NHS
Cornwall and Isles of Scilly

Patient group direction for the supply of sumatriptan 50mg tablets by community pharmacists for the management of acute migraine attacks with or without aura in patients

Documentation details

Reference no: PGD04
Version no: 2.1
Valid from: 1 April 2025
Review date: 1 December 2026
Expiry date: 31 March 2027

Change history

Version number	Date	Details
1	11 Jan 2022	New PGD
2	February 2023	Transfer to ICB stationery Renumber to PGD04 Review of PGD
2.1	Jan 2025	Reviewed (unchanged). Links updated as needed.

Patient group direction development

Date template comes into effect: April 2025
Version no: 2.1
Valid from: 1 April 2025
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Patient group direction working group

January 2025 review (version 2.1)		
Name and role	**Job title**	**Organisation**
Chris Burgin Pharmacist and lead reviewer	Pharmaceutical advisor	NHS Cornwall and Isles of Scilly Integrated Care Board (ICB)
Amanda Fidelis Pharmacist	Senior clinical pharmacist	NHS Cornwall and Isles of Scilly Integrated Care Board (ICB)
Dr Rob White	General practitioner	NHS Cornwall and Isles of Scilly Integrated Care Board (ICB)

This patient group direction (PGD) was developed by a working group involving pharmacists from NHS Cornwall and Isles of Scilly integrated care board (CIOS ICB) and GP clinical leads from CIOS ICB. Version 2.0 approved by medicines optimisation programme board (MOPB), February 2023. Adapted from an existing PGD with permission from NHS Wirral CCG and MLCSU.

Organisational authorisations

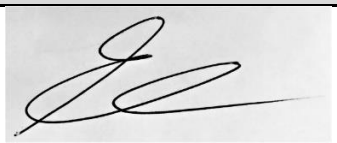
The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

CIOS ICB authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services: Community pharmacies contracted to provide the CIOS ICB community pharmacy PGD service for minor ailments.

Limitations to authorisation: None.

Approved by	Name	Signature	Date of email approval
Chief pharmacist NHS Cornwall and Isles of Scilly Integrated Care Board	Marco Motta		12 February 2025

Approved by	Name	Signature	Date of email approval
Chief medical officer NHS Cornwall and Isles of Scilly Integrated Care Board	Dr Chris Reid		6 March 2025
Chief nursing officer & chief operating officer NHS Cornwall and Isles of Scilly Integrated Care Board	Susan Bracefield		20 March 2025

Local enquiries regarding the use of this PGD may be directed to ciosicb.prescribing@nhs.net

Individual registered health professionals must be authorised by name to work to this PGD. This should be recorded on the authorisation sheet at the end of this document.

Characteristics of staff

Qualifications and professional registration

Registered professional with one of the following bodies:

- Pharmacists registered with the General Pharmaceutical Council (GPhC)

Initial training

- Must be authorised by name as an approved practitioner under the current terms of this PGD before working to it.
- Has undertaken appropriate training and been assessed and declared competent to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this PGD.
- Must be competent in the use of PGDs (see NICE competency framework for health professionals using PGDs).
- Must have access to the PGD and associated online resources.

Competency assessment

All pharmacists operating under this PGD are required to complete a declaration of competence for minor ailments via the Centre Pharmacy Postgraduate Education (CPPE) website and complete the declaration of competence on PharmOutcomes.

Staff operating under this PGD are encouraged to attend specific commissioning organised training events on minor ailments and complete the CPPE common clinical conditions e-learning.

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.

Ongoing training and competency

Practitioners must ensure they are up to date with relevant issues and clinical skills relating to the management of migraine, with evidence of appropriate continued professional development (CPD).

Pharmacists will be required to complete an annual declaration of competence via the CPPE website and PharmOutcomes.

The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.

Clinical condition or situation to which this PGD applies

Condition or situation: Treatment of an acute migraine attack with or without aura.

