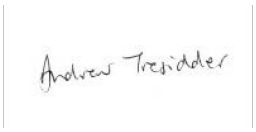
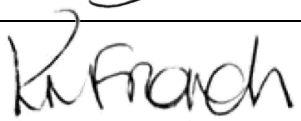
NHS
Somerset
Clinical Commissioning Group

Patient Group Direction: The administration of Triamcinolone Acetonide 40mg in 1ml (Kenalog®) Injection and Triamcinolone Acetonide 10mg in 1ml (Adcortyl®) Injection **by HCPC Registered Physiotherapists providing Musculoskeletal and/or Physiotherapy services in GP practices or CCG commissioned services across NHS Somerset CCG (Version 2.5)**

- Treatment of patients with intra-articular or extra-articular musculoskeletal lesions.

http://www.medicines.org.uk/emc/

Staff involved in the review and development of this PGD for Somerset CCG:

	Name	Signature	Date
Senior Doctor	Dr Andrew Tresidder, Somerset CCG Prescribing and Medicines Management Group Chair		29.6.2022
Senior Pharmacist	Hels Bennett, Medicines Manager, NHS Somerset CCG		24.06.2022
Lead Nurse	Kathy French, Interim Director of Quality & Nursing, NHS Somerset CCG		29.06.22

Name of original author: Somerset NHS Foundation Trust

Expiry Date: 16th June 2024

Authorised for use across NHS Somerset CCG Practices or CCG commissioned services by:

Kathy French, Interim Director of Quality & Nursing for NHS Somerset CCG (Acting as Clinical Governance Lead)

Date of Implementation: 17th June 2022

TO BE COMPLETED BY GP SURGERY / Commissioned service:

I, Doctor ……., as clinical lead for …… surgery, have read and approved this PGD for use by appropriate HCPC Registered Physiotherapists employed at my surgery / commissioned service. I understand that I am responsible for ensuring that staff have adequate training to ensure that this injection is administered to patients in strict accordance with this PGD

Signed…….. Dated……

Patient Group Direction: The administration of Triamcinolone Acetonide 40mg in 1ml (Kenalog®) Injection and Triamcinolone Acetonide 10mg in 1ml (Adcortyl®) Injection **by HCPC Registered Physiotherapists providing Musculoskeletal and/or Physiotherapy services in GP practices or CCG commissioned services across NHS Somerset CCG (Version 2.5)**

Expiry Date: 16th June 2024

The HCPC Registered Physiotherapists named below are authorised to administer as specified under this Patient Group Direction, being employees of …… …… (INSERT SERVICE / PRACTICE NAME)

In signing this document, I confirm the following:

- I have read and understood the above mentioned PGD.
- I agree to practice only within the bounds of my own competence and in accordance with my Code of Professional Conduct.
- I have the qualifications required under the staff characteristics detailed in the PGD
- I am competent to operate under this PGD.
- I agree to administer/supply the above preparations in accordance with this PGD

NAME *(please print)*	TITLE	SIGNATURE	AUTHORISING MANAGER *(please print)*	MANAGER'S SIGNATURE	DATE

- **Complete additional pages as necessary.**
- **Retain original signed pages (1) and (2) with authorising manager.**

NHS Somerset Clinical Commissioning Group

Patient Group Direction: The administration of Triamcinolone Acetonide 40mg in 1ml (Kenalog®) Injection and Triamcinolone Acetonide 10mg in 1ml (Adcortyl®) Injection **by HCPC Registered Physiotherapists providing Musculoskeletal and/or Physiotherapy services in GP practices or CCG commissioned services across NHS Somerset CCG (Version 2.5)**

N.B. You must be authorised by name, under the current version of this PGD before you attempt to work in accordance with it.

1. Clinical Condition

Definition of condition/situation	• Treatment of patients with intra-articular or extra-articular musculo-skeletal lesions • NB. This PGD is not for the treatment of the defined conditions in spinal joints or hip joints.
Criteria for inclusion	• Appropriate consent has been obtained. Refer to the Policy for Consent and Capacity to Consent to Examination and Treatment for further guidance • Adult patients, aged 18 years and over, registered with GP Practices in Somerset: • Seen in GP surgeries or referred to the Physiotherapy Musculoskeletal Service/ Orthopaedic Assessment Service • Where valid consent from patient has been obtained • Where a corticosteroid injection is considered appropriate in order to alleviate: ➢ any individual or combination of symptoms such as joint pain, swelling and stiffness associated with rheumatoid arthritis and osteoarthrosis, with an inflammatory component ➢ bursitis ➢ epicondylitis ➢ tenosynovitis ➢ nerve entrapment
Exclusion criteria	• Children under the age of 18 years • No valid informed consent to treatment • Any individual who has had a true anaphylactic reaction to corticosteroids or to any excipient of the injection(s) • Known hypersensitivity to any component of the injection(s) or having shown hypersensitivity after previous administration • Known or suspected infection in or near the joint to be treated • Known or suspected systemic infection • Local sepsis over injection site • Sepsis elsewhere • Osteomyelitis adjacent to the joint to be treated

	• Haemarthrosis • Prosthetic joint in the adjacent area • Avascular areas e.g. Achilles tendon • Recent trauma to affected area • 3 corticosteroid injections to same joint in previous 12 months • Spinal joints • Unstable joints • Hip joints • Patients with Cushing's disease
Caution	Caution is necessary when using corticosteroids in the following situations, in such cases the health care professional may wish to seek further medical advice before continuing: • Previous history of tuberculosis or characteristic appearance on chest X-ray. The emergence of active tuberculosis can however, be prevented by the prophylactic of anti-tuberculosis therapy • Diabetes mellitus (or a family history of diabetes) • Osteoporosis (post-menopausal females at particular risk) • Hypertension • History of severe affective disorders, especially previous history of steroid psychosis • Glaucoma or a family history of glaucoma • Previous steroid myopathy • Peptic ulceration • Epilepsy • Recent vaccination with live vaccines • Bleeding or blood disorders • Psychogenic pain • Immuno-suppression either by drugs (e.g. oral steroids) or disease (e.g. leukaemia, HIV infection) In immunosuppressed patients, patients should be advised that treatment should be postponed until immune function has recovered • Pregnancy • Breast-feeding • Patient taking any of the following medications (consult current BNF and/or SPC for potential interactions): - Amphotericin - Anticholinesterases - Anticoagulant drugs - Anti-diabetic drugs - Anti-hypertensive drugs - Anti-tubercular drugs - Barbiturates - Ciclosporin

	- Digitalis glycosides - Diuretics (acetazolamide, thiazides, loop diuretics) - Hepatic enzyme inducers e.g. - Aminoglutethimide - Carbamazepine - Phenytoin - Primidone - Rifampicin - Methotrexate - Non-steroidal anti-inflammatory drugs (NSAIDs) - Estrogens including oral contraceptives - Potassium depleting agents - Salicylates - Thyroid drugs - Vaccines • During post marketing use, there have been reports of clinically significant drug interactions in patients receiving triamcinolone acetonide and ritonavir, resulting in systemic corticosteroid effects including Cushing's syndrome and adrenal suppression. Therefore administration of triamcinolone acetonide and ritonavir is not recommended unless the potential benefit of treatment outweighs the risk of systemic corticosteroid
Action if excluded	• Further explanation to gain informed consent, if appropriate • Inform and / or refer to GP or appropriate specialist • Offer patient a copy of any referral letters written, document outcome of offer (acceptance or refusal) in patients notes • Document advice given and / or patient's decision • Document exclusion and the criteria for exclusion in patient's clinical record.
Action if patient refuses medication	• Refer to medical practitioner as appropriate. • Offer patient a copy of any referral letters written, document outcome of offer (acceptance or refusal) in patients notes • Document advice given and / or patient's decision

2. Characteristics of Staff

Professional qualification to be held by staff working under this Patient Group Direction	HCPC Registered Physiotherapists
Additional requirements	• Diploma in Injection Therapy or equivalent, with evidence of CPD in musculo-skeletal injection therapy • Resuscitation skills, with evidence of annual updates • Training and competence in all aspects of drug administration including contraindications and the recognition of anaphylaxis. • The healthcare professional has undertaken appropriate training to carry out clinical assessment of a patient leading to diagnosis that requires treatment according to the indications listed in this PGD • The healthcare professional has undertaken Provider approved training in the supply of medicines under PGDs • You must be authorised by name, under the current version of this PGD before working under it. • Injectors must be fully authorised as competent to inject without supervision to administer the drug under this Patient Group Direction • The healthcare professional must be willing to be professionally accountable for this work and be working within his/her competence • The practitioner should be aware of any change to the recommendations for the medicine listed • Maintenance of own level and updating with evidence of professionals respective continued professional development requirements

Requirements for staff training and competency assessment for administering medicine under this Patient Group Direction.	• Trust PGD Training and theory competency assessment • Competency assessment for this PGD • Successful completion of any medicines management and drug calculation training and competency assessment required for the relevant professional group and area of practice as required by the Trust
System for recording names of individuals authorised to supply and / or administer drugs under this Patient Group Direction	For commissioned service staff Healthcare Professional to complete Individual Authorisation (page 2 of PGD) signed by authorising manager. Copies to be kept by / sent to: • Authorising manager in GP practice • Individual HCPC Registered Physiotherapist • Provider Physiotherapy service lead manager • Provider Medicines Management Team

3. Description of Treatment

Name of Medicine	Triamcinolone Acetonide 40mg in 1ml (Kenalog®) Injection Triamcinolone Acetonide 10mg in 1ml (Adcortyl®) Injection
Legal Class	POM (Prescription Only Medicine)
Storage	Stored in a designated locked medicines cupboard. Do not store above 25°C. Do not freeze. Store in an upright position.
Method or route of administration	All injections listed under this PGD are given by **intra-articular or extra-articular** injection using an appropriately sized needle for the joint or soft tissue following Injection therapy Policy. May be preceded by local anaesthetic injection. • The intra-muscular (IM) needle supplied with the Kenalog Intra-articular / intramuscular 40mg in 1ml or Adcortyl Intra-articular / intramuscular 10mg in 1ml injection pre-filled syringes should be replaced with an appropriately sized needle for intra-articular injection **Note:** • **The injections must not be given intravenously or intrathecally** • Kenalog® is licenced for intra-articular / Intramuscular injection. • Adcortyl® is licenced for intra-articular or intra-dermal injection. • Extra-articular administration of Triamcinolone is unlicensed (‘off label’) but is accepted common practice.
Dose to be used (including criteria for use of differing doses)	The dose of steroid injection is clinically determined for each individual patient by the named Physiotherapist/ Podiatrist, depending on the joint size, size of the intra-articular or extra-articular musculo-skeletal lesion and the severity of the condition: **Triamcinolone acetonide (Kenalog and Adcortyl) for intra-articular administration or injection into tendon sheaths and bursae:** • Recommended dose range 2.5mg to 10mg for smaller joints, and up to 40mg for larger joints with a maximum of 30mg Adcortyl® and 80mg Kenalog® each time • For doses below 5 mg use Adcortyl® Intra-articular/Intradermal injection • Adcortyl® Injection (triamcinolone acetonide 10 mg/ml) should be used for injections given to the sheaths of short tendons • Due to the absence of a true tendon sheath, the Achilles tendon should not be injected with depot corticosteroids. For joint lesions, at least three months between injections, apart from injections to the glenohumeral joint for frozen shoulder, where a successful injection may be repeated after 3-4weeks
Frequency and Dose	• Single injection of corticosteroid • Triamcinolone acetonide: maximum combined total dose of 80mg where multiple joints are injected, with a maximum of 40mg for any individual joint • Where there is multiple joint involvement, treatment may be by intra-articular or extra-articular injection to multiple sites as appropriate
Other information	Manufacturer’s original pack

Advice and information to patient/carer including follow-up

- All patients should be asked to remain in the clinic location for 30 minutes following administration of the injections to allow for observation of an anaphylactic reaction.
- The patient has read and understood the Product Patient Information Leaflet and the Trust leaflet on Anti-inflammatory injections, and consents to treatment.
- Issue patients with a **steroid treatment card**, giving clear guidance on the precautions to be taken to minimise risk. It should also provide details of the prescriber, the name of the drug and the dose administered. It should be shown to anyone treating a patient during or within 3 months of last injection

Patients should be advised:

