

This patient group direction (PGD) must only be used by registered health 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)

For the administration or supply of

Methylprednisolone Acetate 40mg/ml

By registered health care professionals for

Adults with simple musculoskeletal conditions

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 46

1. Change history

| Version number | Change details | Date |
|----------------|--------------------------|------------|
| 1 | Original PGD ratified | June 2021 |
| 2 | Extension to expiry date | March 2024 |
| | | |

2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care [PGD website FAQs](#)

3. PGD development

Refer to the [NICE PGD competency framework for people developing PGDs](#)

| Job Title & organisation | Name | Signature | Date |
|---------------------------------|------|-----------|------|
| Author of the PGD | | | |
| Member of the PGD working group | | | |

4. PGD authorisation

Refer to the [NICE PGD competency framework for people authorising PGDs](#)

| Job Title | Name | Signature | Date |
|--|------|-----------|------|
| Medical Director | | | |
| Chief Pharmacist/ Pharmaceutical Adviser | | | |
| Senior Paramedic | | | |
| Director of Nursing | | | |
| GP Adviser | | | |
| Senior Microbiologist (if PGD contains antimicrobials) | | | |

5. PGD adoption by the provider

Refer to the NICE PGD competency framework for people authorising PGDs

| Job title and organisation | Signature | Date | Applicable or not applicable to area |
|----------------------------|-----------|------|--------------------------------------|
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6. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the NICE PGD competency framework for health professionals using PGDs

| | Requirements of registered Healthcare professionals working under the PGD |
|---|--|
| Qualifications and professional registration | <ul style="list-style-type: none"> Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy Must have successfully completed a recognised post-graduate certificate/diploma in injection therapy, or currently undertaking injection therapy training Adhere to Isle of Man hospitals physiotherapy department injection protocol and governance guidelines based on the NPSA (National patient safety agency) good practice guidelines |
| Initial training | <ul style="list-style-type: none"> Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD Local training in the use of PGDs |
| Competency assessment | Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs |
| Ongoing training and competency | The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years |

7. Clinical Conditions

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| Clinical condition or situation to which this PGD applies | Adult patients with Musculoskeletal conditions that have been assessed as requiring injection therapy with a corticosteroid, periarticular, intra-articular, in the upper and lower limbs |
| Inclusion criteria | <ul style="list-style-type: none"> • Adults over 18 years of age • Intra-articular administration: <ul style="list-style-type: none"> - Rheumatoid arthritis - Osteo-arthritis with an inflammatory component • Periarticular administration: <ul style="list-style-type: none"> - Epicondylitis • Intrabursal administration: <ul style="list-style-type: none"> - Subacromial bursitis - Prepatellar bursitis - Olecranon bursitis • Tendon sheath administration: <ul style="list-style-type: none"> - Tendinitis - Tenosynovitis - Epicondylitis |
| Exclusion criteria | <ul style="list-style-type: none"> • Under 18 years of age • Hypersensitivity to Methylprednisolone Acetate and any excipients • Systemic infection • Absence of tendon sheath, the Achilles tendon • Lack of valid consent • Unstable joint • Women who are pregnant and breastfeed • Prosthetic joint replacement • Recent trauma/injury or forthcoming surgery at the site to be injected • Active tuberculosis or past history of tuberculosis within the last 10 years • Peripheral vascular disease at the site to be injected • Hypovolaemia • Anti-coagulation therapy or coagulation disorders • Severe or unstable heart conditions including heart block, congestive cardiac failure and cardiac conduction disturbances • Immunocompromised patients • For epidural, intranasal, intra-ocular or any other unapproved route of administration |

Cautions (including any relevant action to be taken)
(continued)

- As the product is suspension it **MUST NOT** be given by intravenous route
- Use in the elderly: the common adverse effects of systemic corticosteroids are more likely to occur in the elderly population. Therefore, careful evaluation of risk factors such as Osteoporosis, hypertension, hypokalaemia, diabetes and susceptibility to infection and thinning of the skin should be done before administering the injection
- Special cautions: systemic absorption can occur following intra-articular injection of steroids. Systemic as well as local effects can therefore be expected following all corticosteroids injections. For this reason particular care is especially when considering long term or repeated use of local or systemic corticosteroids in patients with the following conditions:
 - Osteoporosis (post-menopausal females are particularly at risk)
 - Uncontrolled hypertension or congestive heart failure
 - Psychogenic disorder – existing or previous history of severe affective disorder (especially previous steroid psychosis)
 - Diabetes mellitus
 - Glaucoma
 - Previous corticosteroid-induced myopathy
 - Liver failure or cirrhosis
 - Renal insufficiency
 - Epilepsy
 - Peptic ulceration
 - Fresh intestinal anastomoses
 - Predisposition to thrombophlebitis
 - Abscess or other pyogenic infections
 - Ulcerative colitis
 - Diverticulitis
 - Myasthenia gravis
 - Ocular herpes simplex – potential for corneal perforation
 - Hypothyroidism
 - Metastatic carcinoma
 - Recent myocardial infarction

Note – these groups of patients can be treated with injection therapy, but frequent patient monitoring is strictly advocated where repeat injection is indicated.

