



Patient Group Direction PGD212
FOR THE ADMINISTRATION OR SUPPLY OF DICLOFENAC SODIUM

Staff Grade:	Qualified and Year Two Trainee: Advanced Paramedic Practitioners Advanced Nurse Practitioners (Urgent and Primary Care)
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Document Author(s) / Owner	
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Division / Organisation Wide	Advanced Practice (Urgent & Primary Care) only

Health Care Professionals must be HCPC or NMC registered and authorised by name under this PGD before attempting to treat any patient according to it and have signed the relevant declaration.

Before using this PGD, healthcare professionals must ensure they are working within their scope of practice and be competent in the treatment of patients identified as suitable for inclusion under this PGD.

“Your scope of practice is the limit of your knowledge, skills and experience and is made up of the activities you carry out within your professional role. As a health and care professional, you must keep within your scope of practice at all times to ensure you are practising safely, lawfully and effectively. This is likely to change over time as your knowledge, skills and experience develop.” (HCPC 2024)

Staff should not deviate from their training, guidelines and scope of practice without taking professional clinical advice. All staff are expected to maintain their fitness to practice and undertake appropriate professional development to allow them to be fit for the role in which they are practising.

1. Document Control Sheet

1.1 Key Information

Title:	Patient Group Direction PGD212
	Diclofenac Sodium
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1.2 Revision History

Version	Date	Summary of Changes	Name	Changes Marked
0.1	07/10/2024	Initial draft	Craig Brackenridge	N/A
1.0	26/03/2025	Updated to approved version no., guidance comments removed	Craig Brackenridge	Yes
1.0	01/05/2025	First issue – supersedes entry in PGD003	Craig Brackenridge	Yes

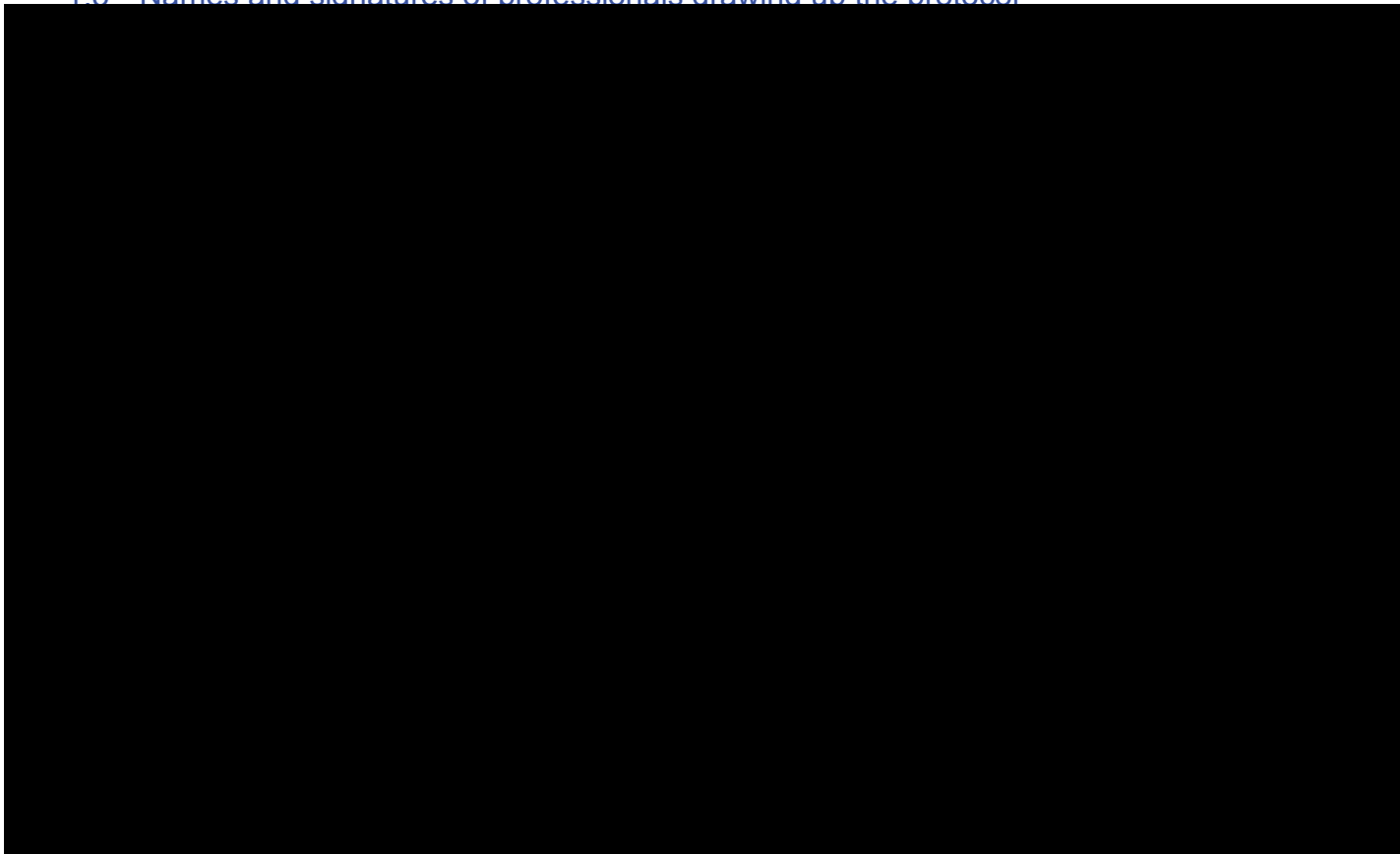
1.3 Approvals: This document requires the following approvals:

