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)

Supply/Administration of LIDOCAINE HYDROCHLORIDE INJECTION 1% (10MG/ML) AND LIDOCAINE HYDROCHLORIDE INJECTION 2% (20MG/ML)

For the treatment of joint conditions

Version Number 2.2

Change History	
Version and Date	**Change details**
V1.0 -1.2	See previous PGDs
V2.0	• Relevant drug interaction see **Drug interactions** section added to cautions

V2.1	• Typographical changes
	• Resuscitative equipment must be available has been removed.
	• Added patients on anticoagulant therapy for primary care only
	• Initial training added:
	  • Must have undertaken training and be competent in basic life support.
	  • Have received recognised professional training in injection therapy

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorized by their organisation to practice under it (See Section 5). The most recent and in date final signed version of the PGD must be used.

PGD DEVELOPMENT GROUP

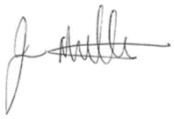
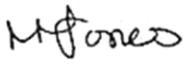
Date PGD template comes into effect:	7th April 2024
Review date	October 2026
Expiry date:	30th March 2027

This PGD template has been peer reviewed by the BNSSG PGD short life working group

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

Name	Designation
Andrea Floyd	Senior Physiotherapist, UHBW
Adam Gold	Clinical Lead, North Somerset MSK Interface Service, Sirona
Lorna Harvey	Advanced Physiotherapist Practitioner, UHBW
Jamie Pierce	Weston MSK Pathway Lead, UHBW
James Ritchie	Consultant Rheumatologist, UHBW
Breda Cronolly	Lead Medicines Information Pharmacist, UHBW
Kate Ellis	Head of Medicines Optimisation, Sirona
Michelle Jones	Principal Medicines Optimisation Pharmacist, BNSSG CCG
Emily Stone	Medicines Optimisation Pharmacy, BNSSG ICB

ORGANISATIONAL AUTHORISATIONS AND OTHER LEGAL REQUIREMENTS

Name	Job title and organisation	Signature	Date
Joanne Medhurst	Chief Medical Officer BNSSG ICB		28/03/2024
Michelle Jones	Principal Medicines Optimisation Pharmacist BNSSG ICB		28/03/2024
Debbie Campbell	Chief Pharmacist BNSSG ICB		28/03/2024

This PGD is for use by the services below:

Authorised for use by the following organisation and/or services
Suitably trained physiotherapists working within a BNSSG GP Practice
Limitations to authorisation
As per PGD

Local enquiries regarding the use of this PGD may be directed to bnssg.medicines-optimisation@nhs.net.

Characteristics of staff

Qualifications and professional registration	• Physiotherapist currently registered with the Health and Care professions Council (HCPC)
Initial training	• Have received recognised professional training in injection therapy. • Must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it • Has undertaken appropriate training and been assessed as competent to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this PGD • Must have undertaken appropriate training for working under PGDs for supply/administration of medicines • Must be competent in the use of PGDs (see NICE Competency framework for health professionals using patient group directions) • Must be competent in the recognition and management of anaphylaxis • Must have undertaken training and be competent in basic life support. • Must have access to the Patient Group Direction and associated online resource. • Have received recognised professional training in injection therapy • .Should fulfil any additional requirements defined by local policy – organisation to add here ***The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate training and successfully completed the competencies to undertake clinical assessment of patient leading to diagnosis of the conditions listed.***
Competency assessment	*Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions* ***Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.***
Ongoing training and competency	Practitioners should be aware of any change to the recommendations for the medicine listed. Practitioners must ensure they are up to date with relevant issues and clinical skills relating to joint injection therapy with evidence of appropriate Continued Professional Development (CPD). Annual updates in anaphylaxis and cardiopulmonary resuscitation to reinforce and update knowledge and skills in this area of practice, with particular reference to changes and national directives.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

1. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	• For pain associated with steroid injection to treat inflammation or pain of peripheral joints or surrounding structures including the joint capsule, synovial membrane, bursae, ligaments and tendons/sheaths • Facilitation of differential diagnosis
Criteria for inclusion	• Patients 18 years and over • Valid informed consent obtained • Clinical assessment indicates that injection of corticosteroid is the treatment of choice for inflammation of peripheral joints or surrounding structures which includes the joint capsule, synovial membrane, bursae, ligaments and tendon/sheaths **and** the use of anaesthetic is required to provide immediate pain relief at the injection site or the use of anaesthetic is required to facilitate diagnosis prior to the administration of corticosteroid. • Diagnosis of each clinical presentation to be made in line with the recommendations of Association of Chartered Physiotherapists in Orthopaedic Medicine and Injection Therapy (ACPOMIT) or other recognised courses • All relevant pathways for conservative management have been explored and evidenced as not appropriate or has completed without reasonable resolution in symptoms. If patient requires lidocaine and a steroid injection these must be given separately using the relevant PGDs. Mixing in the syringe leads to the production of an unlicensed product. Under current legislation unlicensed medicines may not be supplied or administered under a PGD. NB: if using with methylprednisolone, this must be the Depo-Medrone WITH lidocaine preparation
Criteria for exclusion	• No valid consent • Under 18 years of age • Hypersensitivity to anaesthetics of the amide type • Hypersensitivity to any components of the product • Hypovolaemia • Any form of heart block or sinus bradycardia • Pregnancy or breastfeeding • Untreated known or suspected systemic infection • Prosthesis/metal work in joint to be injected • Injection into the Achilles tendon due to the absence of true tendon sheath • Concomitant use with Depo-medrone (methylprednisolone acetate) with lidocaine • **For Primary care only:** Patients on anticoagulant therapy (direct oral anticoagulants (DOACs), warfarin etc)

Cautions including any relevant action to be taken	• For secondary care only: Patients on anticoagulant therapy (warfarin and DOACs). Depending on a suitable INR, joint or soft tissue injections and aspirations in patients taking warfarin are associated with a low risk of haemorrhage. It is important that the INR is within recommended range, preferably at the lower end of the range, and the patient is on stable doses of warfarin. It is advisable to check the INR again 3-4 days after the injection.Lidocaine should be administered with caution in patients with the following conditions. Refer to SPC (Home - electronic medicines compendium (emc)) and discuss with prescriber. • Epilepsy • Myasthenia gravis • Respiratory impairment • Congestive heart failure • Impaired cardiac conduction • Severe shock • Porphyria • Hepatic impairment – avoid or reduce dose in severe liver disease • End renal insufficiency • Reduce dose in the elderly or debilitated • Consider lower dose post cardiac surgery • Relevant drug interaction see **Drug interactions** section **NB** intra-articular administration of lidocaine can cause chondrotoxicity.
Action to be taken if the patient is excluded	• Record reasons for exclusion and any action(s) taken in patient notes • Advise patient on alternative treatment • Refer to a prescriber/supervising doctor if appropriate
Action to be taken if the patient or carer declines treatment	• Document advice given and the decision reached • Advise patient on alternative treatment • Refer to a prescriber/supervising doctor if appropriate
Arrangements for referral for medical advice	• If the patient presents with a recurrence of their symptoms, consider onward referral in line with trust. Provider policy. • If patient falls into exclusion category refer to a prescriber

2. Description of treatment

Name, strength & formulation of drug	Lidocaine hydrochloride injection 1%, 10 mg/mL Lidocaine hydrochloride injection 2%, 20mg/mL
Legal category	Prescription-only medicine (POM).
Route / method of administration	• Intra-articular, peri-articular and soft tissue injection (depending on the site and nature of the problem) by aseptic non-touch technique. • The technique of intra-articular administration should include precautions against injection or leakage into the dermis. • Do not mix with other preparations prior to injection. • Inspect visually for particulate matter and discoloration prior to administration whenever suspension and container permit. • Vials are intended for single dose use only. • **Not** be given via the intrathecal or intravenous route
Indicate any off-label use (if relevant)	Lidocaine is used outside the terms of its license when administered for intra-articular or soft tissue injection. However, it can be used under a PGD as it is considered 'off-label' use of a licensed product. As part of the consent process inform the patient/carer that the drug is being offered in accordance with national guidance but that it is outside of the product license.
Dose and frequency of administration	Reference; Injection Techniques in Musculoskeletal Medicine 5th Edition 2019 Saunders, Stephanie and Longworth, Steve • Large joint (knee, ankle, shoulder): 0-80mg • Medium joint (elbow, wrist): 0-30mg • Small joint (metacarpophalangeal, interphalangeal, sternoclavicular, acromioclavicular): 0-15mg • Peri-articular, intra-bursal and into tendon sheath 0-90mg Maximum doses • 1% lidocaine hydrochloride (maximum of 10 mL (100mg) depending on size of target structure) • 2% lidocaine hydrochloride (maximum of 5 mL (100mg) depending on the size of target structure) The dosage should be adjusted according to the patient and the site of administration. The lowest concentration and smallest dose producing the required effect should be given. Elderly or debilitated patients require smaller doses commensurate with age and physical status. There should be a minimum of a 6-week interval if a repeat injection into the same location is performed.
Duration of treatment	If the first injection is effective but results are temporary, two further injections may be given within a twelve-month period
Quantity to be supplied	Not applicable