- That intra-articular corticosteroid injections are useful for treating localized flares of pain and inflammation associated with intra-articular or extra-articular musculo-skeletal lesions
- That relief of symptoms is rapid, and duration of effect can range from a few days to several months depending on the severity of disease, dosage and preparation used
- Of possible adverse reactions and their management
- That patients may experience a temporary local exacerbation with increased pain and swelling for two to three days after injection and may need oral analgesia e.g. paracetamol, ibuprofen. (Please refer to BNF for a list of cautions and contra-indications regarding any analgesia recommended)
- That there is a possibility of an immediate anaphylactic reaction and it is therefore recommended that the recipient of the injection remain in the clinic location for up to 30 minutes following the injection to allow for observation of such reactions
- That site and route of injection will affect the onset of anaphylactic reactions, which may be delayed for up to 72 hours
- That patients should seek medical attention if the develop early symptoms such as breathlessness, swelling or rash
- Corticosteroids may reduce patient's immune responses. If there is no history of chicken pox they should avoid close personal contact with chicken pox or herpes zoster. If exposed they should seek urgent medical advice
- That patients should not over exert the affected joint(s) or extra-articular musculoskeletal lesion for 7 to 10 days after each treatment episode
- That the therapeutic effects of the injection may not be apparent for up to a week
- That blood glucose control may be affected in patients with diabetes
- That the effectiveness of anti-coagulation pharmacotherapy may be increased or decreased with concomitant corticosteroid therapy
- That local tissue atrophy and depigmentation may occur, particularly when small joints or superficial structures are injected with potent corticosteroids

For pre-menopausal and peri-menopausal females, breakthrough bleeding of the menstrual cycle may occur.

- Patients should be warned that potentially severe psychiatric adverse reactions may occur.
- Serious effects: refer to a doctor straight away
- Steroids including Kenalog IA/IM injection can cause serious mental health problems. These are uncommon in both adults and children.

• Mood changes

• Feeling depressed, including thinking about suicide.
• Feeling high (euphoria and mania) or moods that go up and down.
• Feeling anxious/irritable, having problems sleeping, difficulty in thinking or being confused and losing your memory.
• Feeling, seeing or hearing things which do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone.

Relevant warnings including potential adverse reactions:

- Any serious adverse reaction to the medicine supplied / administered under this PGD should be documented in the patient's treatment record. The managing doctor should also be informed.
- MHRA/CHM advice: Corticosteroids: rare risk of central serous chorioretinopathy with local as well as systemic administration (August 2017)
- In patients who have received more than physiological doses of Kenalog® (more than one injection during a three week period), withdrawal should not be abrupt. The dose should be reduced and the dosage interval increased until a dose of not more than 40 mg and a dosage interval of at least three weeks have been achieved as the dose of systemic corticosteroid is reduced.

  A single dose, which is not repeated within a three week period, is unlikely to lead to clinically relevant HPA-axis suppression in the majority of patients
- Patients should be specifically warned to avoid over-use of joints in which symptomatic benefit has been obtained.
- Severe joint destruction with necrosis of bone may occur if repeated intra-articular injections are given over a long period of time
- Repeated injection into inflamed tendons should be avoided as it has been shown to cause tendon rupture.
- Any serious adverse events that may be attributable to the medicine supplied / administered under this PGD should be reported to the CSM/MHRA using the "Yellow Card" system https://yellowcard.mhra.gov.uk/

Specify method of recording supply /administration including audit trail	The following will be recorded in the patient's clinical records: • Patient's name/address/date of birth and consent • Indications for use • Advice given to patient/carer (to include side effects) (including if Patient Information Leaflet provided) • Name of medicine / dose/ quantity supplied • Signed and dated. (Where computer records are used nurses/health professionals must have individual identifier to enable audit trail) • Document any adverse reactions • All significant events/incidents/near misses occurring in relation to the supply / administration of a medicine under this PGD must be reported to the Trust on the relevant incident form in a timely manner • Record that medicine administered via PGD
References used in the development of this PGD:	• BNF (current version) • Summary of Product Characteristics accessed from emc: www.medicines.org.uk

Please refer to the summary of product characteristics for full information

This Patient Group Direction is operational from 17th June 2022

Version History

Version	Date	Brief Summary of Change	Owner's Name
2.1	May 2020	Somerset Partnership PGD full review	Paul Aldwinckle, Orthopaedic Specialist Podiatrist, SPFT
2.2	July 2020	Minor amendments and transfer to CCG template	
2.3	Aug 2020	Minor amendment to adjust to all suitably qualified physiotherapists and amend typo error	Shaun Green
2.4	May 2022	Somerset Foundation Trust PGD full review. Minor formatting changes by Somerset CCG. Reviewed and approved by Somerset CCG Prescribing & Medicines Management Group	Simon Ingram, First Care Practitioner Clinical Lead, SFT
2.5	June 2022	Lidocaine allergy removed from Exclusion criteria	Hels Bennett