Name	Date	Version
National Advanced Practice Clinical Lead	30/01/2025	1.0
Medicines Management Group	30/01/2025	1.0
Pharmaceutical Advisor	03/03/2025	1.0
Medical Director	27/02/2025	1.0

1.4 Distribution: This document has been distributed to:

Name	Date	Version
Medicines Management Group	28/03/2025	1.0
Advanced Practice Leadership Team	28/03/2025	1.0
All Advanced Practitioners (UPC) & trainees	28/03/2025	1.0

1.5 Names and signatures of professionals drawing up the protocol



1.6 Professional / Advisory groups which have approved the protocol

Scottish Ambulance Service Medicines Management Group	Date	30/01/2025
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2. Using this PGD for Administration and/or Supply of Medicines

3. Characteristics of Staff

Qualifications required	Qualified and Year Two Trainee: Advanced Paramedic Practitioners Advanced Nurse Practitioners (in Urgent and Primary Care)
Specific or additional experience / training required	<p>Undertaken an SCQF Level 11 module in Advanced Clinical Assessment (or equivalent) which included a period of supervised practice and signed off as competent. Passed all relevant written and practical assessments and ratified by a university exam board.</p> <p>Familiarisation with the signs and symptoms of conditions listed in “Criteria for Inclusion” in this PGD and possible differential diagnoses.</p> <p>Familiarisation with the use of Diclofenac Sodium, its indications, contra-indications and other details.</p>
Continuing training requirements	<p>The clinician should be aware of any changes to the evidence base for treatment conditions listed in “Criteria for Inclusion” in this PGD.</p> <p>The individual clinician is responsible for their own CPD and for keeping up to date with the use of medicine(s) in this PGD.</p>
Other	You must be authorised by name under the current version of this PGD before you attempt to work to it