If there is any doubt about the suitability of the patient to receive the medication an orthopaedic/rheumatology consultant or patient's doctor should be consulted as appropriate – particularly regarding any patient receiving concurrent medication including:

- Erythromycin, ketoconazole, anticholinesterases, acetazolamide, hypoglycaemic agents, digoxin
- Drugs that induce hepatic enzymes e.g. rifampicin,

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| Cautions (including any relevant action to be taken) (continued) | <p>carbamazepine, phenytoin</p> <ul style="list-style-type: none"> • Patients on anticoagulant therapy • Patient requiring/receiving live vaccines • Patients with a concomitant or recent course of systemic steroids • Patients diagnosed with hypothyroidism and who are taking NSAID's or salicylates: <ul style="list-style-type: none"> - Injections into joints should be avoided for 6 months prior to surgery - Injections within one week prior to travel abroad should be avoided if possible due to risk of complications while away requiring medical advice and treatment |
| Arrangements for referral for medical advice | Patient should be referred to a more experienced clinical practitioner for further assessment |
| Action to be taken if patient excluded | Patient should be referred to a more experienced clinical practitioner for further assessment |
| Action to be taken if patient declines treatment | <ul style="list-style-type: none"> • A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated |

8. Details of the medicine

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| Name, form and strength of medicine | Methylprednisolone Acetate 40mg/ml |
| Legal category | Prescription Only Medicine (POM) |
| Indicate any <u>off-label use</u> (if relevant) | None |
| Route/method of administration | Intra-articular, periarticular, intrabursal and tendon sheath. |
| Dose and frequency | <p>Intra-articular:</p> <ul style="list-style-type: none"> • Large Joint – 1ml (40mg) • Medium joint – 0.5ml (20mg) • Small joint – 0.25ml (10mg) <p>Periarticular injections:</p> <ul style="list-style-type: none"> • Small soft tissue – 0.25ml (10mg) |
| Quantity to be administered and/or supplied | One off dose based on location and joint size as per doses above |
| Maximum or minimum treatment period | One dose for one episode of care |
| Storage | Room temperature |

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|---------------------------|---|
| Adverse effects | <p>Effect on skin:</p> <ul style="list-style-type: none"> • Hypopigmentation or hyperpigmentation • Subcutaneous and cutaneous atrophy • Sterile abscess <p>Post injection pain: Following intra-articular use, appropriate pain killers are usually suggested for possible post injection pain, if needed</p> <p>Sepsis: Any marked increase in pain accompanied by local swelling, further restriction of joint motion; fever and malaise are suggestive of septic arthritis. Patient should be asked to contact the injection clinic or report to the emergency department as soon as possible</p> <p>Tendon Rupture: If there is any suspicion of tendon rupture, patients are advised to report to accident and emergency or GP as soon as possible</p> <p>Uterine bleeding: Any form of persistent uterine bleeding post injection should be reported to the GP as soon as possible</p> <p>Other possible side effects:</p> <ul style="list-style-type: none"> • Raised blood sugar in diabetic patients • Facial flushing • Mood swings • Osteoporosis can occur – care should be taken to avoid steroid loading in patients with existing osteoporosis <p>In rare cases anaphylactic reaction may occur</p> |
| Records to be kept | The administration of any medication given under a PGD must be recorded within the patient's medical records |

9. Patient information

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| Verbal/Written information to be given to patient or carer | <ul style="list-style-type: none"> • Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request |
| Follow-up advice to be given to patient or carer | If symptoms do not improve or worsen or you become unwell, seek medical advice immediately |

10. Appendix A

References

1. British National Formulary (BNF) available online: <https://bnf.nice.org.uk>
2. Nursing and Midwifery (2018) "The code" available online: <https://www.nmc.org.uk>
3. Current Health Care Professions Council standards of practice
4. General Pharmaceutical Council standards
5. The General Optical Council
6. Electronic medicines compendium available online: <https://www.medicines.org.uk>
7. National patient safety agency (NPSA) www.npsa.nhs.uk/health/alters

11. Appendix B

Health professionals agreed to practice

- Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor
- A mentor is defined within the Manx care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves