Patient Group Direction for

Administration of Methylprednisolone 40mg/mL Injection by Physiotherapists

Valid from: 1st October 2023
Review date: 31st August 2025
Expiry date: 1st October 2025

Version number: 6

THIS PATIENT GROUP DIRECTION HAS BEEN AGREED BY THE FOLLOWING ORGANISATIONS:

East Coast Community Healthcare and Norfolk and Waveney ICB

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING UNDER IT	
CLINICAL DETAILS	
Indication	Treatment of adults with local inflammation of peripheral joints and soft tissues that would benefit from the use of local glucocorticoid. Suppression of local, peripheral inflammation and pain caused by soft tissue, joint and skin conditions. Frequently, methylprednisolone acetate will be administered alongside a local anaesthetic. Where this is the case, the Patient Group Direction (PGD) for that local anaesthetic must also be referred to and adhered to. Physiotherapists working under this PGD must administer Methylprednisolone and local anaesthetic separately and without mixing. Note: A PGD cannot be used for unlicensed medicines. Mixing of two or more licensed medicines constitutes the manufacturer of a new unlicensed product. (Chartered Society of Physiotherapy (CSP) 2016)
Inclusion criteria	Patients aged 18 years and over that have given valid informed consent with benign joint or soft tissue pain including: • Rheumatoid arthritis or osteoarthritis with an inflammatory component in any joint • Bursitis • Capsulitis • Isolated soft tissue pathology of musculoskeletal origin • Entrapment neuropathy • Impingement syndromes • Ganglia • Chronic Ligamentous injury/lesions • Tendonitis/Tendinosis/Tendinopathy • Tenosynovitis • Enthesopathy • Myofascial Pain • Epicondylitis • Synovitis
Exclusion criteria	• Patients under the age of 18 years old • Pregnancy • Breast feeding • Severe / manic depression • Stomach ulcer • Presence of, or suspicion of active local or systemic infection, including Tuberculosis (Within the last 10 years) • Presence of symptoms suggestive of COVID-19: Cough, Temperature ≥ 37.8, Loss of smell or taste, Flu-like symptoms • Injection within 14 days of COVID-19 vaccination

	• Adjacent osteomyelitis • Hypersensitivity / allergic reactions to corticosteroids or any of the ingredients • Recent trauma **(six** weeks) to the area intended for injection including hemarthrosis • Wounds near to the injection site and fractures • Not into a prosthetic joint itself or another site if joint replacement • Surgery performed in the area to be injected within the last 12 months • Planned surgical procedures (time scales depend on proposed injection and surgical procedure) • Unstable joints i.e. ligamentous insufficiency • Avascular area e.g., Achilles tendon, patella tendon • Presence of steroid arthropathy, poor skin condition over the area. • Immunosuppressed patients • Reluctant / non-consenting patients • Unstable blood pressure • Peripheral vascular disease at site to be injected • Severe or unstable heart condition • Sickle Cell disease • Metastatic carcinoma • Patients taking medication with potentially significant interactions with Methylprednisolone: <u>These include</u>: Antibacterial drugs (e.g., erythromycin, clarithromycin), antifungals (e.g., ketoconazole), antivirals (e.g., HIV treatments), ciclosporin; immunosuppressant (e.g., tacrolimus) – except when written GP or Consultant approval is obtained and within 4 weeks of the administration of a live vaccine (e.g., yellow fever, MMR**,** BCG) ➔ This list is not exhaustive - refer to the current British National Formulary (BNF) and/or manufacturer's Summary of Product Characteristics (SPC) for full list of drug interactions.
Precautions	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 SmPC (Home - electronic medicines compendium (emc)) and discuss with a doctor or prescriber if you have concerns. • Adrenal suppression / Cushing syndrome • Broken skin, eczema, history of infection in the area or adjacent to the area to be injected • Poorly controlled / unstable Diabetes Mellitus • Glaucoma/Corneal Perforation • Osteoporosis