4. Clinical Situations / Conditions to Which the Patient Group Direction Applies

Definition of condition / situation to be treated	<p>Acute ureteric colic.</p> <p>Pain and inflammation in rheumatic disease or other musculoskeletal disorders.</p> <p>Acute exacerbation of pain.</p>
Criteria for inclusion	<p>Adults 16 years and over with any of the above conditions / symptoms (tablets).</p> <p>Adults 18 years and over with any of the above conditions / symptoms (injection).</p> <p>Appropriate safety-netting can be made.</p> <p>Can be used in combination with other suitable analgesics as part of a balanced analgesic regimen.</p>
Criteria for exclusion	<ul style="list-style-type: none"> • Children under 16 years of age (tablets) • Children and adults under 18 years of age (injection) • Informed non-consent • Known allergy to Diclofenac or any excipients or ingredients in the preparation, or to any other NSAID • Active, or history of, gastrointestinal ulcers or bleeding • Patients with asthma who are <u>not known</u> to tolerate NSAIDs • Current or history of cerebrovascular disease or bleeding • Pregnancy • Known severe renal (eGFR <30 / CKD 4 or 5) or hepatic impairment or excessive alcohol use • Heart failure • Peripheral arterial disease • Uncontrolled hypertension (persistently >140/90) • Coagulation disorder(s) • Current regular use of Diclofenac or any other NSAID • Use of any NSAID or Diclofenac-containing products (including topical) within the last four hours, or the cumulative daily dose (150mg) already taken – note that this excludes administration to the patient, they may be supplied with Diclofenac Sodium tablets for later use • Patients taking: <ul style="list-style-type: none"> ○ Anti-platelet, anti-coagulant, fibrinolytic or thrombolytics drugs e.g. Aspirin, Clopidogrel, Ticagrelor, Warfarin, Apixaban, Alteplase, etc. ○ Oral anti-diabetic medicines ○ Corticosteroids (including oral, inhaled or topical) ○ Diuretics (e.g. Furosemide, Bendroflumethiazide, Spironolactone, etc.) ○ Quinolones (*floxacin), if the patient has epilepsy or is predisposed to seizure activity ○ SSRIs (e.g. Citalopram, Fluoxetine, Sertraline, etc.)

	<ul style="list-style-type: none"> ○ Any specialist cancer drugs ○ Alprostadil ○ Ciclesonide ○ Ciclosporin ○ Lithium ○ Methotrexate ○ Venlafaxine ○ Tacrolimus ○ Zidovudine <ul style="list-style-type: none"> ● Significantly unwell or injured patients requiring further assessment (blood tests, x-ray, etc.) or admission, although a stat dose may be given prior to hospital referral if appropriate
Action if patient is excluded or declines treatment	Document in ePR / patient record. Discuss alternatives with patient / carer as appropriate and advise on risks of declining treatment. Consider referral to primary care or a community pharmacy. If necessary, consider referral or transfer to a suitable receiving unit.

5. Description of Treatment (including dosage and administration)

Name, form(s) and strength(s) of medicine	Diclofenac Sodium 50mg gastro-resistant oral tablets Diclofenac Sodium 75mg in 3ml ampoule for injection
Legal status	POM
Is the use outwith the SmPC?	No
Storage requirements	Room temperature. Ampoules must be stored out of direct sunlight.
Route(s) / method(s) of administration	Tablets by oral administration only – may be taken with or without a drink. Injection by deep gluteal intramuscular injection only.
Dose and frequency of administration	For oral tablets: 50mg (one tablet) every 8 hours as required up to a maximum of 150mg (three tablets) in 24 hours For intramuscular injection: Single 75mg (one 3ml ampoule) bolus
Maximum dose and number of treatments	As above. Maximum supply of tablets is for 3 days (nine tablets). Clinicians should be aware that this may not be the pack size in use and supply the appropriate number of tablets. Injection ampoules must not be supplied to patients under this PGD. If an injection is administered tablets may also be supplied if appropriate.

