Patient Group Direction: For the administration of **Methylprednisolone Acetate (Depo-Medrone®) 40mg/ml Injection** by **HCPC Registered Physiotherapists** providing Musculoskeletal and/or Physiotherapy services in GP practices or ICB commissioned services across NHS Somerset ICB (Version 3.0)

- **For the treatment of intra-articular or extra-articular musculoskeletal lesions.**

Staff involved in the review and development of this PGD for NHS Somerset ICB:

	Name	Signature	Date
Doctor	Dr Andrew Tresidder, NHS Somerset Prescribing & Medicines Management Group Chair		10/06/2024
Pharmacist	Hels Bennett, Medicines Manager, NHS Somerset ICB		05.06.2024
Physiotherapist	Karen Larsen, Specialist Musculoskeletal Practitioner, OASIS, Somerset NHS FT		06.06.2024

Name of original author: Somerset NHS Foundation Trust

Authorised for use across NHS Somerset ICB Practices or ICB commissioned services by:

Bernice Cooke, Deputy Chief Nursing Officer & Director of Nursing for NHS Somerset ICB (Acting as Clinical Governance Lead)

Signed:  Date: 13/6/24

Valid from: 17th June 2024
Expiry Date: 10th November 2026

TO BE COMPLETED BY GP SURGERY / Commissioned service:

I, Doctor ……, as clinical lead for …… surgery, have read and approved this PGD for use by appropriate HCPC Registered Physiotherapists working at my surgery / commissioned service. I understand that I am responsible for ensuring that staff have adequate training to ensure that this injection is administered to patients in strict accordance with this PGD.

Signed…….. Dated……

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Valid from: 17th June 2024
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The HCPC Registered Physiotherapists named below are authorised to administer as specified under this Patient Group Direction, while working at:

…… (INSERT SERVICE / PRACTICE NAME)

In signing this document, I confirm the following:

- I have read and understood the above mentioned PGD.
- I agree to practice only within the bounds of my own competence and in accordance with my Code of Professional Conduct.
- I have the qualifications required under the staff characteristics detailed in the PGD
- I am competent to operate under this PGD.
- I will provide the service in accordance with this PGD

NAME *(please print)*	TITLE	SIGNATURE	AUTHORISING MANAGER *(please print)*	MANAGER'S SIGNATURE	DATE

- **Complete additional pages as necessary.**
- **Retain original signed pages (1) and (2) with authorising manager.**

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- **For the treatment of intra-articular or extra-articular musculoskeletal lesions.**

N.B. You must be authorised by name, under the current version of this PGD before you attempt to work in accordance with it.

1. Clinical Condition

Definition of condition/situation	• Treatment of patients with intra-articular or extra-articular musculo-skeletal lesions with a local corticosteroid injection.
Criteria for inclusion	• Adult patients, aged 18 years and over, seen in Somerset ICB GP Practices or referred to the Physiotherapy Musculoskeletal Service/ Orthopaedic Assessment Service • Suffering with joint or soft-tissue pain. • Appropriate consent obtained. • Where a corticosteroid injection is considered appropriate to alleviate: - Arthritis - Capsulitis - Bursitis - Tendinopathy and tenosynovitis - Enthesopathy - Neuromas - Ganglion cysts - Entrapment and impingement syndromes of nerve and soft tissues.
Exclusion criteria	• Children under the age of 18 years. • No valid consent to treatment. • First trimester of pregnancy. • Known hypersensitivity, including anaphylaxis to corticosteroids, or any other excipient of the injection or, having shown hypersensitivity after previous administration. • Known or suspected local or systemic infection. • Previously infected joint. • Osteomyelitis adjacent to the joint to be treated. • Active rash/broken skin at site of injection. • Injection into a prosthetic joint. • Haemarthrosis. • Tendon regions at high risk of rupture. • 3 corticosteroid injections to same joint in previous 12 months. • Treatment of spinal joints. • Treatment of fractured or unstable joints. • Treatment of hip joints.

	• Uncontrolled coagulopathy. • Uncontrolled hypertension. • Patients with Cushing's disease. • Due to undergo major surgery to the joint/structure considered for injection within the next 3 months (EULAR guidance 2021)

