

This Patient Group Direction (PGD) must only be used by registered healthcare 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)

Supply/Administration of TRIAMCINOLONE ACETONIDE 10MG/ML (ADCORYL®) AND 40MG/ML (KENALOG®) INJECTION STERILE AQUEOUS SUSPENSION

for the treatment of painful or inflamed joints or soft tissues conditions

Version Number 2.2

Change History	
Version and Date	Change details
V1.0- V1.3	See Previous versions
V2.0	<ul style="list-style-type: none"> • Typographical changes <p>Following added to cautions section</p> <ul style="list-style-type: none"> • Patients with diabetes (including family history of) • Recent myocardial infarction (rupture reported) • Diverticulitis
V2.1	<ul style="list-style-type: none"> • Typographical changes • Resuscitative equipment must be available has been removed. • Added patients on anticoagulant therapy and over 65 years added to exclusions. • Initial training added: <ul style="list-style-type: none"> • Must have undertaken training and be competent in basic life support. • Have received recognised professional training in injection therapy • Received a live vaccine within 4 weeks removed from exclusion and patient information
V2.2	<ul style="list-style-type: none"> • Exclusion added for primary care only: patients on anticoagulation therapy • Updated exclusion, psychiatric conditions not well controlled and/or previous psychosis • Psychogenic disorders and/or previous steroid psychosis (These would include depressive or manic-depressive illness moved to exclusion) • Drug interaction for Potassium-depleting agents e.g. diuretics updated to include; advise patient to report any signs or symptoms of hypokalaemia to their GP e.g. skipped heart beats or palpitations, muscle weakness or spasms or tingling or numbness.

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorized by their organisation to practice under it (See section 5). The most recent and in date final signed version of the PGD must be used.

PGD DEVELOPMENT GROUP

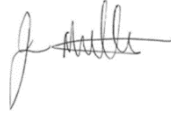
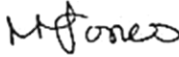

Date PGD template comes into effect:	7 th April 2024
Review date	October 2026
Expiry date:	30 th March 2027

This PGD template has been peer reviewed by the BNSSG PGD short life working group.

This section MUST REMAIN when a PGD is adopted by an organisation.

Name	Designation
Andrea Floyd	Senior Physiotherapist, UHBW
Adam Gold	Clinical Lead, North Somerset MSK Interface Service, Sirona
Lorna Harvey	Advanced Physiotherapist Practitioner, UHBW
James Ritchie	Consultant Rheumatologist, UHBW
Jamie Pierce	Weston MSK Pathway Lead, UHBW
Breda Cronolly	Lead Medicines Information Pharmacist, UHBW
Kate Ellis	Head of Medicines Optimisation, Sirona
Michelle Jones	Principal Medicines Optimisation Pharmacist, BNSSG ICB
Emily Stone	Medicines Optimisation Pharmacist, BNSSG ICB

ORGANISATIONAL AUTHORISATIONS AND OTHER LEGAL REQUIREMENTS

Name	Job title and organisation	Signature	Date
Joanne Medhurst	Chief Medical Officer BNSSG ICB		28/03/2024
Michelle Jones	Principal Medicines Optimisation Pharmacist BNSSG ICB		28/03/2024
Debbie Campbell	Chief Pharmacist BNSSG ICB		28/03/2024

This PGD is for use by the services below:

Authorised for use by the following organisation and/or services
Suitably trained physiotherapists working within a BNSSG GP Practice
Limitations to authorisation
As per PGD

Local enquiries regarding the use of this PGD may be directed to bnssg.medicines-optimisation@nhs.net.

