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 METHYLPREDNISOLONE ACETATE 40MG/ML INJECTION WITH LIDOCAINE 10MG/ML (DEPO-MEDRONE WITH LIDOCAINE®)

For the treatment of painful or inflamed joints or soft tissues

Version Number 2.2

Change History	
Version and Date	**Change details**
V1.0 – V1.3	See previous versions
V2.0	• Resuscitative equipment must be available added to inclusion Drug interactions – information added • Diltiazem can increase methylprednisolone dose • Potassium-depleting agents e.g. diuretics. Observe closely for development of hypokalaemia • Grapefruit could increase levels

V2.1	• Typographical changes
	• Resuscitative equipment must be available has been removed.
	• Added patients on anticoagulant therapy and over 65 years added to exclusions.
	• Initial training added:
	  • Must have undertaken training and be competent in basic life support.
	  • Have received recognised professional training in injection therapy
	• Received a live vaccine within 4 weeks removed from exclusion and patient information

V2.2	• Exclusion added for primary care only: patients on anticoagulation therapy • Updated exclusion, psychiatric conditions not well controlled and/or previous psychosis • Psychogenic disorders and/or previous steroid psychosis (These would include depressive or manic-depressive illness moved to exclusion) • Drug interaction for Potassium-depleting agents e.g. diuretics updated to include; advise patient to report any signs or symptoms of hypokalaemia to their GP e.g. skipped heart beats or palpitations, muscle weakness or spasms or tingling or numbness.

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

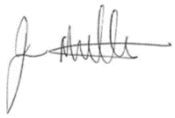
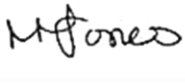
Date PGD template comes into effect:	7th April 2024
Review date	October 2026
Expiry date:	30th March 2027

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 ICB
Emily Stone	Medicines Optimisation Pharmacist, 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.

1. Characteristics of staff

Qualifications and professional registration	• Current contract of employment within a BNSSG provider organisation • Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
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 (PGD) 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 PGD and associated online resource • Have received recognised professional training in injection therapy • Should fulfil any additional requirements defined by local policy ***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 and management of anaphylaxis, 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, including basic resuscitation and anaphylaxis training, 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.	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	• Inflammation or pain of peripheral joints or surrounding structures including the joint capsule, synovial membrane, bursae, ligaments and tendons/sheaths.
Criteria for inclusion	• Patients 18 years and over • Valid informed consent obtained • Inflammation of peripheral joints or surrounding structures due to trauma, overuse or associated with degenerative change. • In patients who following assessment have symptoms that are persistent and likely to respond favourably to the administration of a steroid injection. • All relevant pathways for conservative management have been explored and evidenced as not appropriate or has completed without reasonable resolution in symptoms. • 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.
Criteria for exclusion	• No valid consent • Under 18 years of age • Hypersensitivity to methylprednisolone or corticosteroids or any component of the product • Hypersensitivity to anaesthetics of the amide type Inflammation of any of the stated structures due to infection or active infection in or near the joint • Previously infected joint • Systemic infection • Immediately following trauma to the structure • Prosthesis/metal work in joint to be injected • Unstable joints • Pregnancy and breast feeding • Active tuberculosis • Haemarthrosis • Injection into tendon body • Injection into the Achilles tendon due to the absence of true tendon sheath • Poorly controlled diabetes where there is a risk of hyperglycaemia • Adjacent osteomyelitis • History of active peptic ulcer • Psychiatric conditions not well controlled and/or previous psychosis Surgery in the affected joint within 3 months • **Primary care only:** Patients on anticoagulant therapy (e.g. direct oral anticoagulants (DOACs) and warfarin) **Not** be given via the intrathecal or intravenous route

Cautions including any relevant action to be taken	Methylprednisolone with lidocaine should be administered with caution in patients with the following conditions. Adverse effects are usually associated with systemic use at significant doses. Patients should be informed that their condition can be adversely affected by steroids, however, localised injections at the doses in this PGDs are safe and well tolerated. Refer to SPC (Home – electronic medicines compendium (emc)) and discuss with prescriber if you have concerns. • Patients on interacting drugs see **Error! Reference source not found.** sections • Patients on non-steroidal anti-inflammatory drugs (NSAIDs) – see Drug interactions below. • **Secondary care only:** Patients on anticoagulant therapy. 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 • Psychogenic disorder (These would include depressive or manic-depressive illness – Patients should be advised to monitor for signs of psychiatric alteration or adverse effects and report to GP. See section: advice to patient. • Bleeding disorders or impaired liver/kidney function • Immunosuppressed patients • Patients with diabetes – discuss recent blood glucose/HbA1c results to confirm stable and possible effects on blood glucose • Patients with severe anxiety – consider alternative treatment • Elderly patients (higher risk of side effects) • Osteoporosis (post-menopausal females are particularly at risk) • Hypertension or congestive heart failure • Impaired cardiac conduction • Glaucoma (or a family history of glaucoma) • Previous corticosteroid-induced myopathy • Epilepsy • Fresh intestinal anastomoses • Predisposition to thromboembolic disorders • Ulcerative colitis • Diverticulitis • Myasthenia gravis • Respiratory impairment • Porphyria • Ocular herpes simplex, for fear of corneal perforation • Hypothyroidism • History of tuberculosis • Care should be taken for patients receiving cardioactive drugs such as digoxin because of steroid induced electrolyte disturbance/potassium loss • In the treatment of tenosynovitis and tendinitis, care should be taken to inject Depo-Medrone with Lidocaine into the tendon sheath rather than into the substance of the tendon. • Patients with seizure disorders • Consider lower dose post cardiac surgery