Criteria for inclusion

- Adults who have received a diagnosis of migraine from their GP or pharmacist and who have:
    - Attacks that have not previously responded to OTC analgesia
    - Established pattern of migraine (a history of five or more migraine attacks occurring over a period of at least one year)
- Patient has no more than two of the following cardiovascular risk factors:
    - Women who have reached the menopause
    - Men aged over 40 years
    - Family history of early heart disease – either a father or brother had a heart attack or angina before the age of 55 years, or mother or sister had a heart attack or angina before the age of 65 years
    - Diabetes
    - Known high cholesterol
    - Regularly smoke more than 10 cigarettes per day or use equivalent NRT
    - Obese (BMI>30kg/m2)

See the NICE CKS for migraine for information on symptoms and diagnosis

Criteria for exclusion

- Patients under 18 or over 65 years of age
- First migraine occurs after the age of 50
- Pregnancy or breastfeeding
- Patients with three or more of the above cardiovascular risk factors
- Current prophylactic treatment
- Attacks that last less than 4 hours without treatment
- Attacks occurring on 4 or more days a month
- Patients with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine as it contains lactose.
- Patients whose pattern of symptoms has changed, whose recovery between attacks is incomplete or whose attacks have become more frequent, persistent or severe
- Patients experiencing atypical symptoms which include, but are not limited to:
    - Unilateral motor weakness
    - Double vision
    - Clumsy and uncoordinated movements

    - Tinnitus
    - Reduced level of consciousness
    - Seizure-like movements
    - Recent onset of rash with headache
- Patient is taking interacting medicines. Check appendix 1 of current print edition of British National Formulary (BNF) for full list, or online
- Patient has been diagnosed with:
    - Hemiplegic migraine
    - Basilar migraine
    - Opthalmoplegic migraine
- Patient has been previously prescribed sumatriptan by their GP and supply can be made under the emergency supply service.

Urgent referral to a doctor may be required if any of these are reported

- Known hypersensitivity to sumatriptan or any other excipient in the product
- Known hypersensitivity to sulphonamides
- Taking or planning to take any medicines or other treatments for migraine for example other triptan, ergotamine or ergotamine derivative
- Previous myocardial infarction
- Ischaemic heart disease, angina, cardiac arrhythmias, peripheral vascular disease
- Previous stroke or transient ischaemic attack (TIA)
- Known or uncontrolled hypertension
- Known hepatic or renal impairment
- History of seizures
- Patients taking any of the following medication:
    - Ergotamine or derivatives of ergotamine (including methysergide)
    - Monoamine Oxidase Inhibitors (MAOIs), including discontinuation in the last 2 weeks
    - Any other 5HT1 agonists
    - Selective serotonin receptor inhibitors (SSRIs)
- Rare variants of migraine: hemiplegic migraine, basilar migraine, opthalmoplegic migraine
- Women taking a combined oral contraceptive pill experiencing first migraine, worsening of migraine attacks or migraine with aura
- Previous ineffective treatment with sumatriptan

Cautions including any relevant action to be taken

Discuss with appropriate medical or independent non-medical prescriber any medical condition or medication of which the pharmacist is unsure or uncertain.

Action to be taken if the patient is excluded

- Explain the reasons for exclusion to the individual
- Record reasons for exclusion and any action(s) taken
- Advise patient on alternative treatment
- Refer to a prescriber if appropriate (for example GP or NHS 111 or out of hours (OOH) services)
- Give safety-netting advice

Action to be taken if the patient declines treatment

- Ensure the individual is aware of the need for treatment and the potential consequences of not receiving treatment
- Document the reasons for declining, advice given and the decision reached.

- Advise patient on alternative treatment if appropriate
- Refer to a prescriber if appropriate
- Give safety-netting advice

Arrangements for referral for medical advice

Advise people with acute migraine to seek medical help if symptoms worsen rapidly significantly at any time, or symptoms have not improved after completing a course of treatment, or the attack continues for more than 24 hours.