Caution	**All concurrent medications must be checked for interactions.** A detailed list of drug interactions is available in the BNF www.bnf.org and the individual product SPC, available from the electronic Medicines Compendium www.medicines.org.uk Where a clinically significant interaction is identified discuss with appropriate medical/independent non-medical prescriber. If patients are taking oral, inhaled or topical steroids for 4 weeks or longer or multiple doses of short-term glucocorticoids, they should be asked whether they carry a steroid emergency card. If not, the clinic should provide one. There are data demonstrating HPA axis suppression after a single intra-articular glucocorticoid injection for 14 to 28 days. A single intra-articular glucocorticoid injection is unlikely to permanently suppress the HPA axis, but if a patient has major surgery, trauma or intercurrent illness within 28 days of having an intra-articular glucocorticoid steroid injection, then they may be at risk of adrenal insufficiency. If a patient is receiving repeated intra-articular glucocorticoid injections, they should be considered at risk of HPA axis suppression. If they are also on an additional steroid, for example a moderately high dose of inhaled glucocorticoid, then permanent HPA axis suppression can occur and further assessment should be considered. National guidance on who would be considered at high risk of adrenocortical suppression can be found here: https://www.endocrinology.org/media/4091/spssfe_supporting_sec_-final_10032021-1.pdf If practitioners are in doubt regarding high dose of steroids, the duty pharmacist can be contacted on: 01823 368265 or email: medicinesmanagement@somersetft.nhs.uk Caution is necessary when using corticosteroids in the following situations. In such cases the health care professional may wish to seek further medical advice before continuing: • Due to undergo major surgery within the next 4 weeks (patient would need to inform surgeon)

- With increasing doses of corticosteroids, the rate of occurrence of infectious complications increases. Persons who are on drugs which suppress the immune system are more susceptible to infections than healthy individuals. Chickenpox and measles, for example, can have a more serious or even fatal course in non-immune children or adults on corticosteroids. Patients without a definite history of chickenpox should be advised to avoid close personal contact with chickenpox or herpes zoster and if exposed they should seek urgent medical attention
- Metalwork/arthroplasty within the region of injection is a precaution. Post THR/post surgical intervention the patient must be at least 6 months post-op, with x-rays showing no indication of prosthesis or metal work problems/failure, and no clinical signs or symptoms of infection. Physical examination identifies a separate anatomical structure as the source of pain. If any concern the clinician should take advice from surgical team.
- Previous history of tuberculosis or characteristic appearance on chest X-ray.
- Diabetes mellitus
- Osteoporosis (post-menopausal females at particular risk)
- Hypertension or congestive heart failure
- History of severe affective disorders, especially previous history of steroid psychosis. Rarely, there have been case reports of steroid induced psychosis due to intra-articular injection of corticosteroids
- Glaucoma or Ocular Herpes Simplex
- Previous steroid myopathy
- Peptic ulceration, particularly in combination with NSAIDs
- Epilepsy/seizure disorders
- Recent or planned vaccination with live vaccines
- Recent, or planned vaccination with inactivated vaccines, as antibody response may be diminished
- Bleeding or blood disorders. The available data regarding injections in patients receiving warfarin (INR 2-3) or DOACs suggest that these procedures are generally safe (Up to Date, EULAR, PCRMM). The benefits of injection versus risks of haemorrhage should be discussed with the patient to arrive at a shared decision. A management plan in the event of haemorrhage should be discussed with the patient in advance (PCRMM)
- Psychogenic pain
- Immuno-suppression either by drugs (e.g., oral steroids) or disease (e.g., leukaemia, HIV infection) Immunosuppressed patients should be advised that treatment should be postponed until immune function has recovered
- Pregnancy; second and third trimester. Need to consider, in discussion with patient whether the likely benefits outweigh the potential risk
- Breast-feeding. Need to consider in discussion with patient whether the likely benefits outweigh the potential risk
- Patients with disorders of neuromuscular transmission (e.g. myasthenia gravis), or receiving concomitant therapy with anticholinergics

	• Patients who have or may be predisposed to thromboembolic disorders • Nonspecific ulcerative colitis • Patients with liver failure or cirrhosis • Patients with renal insufficiency • Co-treatment with CYP3A inhibitors is expected to increase the risk of systemic side-effects • Elderly: Steroids should be used cautiously in the elderly, since adverse effects are enhanced in old age
Action if excluded	• Explain the reasons for exclusion to the individual and document in the consultation record. • Refer to supervising prescriber as appropriate. Where necessary refer the individual to a suitable health service provider and/or provide them with information about further options.
Action if patient refuses medication	• Where treatment declined, record reason for decline (where given) in the consultation record. • Refer to medical practitioner/suitable health service provider and/or provide them with information about further options as appropriate.

2. Characteristics of Staff

Professional qualification to be held by staff working under this Patient Group Direction	• HCPC Registered Physiotherapists • Current contract of employment or locum agreement within Somerset NHS Foundation Trust

