraser guidelines
* Individuals 16 years of age and over and assessed as lacking capacity to consent
* Consent not given
* Known hypersensitivity to lidocaine hydrochloride, amide type anaesthetics or any of the excipients in the product
* Individual who had received a previous maximum infiltration of local anaesthetic within 4 hours
* Interacting medicines - see current British National Formulary (BNF) [www.bnf.org](http://www.bnf.org) or individual product SPC <http://www.medicines.org.uk>Existing implant cannot be palpated (for removals only)
* Heart block
* Hypovolaemia
* Porphyria
* Inflammation, infection or skin damage in the tissue to be injected
* Bradycardia
* Impaired cardiac conduction
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| **Actions for patients excluded** | * Discuss/offer an alternative contraceptive method
* If implant preferred choice refer to clinic doctor/independent nurse prescriber or GP if in an outreach setting for further assessment
* Document all action taken in the patient records

If implant unable to be palpated for removal refer into a scanning appointment and consider contraceptive cover  |
| **Action for patients not wishing to receive care under the PGD** | * Record the refusal in the clinical record
* Refer to clinic doctor/independent nurse prescriber if agreed with the client
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| **DESCRIPTION OF TREATMENT** |
| **Name of Medicine** | Lidocaine hydrochloride |
| **Legal Classification** | POM |
| **Licensing information** |  |
| **Is the medicine licensed for the intended use?** | **YES** |  |
| **Does it have a black triangle status?**  |  | **NO** |
|  | **Does it have a Risk Minimisation Measures (RMM) recommendation** | **YES** | **NO** |
| **Form** | Subcutaneous  |
| **Strength** | 1% (10 mg in 1 mL)in 2mL, 5mL or 10 mL ampoules |
| **Dose**  | Single episode of treatment at time of implant insertion, removal or replacement* Recommended dose for insertion 1 to 2mL
* Recommended dose for removal 0.5 to 1mL
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| **Frequency** | Single episode of treatment |
| **Route** |  Subcutaneous or intradermal surface infiltration only |
| **Total Treatment Quantity** | A maximum of 2mL in total may be used as appropriate to ensure insertion or removal can proceed without discomfort **Total maximum dose for concurrent removal and insertion is 40mg (4ml).**  |
| **Interactions with other medicines**(This must include all potentially serious interactions listed in the BNF) | Interactions are rare when used as a local anaesthetic. * 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 [www.bnf.org](http://www.bnf.org) and FSRH CEU Guidance: Drug Interactions with Hormonal Contraception <https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/>
* Also Check any medicines on UpToDate – Drug interactions via staff room under lidocaine

**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) | Allergic reactions are rareToxic effects are rare from small subdermal doses but may include:* Feeling of inebriation, nausea and vomiting, drowsiness light-headedness, nervousness, tremor, blurred vision, paraesthesia, restlessness, dizziness, feeling hot or cold, numbness of the tongue

Serious symptoms may result:confusion* Respiratory depression
* Convulsions
* Hypotension
* Bradycardia
* Hypersensitivity

See Summary of Product Characteristics (SPC) for full details | **Treatment of adverse reactions****Treatment of adverse reactions*** An anaphylaxis treatment kit and facilities for resuscitation should be available
* If necessary seek appropriate emergency advice and assistance
* Refer to ‘Guidelines for the management of severe local anaesthetic toxicity. Association of Anaesthetics

<https://www.aagbi.org/sites/default/files/la_toxicity_2010_0.pdf>* Document any adverse reactions in the client’s records. Inform 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](http://www.mhra.gov.uk/yellowcard)
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| **Advice to Patients:Written and Oral advice** (This should include the provision of a patient information leaflet) | * Explain the mode of action, side effects, benefits and duration of effect (full sensation should return within 2 to 4 hours)
* Explain that anaphylaxis is rare but can occur up to 72hrs after the injection and advise to seek urgent medical advice if symptoms develop
* Offer the lidocaine patient information leaflet (PIL)
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| **Follow up action** | * Provide contact details for the service and advise to return if any problems
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| **Storage** | * Locked drugs cupboard or locked case for outreach use

