PATIENT GROUP DIRECTIONS*

The Supply and Administration of Methylprednisolone acetate 40mg/ml by intra/peri-articular injections

for

Musculoskeletal conditions

by

by First Contact Physiotherapists / Appropriate **Extended Scope Practitioner Physiotherapists at Knutsford PCN**

Version 2

Date of introduction October 2024

(It is intended that this document will be updated in 2 years subject to no amendments in the interim period)

Review Date October 2026 Expiry Date: October 2027

*HSC 2000/026 Patient Group Directions (England Only)

Version Control:

Patient Group Directions for supply of Methylprednisolone acetate 40mg/ml]

| Version | Date of introduction | Author | Status | Comment |
|---------|----------------------|------------------------|--------|----------------------------------------------------------|
| V1 | | Development of new PGD | draft | Review of prev. Cheshire CCG document introduced in 2021 |
| V2 | Oct 2024 | Review | Final | Minor amendments incorporated from PGD working group |
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| Patient Group Direction: | Methylprednisolone acetate 40mg/ml for intra/peri-articular injection |
|------------------------------|---------------------------------------------------------------------------------------------------------|
| Clinical Department/Service: | First Contact Physiotherapist / Appropriate Extended Scope Practitioner Physiotherapists, Knutsford PCN |

1. Clinical Condition

| 1.1 | Define situation/condition | Patients aged 18 years and over with a diagnosis of benign musculoskeletal pain e.g., joint pain, osteoarthritis, rheumatoid arthritis, bursitis, capsulitis, entrapment neuropathy, ganglia, ligamentous injury tendinopathy, tenosynovitis, paratenonitis, fasciitis |
|-----|----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.2 | Criteria for inclusion | Assessed by Extended Scope Practitioner (ESP) physiotherapist Patient 18 years of age or above Patient agrees to treatment under the PGD For use in patients with benign musculoskeletal diseases or conditions who have given consent for injectable treatment where Lidocaine infiltration has been used to confirm the diagnosis or needle target area. Note: this is not a prerequisite. Such infiltration may not be necessary. Injection of a steroid alone is indicated If the above points are fulfilled, the following conditions or needle targets are allowed: Lower limbs Osteoarthritis first metatarsal phalangeal joint Subtalar joint osteoarthritis /inflammation Other smaller joints of the foot/ankle complex Superior tibiofibular joint Osteoarthritis knee Ankle joint osteoarthritis /inflammation Iliotibilal band syndrome Quadriceps expansion Collateral and coronal knee ligaments Ankle ligaments Sinus tarsi syndrome Trochanteric Bursitis, Psoas Bursitis, Gluteal Bursitis Bursitis of the knee Retro-calcaneal bursitis Achilles bursitis Infrapatellar bursitis Pes anserine bursitis Mortons Neuroma Upper limbs Acromioclavicular joint dysfunction |
| | | Sternoclavicular joint dysfunction Osteoarthritis of the first CMC joint |
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| | | Radioulnar joint Other joints of the wrists and fingers Wrist joint capsulitis Glenohumeral joint space Subacromial space De Quervain's tenosynovitis Trigger finger Olecranon Bursitis Articular soft tissue structures Impingement syndrome Subacromial Bursitis Adhesive capsulitis/periarthritis/frozen shoulder Carpal Tunnel Syndrome |
|-----|---------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.3 | Criteria for exclusion | Under 18 years in age Suspicion of infection in the joint Signs/symptoms of concurrent infection Significant systemic infection within the last 3 weeks, as per clinical judgement Prosthetic joint Fracture site Haemarthrosis Patient taking interacting drugs Warfarinsed patients recent INR greater than 3 (INR result within week prior to injection) Known sensitivity/allergy to corticosteroids or to any components in the product Pregnancy Patient declines to be treated under a PGD |
| 1.4 | Cautions/additional information | Poorly controlled diabetes Breast feeding – informed consent obtained and documented Patients taking an anticoagulant medication Patients taking warfarin with a recent INR between 2 and 2.9. (INR result within a week prior to injection) Caution is recommended in patients known to have the following conditions: Recent intestinal anastomoses, ulcerative colitis or diverticulitis, thrombophlebitis, existing or previous history of severe affective disorders (especially previous steroid psychosis), renal impairment, metastatic carcinoma, osteoporosis (post-menopausal females are particularly at risk), patients with an active peptic ulcer (or a history of peptic ulcer), myasthenia gravis. Latent or healed tuberculosis; in the presence of local or systemic viral infection, systemic fungal infections or in active infections not controlled by |

| | | antibiotics. Hypertension, congestive heart failure, glaucoma (or a family history of glaucoma), previous steroid induced myopathy, epilepsy, liver failure, hypothyroidism, immunosuppression due to disease or drugs Systemic effects do not normally occur with intra-articular injections. Must not be injected intrathecally due to risk of neurotoxicity. Patient informed joint replacement may not be possible within 6/12 of joint injection. See BNF and Summary of Product Characteristics (SmPC) for further information. |
|-----|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.5 | Action if patient excluded | Injection is not administered. Reason recorded in patient's notes on EMIS Clinical System. |
| | CACIAGO | Inform and/or refer back to GP |
| 1.6 | Action if patient declines | Injection is not administered. |
| | | Reason recorded in patient's notes on EMIS Clinical System. |
| | | Inform and/or refer back to GP |

2. Characteristics of staff

| 2.1 | Class of Health Professional for whom PGD is applicable (professional qualification and training) | First contact physiotherapist (FCP) or Advanced MSK Practitioner Indemnified as part of membership of the Chartered Society of Physiotherapists or another recognised body Registered with the Health and Care Professions Council (HCPC) |
|-----|---------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | Diploma in Injection therapy or Masters level qualification in injection therapy |
| 2.2 | Additional requirements | Competent to work under Patient Group Direction (PGD), including satisfactory completion of training to administer/supply in accordance with this PGD Attended a recognised joint injection therapy course – e.g. Neuro-Musculoskeletal Injection Therapy, York St John University, Injection therapy masters module, Society of Orthopaedic Medicine - Musculoskeletal Injection Therapy York St John University (yorksj.ac.uk) |
| | | All staff using and overseeing the PGDs are to engage in the audit process |

| | | Understanding of the law that mixing of drugs in a syringe prior to injection is not legal under a PGD |
|-----|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| | | Is authorised by name, under the current version of the PGD |
| | | Accepts personal responsibility for working within the PGD, understands the legal implications of doing so and works within the scope of the PGD |
| | | Competent in recognition and management of anaphylaxis |
| 2.3 | Continued training | Commitment to continual professional development |
| | requirements | Evidence of regular continuing professional development |
| | | Ongoing demonstration of clinical expertise within MSK conditions |
| | | Compliance with Integrated Care Board policies to include information governance, safeguarding and complaints. |
| | | Basic life support training as dictated by the Resuscitation Council (UK) |
| | | Anaphylaxis training |

3. Description of Treatment

| 3.1 | Generic name of medicine and form | Methylprednisolone acetate injection 40mg/ml |
|-----|----------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3.2 | Legal status | Prescription Only Medicine (POM) |
| 3.3 | Storage | Locked cupboards. Store upright below 25°C and protect from freezing. |
| 3.4 | Licensed or unlicensed | Licensed |
| 3.5 | Dose(s) | 0.1 - 2ml dependent on joint/tissue, see dosage guide Appendix 1 Do not mix lidocaine with corticosteroid in the syringe prior to injection as this is not legal under a PGD |
| 3.6 | Route/Method of Administration | Intra-articular or peri-articular |
| 3.7 | Frequency of administration | Single dose per joint/tissue per appointment |
| 3.8 | Total dose and number of times treatment can | Single dose per joint/tissue per appointment |

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| | be administered over what time | Up to a maximum of 3 doses within 12 months on clinical assessment |
|------|----------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3.9 | Side effects of drugs (including potential Adverse Drug Reaction) | Administered not less than 3 monthly intervals Local or systemic infection Localised fat atrophy Hypersensitivity reactions including anaphylaxis Post injection pain Localised discomfort and bruising Possible facial flushing Arthropathy Skin depigmentation Tendon rupture Altered glycaemic control See BNF and SPC for further information |
| 3.10 | Advice/management of adverse reactions/events | Facial flushing, if experienced, is transient and will settle Record any adverse reaction/event in the patient's notes on EMIS Clinical System Steroid injection leaflet given to patient pre-injection, electroniclink or paper copy if required (https://www.versusarthritis.org/media/23676/steroid-injections-information-booklet-june2021.pdf) Patient to contact treating clinician and/or the GP for adverse events Patient to seek urgent medical advice if joint becomes hot and swollen and/or if develops a fever seek advice from GP practice |
| 3.11 | Procedure for reporting Adverse Drug Reactions (ADR's) | Report serious suspected adverse drug reactions (or all suspected ADRs if the medicine is black triangle ▼) to the MHRA using either the yellow cards or via www.yellowcard.gov.uk Record any adverse drug reaction in the patient's consultation record Inform the GP |
| 3.12 | Information on follow up treatment | Patient advised to contact GP practice if injection fails (2/52-time scale required to allow for effect) and patient would like further intervention/review. |

| 3.13 | Written/verbal advice for patient/carer before/after treatment. | Prior to administration That the drug is being administered under a PGD Verbal warning of possible side effects or cautions including local or systemic infection Advise benefit may take several days, patient may ring the service for advice |
|------|------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | During the administration Verbal advice and reassurance about any pain or discomfort felt |
| | | Recommend relative rest of area injected as per current clinical practice Verbal and written instructions to contact treating clinician or GP in the event of adverse reaction or concern Ask patient to contact treating clinician or GP to report any redness, swelling, pain or heat at the injection site or in general Advise the patient to seek medical attention urgently if side effects develop, especially arrhythmias or convulsions Steroid Emergancy Card supplied if appropriate |
| 3.14 | Specify method of recording supply/ administration, names of health professional, patient identifiers, sufficient to enable audit trail. | Record on patient consultation notes in EMIS Clinical System (electronically where possible): • Written consent documented for all injections administered • Date of administration including site of administration, approach, drug used, and dose • Batch number and expiry date • Signature of clinican administering the medicine, including name and designation • Aseptic no touch technique (ANTT) • A record that supply/administration was under a PGD |



4. Development of the PGD

Multidisciplinary Group:

The group who have been involved in the development of this PGD included the following people:

| Name | Designation | Signature | Date |
|---------------------|-------------------------------|-----------------------|------------|
| Rebecca Lees | First Contact Physiotherapist | Signed Electronically | 08/12/2021 |
| Rob Jones | Pharmacist | Signed Electronically | 08/12/2021 |
| Dr Geraint Allan | GP | Signed Electronically | 08/12/2021 |
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5. References

- SPC for Depo-Medrone available at <u>Depo-Medrone 40mg/ml Suspension for Injection Summary of Product Characteristics (SmPC) (emc) (medicines.org.uk)</u> accessed on 26/08/2021.
- 2. BNF On-line current version. <u>METHYLPREDNISOLONE | Drug | BNF content published by NICE</u> Accessed on 26/08/2021
- 3. InHealth. PGD for the administration of methylprednisolone injection by registered physiotherapists and nurses. January 2017.
- 4. The Prescription Only Medicines (Human Use) Order 1997. No 1830. Available at www.legislation.gov.uk. Accessed 26/08/2021
- 5. *Statutory Instrument 2009, No. 3062. The Medicines (Exemptions and Miscellaneous Amendments) Order 2009. Available at www.legislation.gov.uk. Accessed 26/08/2021.
- 6. Patient Information Leaflet, https://www.versusarthritis.org/media/23676/steroid-injections-information-booklet-june2021.pdf. Accessed 16/09/2021
- 7. Chartered Society of Physiotherapy. Information Paper PD003. The use of medicines with injection-therapy within physiotherapy services. 6th edition. Feb 2021

Appendix 1. Drug dosage tables.

| Joint | Volume of Methylprednisolone 40mg/ml | Dose of Methylprednisolone ¹ |
|-------------------------------|-----------------------------------------|--------------------------------------------|
| Glenohumeral (shoulder joint) | 0.5 - 2ml | 20 – 80mg |
| Subacromial bursa/space | 0.1 - 1ml | 4 – 40mg |
| Acromioclavicular joint (ACJ) | 0.1 - 0.5ml | 4 - 20mg |
| Elbow | 0.25 - 1ml | 10 - 40mg |
| Wrist | 0.25 - 1ml | 10 - 40mg |
| Carpal metacarpal | 0.1 - 0.5ml | 4 - 20mg |
| Metacarpal interphalangeal | 0.1 - 0.25ml | 4 - 10mg |
| Proximal interphalangeal | 0.1 - 0.25ml | 4 - 10mg |
| Knee | 0.5 - 2ml | 20 - 80mg |
| Ankle | 0.5 - 2ml | 20 - 80mg |



Responsible Organisation:

NHS Cheshire and Merseyside Integrated Care Board

Responsibilities of each Organisation:

Each organisation is required to:

- 1. Approve the contents of this documentation (in the knowledge that it has been prepared by a multidisciplinary group as above).
- 2. Ensure that every PGD is approved and signed by a nominated Senior Pharmacist and Senior Doctor.
- 3. Ensure that the PGD is approved and signed by a senior member of staff, representative of the staff to whom the PGD relates e.g. nurses, chiropodists etc.
- 4. Ensure that the PGD is approved and signed by the Clinical Governance Lead for the Organisation.
- 5. Ensure that individual health professionals working under the direction sign appropriate documentation.

| Organisation (s) | NHS Cheshire and Merseyside Integrated Cal |
|------------------|--------------------------------------------|
| Approved by | |

| Organisation (s) | NHS Cheshire and Merseyside Integrated Care Board |
|----------------------------------------|---------------------------------------------------|
| Approved by | |
| Patient Group Direction Subgroup Chair | |
| Name Chris Haigh | |
| Position | |
| Deputy Chief Pharmacist | |
| Signature Date 30/10/24 | |
| Clinical Governance Lead | |
| Name Prof Rowan Pritchard Jones | |
| Position Executive Medical Director | |
| Signature | |
| R. Pona Sons. | |
| Date 30.10.24 | |