Additional requirements	**Initial training** • Trust PGD training (online via LEAP) • Appropriate training to carry out clinical assessment of a patient leading to diagnosis that requires treatment according to the indications listed in this PGD • Has undertaken specific teaching and has been assessed as competent to administer injectable medications to patients presenting with appropriate musculoskeletal conditions. The specific training • requirements for each distinct profession will be reflected in local SOPs. • Training and competence in all aspects of drug administration for the medicine covered by this PGD including contraindications and the recognition of anaphylaxis. • Trust Adult Basic Life Support (Level 2) training. • Trust Anaphylaxis training. • The practitioner should be aware of any change to recommendations or professional guidelines for the medication listed. **Competency assessment** • Successful completion of Trust generic PGD training • Demonstration of all necessary competencies to administer the product under this PGD **Ongoing training and competency** • Individuals operating under this PGD are personally responsible for keeping up to date with the use of all medicines included in the PGD and to work within the limitations of individual scope or practice. • If any training needs are identified these should be discussed with the PGD authorising manager/line manager and further training provided as required • Organisational PGD and/or medication training as required by the Trust. • Evidence of CPD in Musculoskeletal Injection therapy as required by Somerset NHS Foundation Trust. • Injection competency assessment every two years • Annual resuscitation training. • Annual anaphylaxis training. • Annual infection control training. • Completion and submission of Continuous Professional Development as required by the HCPC

System for recording names of individuals authorised to supply and / or administer drugs under this Patient Group Direction	For commissioned service staff Healthcare Professional to complete Individual Authorisation (page 2 of PGD) signed by authorising manager. Copies to be kept by / sent to: • Authorising manager in GP practice • Individual HCPC Registered Physiotherapist • Provider Physiotherapy service lead manager • Provider Medicines Management Team

3. Description of Treatment

Name of Medicine	Methylprednisolone Acetate (Depo-Medrone®) 40mg/ml in suspension for injection
Legal Class	POM (Prescription Only Medicine)
Storage	• Store in designated locked medicines cupboard • Do not store above 25°C • Do not freeze
Method or route of administration	Depo-Medrone may be used by any of the following routes: intra-articular, periarticular, intrabursal, intralesional and into the tendon sheath. Intra-articular administration: • Rheumatoid arthritis • Osteo-arthritis with an inflammatory component Soft tissue administration (intrabursal, periarticular, into tendon sheath): • Synovitis not associated with infection • Epicondylitis • Tenosynovitis • Plantar fasciitis • Bursitis

Dose to be used (including criteria for use of differing doses)	The dose of Depo-Medrone depends upon the size of the joint and the severity of the condition. **Intra-articular:** • large joint (knee, ankle, shoulder), 20 – 80 mg (0.5 – 2 ml); • medium joint (elbow, wrist), 10 – 40 mg (0.25 – 1 ml); • small joint (metacarpophalangeal, interphalangeal, sternoclavicular, acromioclavicular), 4 – 10 mg (0.1 – 0.25 ml). **Intrabursal:** • Subdeltoid bursitis, prepatellar bursitis, olecranon bursitis. For administration directly into bursae, 4 – 30 mg (0.1 – 0.75 ml). **Peri-articular:** • Epicondylitis. Infiltrate 4 – 30 mg (0.1 – 0.75 ml) into the affected area. **Into the tendon sheath:** • Tenosynovitis, epicondylitis. For administration directly into the tendon sheath, 4 – 30 mg (0.1 – 0.75 ml). In recurrent or chronic conditions, repeat injections may be necessary.
Frequency	• Methylprednisolone Acetate maximum combined total dose of 80mg where multiple joints are injected, with a maximum of 40mg for any individual joint. • Where there is multiple joint involvement, treatment may be by intra-articular or extra-articular injection to multiple sites as appropriate. **Maximum or minimum treatment period** • Intra-articular at least three months between injections, apart from injections to the glenohumeral joint for frozen shoulder, where a successful injection may be repeated after 3-4 weeks. • Extra-articular injections can be repeated when necessary if symptoms do not fully resolve, up to a maximum of three injections per episode

Other information

Interactions

All concurrent medications must be checked for interactions.

A detailed list of drug interactions is available in the BNF www.bnf.org and the individual product SPC, available from the electronic Medicines Compendium www.medicines.org.uk

Co-treatment with CYP3A inhibitors is expected to increase the risk of systemic side-effects

Refer to cautions section for information regarding concomitant use of corticosteroid injections alongside other corticosteroid treatment

Where a clinically significant interaction is identified discuss with appropriate medical/independent non-medical prescriber

Adverse effects

Significant adverse effects are rare

- The most common adverse effect is a temporary local exacerbation with increased pain and swelling. Normally this subsides after a few hours to days.
- Hyper- or hypo-pigmentation, Charcot-like arthropathy.
- Soft tissue atrophy, nodule formation
- Local fat atrophy may occur if the injection is not administered into the joint space, but this is temporary and may disappear within a few weeks to months
- The most serious complication is infection, with an incidence of 1 in 3,000 to 1 in 50,000 injections.
- Menstrual irregularity
- MHRA/CHM advice (August 2017): Corticosteroids: rare risk of central serous chorioretinopathy with local as well as systemic administration - GOV.UK (www.gov.uk)
- In a few instances, transient flushing (including facial flushing) and dizziness have occurred – usually 24-72 hours post injection and predominantly women.
- Elevated blood sugar in diabetic patients.
- Fainting.
- Steroid induced osteonecrosis or arthropathy.
- Corticosteroids may reduce patient's immune responses. If there is no history of chicken pox, they should avoid close personal contact with chicken pox or herpes zoster. If exposed, they should seek urgent medical advice