6. Cautions and Identification & Management of Adverse Reactions

Cautions	<p>Should be used with caution in:</p> <ul style="list-style-type: none">• Breastfeeding (only use if essential)• Cardiac impairment• Connective tissue disorders• Dehydration• Elderly patients• GI disorders other than bleeding (e.g. Crohn's)• Hypertension• Oedema <p>Patients with a moderate risk of adverse GI events should also be supplied with Omeprazole, if suitable. Refer to PGD227 for guidance.</p>
Drug interactions	<p>No significant interactions for short courses other than drugs listed in the exclusion criteria</p>
Identification and management of adverse reactions	<p>Anaphylactic reactions to Diclofenac (by either route) are extremely rare and should be managed as per standard protocol / JRCALC guidance.</p> <p>Common or very common side-effects include: Decreased appetite, Diarrhoea, Dizziness, GI discomfort, GI disorders, Headache, Nausea, Oedema, Rash, Skin reactions, Vertigo, Vomiting</p> <p>Rare or very rare: Abnormal sensation, Acute kidney injury, Agranulocytosis, Alopecia, Altered taste, Anaemia, Angioedema, Anxiety, Aplastic anaemia, Asthma, Chest pain, Constipation, Depression, Drowsiness, Dyspnoea, Haemolytic anaemia, Haemorrhage, Hearing impairment, Heart failure, Hepatic disorders, Hypersensitivity, Hypertension, Hypotension, Irritability, Leucopenia, Memory loss, Meningitis aseptic, Myocardial infarction, Nephritis tubulointerstitial, Nephrotic syndrome, Oral disorders, Palpitations, Pancreatitis, Photosensitivity, Proteinuria, Psychotic disorder, Renal papillary necrosis, Seizure, Severe cutaneous adverse reactions, Shock, Sleep disorders, Stroke, Thrombocytopaenia, Tinnitus, Tremor, Vasculitis, Vision disorders</p> <p>A detailed list of adverse reactions can be found in the product's SmPC and PIL, see references below.</p> <p>Any adverse reactions, and action taken, are recorded in the patient's notes and other appropriate documentation e.g.: clinical incident form, Yellow Card scheme, etc.</p>

7. Patient Advice and Documentation

Patient advice (verbal and written)	<ul style="list-style-type: none"> • Explain treatment plan and gain consent • Clinician should inform the patient / carer of the realistic timeframe for improvement of symptoms being treated • Must see medical practitioner if symptoms worsen or do not resolve within the expected timeframe • Tablets should be taken with or just after food • Advise patient not to take Omega-3 supplements while taking Diclofenac • Advise that the patient <u>must not</u> take or use any other NSAID-containing products and that not all items are obvious that they contain an NSAID. These include: <ul style="list-style-type: none"> ○ branded medicines such as Anadin, Arthrotec, Beechams powders, Boots Period Pain Reliever, Calprofen, Combogesic, Disprin, Econac, Naprosyn, Nurofen, Nuromol, Solaraze, Stirlescent, Sudafed, Vimovo, Voltarol (refer them to the specific ingredients) ○ medicinal items such as Ibuprofen or Diclofenac gels or creams (e.g. Ibuleve, Voltarol) ○ Less-commonly known NSAIDs (e.g. celecoxib, etoricoxib, Indometacin, Mefenamic acid, etc.) • Advised to be especially cautious regarding any medicines purchased overseas which may include Diclofenac • Advised to avoid excessive alcohol while taking Diclofenac • Advise to contact GP / nurse / pharmacist / out-of-hours service if side effects occur • Advised to call 999 if any life-threatening side-effects occur • It is not necessary to leave a copy of the manufacturer's Patient Information Leaflet if only administering a single dose, but the patient / carer may be signposted to an electronic copy on EMC if requested • Patients should be given a copy of the manufacturer's Patient Information Leaflet where available or signposted to an electronic copy if not • Patients should be advised to maintain adequate hydration
Arrangements for referral to medical advice	Local arrangements apply
Additional facilities / supplies required	<p>For oral tablets: Drinking water (if required)</p> <p>For IM injection:</p> <ul style="list-style-type: none"> • 70% alcohol pre-injection swab • 5ml syringe • Blunt-fill filter needle • Hypodermic injection needle – recommended size 23G x 3016mm (blue) • Sharps disposal box

	<p>Diclofenac Sodium is available in multiple other forms not covered by this PGD:</p> <ul style="list-style-type: none"> • 25mg oral tablets • 75mg or 100mg modified-release oral tablets or capsules • 75mg in 1ml ampoule for injection • 1%, 1.16%, 2.32% and 3% cutaneous gels • 12.5mg, 25mg, 50mg and 100mg suppositories • 140mg medicated plaster <p>If any of the above are required, refer to the patient's GP or a SAS prescriber – note that some Diclofenac gels and medicated plasters may be purchased from a pharmacy.</p> <p>Clinicians must be cautious not to confuse Diclofenac Sodium with Diclofenac Potassium which is not covered by this PGD.</p> <p>Note that not all SAS APs will carry Diclofenac Sodium 50mg tablets if Naproxen 250mg is the preferred strong NSAID in their area.</p>
Monitoring	No specific monitoring required
Follow up	No specific follow-up required
Details of treatment records required	<p>The ePR, or other patient record, must contain the following:</p> <ul style="list-style-type: none"> • Name of the HCP using this PGD • Patient's name, address and date of birth. CHI number is also preferred • Name of medication and expiry date • Date and time of administration / supply • Dose (and volume if liquid preparation), form and route (and site if parenteral) of administration • If supplying medicine: <ul style="list-style-type: none"> ○ Dose and frequency to take ○ Number of items supplied • That it is administered and/or supplied under this PGD and not prescribed or via an exemption <p>The ePR, or other patient record, must also contain:</p> <ul style="list-style-type: none"> • The patient's medical and medication history • Medication and safety-netting / worsening advice given to the patient / carer <p>All records must be clear, legible and contemporaneous.</p>

8. References and Further Reading

NICE Medicines Practice Guideline MPG2: Patient group directions

[Overview](#) | [Patient group directions](#) | [Guidance](#) | [NICE](#)

Diclofenac Sodium in BNF

[Diclofenac Sodium](#) | [Drugs](#) | [BNF](#) | [NICE](#)

Diclofenac Sodium on EMC

[Diclofenac Sodium 50mg Tablets SmPC](#) ([medicines.org.uk](https://www.medicines.org.uk))

[Diclofenac Sodium 50mg Tablets Patient Information Leaflet](#) ([medicines.org.uk](https://www.medicines.org.uk))

[Diclofenac Sodium 75mg in 3ml Ampoule for Injection SmPC](#) ([medicines.org.uk](https://www.medicines.org.uk))

[Diclofenac Sodium 75mg in 3ml Ampoule Patient Information Leaflet](#) ([medicines.org.uk](https://www.medicines.org.uk))

BNF Treatment Summaries

[Analgesics](#) | [Treatment summaries](#) | [BNF](#) | [NICE](#)

[Analgesics](#) | [Nurse Prescribers' Formulary](#) | [BNF](#) | [NICE](#)

[Gallstones](#) | [Treatment summaries](#) | [BNF](#) | [NICE](#)

[Non-steroidal anti-inflammatory drugs](#) | [Treatment summaries](#) | [BNF](#) | [NICE](#)

[Pain, chronic](#) | [Treatment summaries](#) | [BNF](#) | [NICE](#)

[Renal and ureteric stones](#) | [Treatment summaries](#) | [BNF](#) | [NICE](#)

NICE Clinical Knowledge Summary/Summaries (CKS)

[Analgesia - mild-to-moderate pain](#) | [Health topics A to Z](#) | [CKS](#) | [NICE](#)

[Back pain - low \(without radiculopathy\)](#) | [Health topics A to Z](#) | [CKS](#) | [NICE](#)

[Gallstones](#) | [Health topics A to Z](#) | [CKS](#) | [NICE](#)

[Renal or ureteric colic - acute](#) | [Health topics A to Z](#) | [CKS](#) | [NICE](#)

[Shoulder pain](#) | [Health topics A to Z](#) | [CKS](#) | [NICE](#)

[Sprains and strains](#) | [Health topics A to Z](#) | [CKS](#) | [NICE](#)

NICE Clinical Guidelines

[CG173 Neuropathic pain in adults: Pharmacological management in non-specialist settings](#) | [Guidance](#) | [NICE](#)

[NG59 Low back pain and sciatica in over 16s: Assessment and management](#) | [Guidance](#) | [NICE](#)

[NG118 Renal and ureteric stones: Assessment and management](#) | [Guidance](#) | [NICE](#)

[NG193 Chronic pain \(primary and secondary\) in over 16s: Assessment of all chronic pain and management of chronic primary pain](#) | [Guidance](#) | [NICE](#)

Other Useful Links

[NSAIDs](#) | [NHS inform](#)

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