1. Characteristics of staff

Qualifications and professional registration	<ul style="list-style-type: none"> Physiotherapist currently registered with the Health and Care professions Council (HCPC)
Initial training	<ul style="list-style-type: none"> Have received recognised professional training in injection therapy. Must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction (PGD) before working to it Has undertaken appropriate training and been assessed as competent to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this PGD Must have undertaken appropriate training for working under PGDs for supply/administration of medicines Must be competent in the use of PGDs (see NICE Competency framework for health professionals using patient group directions) Must be competent in the recognition and management of anaphylaxis Must have undertaken training and be competent in basic life support. Must have access to the PGD and associated online resource Must have undertaken training and be competent in injection therapy. Should fulfil any additional requirements defined by local policy <p><i>The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate training and successfully completed the competencies to undertake clinical assessment of patient leading to diagnosis of the conditions listed.</i></p>
Competency assessment	<p>Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions</p> <p><i>Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.</i></p>
Ongoing training and competency	<p>Practitioners should be aware of any change to the recommendations for the medicine listed.</p> <p>Practitioners must ensure they are up to date with relevant issues and clinical skills relating to joint injection therapy and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD).</p> <p>Annual updates in anaphylaxis and cardiopulmonary resuscitation to reinforce and update knowledge and skills in this area of practice, including basic resuscitation and anaphylaxis training, with particular reference to changes and national directives.</p>
<p><i>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.</i></p>	

2. Clinical condition or situation to which this PGD applies

<p>Clinical condition or situation to which this PGD applies</p>	<ul style="list-style-type: none"> • Inflammation of peripheral joints or surrounding structures including the joint capsule, synovial membrane, bursae, ligaments and tendons/sheaths.
<p>Criteria for inclusion</p>	<ul style="list-style-type: none"> • Patients 18 years and over • Valid informed consent obtained • Inflammation of peripheral joints or surrounding structures due to trauma, overuse or associated with degenerative change. • In patients who following assessment have symptoms that are persistent and likely to respond favourably to the administration of a steroid injection. • All relevant pathways for conservative management have been explored and evidenced as not appropriate or has completed without reasonable resolution in symptoms. • Diagnosis of each clinical presentation to be made in line with the recommendations of Association of Chartered Physiotherapists in Orthopaedic Medicine and Injection Therapy (ACPOMIT) or other recognised courses.
<p>Criteria for exclusion</p>	<ul style="list-style-type: none"> • No valid consent • Under 18 years of age • Hypersensitivity to triamcinolone, corticosteroids or any component of the product • Inflammation of any of the stated structures due to infection • Systemic infection or active infection on or near joints • Immediately following trauma to the structure • Prosthesis/metal work in joint to be injected • Unstable joints • Pregnancy and breast feeding • Active tuberculosis • Haemarthrosis • Injection into tendon body and other classic avascular areas • Injection into the Achilles tendon due to the absence of true tendon sheath • Poorly controlled diabetes where there is a risk of hyperglycaemia • Adjacent osteomyelitis • History of active peptic ulcer • Psychogenic disorders and/or previous steroid psychosis (These would include depressive or manic-depressive illness) • Surgery in the affected joint within 3 months • Primary care only: Patients on anticoagulant therapy (e.g. direct oral anticoagulants (DOACs) and warfarin) <p>Not be given via the intrathecal or intravenous route</p>

