PATIENT GROUP DIRECTIONS*

The Supply and Administration of Methylprednisolone acetate 40mg/ml with Lidocaine 1% 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:

[Methylprednisolone acetate 40mg/ml with Lidocaine 1%]

Version	Date of introduction	Author	Status	Comment
V1	2021	Development of new PGD	Draft	Review of previous Cheshire CCG approved document
V2	Oct 2024	Review	Final	Inclusion of minor amendments following PGD working group approval

Patient Group Direction:	Methylprednisolone acetate 40mg/ml with Lidocaine 1% 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 First contact physiotherapist (FCP) or Advanced MSK Practitioner 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: A combination of a steroid and local anaesthetic is indicated as a single injection 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 Achilles peri-tendonitis 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 bursa Mortons Neuroma
		 Upper limbs Acromioclavicular joint dysfunction Sternoclavicular joint dysfunction Osteoarthritis of the first CMC joint 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 treatment 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 (postmenopausal 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, bradycardia, acute porphyria, glaucoma (or a family history of glaucoma), previous steroid induced myopathy, epilepsy, liver failure, hypothyroidism,

		 immunosuppression due to disease or drugs, impaired respiratory function, Patients taking Class 3 anti-arrhythmic drugs e.g. amiodarone Must not be injected intravenously as convulsions and cardiovascular collapse may occur very rapidly. Must not be injected intrathecally due to risk of neurotoxicity.
		 Systemic effects do not normally occur with intra-articular injections Patient informed Joint replacement surgery 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	Injection is not administered
	excluded	Reason recorded in patient's notes on EMIS Clinical System Inform and/or refer to GP
1.6	Action if patient	Injection is not administered
	declines	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	First contact physiotherapist (FCP) or Advanced MSK Practitioner	
	PGD is applicable (professional qualification and	Indemnified as part of membership of the Chartered Society of Physiotherapists or another recognised body	
	training)	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)	
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		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 the 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 and Lidocaine Hydrochloride solution for injection (10mg/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 of methylprednisolone acetate 40mg/ml with lidocaine 1% dependent on joint/tissue, see dosage guide Appendix 1	
		Do not mix additional lidocaine with this product in the syringe prior to injection as this is not legal under a PGD	
		This PGD is for licensed, pre-mixed methylprednisolone and lidocaine	
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 be administered over what time	Single dose per joint/tissue per appointment Up to a maximum of 3 doses within 12 months on clinical assessment Administered not less than 3 monthly intervals	
3.9	Side effects of drugs (including potential Adverse Drug Reaction)	 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 	
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 Following administration	
		 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 	
		convulsionsSupply a Steroid Emergency Card 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 on 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	

NHS Cheshire and Merseyside Integrated Care Board

4. Development of the PGD

Multidisciplinary Group:

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

Name	Designation	Signature	Date
Rebecca Lees	First Contact Physiotherapist	Signed Electronically	08/21/2021
Rob Jones	Pharmacist	Signed Electronically	08/12/2021
Dr Geraint Allan	GP	Signed Electronically	08/12/2021

5. References

- SPC for Depo-Medrone with lidocaine (methylprednisolone 40mg/ml and lidocaine 1%) available at <u>Depo-Medrone with Lidocaine Suspension for Injection - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)</u> Accessed 26/08/2021
- 2. BNF On-line current version. <u>METHYLPREDNISOLONE WITH LIDOCAINE | 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
- Chartered Society of Physiotherapy. Information Paper PD026. Practice Guidance for Physiotherapist Supplementary and/or Independent Prescribers in the safe use of medicines. 3rd edition. October 2016

Appendix 1. Drug dosage tables.

Joint	Volume of Methylprednisolone 40mg/ml and Lidocaine 1% ¹	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

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NHS Cheshire and Merseyside Integrated Care Board

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 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. Pmad Sons.	
Date 30.10.24	