Do not store above 25ºC |
| **Records to be Kept** | The following details specific to the administration of lidocaine should be documented in the client’s clinical record:* Assessment of client request in relation to the implant procedure
* Consent of the individual
* Any reason for exclusion and action taken
* Any known allergies
* Inclusion or exclusion form the PGD
* Relevant past and present medical and family history, including drug history
* Consent of the individual
* Date
* On the prescription, record drug name and quantity administered
* Batch number and expiry date
* That the lidocaine was administered under a PGD
* Route and site of administration
* Advice given about the medication including side effects and what to do if any concerns
* Any referral arrangements
* Any off label use
* 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)
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| **Audit Arrangements** | As per current Trust PGD Policy |
| **References**  | * Faculty of Sexual and Reproductive Healthcare UK Medical Eligibility Criteria for Contraceptive Use (2016)
* Faculty of Sexual and Reproductive Healthcare Clinical guidance Progestogen-only implants (2014)
* Faculty for Sexual and Reproductive Healthcare (2016) Standards for Resuscitation in Sexual Health Services
* British National Formulary (BNF) www.bnf.org.uk
* NICE Guideline on Long Acting Reversible Contraception October 2005
* Manufacturer’s Summary of Product Characteristics (SPC) Lidocaine 1%: Electronic Medicines Compendium
* Faculty of Sexual and Reproductive Healthcare e-lfh/SHR Module 17
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| **Competency Requirements**(attach any competency frameworks / documents) | The Nurse must be authorised by name under the current version of this PGD before working to itEducation, training, qualifications and competencies:* Sexual health Nurse
* Clinical competence in sexual history taking.

 * Completion of the Trust PGD awareness session or Trust HUB e-learning.
* Knowledge base of the interaction of lidocaine with other drugs, and other exclusions and contraindications to lidocaine
* 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
* Knowledge of the current FSRH Progestogen Only implant guidance. keeps up to date with any changes to FSRH/manufacturers guidance relevant to this PGD
* 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)
* Maintain professional accountability with the NMC and ensure continual professional development
* Up to date certificate for Basic Life Support (BLS) and anaphylaxis as required by the employing Trust/organisation
* 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 the tri annual educational clinical governance
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| **AUTHORISATION OF THE PATIENT GROUP DIRECTION (PGD) FOR ADMINISTRATION OF:** lidocaine hydrochloride 1% prior to the insertion or removal of the etonogestrel subdermal contraceptive implant |
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| **PGD Development / Review Team – responsible for PGD content** |
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| **Title** | **Name** | **Signature** | **Date** |
| **Lead Author** |  |  |  |
| **Clinical Director Lead Approval** |  |  |  |
| **Directorate Pharmacy Lead Approval** | Jill McEnanney |  |  |
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| **PGD Approved by the NMP/PGD Group** |
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| **Title** | **Name** | **Signature** | **Date** |
| **NMP Lead /** **Lead Nurse Medicines Management** | Jennie Booth |  |  |
| **Chief Pharmacist / Deputy Chief Pharmacist** | Stuart Parkes |  |  |
| **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
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| **Staff authorised to work under this PGD** |
| **Ward / Department** | Sexual heath and HIV outreach services within contraceptive and sexual health clinics, and in sexual health outreach services/locations |
| **Professionals to whom this Patient Group Direction applies** | Registered nurses Band 5 or above |
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| ***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:*** |
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| **Name (Capitals)** | **Sign** | **Job Title** | **Authorising Manager** | **Date** |
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| **When the review date is exceeded, this PGD ceases to be a legal document** |
| **TEMPLATE DOCUMENTATION CONTROL** |
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| The template documentation control refers to the PGD template not the completed PGD.**\*\*Do not alter the section below for NMP/PGD Group use only\*\***  |
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| **Author:** | Jennie Booth, Lead Nurse Medicines ManagementCarol Belt, Principal Pharmacy TechnicianStuart Parkes, Deputy Chief Pharmacist |
| **Owner:**  | NMP/PGD Group |
| **Date of issue:** | June 2021 |
| **Version:** | 4 |
| **Approved by** | NMP/PGD Group |
| **Review date:** | June 2024 |

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