

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

Lidocaine Hydrochloride injection BP 1%w/v

by registered nurses/pharmacists for

local anaesthetic for insertion and/or removal of subdermal contraceptive implant

in GP practices in Sunderland

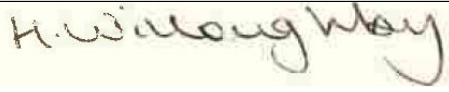



Version number: 1.1

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
Senior medicines optimisation pharmacist Sunderland CCG	Samantha O'Connell (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
Senior medicines optimisation pharmacist Sunderland CCG	Samantha O'Connell (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	<p>Registered nurses/pharmacists using this PGD must:</p> <ul style="list-style-type: none"> • Have a current contract of employment with a GP practice within Sunderland CCG • Be currently registered with their relevant professional body <ul style="list-style-type: none"> ○ Nurses: the Nursing & Midwifery Council (NMC) ○ 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: <ul style="list-style-type: none"> ○ Holds a recognised post-registration qualification in contraception/sexual health (an introduction to contraception is not sufficient). <p>OR</p> <ul style="list-style-type: none"> ○ Significant training and experience in contraception and sexual health. This should be confirmed by documentation on individuals personal file.
Initial training	<ul style="list-style-type: none"> • Has had training in the use of PGDs • 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. • Has undergone regular training and updating in safeguarding children and vulnerable adults • Has undergone regular updating in basic life support and anaphylaxis • The use of lidocaine injection for insertion of etonogestrel 68mg subdermal implant should be performed under aseptic conditions and only by a qualified healthcare professional who is familiar with the procedure. • Nurse/pharmacist should ensure facilities for resuscitation are available when administering local anesthetics
Competency assessment	<p>Must have demonstrated an appropriate level of competence to the senior medical representative in the practice in contraceptive services.</p>
Ongoing training and competency	<ul style="list-style-type: none"> • The registered nurse/pharmacist should ensure she/he is aware of any changes to the recommendations for

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	<p>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.</p> <ul style="list-style-type: none">• Continuous professional development completed as per governing body.• Revalidation of professional qualification as dictated by governing body.
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Clinical condition

Clinical condition or situation to which this PGD applies	Local anaesthetic for insertion and/or removal of subdermal contraceptive implant
Inclusion criteria	<ul style="list-style-type: none"> • Any individual requiring the insertion and/or removal of subdermal contraceptive implant. • Individual requiring insertion and /or removal of subdermal contraceptive implant should also meet the inclusion criteria of the subdermal contraceptive implant PGD
Exclusion criteria	<p>Personal Characteristics & Reproductive History</p> <ul style="list-style-type: none"> • Known hypersensitivity to lidocaine hydrochloride • Known hypersensitivity to amide anaesthetics • Individual who had received a previous maximum infiltration of local anaesthetic within 4 hours • Individuals not competent to consent • Existing implant cannot be palpated (for removals only) • Pregnant patients • Breast-feeding patients <p>Cardiovascular Disease</p> <ul style="list-style-type: none"> • Complete heart block • Hypovolaemia <p>Other conditions</p> <ul style="list-style-type: none"> • Porphyria • Inflammation or infection in the tissues to be injected • Individual wishes to see a doctor
Cautions (including any relevant action to be taken)	<ul style="list-style-type: none"> • Myasthenia gravis • Epilepsy • Congestive heart failure • Bradycardia • Respiratory depression • Patients who take drugs which interact with lidocaine – see SPC/BNF for full details (including but not limited to; cimetidine, propranolol, ranitidine, anti-viral agents, diuretics, anti-arrhythmics, amiodarone, antipsychotics which do/may prolong the QT interval, 5HT3 antagonists, quinupristin/dalfopristin, suxamethonium, verapamil, timolol, dopamine, narcotics, opioid/antiemetic combinations), phenytoin, fentanyl. • Hepatic and renal insufficiency • Hypokalaemia, hypoxia and disorder of acid-base balance • Discuss with appropriate doctor/independent non-

	<p>medical prescriber any medical condition or medication of which the nurse/pharmacist is unsure/uncertain</p> <ul style="list-style-type: none"> • Ensure emergency drugs and equipment, including adrenaline are available for the treatment of anaphylaxis and emergencies according to local policy • Use only the lowest effective dose (not to exceed 2ml)
Arrangements for referral for medical advice	N/A
Action to be taken if patient excluded	<ul style="list-style-type: none"> • Refer to appropriate doctor / independent non-medical prescriber • Document all actions taken
Action to be taken if patient declines treatment	<ul style="list-style-type: none"> • Record the refusal in the clinical record • Refer to appropriate doctor/independent non-medical prescriber where required.

Details of the medicine

Name, form and strength of medicine <i>Include ▼ for black triangle medicines</i>	Lidocaine (lignocaine) 1% w/v (10 mg in 1 mL) in 5 mL or in 10 mL ampoules
Legal category	Prescription only medicine
Indicate any off-label use (if relevant)	N/A
Route/method of administration	Subcutaneous or intradermal surface infiltration only
Dose and frequency	Single episode of treatment
Quantity to be administered and/or supplied	Maximum dose not to exceed 2 mL for insertion and/or removal
Maximum or minimum treatment period	Single episode of treatment
Adverse effects	<p>Refer to current summary of product characteristics (SPC) of relevant product and current British National Formulary (BNF) for full list and further information.</p> <p>In common with other local anaesthetics, adverse reactions to lidocaine are rare and are usually the result of raised plasma concentrations due to 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>This list does not represent all reported side effects of this medicine.</p> <p>Serious symptoms</p> <p>When used for surface anaesthesia rapid and extensive absorption may result in systemic side effects.</p> <p>CNS effects include:</p> <ul style="list-style-type: none"> • Confusion • Respiratory depression • Convulsions • Hypotension • Bradycardia • Drowsiness <p>Other effects include:</p> <ul style="list-style-type: none"> • Hypersensitivity

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- Rash
- Urticaria

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 procedure 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.

<p>Records to be kept</p>	<p>The authorised registered nurse/pharmacist must ensure the following is documented in the clinical record:</p> <ul style="list-style-type: none"> • 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 (where appropriate) • 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 terms of the marketing authorisation • The consent of the individual • If individual is and not competent, record action taken • Record the name/brand, dose of the medication and quantity supplied • 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 or administering the medicine • "Supplied under PGD"
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Patient information

Written information to be given to patient or carer	<ul style="list-style-type: none">• Provide manufacturer's patient information leaflet (PIL) and discuss
Follow-up advice to be given to patient or carer	<ul style="list-style-type: none">• Explain mode of action, side effects, and benefits of the medicine• 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

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| 1) London contraception and sexual health patient group direction PGD for the supply and administration of Lidocaine Hydrochloride injection 1% BP
2) Lidocaine hydrochloride BP 1% w/v SPC: www.medicines.org.uk/emc/medicine/25036 |
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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