

Patient Group Direction For The Administration Of Medications As Included in the PGD formulary Of Local Corticosteroid Injections And/Or Lidocaine By Approved Healthcare Professionals Working Within NHS Grampian and NHS Western Isles

Lead Author:

Advanced Practice
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Consultation Group:

See relevant page in the PGD

Approver:

Medicines Guidelines and Policies Group

Authorisation: NHS Grampian

Signature:

MGPG1248

Muri

Signature:

NHSG Identifier: NHSG/PGD/CorticoLido/

Review Date: April 2024 Date Approved: April 2022

Expiry Date: April 2025

NHS Grampian and NHS Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Board. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 2

#### **Revision History:**

2021

2021

December

| Reference and approval date of PGD that has been adapted and/or superseded |              | PGD supersedes NoS/PGD/CorticoLido/MGPG1010 V1.1 |                 |
|--|--------------|--|-----------------|
| Date of change   | Summary o    | f Changes  | Section heading |
| October<br>2021  | Review and   | transfer to new PGD template.                    |                 |
| December<br>2021   | Add Adcorty  | 1.   | Monographs      |
| December<br>2021   | Change to c  | onditions to be treated to include ankle.        | Inclusions      |
| December   | Added signif | icant to trauma/injury.                          | Exclusions      |

NHGS Identifier: NHSG/PGD/CorticoLido/MGPG1248

COVID precautions added.

**Keyword(s):** PGD Patient Group Direction Methylprednisolone Depo-Medrone

triamcinolone Kenalog Hydrocortisone Hydrocortistab Lidocaine

**Exclusions** 

Physiotherapist Radiographer

**Policy Statement:** It is the responsibility of the individual healthcare professionals and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

**Review date:** The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document: Drafted: October 2021

Completed: April 2022

Approved: April 2022 (published – May 2022)

Amended and reauthorised:

# **Organisational Authorisations**

This PGD is not legally valid until it has had the relevant organisational authorisation.

#### PGD Developed/Reviewed by;

| Medical practitioner             | Name: Mr Scott Barker                    |
|----------------------------------|--|
| medical practitioner             | Health Board: NHSG                       |
|                                  | Title: Orthopaedic Consultant            |
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|                                  | Signature:                               |
|                                  | Date: 11/05/2022                         |
| Senior representative of the     | Name: Amie Long                          |
| professional group who will      | Health Board: NHSG                       |
| provide care under the direction | Title: Radiographer                      |
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|                                  | Signature:                               |
|                                  | Date: 15/05/2022                         |
| Lead author                      | Name: Ann Quirk                          |
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| Pharmacist                       | Name: Liam Callaghan                     |
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|                                  | Signature:                               |

#### Approved and authorised for use within NHSG by;

| Medicines Guidelines and Policies Group Chair | Signature | Date Signed |
|---|-----------|-------------|
| Lesley Coyle                                  |           | 06/05/2022  |

#### Approved and authorised for use within NHSWI by;

| Realistic Medicine & Therapeutics Clinical Lead | Signature | Date Signed |
|---|-----------|-------------|
| David Rigby                                     | 25        | 19/05/2022  |
|   |           |             |

#### **Management and Monitoring of Patient Group Direction**

#### **PGD Consultative Group**

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

| Name:   | Title:  |
|---|---|
| Ann Quirk<br>Liam Callaghan<br>Mr Scott Barker<br>Aimee Urguhart    | Lead Author: Advanced Practice Physiotherapist NHSG Pharmacist: Chief Pharmacist Western Isles NHSWI Medical Practitioner: Orthopaedic Consultant NHSG Physiotherapist NHSG |
| Amie Long   | Senior Representative of the Professional Group Radiographer NHSG   |
| Frances Adamson<br>Dr Alison Black<br>Alan Bulcraig<br>Jenny Murray | Medicines Management Specialist Nurse NHSG Consultant Rheumatologist NHSG First Contact Practitioner Physiotherapist, NHSG Physiotherapist NHSWI                            |

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#### Clinical indication to which this PGD applies

# Definition of situation/Condition

This Patient Group Direction (PGD) will authorise physiotherapists and radiographers to administer local corticosteroid injections and/or lidocaine contained in the PGD Formulary in <a href="Appendix 3">Appendix 3</a> to individuals aged 18 years and over.

Injection therapy with corticosteroids and/or local anaesthetic would be considered for individuals presenting with musculoskeletal conditions that are not responding to conservative treatment such as physiotherapy and/or simple oral analgesics and/or non-steroidal anti-inflammatory drugs (NSAIDs). Physiotherapists and radiographers are ideally placed to carry out this treatment to facilitate the individuals continued rehabilitation without the need for referral to a doctor.

This PGD will authorise appropriately qualified physiotherapists and radiographers to undertake these injections leading to a reduced workload for GPs and hospital doctors.

This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF) and individual Summary of Product Characteristics (SmPC).

#### Inclusion criteria

Individuals, aged 18 years or over, who present with the following conditions:

- Soft tissue or osteoarthritic conditions around the shoulder
- Acromio-clavicular joint sprain or capsulitis
- Soft tissue conditions around the elbow
- Thumb joint capsulitis or arthritis
- Soft tissue conditions around the hand
- Soft tissue conditions around the hip
- Soft tissue or osteoarthritic conditions around the knee
- Plantar fasciitis
- Soft tissue or osteoarthritic conditions around the ankle
- Metatarsophalangeal joint of first toe.

**Note:** Diagnosis must be made by a senior physiotherapist with post graduate training and experience in the management of the conditions as listed above.

Radiographers will use ultrasound to diagnose the lesion prior to injection.

The final diagnosis and decision to inject must be made by the individual healthcare professional. The physiotherapist or radiographer trained to undertake the injection therapy must fully assess the individual's condition and determine that injection therapy is the most appropriate management.

The medicines may only be used within individual product monograph recommendations.

Prior to the administration of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Board consent policy.

#### **Exclusion criteria**

Individuals may be administered local corticosteroid injection and/or lidocaine under this PGD unless:

- They are under 18 years of age
- They have signs of current, local infection within the joint or site to be injected
- They have received a steroid injection for the condition within the last 3 months from any other source, i.e. pain clinic, GP, etc
- There is local or general sepsis such as chest infection, UTI or unexplained fever
- There are any skin lesions such as abrasions, ulcers, infected ingrown toenails (source of bacteraemia at time of injection)
- They have known or suspected allergy or hypersensitivity to any of the medicines or excipients within the formulations
- They have previously experienced an adverse reaction to the medicine or any of its excipients
- There is adjacent osteomyelitis
- They have Myasthenia Gravis
- The joint is prosthetic or unstable
- There is active tuberculosis or past medical history of tuberculosis within the last 10 years
- They are pregnant or breast feeding
- There is peripheral vascular disease at the site to be injected
- There is recent significant trauma/injury at site to be injected
- They are showing signs of hypovolaemia
- They have a severe or unstable heart condition including heart block, congestive cardiac failure or cardiac conduction disturbances

|                                   | <ul> <li>They have had a previous steroid induced myopathy</li> <li>They are immunocompromised</li> <li>They are currently prescribed anticoagulants such as warfarin, apixaban, edoxaban, rivaroxaban, dabigatran, heparin, fondaparinux or dalteparin</li> <li>They have a known bleeding disorder</li> <li>They are within 2 weeks either side of Covid vaccination</li> <li>Where there is no valid consent.</li> </ul> |  |
|-----------------------------------|---|--|
| Precautions and special warnings  | Individuals with diabetes should be warned that they may be prone to hyperglycaemia over the hours following corticosteroid injection and they should regularly monitor their blood glucose levels.   |  |
|                                   | Hypertension control after injection - Corticosteroids can raise blood pressure; although the effect is typically transient the physiotherapist/radiographer must discuss blood pressure control with the individual with respect to stability of symptoms and medication post-injection.   |  |
|                                   | Caution should be taken in individuals prescribed antiplatelet medicines such as aspirin, ticagrelor, clopidogrel or dipyridamole as there is an increased risk of bleeding.  |  |
|                                   | Patients should be counselled that covid appears to be worse in people on steroids so to be aware that for around 8 weeks post injection this extra risk factor may exists.   |  |
|                                   | <b>Note:</b> The physiotherapist or radiographer should ensure that they have checked as far as possible if the individual has received a steroid injection within the last three months from another source, such as via pain clinic, GP or consultant.  |  |
|                                   | See individual medicine monographs for further precautions and warnings.  |  |
| Action if excluded from treatment | Medical advice must be sought – refer to General Practitioner (GP) or relevant medical practitioner.  |  |
|                                   | Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.  |  |
| Action if treatment is declined   | Inform GP/refer to the relevant medical practitioner if individual declines treatment.  |  |
|                                   | Document that the administration was declined, the reason and advice given in appropriate clinical records.   |  |

## Description of treatment available under the PGD

| Name form and strength of medicine      | See individual medicine monographs.  |  |
|---|--|--|
| Legal status                            | The medicines included in this PGD formulary are all Prescription-only Medicines (POM).  |  |
| Dosage/Maximum total dose               | See individual medicine monographs.  |  |
| Frequency of dose/Duration of treatment | Repeated injections may be given at three month intervals, but no more than 3 injections may be given in any one episode of care depending on the degree of relief obtained from the initial injection.  For the purposes of this PGD an episode of care is defined as the period from referral/diagnosis through to the completion of the last encounter related to that problem.  For weight bearing joints such as the knee, a minimum of three   |  |
|   | months is needed between intra-articular injections. No more than 3 injections should be given in any one site in one year.  Note: The steroid load in regard to weight bearing joints should also be considered prior to injection.   |  |
| Maximum or minimum treatment period     | See individual medicine monographs.  |  |
| Route/Method of administration          | The route of administration is intra-articular, periarticular, intrabursal injection or injection into the tendon sheath/enthesis. The therapist must maintain a clean working environment, ensure a safe injection technique, and minimise the infection risk as appropriate for that procedure.  Where local corticosteroid and lidocaine are both to be administered, they <b>must not be mixed in the same syringe</b> as this would result in an unlicensed product. Lidocaine may be given first, followed by injection of the steroid.  If the required doses and choice of medicinal product are appropriate, the pre-mixed methylprednisolone with lidocaine preparation may be used. |  |
|   | See individual medicine monographs.  |  |
| Quantity to be administered             | See individual medicine monographs.  |  |

