

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 (DEPOMEDRONE®)

for the treatment of painful or inflamed joints or soft tissues

Version Number 2.2

Change History	
Version and Date	Change details
V1.0 and V1.2	See previous versions
V2.1	<ul style="list-style-type: none"> <li>• Typographical changes</li> <li>• Resuscitative equipment must be available has been removed..</li> <li>• Initial training added:</li> <li>• Must have undertaken training and be competent in basic life support.</li> <li>• Have received recognised professional training in injection therapy</li> <li>• Received a live vaccine within 4 weeks removed from exclusion and patient information</li> </ul>
V2.2	<ul style="list-style-type: none"> <li>• Exclusion added for primary care only: patients on anticoagulation therapy</li> <li>• Updated exclusion, psychiatric conditions not well controlled and/or previous psychosis</li> <li>• Psychogenic disorders and/or previous steroid psychosis (These would include depressive or manic-depressive illness moved to exclusion)</li> <li>• Drug interaction for Potassium-depleting agents e.g. diuretics updated to include; advise patient to report any signs or symptoms of hypokalemia to their GP e.g. skipped heart beats or palpitations, muscle weakness or spasms or tingling or numbness.</li> </ul>

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

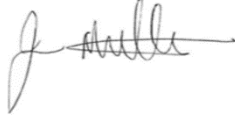
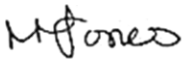

Date PGD template comes into effect:	7 <sup>th</sup> April 2024
Review date:	October 2026
Expiry date:	30 <sup>th</sup> March 2027

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
<b>Joanne Medhurst</b>	Chief Medical Officer BNSSG ICB		28/03/2024
<b>Michelle Jones</b>	Principal Medicines Optimisation Pharmacist BNSSG ICB		28/03/2024
<b>Debbie Campbell</b>	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](mailto:bnssg.medicines-optimisation@nhs.net)

## 1. Characteristics of staff

<b>Qualifications and professional registration</b>	<ul style="list-style-type: none"> <li>Physiotherapist currently registered with the Health and Care professions Council (HCPC)</li> </ul>
<b>Initial training</b>	<ul style="list-style-type: none"> <li>Have received recognised professional training in injection therapy.</li> <li>Must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction (PGD) before working to it</li> <li>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</li> <li>Must have undertaken appropriate training for working under PGDs for supply/administration of medicines</li> <li>Must be competent in the use of PGDs (see <a href="#">NICE Competency framework</a> for health professionals using patient group directions)</li> <li>Must be competent in the recognition and management of anaphylaxis</li> <li>Must have undertaken training and be competent in basic life support.</li> <li>Must have access to the PGD and associated online resource</li> <li>Have received recognised professional training in injection therapy</li> <li>Should fulfil any additional requirements defined by local policy</li> </ul> <p><b><i>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.</i></b></p>
<b>Competency assessment</b>	<p>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></p> <p><b><i>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.</i></b></p>
<b>Ongoing training and competency</b>	<p>Practitioners should be aware of any change to the recommendations for the medicine listed.</p> <p>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).</p> <p>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.</p>
<p><b><i>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.</i></b></p>	

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

<p><b>Clinical condition or situation to which this PGD applies</b></p>	<ul style="list-style-type: none"> <li>Inflammation or pain of peripheral joints or surrounding structures including the joint capsule, synovial membrane, bursae, ligaments and tendons/sheaths.</li> </ul> <p>Methylprednisolone (alone) should be used only when it is considered advantageous over the use of methylprednisolone WITH lidocaine.</p>
<p><b>Criteria for inclusion</b></p>	<ul style="list-style-type: none"> <li>Patients 18 years and over</li> <li>Valid informed consent obtained</li> <li>Inflammation of peripheral joints or surrounding structures due to trauma, overuse or associated with degenerative change.</li> <li>In patients who following assessment have symptoms that are persistent and likely to respond favourably to the administration of a steroid injection</li> <li>All relevant pathways for conservative management have been explored and evidenced as not appropriate or has completed without reasonable resolution in symptoms.</li> <li>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</li> </ul>
<p><b>Criteria for exclusion</b></p>	<ul style="list-style-type: none"> <li>No valid consent</li> <li>Under 18 years of age</li> <li>Hypersensitivity to methylprednisolone or corticosteroids or any component of the product</li> <li>Inflammation of any of the stated structures due to infection or active infection in or near the joint</li> <li>Previously infected joint</li> <li>Systemic infection</li> <li>Immediately following trauma to the structure</li> <li>Prosthesis/metal work in joint to be injected</li> <li>Unstable joints</li> <li>Pregnancy and breast feeding</li> <li>Active tuberculosis</li> <li>Haemarthrosis</li> <li>Injection into tendon body</li> <li>Injection into the Achilles tendon due to the absence of true tendon sheath</li> <li>Poorly controlled diabetes where there is a risk of hyperglycaemia</li> <li>Adjacent osteomyelitis</li> <li>History of active peptic ulcer</li> <li>Psychiatric conditions not well controlled and/or previous psychosis</li> <li>Surgery in the affected joint within 3 months</li> <li><b>For primary care only:</b> Patients on anticoagulant therapy (e.g. DOACs and warfarin)</li> </ul> <p><b>Not</b> be given via the intrathecal or intravenous route</p>

<p><b>Cautions including any relevant action to be taken</b></p>	<p>Methylprednisolone 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 (<a href="#">Home - electronic medicines compendium (emc)</a>) and discuss with prescriber if you have concerns.</p> <ul style="list-style-type: none"> <li>• Patients on interacting drugs see Drug Interactions section.</li> <li>• Patients on non-steroidal anti-inflammatory drugs (NSAIDs) and/or aspirin – see interactions below.</li> <li>• <b>For Secondary care only:</b> 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 hemorrhage. 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</li> <li>• Psychogenic disorders (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.</li> <li>• Bleeding disorders or impaired liver/kidney function</li> <li>• Immunosuppressed patients</li> <li>• Patients with diabetes – discuss recent blood glucose/HbA1c results to confirm stable and possible effects on blood glucose</li> <li>• Patients with severe anxiety – consider alternative treatment</li> <li>• Elderly patients (higher risk of side effects)</li> <li>• Osteoporosis (post-menopausal females are particularly at risk)</li> <li>• Hypertension or congestive heart failure</li> <li>• Glaucoma (or a family history of glaucoma)</li> <li>• Previous corticosteroid-induced myopathy</li> <li>• Fresh intestinal anastomoses</li> <li>• Predisposition to thromboembolic disorders</li> <li>• Ulcerative colitis</li> <li>• Diverticulitis</li> <li>• Myasthenia gravis</li> <li>• Ocular herpes simplex, for fear of corneal perforation</li> <li>• Hypothyroidism</li> <li>• Care should be taken for patients receiving cardioactive drugs such as digoxin because of steroid induced electrolyte disturbance/potassium loss</li> <li>• Patients with seizure disorders</li> <li>• History of tuberculosis</li> </ul>
<p><b>Action to be taken if the patient is excluded</b></p>	<ul style="list-style-type: none"> <li>• Record reasons for exclusion and any action(s) taken in patient notes</li> <li>• Advise patient on alternative treatment</li> <li>• Refer to a prescriber/supervising doctor if appropriate</li> </ul>

<b>Action to be taken if the patient or carer declines treatment</b>	<ul style="list-style-type: none"> <li>• Document advice given and the decision reached</li> <li>• Advise patient on alternative treatment</li> <li>• Refer to a prescriber/supervising doctor if appropriate</li> </ul>
<b>Arrangements for referral for medical advice</b>	<ul style="list-style-type: none"> <li>• Consider onward referral in line with trust/provider policy where treatment under the PGD is not effective</li> <li>• If patient falls into exclusion category refer to prescriber</li> </ul>

### 3. Description of treatment

<b>Name, strength &amp; formulation of drug</b>	Methylprednisolone acetate 40mg/ml suspension for injection
<b>Legal category</b>	Prescription-only medicine (POM).
<b>Route / method of administration</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Do not mix with other preparations prior to injection</li> <li>• Inspect visually for particulate matter and discoloration prior to administration whenever suspension and container permit.</li> <li>• Vials are intended for <b>single dose</b> use only.</li> <li>• <b>Not</b> be given via the intrathecal or intravenous route</li> </ul>
<b>Indicate any off-label use (if relevant)</b>	Not applicable
<b>Dose and frequency of administration</b>	<p>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.</p> <p>Refer to the Summary of product characteristics – section 4.2 Posology and method of administration <a href="https://www.medicines.org.uk/emc/product/8957/smpc">https://www.medicines.org.uk/emc/product/8957/smpc</a> (Depo-medrone 40mg/ml)</p> <p>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.</p> <p>There should be a minimum of a 6-week interval if a repeat injection into the same location is performed</p>
<b>Duration of treatment</b>	If first injection is effective but results are temporary two further injections may be given within a twelve-month period
<b>Quantity to be supplied</b>	Not applicable