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 • If patient falls into exclusion category refer to prescriber
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 prescriber

3. Description of treatment

Name, strength & formulation of drug	Methylprednisolone acetate 40mg/ml with lidocaine hydrochloride 10 mg/ml suspension for injection
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)	Not applicable
Dose and frequency of administration	The dose may vary from 4 mg to 80 mg of steroid depending on the disease entity being treated and the size of the structure being treated. Refer to the Summary of product characteristics (SPC) – section 4.2 Posology and method of administration https://www.medicines.org.uk/emc/product/1081/smpc (Depo-medrone with lidocaine) The lowest dose that is effective should be used to limit the risk of adverse effects. Severity of pain/condition and previous response to injection should also be considered. There should be a minimum of a 6-week interval if a repeat injection into the same location is performed.
Duration of treatment	If 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 there are concerns:*** • Convulsions have been reported with concurrent use of methylprednisolone and ciclosporin. Since concurrent administration of these agents results in a mutual inhibition of metabolism, it is possible that convulsions and other adverse effects associated with the individual use of either drug may be more apt to occur. • Drugs that induce hepatic enzymes, such as rifampicin, rifabutin, carbamazepine, phenobarbitone, phenytoin, primidone, and aminoglutethimide enhance the metabolism of corticosteroids and its therapeutic effects may be reduced. • Drugs such as clarithromycin, erythromycin, itraconazole and ketoconazole may inhibit the metabolism of corticosteroids and thus decrease their clearance. • Steroids may reduce the effects of anticholinesterases in myasthenia gravis. The desired effects of hypoglycaemic agents (including insulin), anti-hypertensives and diuretics are antagonised by corticosteroids, and the hypokalaemia effects of acetazolamide, loop diuretics, thiazide diuretics and carbenoxolone are enhanced. • The effect of methylprednisolone on oral anticoagulants is variable. The efficacy of coumarin anticoagulants may be enhanced by concurrent corticosteroid therapy and close monitoring of the INR is required to avoid spontaneous bleeding • The renal clearance of salicylates is increased by corticosteroids and steroid withdrawal may result in salicylate intoxication. Salicylates and non-steroidal anti-inflammatory (NSAIDs) agents should be used cautiously in conjunction with corticosteroids in hypothrombinaemia. • Steroids have been reported to interact with neuromuscular blocking agents such as pancuronium with partial reversal of the neuromuscular block • There may be increased incidence of gastrointestinal bleeding and ulceration when corticosteroids are given with NSAIDs. • Isoniazid clearance may be increased by methylprednisolone • HIV protease inhibitors – check SPC of individual drugs for details. Some can increase corticosteroid plasma levels, and corticosteroids can reduce some plasma concentrations of HIV protease inhibitors.

Drug interactions continued	• Diltiazem can increase methylprednisolone dose • Potassium-depleting agents e.g. diuretics. Advise patient to report any signs or symptoms of hypokalaemia to their GP e.g. skipped heart beats or palpitations, muscle weakness or spasms or tingling or numbness. • Grapefruit could increase levels of methylprednisolone **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	***The following side effects are possible with Methylprednisolone and Lidocaine:*** • Temporary local exacerbation with increased pain and swelling which normally subsides after a few hours • Anaphylactic/allergic reactions • Sterile abscess • Charcot-like arthropathy • Sepsis (local or systemic) • Raised blood sugar in diabetes • Post-injection flare • Subcutaneous atrophy and/or skin depigmentation • Facial flushing • Tendon rupture • Steroid arthropathy • Uterine bleeding • Possible psychiatric disturbances • Methylprednisolone may mask some of the signs of infection and patients may become susceptible to fungal, viral and bacterial infections which may reach an advanced stage before being recognised • 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. **NB:** With high or prolonged local dosage, corticosteroids can be absorbed in amounts sufficient to produce systemic effects **This list is not exhaustive. 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. • Provide 'Steroid Treatment' cards which give clear guidance on the precautions to be taken to minimise risk and which provide details of healthcare professional, drug, dosage and the duration of treatment. • Provide Steroid Emergency Card if appropriate. Further guidance can be found here: https://www.endocrinology.org/adrenal-crisis
Patient advice / follow up treatment	• Observe the patient post-injection for signs of potential adverse reactions • Request patient to stay in department for 30 minutes following injection • Provide patient with steroid treatment card • Provide steroid emergency card if appropriate • Provide patient information leaflet • Explain treatment, course of action, potential side-effects and their management. • The individual/carer should be advised to seek medical advice in the event of an adverse reaction. • Warn them of the risk of severe psychiatric alteration or adverse reactions ((Details of possible symptoms are in the patient information leaflet) emerging within a few days or weeks of treatment, and advise to seek medical help if they occur • 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. • To seek medical advice should there be an increase in pain following injection, swelling, fever and malaise • Advise patient to inform any health professional who offers treatment (doctor, nurse, dentist, pharmacist) during the course of the injections and for 3 months after the last injection that they have received a steroid injection. • Advise patient to avoid contact with known cases of chickenpox (unless they have had it), shingles (unless they have had chickenpox) or measles whilst receiving steroid treatment and for 3 months afterwards [if they have had exposure and have not had chickenpox before, they will need to seek advice from their GP as soon as possible]. • Healthcare professional will inform GP of treatment • 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 administered • Date of supply/administration • Dose, form and route of administration • Site at which injection given • Quantity 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 • 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.

4. 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/Green Book chapter 6: Contraindications and special considerations Greenbook_chapter_6.pdf (publishing.service.gov.uk)

5. Registered health professional authorisation sheet

PGD Name/Version: Methylprednisolone with lidocaine injection 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.