| Storage requirements                | See individual medicine monographs.  |
|-------------------------------------|--|
| Follow-up (if applicable)           | Individuals should remain on the premises for 30 minutes following the injection and should not leave if they are feeling unwell without speaking to the healthcare professional who administered the medicine first. If necessary a doctor or the individuals GP should be contacted for advice.  Follow up with physiotherapy should be arranged and a review arranged with the injecting therapist/referring clinician if |
|                                     | necessary. Individuals who do not respond to the injection will need to be followed up appropriately with liaison between the physiotherapist/radiographer and medical staff.  |
|                                     | <b>Note:</b> It is important that there are clear lines of communication as to what treatment(s) the physiotherapist or radiographer have provided for individuals with their GP, so as to avoid repeat treatments within a 3 month timescale.   |
| Advice (Verbal)                     | Advise individual what to expect and what to do for minor and major reactions.   |
|                                     | Individuals should be safe to drive unless they have a hypersensitivity reaction to the injection or feel light headed in which case they must be advised against driving.   |
|                                     | Individuals are advised to rest the injected area for the first few days. They may then begin increased use with rehabilitation usually under the instruction of a physiotherapist. Often this rehabilitation should start 2-3 weeks after the injection to give it time to take effect.   |
|                                     | If serious adverse or persistent effects occur, the individual should be advised to contact the physiotherapist/radiographer or GP/Accident and Emergency department/NHS24.  |
| Advice (Written)                    | The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.  |
| Identifying and                     | See individual medicine monographs.  |
| managing possible adverse reactions | This list is not exhaustive. Please also refer to current BNF and manufacturers SmPC for details of all potential adverse reactions.   |
|                                     | BNF: BNF British National Formulary - NICE   |

|                                  | SmPC/PIL/Risk Minimisation Material:  Home - electronic medicines compendium (emc)  MHRA Products   Home  RMM Directory - (emc)  If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.  Report any severe reactions using the Yellow Card System.  Yellow Card Scheme - MHRA   |
|----------------------------------|---|
| Facilities and supplies required | <ul> <li>The following are to be available at sites where the medicine is to be administered:</li> <li>Appropriate storage facilities</li> <li>An acceptable level of privacy to respect individual's right to confidentiality and safety</li> <li>Basic airway resuscitation equipment (e.g. bag valve mask)</li> <li>Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection</li> <li>Access to a working telephone</li> <li>Another competent adult, who can summon urgent emergency support if required should ideally be present</li> <li>Access to medical support (this may be via the telephone)</li> <li>Approved equipment for the disposal of used materials</li> <li>Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel</li> <li>A copy of this current PGD in print or electronically.</li> </ul> |

## Characteristics of staff authorised to administer medicine(s) under PGD

| Professional qualifications | Registered Physiotherapists and Radiographers as recognised by the Health and Care Professions Council (HCPC).  |  |
|-----------------------------|---|--|
| Specialist competencies     | <ul> <li>Approved by the organisation as:</li> <li>Competent to assess the individual's capacity to understand the nature and purpose of the medicine administration in order to give or refuse consent</li> <li>Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual</li> <li>Physiotherapists and radiographers who have undertaken specialist musculoskeletal (MSK) training and worked in MSK service for more than a year</li> <li>Competent to undertake administration of the medicine</li> <li>Competent to work under this PGD.</li> </ul> |  |

## Additionally: Physiotherapists and radiographers working under this PGD must have additional postgraduate training and certification of competence in injection therapy. The level of training will be determined and approved by each individual professional body, and Health Board. Ongoing training All professionals working under this PGD must: and competency Have undertaken NoS PGD module training on TURAS Have attended basic life support training either face to face or online and updated in-line with Board requirements Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis in-line with Board requirements Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct Have knowledge and familiarity of the following; SmPC for the medicine(s) to be supplied/administered in accordance with this PGD. Responsibilities of Professional manager(s) will be responsible for; professional manager(s) Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintain up to date record of all staff authorised to administer

the medicine(s) specified in this direction.

#### **Documentation**

# Authorisation of administration

Physiotherapists working within NHS Grampian and NHS Western Isles can be authorised to administer the medicine(s) specified in this PGD by their Clinical Manager or Consultant.

Radiographers working within **NHS Grampian only** can be authorised to administer the medicine(s) specified in this PGD by their Clinical Manager or Consultant Radiologist.

All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1).

|                          | A Certificate of Authorisation ( <u>Appendix 2</u> ) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records   |                  |               |
|--------------------------|---|------------------|---------------|
|                          | should be held in the individual health professional's records, or as agreed locally.   |                  |               |
| Record of administration | An electronic or paper record for recording the screening of individuals and the subsequent administration, or not of the medicine(s) specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum:  Date and time of administration  Individuals name and CHI  Exclusion criteria, record why the medicine was not administered (if applicable)  Record that valid consent to treatment under this PGD was obtained  The name, dose, form, route (batch number, expiry date and site where appropriate for injectable medicines) of the medicine administered  Advice given, including advice given if excluded or declined treatment under this PGD  Signature and name in capital letters of the healthcare professional who supplied/administered the medicine  Record of any adverse effects (advise individuals GP/relevant medical practitioner).  Depending on the clinical setting where supply/administration is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate:  Individual's GP records if appropriate  Secondary Care Medical Notes |                  |               |
| Audit                    | All records of the medicine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.   |                  |               |
| References               | Electronic Medicines Compendium <a href="http://www.medicines.org.uk">http://www.medicines.org.uk</a>   |                  |               |
|                          | Medicine  | Date of Revision | Date Accessed |
|                          | Methylprednisolone acetate (Depo-Medrone®)  April 2021  19/10/21  |                  |               |
|                          |   |                  |               |

| Medicine  | Date of Revision | Date Accessed |
|---|------------------|---------------|
| Triamcinolone<br>acetonide<br>(Kenalog <sup>®</sup> )<br>40mg/mL                            | 04/10/21         | 19/10/21      |
| Hydrocortisone<br>acetate<br>(Hydrocortistab®)  | 12/09/19         | 19/10/21      |
| Lidocaine<br>Hydrochloride<br>Injection BP 1%<br>w/v (ADVANZ<br>Brand)                      | 07/07/21         | 19/10/21      |
| Methylprednisolone<br>acetate (Depo-<br>Medrone® 4% with<br>Lidocaine 1%)<br>(Pfizer Brand) | September 2019   | 19/10/21      |
| Adcortyl 10mg/mL  | December 2021    | 25/02/22      |

British National Formulary accessed 19/10/2021.

Add additional references where applicable

Chakravarthy K, Strand N, Frosch A, et al. Recommendations and Guidance for Steroid Injection Therapy and COVID-19 Vaccine Administration from the American Society of Pain and Neuroscience (ASPN). *J Pain Res.* 2021;14:623-629. Published 2021 Mar 5. doi:10.2147/JPR.S302115

Foremny GB, Pretell-Mazzini J, Jose J, Subhawong TK (2015) Risk of bleeding associated with interventional musculoskeletal radiology procedures. A comprehensive review of the literature. Skeletal Radiology 44 619-627



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## Appendix 1

## Healthcare Professional Agreement to Administer Medicine(s) Under **Patient Group Direction**

| l:  | (Insert name)   |
|---|---|
| Working within:                             | e.g. Area, Practice   |
| Agree to administer the medic               | ine(s) contained within the following Patient Group Direction:  |
| Included in the PGD fo Lidocaine By Approve | ction For The Administration Of Medications As<br>rmulary Of Local Corticosteroid Injections And/Or<br>ed Healthcare Professionals Working Within NHS<br>ampian and NHS Western Isles |
| administer the medicine(s) und              | ate training to my professional standards enabling me to der the above direction. I agree not to act beyond my out with the recommendations of the direction.                         |
| Signed:                                     |   |
| Print Name:                                 |   |
| Date:                                       |   |
| Profession:                                 |   |
| Professional Registration number/PIN:       |   |



#### Appendix 2

## Healthcare Professionals Authorisation to Administer Medicine(s) Under **Patient Group Direction**

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.

The Senior Nurse/Professional who approves a healthcare professional to administer the medicine(s) under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.

The Healthcare Professional that is approved to administer the medicine(s) under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.

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Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

| Name of<br>Healthcare<br>Professional | Signature | Date | Name of<br>Manager | Signature | Date |
|---------------------------------------|-----------|------|--------------------|-----------|------|
|                                       |           |      |                    |           |      |
|                                       |           |      |                    |           |      |
|                                       |           |      |                    |           |      |

## **Patient Group Direction For The Administration Of Medications As** Included in the PGD formulary Of Local Corticosteroid Injections And/Or Lidocaine By Approved Healthcare Professionals Working Within NHS **Grampian and NHS Western Isles**

| Name of<br>Healthcare<br>Professional | Signature | Date | Name of<br>Manager | Signature | Date |
|---------------------------------------|-----------|------|--------------------|-----------|------|
|                                       |           |      |                    |           |      |
|                                       |           |      |                    |           |      |
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|                                       |           |      |                    |           |      |



## **Appendix 3**

#### **Medicine Monographs**

| Hydrocortisone (Hydrocortistab® 25mg/mL Suspension For Injection) (Administer)                        | 14 |
|---|----|
| Lidocaine Hydrochloride BP 1% W/V For Injection (Administer) 1mL, 2mL, 5mL Ampoule                    |    |
| Methylprednisolone Acetate (Depo-Medrone® 40mg/mL Suspension For Injection) (Administer)              |    |
| Methylprednisolone Acetate (Depo-Medrone® 4% with Lidocaine 1% Suspension For Injection) (Administer) | 21 |
| Triamcinolone Acetonide (Kenalog® 40mg/mL Suspension For Injection) (Administer)2                     | 24 |
| Triamcinolone Acetonide (Adcortyl Intra-Articular/Intradermal Injection 10mg/mL) (Administer)         | 27 |

| Hydrocortisone (Hydrocortistab <sup>®</sup> 25mg/mL Suspension For Injection)<br>(Administer) |  |  |
|---|--|--|
| Indication  | This medicine is indicated for the local treatment, by intra-<br>articular or periarticular injection, of arthritic conditions such as<br>rheumatoid arthritis and osteoarthritis when few joints are<br>involved. |  |
|   | It is also suitable for the symptomatic treatment, by local injection, of certain non-articular inflammatory conditions such as inflamed tendon sheaths/enthesis and bursae.                                       |  |
| Inclusion Criteria  | See section in PGD   |  |
| Exclusion Criteria  | Medical advice should be sought immediately for any individual who is excluded from the PGD due to the following;  |  |
|   | See list in main PGD.  |  |
| Legal Status  | Hydrocortisone (Hydrocortistab® 25mg/mL) suspension for injection) is a Prescription-only Medicine (POM).  |  |
| Dose/Maximum total dose   | <ul> <li>Tendon enthesis at the medial and lateral epicondyle:</li> <li>25mg</li> </ul>  |  |
|   | Trapeziometacarpal joint: 25mg.  |  |
|   | Maximum of 25mg only allowed under this PGD.   |  |
| Frequency of dose/Duration of treatment   | No more than one joint should be treated in one day. The injection may be repeated at an interval of 3 months.   |  |
| Maximum or minimum treatment period   | No more than 3 injections should be given in any one site in one year.   |  |
| Route/Method of Administration  | For intra-articular or periarticular injection. This medicine may also be injected into non-articular tissues (e.g. tendon sheaths/bursae).  |  |
|   | This medicine must not be injected directly into tendons, nor should it be injected into spinal or other non-diarthrodial joints.  |  |
| Quantity to be administered   | See Dose/Maximum total dose section above.   |  |

| Hydrocortisone (Hydrocortistab <sup>®</sup> 25mg/mL Suspension For Injection) (Administer) |   |  |
|--|---|--|
| Potential Adverse<br>Reactions   | With intra-articular or other local injections, the principal side effect encountered is a temporary local exacerbation with increased pain and swelling. This normally subsides after a few hours.   |  |
|  | The incidence of predictable undesirable effects, including hypothalamic-pituitary-adrenal suppression correlates with the relative potency of the drug, dosage, timing of administration and the duration of treatment.  |  |
|  | A reported common adverse event which has been associated with hydrocortisone use is psychiatric disorders.   |  |
| Advice   | As previously listed in PGD.  |  |
|  | Additionally, advise about relative rest; wait for 30 minutes following the injection to ensure no immediate adverse drug reaction and avoidance of over-use of the area in which symptomatic benefit has been obtained.  |  |
|  | Undesirable effects, such as dizziness, vertigo, visual disturbances and fatigue are possible after treatment with corticosteroids. If affected advise the individual not to drive or operate machinery.  |  |
|  | Suppression of inflammatory response and immune function increases the susceptibility to infections and their severity. Individuals should be advised to take particular care to avoid exposure to measles and to seek immediate medical advice if exposure occurs. |  |
| Monitoring (If applicable)   | N/A   |  |
| Follow up (If applicable)  | As previously listed in PGD.  |  |
| Storage  | Store at +15 to +25° C. Do not freeze. Protect from light.  |  |

| Lidocaine Hydrochloride BP 1% W/V For Injection (Administer) 1mL, 2mL, 5mL Ampoules |   |  |  |
|---|---|--|--|
| Indication  | To alleviate pain associated with the intra-articular or periarticular administration of steroid.   |  |  |
| Inclusion Criteria  | See section in PGD  |  |  |
| Exclusion Criteria  | Medical advice should be sought immediately for any individual who is excluded from the PGD due to the following;   |  |  |
|   | Porphyria   |  |  |
|   | Hypovolaemia  |  |  |
|   | Known allergy or hypersensitivity to lidocaine or anaesthetics of the amide type.   |  |  |
|   | Lidocaine is metabolised in the liver and it should be used with caution in individuals with impaired hepatic function.   |  |  |
| Legal Status  | Lidocaine Hydrochloride BP 1% W/V for Injection is a Prescription-only Medicine (POM).  |  |  |
|   | The individual must be advised that lidocaine injection is <b>not licensed</b> to be given via the intra-articular route except in the premix with Depo-Medrone. It is however an accepted clinical practice to administer lidocaine intra-articularly, this constitutes an off-label use of lidocaine. It is important to document that this has been explained to the individual. |  |  |
| Dose/Maximum total dose   | Large joints/bursae/periarticular lesions: 40mg (4mL).  |  |  |
| total dose  | Medium joint/bursae/periarticular lesions: 20mg (2mL).  |  |  |
|   | Small joints/bursae/periarticular lesions: 10mg (1mL).  |  |  |
|   | Maximum dose of Lidocaine 1% w/v allowed under this PGD is 40mg (4mL).  |  |  |
| Frequency of dose/Duration of treatment   | No more than one joint should be treated in one day. The injection may be repeated at an interval of three months.  |  |  |
| Maximum or minimum treatment period   | No more than 3 injections should be given in any one site in one year.  |  |  |

| Lidocaine Hydrochloride BP 1% W/V For Injection (Administer) 1mL, 2mL, 5mL Ampoules |   |  |
|---|---|--|
| Route/Method of Administration  | Intra-articular or periarticular (soft tissue) injection only.  |  |
| Quantity to be administered   | See Dose/Maximum total dose section above.  |  |
| Potential Adverse<br>Reactions  | Adverse effects are rare and usually the result of excessively high blood concentration due to inadvertent intravascular injection, excessive dosage, rapid absorption or occasionally due to hypersensitivity. |  |
|   | Side effects include nervousness, dizziness, confusion, respiratory depression, convulsions, hypotension and bradycardia. Allergic reactions can include urticaria, oedema and anaphylactic reactions.          |  |
| Advice  | As previously listed in PGD.  |  |
| Monitoring (If applicable)  | N/A   |  |
| Follow up (If applicable)   | As previously listed in PGD.  |  |
| Storage   | Store at less than 25°C. Protect from light.  |  |

| Methylprednisolone Acetate (Depo-Medrone® 40mg/mL Suspension For Injection) (Administer) |  |  |  |
|--|--|--|--|
| Indication   | Intra-articular administration:  |  |  |
|  | Rheumatoid arthritis   |  |  |
|  | Osteoarthritis with an inflammatory component.   |  |  |
|  | Soft tissue administration (intrabursal, periarticular, into tendon sheath):   |  |  |
|  | Synovitis not associated with infection  |  |  |
|  | Epicondylitis  |  |  |
|  | Tenosynovitis  |  |  |
|  | Plantar fasciitis  |  |  |
|  | Bursitis   |  |  |
|  | Capsulitis.  |  |  |
| Inclusion Criteria   | See section in PGD   |  |  |
| Exclusion Criteria   | Medical advice should be sought immediately for any individual who is excluded from the PGD due to the following;  |  |  |
|  | Known allergy or hypersensitivity to lidocaine or anaesthetics of the amide type.  |  |  |
|  | Achilles Tendon injury.  |  |  |
| Legal Status   | Methylprednisolone Acetate (Depo-Medrone® 40mg/mL Suspension for Injection) is a Prescription-only Medicine (POM).   |  |  |
|  | The individual must be advised that methylprednisolone injection is <b>not licensed</b> to be given via the bursae at a dose of greater than 30mg (0.75mL). It is however an accepted clinical practice this constitutes an off-label use of methylprednisolone. It is important to document that this has been explained to the individual. |  |  |
| Dose/Maximum total dose  | Large joints/bursae/periarticular lesions: 20-80mg (0.5-2mL).  |  |  |
|  | Medium joint/bursae/periarticular lesions: 10-40mg (0.25-<br>1mL)  |  |  |
|  | Small joints/bursae/periarticular lesions: 4-10mg (0.1-<br>0.25mL)   |  |  |
|  | Maximum dose of methylprednisolone acetate allowed under this PGD is 80mg (2mL).   |  |  |

| Methylprednisolone Acetate (Depo-Medrone <sup>®</sup> 40mg/mL Suspension For Injection) (Administer) |  |  |
|--|--|--|
| Frequency of dose/Duration of treatment  | No more than one joint should be treated in one day. The injection may be repeated at an interval of three months.   |  |
| Maximum or minimum treatment period  | No more than 3 injections should be given in any one site in one year.   |  |
| Route/Method of Administration   | Intra-articular, periarticular, intrabursal injection or injection into the tendon sheath.   |  |
| Quantity to be administered  | See Dose/Maximum total dose section above.   |  |
| Potential Adverse<br>Reactions   | Common: With intra-articular or other local injections, the principal side effect encountered is a temporary local exacerbation with increased pain and swelling. This normally subsides after a few hours.  |  |
|  | Systemic absorption of methylprednisolone occurs following intra-articular injection of Depo-Medrone. Systemic as well as local effects can therefore be expected.   |  |
|  | Local Effects: Joint sepsis, soft tissue infections, subcutaneous atrophy/skin depigmentation, post injection pain at injection site, tendon rupture, steroid arthropathy.   |  |
|  | Systemic Effects: Facial flushing, alteration in glycaemic control (diabetics), menstrual irregularities, syncope. Osteoporosis can occur with the systemic use of corticosteroids. Systemic effects do not ordinarily occur with intra-articular injections when the proper techniques of administration and the recommended dosage regimens are observed. However care should be taken to avoid steroid loading in those with existing osteoporosis. |  |
|  | This list may not represent all reported side effects of this medicine. Refer to the most current SmPC for more information.   |  |
| Advice   | As previously listed in PGD.   |  |
|  | Additionally, advise about relative rest; wait for 30 minutes following the injection to ensure no immediate adverse drug reaction and avoidance of over-use of the area in which symptomatic benefit has been obtained.   |  |

| Methylprednisolone Acetate (Depo-Medrone® 40mg/mL Suspension For Injection) (Administer) |   |  |
|--|---|--|
|  | Undesirable effects, such as dizziness, vertigo, visual disturbances and fatigue are possible after treatment with corticosteroids. If affected advise the individual not to drive or operate machinery.  |  |
|  | Suppression of inflammatory response and immune function increases the susceptibility to infections and their severity. Individuals should be advised to take particular care to avoid exposure to measles and to seek immediate medical advice if exposure occurs. |  |
| Monitoring (If applicable)   | N/A   |  |
| Follow up (If applicable)  | As previously listed in PGD.  |  |
| Storage  | Protect from freezing.  |  |

| Methylprednisolone Acetate (Depo-Medrone® 4% with Lidocaine 1% Suspension For Injection) (Administer) |  |  |  |
|---|--|--|--|
| Indication  | Intra-articular administration:  |  |  |
|   | Rheumatoid arthritis   |  |  |
|   | Osteoarthritis with an inflammatory component.   |  |  |
|   | Soft tissue administration (intrabursal, periarticular, into tendon sheath):   |  |  |
|   | Synovitis not associated with infection  |  |  |
|   | Epicondylitis  |  |  |
|   | Tenosynovitis  |  |  |
|   | Plantar fasciitis  |  |  |
|   | Bursitis   |  |  |
|   | Capsulitis.  |  |  |
| Inclusion Criteria  | See section in PGD   |  |  |
| Exclusion Criteria  | Medical advice should be sought immediately for any individual who is excluded from the PGD due to the following;  |  |  |
|   | Known allergy or hypersensitivity to lidocaine or anaesthetics of the amide type   |  |  |
|   | Achilles tendon injury.  |  |  |
| Legal Status  | Methylprednisolone Acetate (Depo-Medrone® 4% with Lidocaine 1% Suspension for injection) is a Prescription-only Medicine (POM).  |  |  |
|   | The individual must be advised that methylprednisolone injection is <b>not licensed</b> to be given via the bursae at a dose of greater than 30mg (0.75mL). It is however an accepted clinical practice this constitutes an off-label use of methylprednisolone. It is important to document that this has been explained to the individual. |  |  |
| Dose/Maximum total dose   | Large joints/bursae/periarticular lesions: 20-80mg steroid (0.5-2mL)   |  |  |
|   | Medium joint/bursae/periarticular lesions: 10-40mg steroid (0.25-1mL)  |  |  |
|   | Small joints/bursae/periarticular lesions: 4-10mg steroid (0.1-0.25mL)   |  |  |
|   | Maximum dose of steroid (methylprednisolone acetate) allowed under this PGD is 80mg (2mL).   |  |  |

| Methylprednisolone Acetate (Depo-Medrone <sup>®</sup> 4% with Lidocaine 1% Suspension For Injection) (Administer) |  |  |
|---|--|--|
| Frequency of dose/Duration of treatment   | No more than one joint should be treated in one day. The injection may be repeated at an interval of three months.   |  |
| Maximum or minimum treatment period   | No more than 3 injections should be given in any one site in one year.   |  |
| Route/Method of Administration  | Intra-articular, periarticular, intrabursal injection or injection into the tendon sheath.   |  |
| Quantity to be administered   | See Dose/Maximum total dose section above.   |  |
| Potential Adverse<br>Reactions  | <b>Lidocaine Common:</b> Adverse effects are rare and usually the result of excessively high blood concentration due to inadvertent intravascular injection, excessive dosage, rapid absorption or occasionally due to hypersensitivity.   |  |
|   | Side effects include nervousness, dizziness, confusion, respiratory depression, convulsions, hypotension and bradycardia. Allergic reactions can include urticaria, oedema and anaphylactic reactions.   |  |
|   | Steroid Common: With intra-articular or other local injections, the principal side effect encountered is a temporary local exacerbation with increased pain and swelling. This normally subsides after a few hours.  |  |
|   | Systemic absorption of methylprednisolone occurs following intra-articular injection of Depo-Medrone. Systemic as well as local effects can therefore be expected.   |  |
|   | Local Effects: Joint sepsis, soft tissue infections, subcutaneous atrophy/skin depigmentation, post injection pain at injection site, tendon rupture, steroid arthropathy.   |  |
|   | Systemic Effects: Facial flushing, alteration in glycaemic control (diabetics), menstrual irregularities, syncope. Osteoporosis can occur with the systemic use of corticosteroids. Systemic effects do not ordinarily occur with intra-articular injections when the proper techniques of administration and the recommended dosage regimens are observed. However care should be taken to avoid steroid loading in those with existing osteoporosis. |  |

| Methylprednisolone Acetate (Depo-Medrone <sup>®</sup> 4% with Lidocaine 1% Suspension For Injection) (Administer) |   |  |
|---|---|--|
|   | This list may not represent all reported side effects of this medicine. Refer to the most current SmPC for more information.  |  |
| Advice  | As previously listed in PGD.  |  |
|   | Additionally, advise about relative rest, wait for 30 minutes following the injection to ensure no immediate adverse drug reaction and avoidance of over-use of the area in which symptomatic benefit has been obtained   |  |
|   | Undesirable effects, such as dizziness, vertigo, visual disturbances and fatigue are possible after treatment with corticosteroids. If affected advise the individual not to drive or operate machinery.  |  |
|   | Suppression of inflammatory response and immune function increases the susceptibility to infections and their severity. Individuals should be advised to take particular care to avoid exposure to measles and to seek immediate medical advice if exposure occurs. |  |
| Monitoring (If applicable)  | N/A   |  |
| Follow up (If applicable)   | As previously listed in PGD.  |  |
| Storage   | Do not store above 25°C. Do not freeze.   |  |

| Triamcinolone Acetonide (Kenalog <sup>®</sup> 40mg/mL Suspension For Injection) (Administer) |  |  |
|--|--|--|
| Indication   | Intra-articular use: for alleviating the joint pain, swelling and stiffness associated with rheumatoid arthritis and osteoarthrosis, with an inflammatory component; also for bursitis, epicondylitis, capsulitis and tenosynovitis. |  |
| Inclusion Criteria   | See section in PGD   |  |
| Exclusion Criteria   | Medical advice should be sought immediately for any individual who is excluded from the PGD due to the following;  |  |
|  | See list in main PGD.  |  |
| Legal Status   | Triamcinolone Acetonide (Kenalog® 40mg/mL suspension for injection) is a Prescription-only Medicine (POM).   |  |
| Dose/Maximum total dose  | Large joints/bursae/periarticular lesions: 10-40mg     (0.25-1mL)  |  |
|  | Medium joint/bursae/periarticular lesions: 10-40mg     (0.25-1mL)  |  |
|  | Small joints/bursae/periarticular lesions: 4-10mg  |  |
|  | • (0.1-0.25mL)   |  |
|  | Maximum dose of 40mg (1mL) only allowed under this PGD.  |  |
| Frequency of dose/Duration of treatment  | No more than one joint should be treated in one day. The injection may be repeated at an interval of three months.   |  |
| Maximum or minimum treatment period  | No more than 3 injections should be given in any one site in one year.   |  |
| Route/Method of Administration   | Intra-articular., periarticular, intrabursal injection or injection into the tendon sheath.  |  |
| Quantity to be administered  | See Dose/Maximum total dose section above.   |  |

# Triamcinolone Acetonide (Kenalog® 40mg/mL Suspension For Injection) (Administer)

# Potential Adverse Reactions

**Common:** With intra-articular or other local injections, the principal side effect encountered is a temporary local exacerbation with increased pain and swelling. This normally subsides after a few hours. Headache post injection is also commonly reported.

Systemic absorption of triamcinolone may occur following intra-articular injection of Kenalog into large joints at high doses. Systemic as well as local effects may therefore be expected.

#### **Local Effects:**

Joint sepsis, soft tissue infections, subcutaneous atrophy/skin depigmentation, post injection pain at injection site, tendon rupture, steroid arthropathy.

#### **Systemic Effects:**

Facial flushing, alteration in glycaemic control (diabetics), menstrual irregularities, syncope. Osteoporosis can occur with the systemic use of corticosteroids. Systemic effects do not ordinarily occur with intra-articular injections when the proper techniques of administration and the recommended dosage regimens are observed. However care should be taken to avoid steroid loading in those with existing osteoporosis.

This list may not represent all reported side effects of this medicine. Refer to the most current SmPC for more information.

#### **Advice**

As previously listed in PGD.

Additionally, advise about relative rest, wait for 30 minutes following the injection to ensure no immediate adverse drug reaction and avoidance of over-use of the area in which symptomatic benefit has been obtained.

Undesirable effects, such as dizziness, vertigo, visual disturbances and fatigue are possible after treatment with corticosteroids. If affected advise the individual not to drive or operate machinery.

Suppression of inflammatory response and immune function increases the susceptibility to infections and their severity. Individuals should be advised to take particular care to avoid exposure to measles and to seek immediate medical advice if exposure occurs.

| Triamcinolone Acetonide (Kenalog <sup>®</sup> 40mg/mL Suspension For Injection)<br>(Administer) |   |
|---|---|
| Monitoring (If applicable)  | N/A   |
| Follow up (If applicable)   | As previously listed in PGD.  |
| Storage   | Do not store above 25°C. Do not freeze. Store in an upright position. |

| Triamcinolone Acetonide (Adcortyl Intra-Articular/Intradermal Injection 10mg/mL) (Administer) |  |  |
|---|--|--|
| Indication  | Intra-articular use: for alleviating the joint pain, swelling and stiffness associated with rheumatoid arthritis and osteoarthrosis, with an inflammatory component; also for bursitis, epicondylitis, capsulitis and tenosynovitis. |  |
| Inclusion Criteria  | See section in PGD   |  |
| Exclusion Criteria  | Medical advice should be sought immediately for any individual who is excluded from the PGD due to the following;  |  |
|   | See list in main PGD.  |  |
| Legal Status  | Triamcinolone Acetonide (Adcortyl Intra-Articular/Intradermal Injection 10mg/mL) is a Prescription-only Medicine (POM).  |  |
| Dose/Maximum total dose   | Large joints/bursae/periarticular lesions: 10-15mg     (1-1.5mL)   |  |
|   | Medium joint/bursae/periarticular lesions: 10-15mg     (1-1.5mL)   |  |
|   | Small joints/bursae/periarticular lesions: 4-10mg (0.4-1mL)  |  |
|   | Maximum dose of 15mg (1.5mL) only allowed under this PGD.  |  |
| Frequency of dose/Duration of treatment   | No more than one joint should be treated in one day. The injection may be repeated at an interval of three months.   |  |
| Maximum or minimum treatment period   | No more than 3 injections should be given in any one site in one year.   |  |
| Route/Method of Administration  | Intra-articular, periarticular, intrabursal injection or injection into the tendon sheath.   |  |
| Quantity to be administered   | See Dose/Maximum total dose section above.   |  |

# Triamcinolone Acetonide (Adcortyl Intra-Articular/Intradermal Injection 10mg/mL) (Administer)

# Potential Adverse Reactions

**Common:** With intra-articular or other local injections, the principal side effect encountered is a temporary local exacerbation with increased pain and swelling. This normally subsides after a few hours. Headache post injection is also commonly reported.

Systemic absorption of triamcinolone may occur following intra-articular injection of Adcortyl into large joints at high doses. Systemic as well as local effects may therefore be expected.

#### Local Effects:

Joint sepsis, soft tissue infections, subcutaneous atrophy/skin depigmentation, post injection pain at injection site, tendon rupture, steroid arthropathy.

#### **Systemic Effects:**

Facial flushing, alteration in glycaemic control (diabetics), menstrual irregularities, syncope. Osteoporosis can occur with the systemic use of corticosteroids. Systemic effects do not ordinarily occur with intra-articular injections when the proper techniques of administration and the recommended dosage regimens are observed. However care should be taken to avoid steroid loading in those with existing osteoporosis.

This list may not represent all reported side effects of this medicine. Refer to the most current SmPC for more information.

#### **Advice**

As previously listed in PGD.

Additionally, advise about relative rest, wait for 30 minutes following the injection to ensure no immediate adverse drug reaction and avoidance of over-use of the area in which symptomatic benefit has been obtained.

Undesirable effects, such as dizziness, vertigo, visual disturbances and fatigue are possible after treatment with corticosteroids. If affected advise the individual not to drive or operate machinery.

Suppression of inflammatory response and immune function increases the susceptibility to infections and their severity. Individuals should be advised to take particular care to avoid exposure to measles and to seek immediate medical advice if exposure occurs.

| Triamcinolone Acetonide (Adcortyl Intra-Articular/Intradermal Injection 10mg/mL) (Administer) |  |
|---|--|
| Monitoring (If applicable)  | N/A  |
| Follow up (If applicable)   | As previously listed in PGD.   |
| Storage   | In an upright position. Do not store above 25°C. Do not freeze or refrigerate. Protect from light. |