<p>Cautions including any relevant action to be taken</p>	<p>Triamcinolone should be administered with caution in patients with the following conditions. Adverse effects are usually associated with systemic use at significant doses. Patients should be informed that their condition can be adversely affected by steroids, however, localised injections at the doses in this PGDs are safe and well tolerated. Refer to SPC (Home - electronic medicines compendium (emc)) and discuss with prescriber if you have concerns.</p> <ul style="list-style-type: none"> • Patients on interacting drugs see Drug interactions sections. • Patients on non-steroidal anti-inflammatory drugs (NSAIDs) and/or aspirin – see interactions below. • Secondary care only: Patients on anticoagulant therapy. Depending on a suitable INR, joint or soft tissue injections and aspirations in patients taking warfarin are associated with a low risk of haemorrhage. It is important that the INR is within range, preferably at the lower end of the range, and the patient is on stable doses of warfarin. It is advisable to check the INR again 3-4 days after the injection. • Psychogenic disorders (These would include depressive or manic-depressive illness – Patients should be advised to monitor for signs of psychiatric alteration or adverse effects and report to GP. See section: advice to patient. • Bleeding disorders or impaired liver/kidney function • Immunosuppressed patients • Patients with diabetes (– discuss recent blood glucose/HbA1c results to confirm stable and possible effects on blood glucose • Patients with severe anxiety – consider alternative treatment • Elderly patients (higher risk of side effects) • Osteoporosis (post-menopausal females are particularly at risk) • Hypertension, congestive heart failure or recent myocardial infarction (rupture reported) • Glaucoma (or a family history of glaucoma) • Previous corticosteroid-induced myopathy • Fresh intestinal anastomoses • Predisposition to thromboembolic disorders • Ulcerative colitis • Diverticular disease and diverticulitis • Myasthenia gravis • Ocular herpes simplex, for fear of corneal perforation • Hypothyroidism • Care should be taken for patients receiving cardioactive drugs such as digoxin because of steroid induced electrolyte disturbance/potassium loss • Patients with seizure disorders
<p>Action to be taken if the patient is excluded</p>	<ul style="list-style-type: none"> • Record reasons for exclusion and any action(s) taken in patient notes • Advise patient on alternative treatment • Refer to a prescriber/supervising doctor if appropriate
<p>Action to be taken if the patient or carer declines treatment</p>	<ul style="list-style-type: none"> • Document advice given and the decision reached • Advise patient on alternative treatment • Refer to a prescriber/supervising doctor if appropriate

Arrangements for referral for medical advice	<ul style="list-style-type: none"> • If the patient presents with a recurrence of their symptoms, consider onward referral in line with trust/provider policy • If patient falls into exclusion category refer to prescriber
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3. Description of treatment

Name, strength & formulation of drug	<p>Triamcinolone acetonide injection:</p> <ul style="list-style-type: none"> • Adcortyl® injection 10 mg/ml (1ml vials) • Kenalog® injection 40mg/ml (1ml vials)
Legal category	Prescription-only medicine (POM).
Route / method of administration	<ul style="list-style-type: none"> • Injection into the joint cavity (intra-articular) or into the affected structure (bursae ligaments or tendons/sheath) by aseptic non touch technique. • Do not mix with other preparations prior to injection • Inspect visually for particulate matter and discoloration prior to administration whenever suspension and container permit. • Vials are intended for single dose use only. • Not be given via the intrathecal or intravenous route
Indicate any off-label use (if relevant)	<p>Not all doses are licensed for both products. Adcortyl® is only licensed to a dose of 15mg but is sometimes used at doses up to 40mg and via this PGD is approved for use at this dose by appropriately trained healthcare professionals if indicated. If using unlicensed doses patients need to be informed that the dose is approved and clinically accepted but not within the manufacturer's license and the PIL will not include the dose used.</p>
Dose and frequency of administration	<p>The dose may vary from 5 mg to 80 mg depending on the disease entity being treated and the size of the structure being treated. Refer to the relevant Summary of product of characteristics (SPC) - section 4.2 Posology and method of administration.</p> <p>https://www.medicines.org.uk/emc/product/1410 (Adcortyl) https://www.medicines.org.uk/emc/product/6748 (Kenalog)</p> <p>Kenalog® is recommended for doses over 15 mg to reduce the volume administered.</p> <p>There should be a minimum of a 6-week interval if a repeat injection into the same location is performed</p>
Duration of treatment	If first injection is effective but results are temporary 2 further injections may be given within a twelve-month period.
Quantity to be supplied	Not applicable
Storage	<ul style="list-style-type: none"> • Do not store above 25°C • Keep in the outer carton • Protect from freezing <p>Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk</p>