	• Liver failure or cirrhosis • Renal impairment • Myasthenia gravis • Epilepsy • Recent Implants e.g., mitral valve replacement, pacemaker • Planned surgical procedures within next 6 weeks (time scales depend on proposed injection and surgical procedure) • Anxious patients with signs of vagal over activity / needle phobia • If COVID-19 vaccination is imminent, it may be appropriate to delay a non-essential steroid injection, as part of a shared decision, so that the response to the vaccine is more effective • Concurrent steroid use (standard doses of inhaled corticosteroid are not significant) • Bleeding disorders • Ocular Herpes Simplex **Anticoagulants:** Warfarin (or any other Vitamin K antagonist): • Patients must be on a stable dose with an INR result between 2 and 3 in the 7 days prior to treatment. • It is advisable to check the INR again 3-4 days after the injection as corticosteroids may increase or decrease anticoagulant action Direct Oral Anti-Coagulants (DOAC): • Rivaroxaban, apixaban, Edoxaban and dabigatran • Patients should not have taken their DOAC in the 12 hours preceding their injection • The DOAC can be resumed at the previous dosing schedule when their next dose is due Enzyme inducing medications including antiepileptic drugs (e.g., carbamazepine; phenobarbital); Antiviral drugs (ritonavir; efavirenz and nevirapine) cytotoxic drugs (e.g., methotrexate) ➔ Always refer to accompanying product information ➔ Therapy with Methylprednisolone does not obviate the need for the conventional measures. Although this method of treatment will ameliorate symptoms, it is in no sense a cure and the steroid has no effect on the cause of the inflammation.

Management of excluded patients	Consider alternative treatment. Document in patient physiotherapy record. Inform patient's GP and referrer (if different) in discharge summary or earlier if appropriate. If no alternative treatment within physiotherapy available, refer to General Practitioner with a Special Interest (GPwSI), Orthopaedic Consultant, Pain Clinic, Back Pain Service, other provider or back to GP depending clinical relevance and patient choice.
Action for patients not wishing to receive care under this PGD	Consider alternative treatment. Document in patient physiotherapy record. Inform patient's GP and referrer (if different) in discharge summary or earlier if appropriate. If no alternative treatment within physiotherapy available, refer to GPwSI, Orthopaedic Consultant, Pain Clinic, Back Pain Service, other provider or back to GP depending clinical relevance and patient choice.
DESCRIPTION OF TREATMENT	
Name of medicine	Methylprednisolone Acetate (Depo-Medrone®)
Formulation and route	Using aseptic technique: • Intra-articular injection • Peri-articular • Soft Tissue Injection **DO NOT ADMINISTER VIA THE INTRATHECAL OR INTRAVENOUS ROUTES**
Strength	40mg/ml
Dosage	The dose is dependent on the size of the joint to be treated, severity of the pain/ condition and previous response (if appropriate) Recommended doses for intra-articular injection: • 4 - 10mg (0.1 - 0.25 ml) for a smaller joint • 10 - 40mg (0.25 - 1 ml) for a medium joint • 20 - 80mg (0.5 - 2 ml) for a larger joint Recommended dosage for periarticular, intrabursal and tendon sheath injections: • 4 - 30mg of steroid (0.1 - 0.75 ml) Specific recommendations for dosages can be found within Saunders and Longworth (20016) and the Summary of Product Characteristics
Repeated dose instructions	Maximum of 3 injections per site (joint) per year

	Repeat injections are used as infrequently as possible in accordance with accepted clinical practice. Weight bearing structures being injected at no less than 4 monthly intervals. Referral for specialist opinion should be considered when the patient's condition does not respond positively to the injection.
Duration of treatment	See sections above and below
Quantity to administer	• The **total maximum** dose to be used is 80mg of steroid (total volume 2ml) per treatment as a single dose • The **maximum number** of injections per episode, per anatomical structure except bursae will be three. • Injections to bursae may be conducted as often as necessary providing significant relief results. **Injections are not to be repeated if there is no benefit or change condition.** Referral for specialist opinion should be considered when the patient's condition does not respond positively to the injection
Legal status	Prescription only medicine (POM)
Special Precautions	Always check patient's allergy status before treatment. Facilities for treating anaphylaxis must be available.
Adverse effects	**Potential adverse drug reactions**: • Transient flushing and dizziness • Infection • Anaphylaxis • Hyper or Hyoppigmentation • Bleed / bruise • Subcutaneous atrophy • Post-injection flare • Irregular menstration • Severe joint destruction with necrosis of bone may occur if repeated intra-articular injections are given over a long period of time **This list is not exhaustive. Refer to BNF and SPC via www.medicines.org.uk/emc for complete list.** Use the Yellow Card System via www.mhra.gov.uk/yellowcard to report adverse drug reactions directly to the MHRA. Yellow Cards and guidance on its use are available at the back of the BNF.