Description of treatment

Name, strength and formulation of drug

Sumatriptan 50mg tablets

Legal category

Prescription only medicine (POM)

Route and method of administration

Oral

Indicate any off-label use (if relevant)

Not applicable

Dose and frequency of administration

- One 50mg tablet taken as soon as possible after the onset of a migraine headache, although it is effective at whatever stage of the headache it is taken
- If there is a response to the first dose, but symptoms recur, a second 50mg tablet may be taken. This must be at least 2 hours after the first tablet
- No more than 300mg should be taken in any 24 hour period or to treat the same attack
- If there is no response to the first tablet, a second tablet **should not** be taken for the same attack

Duration of treatment

As per dose and frequency of administration above

Quantity to be supplied

6 tablets per treatment episode
2 treatment courses under this PGD in any 12 month period

Storage

Stock must be stored in conditions in line with the summary of product characteristics (SPC)

Drug interactions

- Sumatriptan has a number of drug-drug interactions which may be clinically significant, and all concurrent medications should be reviewed for interactions.
- Where a significant interaction is identified which may require dosage amendment or additional monitoring refer to appropriate medical or independent non-medical prescriber
- A detailed list of all drug interactions is available in the BNF online or the product SmPC, which is available from the electronic medicines compendium (EMC) website www.medicines.org.uk

Increased risk of adverse reactions

A detailed list of adverse reactions is available in the SPC, which is available from the EMC website www.medicines.org.uk and BNF www.bnf.org

Identification and management of adverse reactions

- Common
  - Sensation of tightness, pressure, tingling, heaviness, heat or pain in any part of the body, including the chest and throat (discontinue if intense)
  - Flushing, dizziness, feeling of weakness, fatigue
  - Nausea and vomiting (may also be due to the migraine)
  - Drowsiness
  - Transient increase in blood pressure
  - Dyspnoea
  - Myalgia
- Rare
  - Visual disturbances, flickering, reduced vision, double vision or loss of vision (may also be due to the migraine)
  - Tremor, seizures, stiff neck, tachycardia or bradycardia, palpitations, irregular heartbeat
- This list is not exhaustive; refer to BNF or SmPC for full details.

Management of and reporting procedure for adverse reactions

- Healthcare professionals and patients or carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme
- Record all adverse drug reactions (ADRs) in the patient's medical record (and inform the patient's GP)
- Report via organisation incident policy

Written information to be given to the patient

The marketing authorisation holder's patient information leaflet provided with the product if treatment is to be supplied and advise patient to read the leaflet
Patient information on migraine can be viewed and printed from the NHS website and The Migraine Trust

Patient advice and follow up treatment

- Advise the patient how to take the product and discuss side effects
- Can cause drowsiness – if affected do not drive or operate machinery
- If there is no response to the first dose a second dose **should not** be taken; the attack may be treated with simple analgesics. See GP for reconsideration of migraine diagnosis
- If the attack persists longer than 24 hours seek medical advice
- Four or more attacks in any one month **must** be reported to the GP
- Discuss the possibility of medication overuse headache
- Consider using a headache diary
- Give practical advice on avoidance of triggers where possible for example stress, cheese, caffeine, chocolate, alcohol, strong smells, bright light
- Contact GP if no improvement after 24 hours, or sooner if symptoms worsen

Records

- Completion of PGD checklist on PharmOutcomes

- Completion of patient medication record
- Label the pack being supplied appropriately:
    - dose, form and route of supply or administration
    - quantity supplied or administered
    - supplied via PGD
- Record details of any adverse drug reactions and actions taken.
- Referral arrangements (including self-care)
- Batch number and expiry date (if applicable)
- Completion of consent form and completion of the audit claim on PharmOutcomes
- Records should be signed and dated (or a password controlled e-records).
- All records should be clear, legible and contemporaneous
- A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy

Audit trail

- PMR entry
- Patient's GP should be notified using the notification form on PharmOutcomes within 48 hours of supply for inclusion in the patients notes

Key references

- NICE CKS – migraine in adults
- NHS UK - migraine
- The Migraine Trust
- BNF – sumatriptan monograph
- Electronic Medicines Compendium (EMC)
- NICE PGD medicines practice guideline [MPG2]
- NHS Wirral Clinical Commissioning Group website

Registered health professional authorisation sheet

PGD: Supply of sumatriptan 50mg tablets by community pharmacists for the management of acute migraine attacks with or without aura.

Valid from: 1 April 2025
Expiry: 31 March 2027

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

Authorisation

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 PGD and that I am willing and competent to work to it within my professional code of conduct.

Name	Designation	Signature	Date
Click or tap here to enter text.			
Click here to enter text.			
Click here to enter text.			
Click here to enter text.			

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