<p><b>Storage</b></p>	<ul style="list-style-type: none"> <li>• Do not store above 25°C</li> <li>• Keep in the outer carton</li> <li>• Protect from freezing</li> </ul> <p><b><i>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: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></i></b></p>
<p><b>Drug interactions</b></p>	<p><b><i>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.</i></b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• Drugs such as clarithromycin, erythromycin, itraconazole and ketoconazole may inhibit the metabolism of corticosteroids and thus decrease their clearance.</li> <li>• Steroids may reduce the effects of anticholinesterases in myasthenia gravis.</li> <li>• The desired effects of hypoglycaemic agents (including insulin), anti-hypertensives and diuretics are antagonised by corticosteroids, and the hypokalaemic effects of acetazolamide, loop diuretics, thiazide diuretics and carbenoxolone are enhanced.</li> <li>• The effect of methylprednisolone on oral anticoagulants is variable. The efficacy of coumarin anticoagulants e.g. warfarin may be enhanced by concurrent corticosteroid therapy and close monitoring of the INR is required to avoid spontaneous bleeding</li> <li>• The renal clearance of salicylates (e.g. aspirin) 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 hypothermia (rare clotting disorder).</li> <li>• Steroids have been reported to interact with neuromuscular blocking agents such as pancuronium with partial reversal of the neuromuscular block</li> <li>• There may be increased incidence of gastrointestinal bleeding and ulceration when corticosteroids are given with NSAIDs.</li> <li>• Isoniazid clearance may be increased by methylprednisolone</li> <li>• 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.</li> <li>• Diltiazem can increase methylprednisolone dose</li> </ul>



<p><b>Drug interactions continued</b></p>	<ul style="list-style-type: none"> <li>• Potassium-depleting agents e.g. diuretics. Advise patient to report any signs or symptoms of hypokalemia to their GP e.g. skipped heart beats or palpitations, muscle weakness or spasms or tingling or numbness.</li> <li>• Grapefruit could increase levels of methylprednisolone</li> </ul> <p><b>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: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></b></p>
<p><b>Identification &amp; management of adverse reactions</b></p>	<p><b>The following side effects are possible with Methylprednisolone:</b></p> <ul style="list-style-type: none"> <li>• Temporary local exacerbation with increased pain and swelling which normally subsides after a few hours</li> <li>• Anaphylactic/allergic reactions</li> <li>• Sterile abscess</li> <li>• Charcot-like arthropathy</li> <li>• Sepsis (local or systemic)</li> <li>• Raised blood sugar in diabetes</li> <li>• Post-injection flare</li> <li>• Subcutaneous atrophy and/or skin depigmentation</li> <li>• Facial flushing</li> <li>• Tendon rupture</li> <li>• Steroid arthropathy</li> <li>• Uterine bleeding</li> <li>• Possible psychiatric disturbances</li> <li>• 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</li> </ul> <p><b>NB:</b> With high or prolonged local dosage, corticosteroids can be absorbed in amounts sufficient to produce systemic effects</p> <p><b>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: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></b></p>
<p><b>Management of and reporting procedure for adverse reactions</b></p>	<ul style="list-style-type: none"> <li>• Access to adrenaline 1:1000 must be available for anaphylaxis management.</li> <li>• 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: <a href="https://yellowcard.mhra.gov.uk">https://yellowcard.mhra.gov.uk</a></li> <li>• Record all adverse drug reactions (ADRs) in the patient's medical record.</li> <li>• Report via organisation incident policy.</li> </ul>