Advice to be given	• Assessment and preceding interventions will lead to a clinical decision that injection therapy may be of benefit to the patient. This clinical reasoning, alongside evidence-based practice, will be used to identify to the patient the suspected cause of their symptoms and why an injection may be of benefit as part of gaining valid informed consent. • The risks and benefits associated with injection therapy including the possible adverse effects listed above will be discussed with the patient including what to watch for in relation to anaphylaxis and infection (see below) • Advice regarding what to watch for in relation to anaphylaxis (itching acute skin changes, swelling, difficulty breathing, nausea, confusion), and infection (marked increase in pain accompanied by local swelling, further restriction of joint motion, fever, and malaise) • That there is a potential increased risk of and lack of clear evidence relating to COVID-19 and steroid injection • They will be given a patient information leaflet 'Information for patients receiving injection therapy' to reinforce what has been discussed and/or product information leaflet. • The leaflet will include details of local and systemic side effects. • Patient will be given a patient information leaflet, “Corticosteroid Injection Therapy: COVID-19 Information Sheet” • Valid informed written consent will be gained prior to an injection being performed and a carbon copy of the consent form given to the patient. • The patient will be advised that they can stop the procedure and withdraw their consent at any point during the procedure. • The patient will be advised about 'relative rest' and how to manage between injection and follow-up appointment, advice will depend on clinical condition and aims of treatment. • Following the procedure, the patient will be advised to remain in department for 30 minutes following injection to assess and monitor any adverse reactions. • The patient will be reminded of what to look for in relation to infection and advised to contact their GP for immediate assistance should infection occur. • A follow up appointment will be arranged, and the patient will be given a contact telephone number and advised to contact the

	department should they have any queries or concerns before their follow up appointment. • Patients will be given the manufacturer's Patient information leaflet and advised about possible side-effects. • Patients should be advised to report any blurred vision or other visual disturbances (a rare retinal disorder associated with corticosteroid treatment) • Patients should be specifically warned to avoid over-use of joints in which symptomatic benefit has been obtained.
RECORDS AND FOLLOW UP	
Referral arrangements	Refer to supervising doctor / facility or Accident & Emergency Department as appropriate
Records to be kept	The following information will be documented in the physiotherapy records: • Diagnosis or working diagnosis • Consent given • Name of medication • Dose and form (amount/ strength/ total volume) • Batch number • Expiry date • Site injected and approach / technique • Advice given to patient (including side effects) • Signature/name of staff who administered or supplied the medication • Copy of the signed consent form • Details of any adverse drug reaction and actions taken including documentation in the patient's record • Referral arrangements (including self-care) • The signed consent form will be kept in the physiotherapy record • A record of patients receiving injection therapy will be kept on systm1 and can be identified by Business Intelligence, alongside an MSK Services audit document for review purposes
Follow up	• A follow up appointment will be booked with the patient at a time that is mutually acceptable for the patient and physiotherapist to assess the outcome of treatment • The patient will be advised on what to look for in relation to infection and advised to contact their GP for immediate assistance should infection occur

	• Timescales for the follow up appointment will be determined according to clinical relevance (usually two weeks post injection) • The patient will be given a contact telephone number and advised to contact the department should they have any queries or concerns before their follow up appointment • Outcome of treatment will determine future management and the care pathway will be discussed with the patient as part of the valid informed consent process. Follow-up treatment may involve further injection therapy, physiotherapy, referral to secondary care provider or back to GP • Patient choice and valid informed consent processes will be complied with at all times. • The patient's medical practitioner will be informed of the injection procedure that includes date, drug name, dosage and site of administration in a timely manner.
PROFESSIONAL REQUIREMENTS	
STAFF CHARACTERISTICS	Qualifications required: • Registered Physiotherapist with a current Health Care Professions Council registration • Experienced extended scope physiotherapist in injection therapy OR any physiotherapist who has completed an injection therapy course accredited by Chartered Society of Physiotherapists OR is working towards a recognised certificate in injection therapy (requiring at least 10 mentored injections) whilst under the supervision of a named mentor Additional requirements: • Has undertaken appropriate training/education for working under patient group directions for the supply and administration of medicines • Understanding of pharmacology of drugs issued to patients and relevant medical condition • **Immediate** access to Adrenaline/Epinephrine 1:1000 (1mg/mL) injection and trained in the treatment of anaphylaxis • Access to Resuscitation Council (UK) Emergency Treatment of anaphylactic reactions Guidelines for healthcare providers

	https://www.resus.org.uk/anaphylaxis/emergency-treatment-of-anaphylactic-reactions/ Continued training requirements: • Annual mandatory training on cardio-pulmonary resuscitation (CPR) and anaphylaxis. • It is the responsibility of the individual to maintain competence and skills required to administer the medicine included in this PGD. • A commitment to relevant CPD to include updating of relevant knowledge from current edition of British National Formulary (BNF) and awareness of any change to the recommendations for the medicine listed. • It is the responsibility of the individual to keep up to date with continued professional development and to work within the limitations of individual scope of practice