Storage	• Do not store above 25°C • Keep in the outer carton • Protect from freezing ***Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website:*** www.medicines.org.uk
Drug interactions	***The following interactions have been identified and should be considered where it is known a patient is on the following medicines. Discuss with prescriber if you have concerns:*** **Other antiarrhythmics** • increased myocardial depression **Other local anaesthetics** • Increased risk of additive systemic toxic effects **Beta blockers** • increased risk of myocardial depression • increased risk of lidocaine toxicity with propranolol **Diuretics** • Effects of lidocaine antagonised by hypokalaemia with loop and thiazide diuretics **Cimetidine** • Metabolism of lidocaine inhibited leading to toxicity **Antivirals** • Increased serum levels of lidocaine **Antipsychotics** • Increased risk of ventricular arrhythmia **Muscle relaxants** Enhanced or prolonged neuromuscular blockade **This list is not exhaustive*. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website:*** *www.medicines.org.uk*
Identification & management of adverse reactions	Adverse effects relating to the injection procedure include: • Pain and discomfort for a few days • Temporary bruising or a collection of blood under the skin • Infection • Damage to nearby instructions • Bleeding 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

Identification & management of adverse reactions continued	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. **The following side effects may be associated with Lidocaine Hydrochloride:** • Central nervous system effects include dizziness, light-headedness, nervousness, drowsiness, confusion, respiratory depression and convulsions • Cardiac and vascular effects - hypotension, bradycardia (may lead to cardiac arrest) and arrhythmias • Temporary sensory disturbance – tinnitus, blurred vision, nystagmus, feeling hot/ cold or numb • Nausea / Vomiting • Local infection • Hypersensitivity reactions are rare but include urticaria, oedema, cutaneous lesions and anaphylactoid reactions **A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website:** www.medicines.org.uk
Management of and reporting procedure for adverse reactions	• Access to adrenaline 1:1000 must be available for anaphylaxis management. • Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report via organisation incident policy.
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the product.
Patient advice / follow up treatment	• Explain treatment, course of action, potential side-effects, and their management. • Advise to read patient information leaflet • Advise that infiltration may be uncomfortable, and that pain and discomfort may continue for a few days. Paracetamol may help with this • Advise there may be bruising or a collection of blood under the skin after injection. • Remain in department and rest for a period of half an hour • Advise client not to drive or operate machinery until full sensation is restored • Contact healthcare professional if pain exacerbates for more than four days after injection • Healthcare professional will inform GP of treatment • The individual/carer should be advised to seek medical advice in the event of an adverse reaction. • Advise patient of any follow up requirements in line with trust/provider policy

	• Advise on action to be taken if target lesion is unresponsive as per trust/provider policy
Records	**Record:** • That valid informed consent was given • Name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • Name of registered health professional • Name and brand of medication supplied/administered • Date of administration • Dose, form and route of supply/administration • Site at which injection given • Quantity supplied/administered • Batch number and expiry date (if applicable) • Advice given, including advice given if excluded or declines treatment • Referral arrangements (including self-care) • Details of any adverse drug reactions and actions taken • That it was supplied via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled e-records). 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.

3. Key references

Key references	• *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 • Chartered Society of Physiotherapy. Medicines, prescribing and physiotherapy. Medicines, prescribing and injection therapy | The Chartered Society of Physiotherapy (csp.org.uk) • Chartered Society of Physiotherapy. October 2016. The use of medicines with injection-therapy in physiotherapy services. 5th Edition http://www.csp.org.uk/ • Injection Techniques in Musculoskeletal Medicine 5th Edition 2019 Saunders, Stephanie and Longworth, Steve • Chartered Society of Physiotherapy. November 2018. Practice Guidance for Physiotherapist Supplementary and/or Independent Prescribers. 4th Edition http://www.csp.org.uk/

4. Registered health professional authorisation sheet

PGD Name/Version: Lidocaine HCL injection 1% and 2% Version 2.2

Valid from: 7th Apr 24 **Expiry: 30th Mar 27**

Before signing this PGD, check that the document has had the necessary authorisations in section 2. 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.

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.			
Name	**Designation**	**Signature**	**Date**

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

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.