<p>Drug interactions</p>	<p><i>The following interactions have been identified and should be considered where it is known a patient is on the following medicines. Discuss with prescriber if there are concerns:</i></p> <ul style="list-style-type: none"> • Amphotericin B injection and potassium-depleting agents: Patients should be observed for hypokalaemia. • Anticholinesterases: Effects of anticholinesterase agent may be antagonised. • Anticoagulant (oral): Corticosteroids may increase or decrease anticoagulant action. Patients should be closely monitored • Antidiabetics: Corticosteroids may increase blood glucose; diabetic control should be monitored, especially when corticosteroids are initiated, discontinued, or changed in dosage. • Antihypertensives, including diuretics: corticosteroids antagonise the effects of antihypertensives and diuretics. The hypokalaemic effect of diuretics, including acetazolamide, is enhanced. • Anti-tubercular drugs: Isoniazid serum concentrations may be decreased. • Ciclosporin: Monitor for evidence of increased toxicity of cyclosporin when the two are used concurrently. • Digitalis glycosides: Co-administration may enhance the possibility of digitalis toxicity. • Oestrogens, including oral contraceptives: Corticosteroid half-life and concentration may be increased and clearance decreased. • Hepatic Enzyme Inducers (e.g. barbiturates, phenytoin, carbamazepine, rifampicin, primidone, aminoglutethimide): There may be increased metabolic clearance of triamcinolone. Patients should be carefully observed for possible diminished effect of steroid, and the dosage should be adjusted accordingly. • Human growth hormone: The growth-promoting effect may be inhibited. • CYP3A4 inhibitors (e.g. ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, ketoconazole, telithromycin, grapefruit juice): Corticosteroid clearance may be decreased, resulting in increased effects. • Non-depolarising muscle relaxants: Corticosteroids may decrease or enhance the neuromuscular blocking action. • Non-steroidal anti-inflammatory agents (NSAIDS) / aspirin: Corticosteroids may increase the incidence and/or severity of GI bleeding and ulceration associated with NSAIDS. Also, corticosteroids can reduce serum salicylate levels and therefore decrease their effectiveness. Conversely, discontinuing corticosteroids during high-dose salicylate therapy may result in salicylate toxicity. Aspirin should be used cautiously in conjunction with corticosteroids in patients with hypoprothrombinaemia. • Thyroid drugs: Metabolic clearance of adrenocorticoids is decreased in hypothyroid patients and increased in hyperthyroid
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<p>Drug interactions continued</p>	<p>patients. Changes in thyroid status of the patient may necessitate adjustment in adrenocorticoid dosage.</p> <p>This list is not exhaustive. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk</p>
<p>Identification & management of adverse reactions</p>	<p>The following side effects are possible with Triamcinolone:</p> <ul style="list-style-type: none"> • Reactions following intra-articular administration have been rare. In a few instances, transient flushing and dizziness have occurred. Local symptoms such as post-injection flare, transient pain, irritation, sterile abscesses, hyper- or hypopigmentation, Charcot-like arthropathy and occasional increase in joint discomfort may occur. Local fat atrophy may occur if the injection is not given into the joint space but is temporary and disappears within a few weeks to months. • Possible allergic reaction including serious anaphylaxis and anaphylactic shock, particularly where there is a history of drug allergy. • Triamcinolone may mask some of the signs of infection and patients may become susceptible to fungal, viral and bacterial infections which may reach an advanced stage before being recognised <p>NB: With high or prolonged local dosage, corticosteroids can be absorbed in amounts sufficient to produce systemic effects</p> <p>This list is not exhaustive. A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk</p>
<p>Management of and reporting procedure for adverse reactions</p>	<ul style="list-style-type: none"> • Access to adrenaline 1:1000 must be available for anaphylaxis management. • Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report via organisation incident policy.
<p>Written information to be given to patient or carer</p>	<ul style="list-style-type: none"> • Offer marketing authorisation holder's patient information leaflet (PIL) provided with the product. • Provide 'Steroid Treatment' cards which give clear guidance on the precautions to be taken to minimise risk and which provide details of healthcare professional, drug, dosage and the duration of treatment. • Provide Steroid Emergency Card if appropriate. Further guidance can be found here: https://www.endocrinology.org/adrenal-crisis
<p>Patient advice / follow up treatment</p>	<ul style="list-style-type: none"> • Provide patient with steroid treatment card • Provide steroid emergency card if appropriate • Provide patient information leaflet