<p><b>Written information to be given to patient or carer</b></p>	<ul style="list-style-type: none"> <li>• Offer marketing authorisation holder's patient information leaflet (PIL) provided with the product.</li> <li>• 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.</li> <li>• Provide Steroid Emergency Card if appropriate. Further guidance can be found here: <a href="#">Adrenal crisis   Society for Endocrinology</a></li> </ul>
<p><b>Patient advice / follow up treatment</b></p>	<ul style="list-style-type: none"> <li>• Provide patient with steroid treatment card</li> <li>• Provide steroid emergency card if appropriate</li> <li>• Provide patient information leaflet</li> <li>• Explain treatment, course of action, potential side-effects and their management.</li> <li>• The individual/carer should be advised to seek medical advice in the event of an adverse reaction.</li> <li>• Warn them of the risk of severe psychiatric adverse reactions and alteration. ((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.</li> <li>• Advise that infiltration may be uncomfortable, and that pain and discomfort may continue for a few days. Paracetamol may help with this.</li> <li>• Advise there may be bruising or a collection of blood under the skin after injection.</li> <li>• To seek medical advice should there be an increase in pain following injection, swelling, fever and malaise</li> <li>• Observe the patient post-injection for signs of potential adverse reactions</li> <li>• Request patient to stay in department for 30 minutes following injection</li> <li>• Advise patient to inform any health professional who offers treatment (doctor, nurse, dentist, pharmacist) during the course of injections and for 3 months after the last injection that they have received a steroid injection.</li> <li>• 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].</li> <li>• Healthcare professional will inform GP of treatment</li> <li>• Advise patient of any follow up requirements in line with trust/provider policy</li> <li>• Advise on action to be taken if target lesion is unresponsive as per trust/provider policy</li> </ul>

<b>Records</b>	<p><b>Record:</b></p> <ul style="list-style-type: none"> <li>• That valid informed consent was given</li> <li>• Name of individual, address, date of birth and GP with whom the individual is registered (if relevant)</li> <li>• Name of registered health professional</li> <li>• Name and brand of medication administered</li> <li>• Date of supply/administration</li> <li>• Dose, form and route of administration</li> <li>• Site at which injection given</li> <li>• Quantity administered</li> <li>• Batch number and expiry date (if applicable)</li> <li>• Advice given, including advice given if excluded or declines treatment</li> <li>• Referral arrangements (including self-care)</li> <li>• Details of any adverse drug reactions and actions taken</li> <li>• Supplied via Patient Group Direction (PGD)</li> </ul> <p>Records should be signed and dated (or a password controlled e-records).</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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#### 4. Key references

<b>Key references</b>	<ul style="list-style-type: none"> <li>• <i>Electronic Medicines Compendium</i> <a href="http://www.medicines.org.uk/">http://www.medicines.org.uk/</a></li> <li>• <i>Electronic BNF</i> <a href="https://bnf.nice.org.uk/">https://bnf.nice.org.uk/</a></li> <li>• <i>NICE Medicines practice guideline "Patient Group Directions"</i> <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li> <li>• Chartered Society of Physiotherapy. Medicines, prescribing and physiotherapy. <u>Medicines, prescribing and injection therapy   The Chartered Society of Physiotherapy (csp.org.uk)</u></li> <li>• Chartered Society of Physiotherapy. October 2016. The use of medicines with injection-therapy in physiotherapy services. 5th Edition <a href="http://www.csp.org.uk/">http://www.csp.org.uk/</a></li> <li>• <i>Injection Techniques in Musculoskeletal Medicine 5<sup>th</sup> Edition 2019</i> Saunders, Stephanie and Longworth, Steve</li> <li>• Chartered Society of Physiotherapy. November 2018. Practice Guidance for Physiotherapist Supplementary and/or Independent Prescribers. 4<sup>th</sup> Edition <a href="http://www.csp.org.uk/Green Book chapter 6: Contraindications and special considerations Greenbook chapter 6.pdf (publishing.service.gov.uk)">http://www.csp.org.uk/Green Book chapter 6: Contraindications and special considerations <u>Greenbook chapter 6.pdf (publishing.service.gov.uk)</u></a></li> </ul>
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**5. Registered health professional authorisation sheet**  
**PGD Name/Version: Methylprednisolone injection Version 2.2**

**Valid from: 7<sup>th</sup> Apr 24**

**Expiry: 30<sup>th</sup> 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.