REFERENCES / RESOURCES

Summary Product Characteristics Depo-Medrone 40mg/ml injection Updated 07/2019 https://www.medicines.org.uk/emc/product/8957/smpc Updated 9th June 2023 accessed 22/08/2023)

Chartered Society of Physiotherapy https://www.csp.org.uk/professional-clinical/professional-guidance/medicines-prescribing-and-injections

Injection Techniques in Musculoskeletal Medicine: A Practical Manual For Clinicians in Primary and Secondary Care. Saunders and Longworth, Churchill Livingstone Elsevier, 2016

The British Society for Rheumatology: Clinical guide during the COVID-19 pandemic for the management of patients with musculoskeletal and rheumatic conditions who are:

already taking corticosteroids, or require initiation of oral/IV corticosteroids, or require an intra-articular or intra-muscular corticosteroid injection 2020

https://www.rheumatology.org.uk/Portals/0/Documents/COVID-19/MSK_rheumatology_corticosteroid_guidance.pdf

The British Society for Rheumatology: COVID-19: Guidance For Rheumatologists 2021 https://www.rheumatology.org.uk/practice-quality/covid-19-guidance

PGD DEVELOPMENT		
Details of Patient Group Direction owner	Name: Mr Martin MacDonald Position: Extended Scope Practitioner and Team Lead MSk Triage Service Contact Email: martin.macdonald@ecchcic.nhs.uk Contact Address: East Coast Community Healthcare (ECCH)	
Patient Group Direction peer reviewed on behalf of ECCH by		
Name	**Position**	**Date**
	Physio/ Podiatry development virtual group	
	Medicines Management Group	
This patient group direction must be agreed to and signed by all health care professionals involved in its use. East Coast Community Health Care CIC should hold the original signed copy. The PGD must be easily accessible in the clinical setting		
Organisation	East Coast Community Healthcare	
Lead Doctor	Name: Dr Rupert Talboys Position: GP Associate Signature: *wet signature* Date:	
Lead Pharmacist	Name: Ms Françoise Price Position: Head of Pharmacy and Medicines Optimisation Signature: *wet signature* Date:	
Lead Practitioner of the professional group to supply medicines under this PGD	Name: Mr Martin MacDonald Position: Extended Scope Practitioner and Team Lead MSk Triage Service Signature: *wet signature* Date:	

This PGD has been agreed to be appropriate, necessary and an advantage to patient care by the East Coast Community Healthcare Medicines Management Group

PGD AUTHORISATION

This PGD is authorised by:

NHS Norfolk and Waveney ICB

Director of Nursing	Name: Tricia D'Orsi Signature:  Date: 18/10/2023
Associate Director of Pharmacy and Medicines Optimisation (Chief Pharmacist)	Name: Michael Dennis Signature:  Date: 20/20/2023

INDIVIDUAL AUTHORISATION

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING UNDER IT

BY SIGNING THIS PATIENT GROUP DIRECTION YOU ARE INDICATING THAT YOU AGREE TO ITS CONTENTS AND THAT YOU WILL WORK WITHIN IT

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

IT IS THE RESPONSIBILITY OF EACH PROFESSIONAL TO PRACTICE ONLY WITHIN THE BOUNDS OF THEIR OWN COMPETENCE

IF THIS IS AN UPDATED OR REPLACEMENT PGD ENSURE THAT ALL OLDER VERSIONS ARE WITHDRAWN FROM USE WITH IMMEDIATE EFFECT

IT IS YOUR REPONSIBILITY TO MAKE SURE YOU ARE USING THE CURRENT VERSION

NOTE TO AUTHORISING MANAGERS: AUTHORISED STAFF SHOULD BE PROVIDED WITH AN INDIVIDUAL COPY OF THE CLINICAL CONTENT OF THE PGD AND A PHOTOCOPY OF THE

AUTHORISATION SHEET SHOWING THEIR AUTHORISATION. BY SIGNING BELOW YOU ARE CONFIRMING THAT YOU HAVE ASSESSED THE STAFF MEMBER AS COMPETENT TO WORK UNDER THIS PGD AND THAT THEY HAVE THE ORGANISATIONAL APPROVAL TO DO SO

Name of Professional	Signature	Authorising Manager	Date