Advice and information to patient/carer including follow-up	• The patient has been given, read and understood the Product Patient Information Leaflet and the Trust Patient Information Leaflet on Joint and Soft Tissue Injections (available in PGD section here), and consents to treatment. • Issue patients with a **steroid emergency card** to all patients who have been taking oral, inhaled or topical steroids for 4 weeks or longer or multiple doses of short-term glucocorticoids, giving clear guidance on the precautions to be taken to minimise risk. It should also provide details of the prescriber, the name of the drug and the dose administered. It should be shown to anyone treating a patient during or within 3 months of last injection. • If patients are not using concomitant steroids, they should be issued with a **blue Steroid Treatment card** if they are receiving a second steroid joint or soft tissue injection, within one month of each other. • When a patient is suspected of suffering from adrenal insufficiency and concurrently shows signs of possible adrenal crisis (typically, persistent vomiting with profound muscle weakness, low blood pressure or even shock, extreme sleepiness or even coma) the patient should seek urgent medical advice. A patient leaflet will be provided to the patient in clinic. • If condition worsens or symptoms persist then seek further medical advice or any adverse effect experienced. • Give appropriate advice leaflets and arrange necessary ongoing care. **Adverse effects:** Any serious adverse reaction should be documented e.g. in the consent forms, patient's medical record and the GP should also be informed. Unusual /persistent side effects should be followed up with a medical practitioner. Any **serious** adverse events that may be attributable to the drug should be reported to the MHRA using the yellow card system https://yellowcard.mhra.gov.uk/ and also follow the local incident reporting procedure.

Specify method of recording supply /administration including audit trail	It is a legal requirement to keep auditable records of administration and supply of medication via a PGD. All records should be kept in line with national guidance. This includes individual data, master copies of the PGD and lists of authorised practitioners. All records should be clear, legible and contemporaneous and made in appropriate patient notes. The following will be recorded in the patient's clinical records: • Record that supply/administration is via Patient Group Direction (PGD) • Patient's name, address, date of birth & NHS number • Written Consent, NHS Consent form no 3. • Indications for use • Advice given to patient/carer (to include side effects and Patient Information Leaflet if provided) • Name of medicine / dose/ quantity supplied or administered • Brand, batch number and expiry date of medicine • Name of registered professional, signature, and date. Electronic records must have individual identifiers for healthcare professionals for audit trail • Document any adverse reactions and actions taken • All significant events/incidents/near misses occurring in relation to the supply / administration of a medicine under this PGD must be reported to the Trust on the relevant incident form in a timely manner • Aftercare and any referral arrangements made
References used in the development of this PGD:	• Summary of Product Characteristics Depo-Medrone 40mg/ml Suspension for Injection • EULAR recommendations for intra-articular therapies 2021 EULAR • PCRMM Joint and soft tissue Injection recommendations 2021 PCRMM link • Evidence search: Corticosteroid injections for greater trochanteric pain syndrome/trochanteric bursitis in patients who have had total hip replacements. April Cursons (27/07/2023). Yeovil, Somerset, UK: Somerset Foundation Trust Knowledge and Library Services.

Please refer to the summary of product characteristics for full information

This Patient Group Direction is operational from 17th June 2024 and expires 10th November 2026

NHS Somerset Integrated Care Board

Version History

Version	Date	Brief Summary of Change	Owner's Name
1.2	May 2020	Somerset Partnership PGD full review	Paul Aldwinckle, Orthopaedic Specialist Podiatrist, SPFT
2.2	July 2020	Minor amendments and transfer to CCG template	
2.3	Aug 2020	Minor amendment to allow all qualified physiotherapists and amend typo	Shaun Green
2.4	May 2022	Somerset Foundation Trust PGD full review. Minor formatting changes by Somerset CCG. Reviewed and approved by Somerset CCG Prescribing & Medicines Management Group	Simon Ingram, First Care Practitioner Clinical Lead, SFT
2.5	June 2022	Lidocaine allergy removed from Exclusion criteria	Hels Bennett
3.0	May 2024	Full review & update to align with Somerset NHS Foundation Trust PGD including guidance on providing steroid cards, injection in region of metalwork and for anticoagulated patients. Expiry date aligned with SFT PGD. Formatting changes. Reviewed & approved by Somerset Medicines Programme Board. Link added to SFT Joint & Soft Tissue Injection patient leaflet. ICB signatory updated.	Karen Larsen, Specialist Musculoskeletal Practitioner, OASIS, SFT