	<ul style="list-style-type: none"> • Explain treatment, course of action, potential side-effects and their management. • The individual/carer should be advised to seek medical advice in the event of an adverse reaction. • Warn them of the risk of severe psychiatric alteration or adverse reactions (Details of possible symptoms are in the patient information leaflet) emerging within a few days or weeks of treatment, and advise to seek medical help if they occur • Advise that infiltration may be uncomfortable and that pain and discomfort may continue for a few days. Paracetamol may help with this • Advise there may be bruising or a collection of blood under the skin after injection. • To seek medical advice should there be an increase in pain following injection, swelling, fever and malaise • Observe the patient post-injection for signs of potential adverse reactions • Request patient to stay in department for 30 minutes following injection • Advise patient to inform any health professional who offers treatment (doctor, nurse, dentist, pharmacist) during the course of the injections and for 3 months after the last injection that they have received a steroid injection. • Advise patient to avoid contact with known cases of chickenpox (unless they have had it), shingles (unless they have had chickenpox) or measles whilst receiving steroid treatment and for 3 months afterwards [if they have had exposure and have not had chickenpox before, they will need to seek advice from their GP as soon as possible]. • Healthcare professional will inform GP of treatment • Advise patient of any follow up requirements in line with trust/provider policy • Advise on action to be taken if target lesion is unresponsive as per trust/provider policy
<p>Records</p> <p>Records continued</p>	<p>Record:</p> <ul style="list-style-type: none"> • That valid informed consent was given • Name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • Name of registered health professional • Name and brand of medication administered • Date of supply/administration • Dose, form and route of administration • Site at which injection given • Quantity administered • Batch number and expiry date (if applicable) • Advice given, including advice given if excluded or declines treatment • Referral arrangements (including self-care) • Details of any adverse drug reactions and actions taken • Supplied via Patient Group Direction (PGD)

	<p>Records should be signed and dated (or a password controlled e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>
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4. Key references

Key references	<ul style="list-style-type: none"> • <i>Electronic Medicines Compendium</i> http://www.medicines.org.uk/ • <i>Electronic BNF</i> https://bnf.nice.org.uk/ • <i>NICE Medicines practice guideline "Patient Group Directions"</i> https://www.nice.org.uk/guidance/mpg2 • Chartered Society of Physiotherapy. Medicines, prescribing and physiotherapy. Medicines, prescribing and injection therapy The Chartered Society of Physiotherapy (csp.org.uk) • Chartered Society of Physiotherapy. October 2016. The use of medicines with injection-therapy in physiotherapy services. 5th Edition http://www.csp.org.uk/ • <i>Injection Techniques in Musculoskeletal Medicine</i> 5th Edition 2019 Saunders, Stephanie and Longworth, Steve • Chartered Society of Physiotherapy. November 2018. Practice Guidance for Physiotherapist Supplementary and/or Independent Prescribers. 4th Edition http://www.csp.org.uk/Green Book chapter 6: Contraindications and special considerations Greenbook chapter 6.pdf (publishing.service.gov.uk)
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5. Registered health professional authorisation sheet
PGD Name/Version: Triamcinolone 10mg/ml and 40mg/ml injection Version 2.2

Valid from: 7th Apr 24

Expiry: 30th Mar 27

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

Registered health professional

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

Name	Designation	Signature	Date

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation for the above named health care professionals who have signed the PGD to work under it.

Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.