Hertfordshire and West Essex Integrated Care System

NHS Hertfordshire and West Essex Integrated Care Board

Rimegepant (Vydura®) for preventing episodic migraine

PRESCRIBING CRITERIA:

In line with TA906, rimegepant is recommended as an option for preventing episodic migraine in adults who have at least 4 and fewer than 15 migraine attacks per month, **only** if at least 3 preventive treatments have not worked.

Prescribing of rimegepant for preventing migraine is to be initiated by a neurology specialist.

Rimegepant must only be initiated after unsuccessful trials of at least 3 standard preventatives at sufficient dose and duration.

Rimegepant should be stopped after 12 weeks if the frequency of migraine attacks does not reduce by at least 50%.

Prescribing will be maintained by the specialists until the patient is reviewed at 3 months and it is confirmed that the patient is responding and meets the continuation criteria outlined above.

Neurology specialist

Patient reviewed in specialist clinic.
History confirmed and patient meets the prescribing criteria.
Drug history confirmed to ensure they are not on any interacting drugs.

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Rimegepant initiated within secondary care by specialist team & Blueteq form completed.

Rimegepant is supplied in packets of 8, repeat prescriptions should not exceed 2 packets (16 tablets) per month.

If rimegepant is being taken for treatment of acute migraine advise patient & GP on any changes to recommendations for acute treatment.

Provide counselling to the patient to improve adherence and manage any adverse effects, emphasise the importance of keeping a headache diary.

Advise patient to read the patient information leaflet inside the medicine pack

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Review at 3 months to confirm efficacy and tolerability.

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Primary Care

TRANSFER OF CARE:

- Specialist provides GP with the baseline investigations and monitoring results (i.e. pre- and post-treatment migraine frequency & confirmation of at least a 50% reduction), rationale of treatment choice, dose to be prescribed and any other information deemed necessary to ensure safe transfer of prescribing responsibility.
- GP takes over prescribing responsibility and review of ongoing treatment. Patients should be reviewed within 9 to 12 months of starting treatment and then annually.

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Problems in Primary Care:

- Seek advice and discuss management plan with the specialist team if concerns arise around adherence, tolerability issues and/or new contra-indications, drug interactions, loss of response, adverse drug events, or if the patient's clinical condition has changed.

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Rimegepant (Vydura®) for preventing episodic migraine

Prescribing Support Document

The aim of this prescribing support document is to ensure sufficient information is provided to enable GPs to be confident to take on the clinical and legal responsibility for prescribing rimegepant in stable patients.

This information does not replace the Summary of Product Characteristics (SmPC) and should be read in conjunction with it. Please see BNF & SmPC for comprehensive information.

BACKGROUND AND INDICATION(S) FOR USE

Rimegepant is a calcitonin gene-related peptide (CGRP) receptor antagonist which inhibits the function of CGRP, thereby preventing migraine attacks.

Migraine can be classed as chronic (defined as 15 or more headache days per month, with at least 8 of those having features of migraine, over at least a 3 month period) or episodic (defined as more than 4 migraine days per month but less than 15 headache days [including migraine] per month).

Rimegepant is licensed for preventative treatment of episodic migraine in adults who have at least 4 migraine attacks per month[1].

Rimegepant is also licensed for the acute treatment of migraine with or without aura in adults (see Treatment of migraine in adults guidelines[2] & NICE TA919[3] for more information).

SUPPORTING INFORMATION

Criteria for patient selection in line with NICE and local recommendations

NICE TA 906[4] states that rimegepant is recommended as an option for preventing episodic migraine in adults who have at least 4 and fewer than 15 migraine attacks per month, only if at least 3 preventative treatments have not worked.

Rimegepant should be stopped after 12 weeks if the frequency of migraines does not reduce by at least 50%.

Rimegepant must only be initiated after unsuccessful trials of at least 3 standard preventatives at sufficient dose and duration, unless there have been issues with intolerance (refer to Treatment of migraine in adults guideline[2] for details).

RESPONSIBILITIES

Specialist Responsibilities	
1	Confirm patient adherence with trials of at least 3 standard oral preventative therapy prior to considering rimegepant.
2	Assess the clinical need and suitability of the patient for rimegepant and ensure recommendation is in line with local recommendations and criteria recommended in NICE TA906.
3	Complete baseline investigations.
4	Review drug history (including OTC and herbal items) to check for any interactions which may preclude rimegepant use.
5	Initiate and prescribe rimegepant for the initial 3 month trial period.
6	Prescribe rimegepant using the generic name so any concomitant prescribing of additional gepant therapy is more easily identified.
7	Inform the GP at initiation of 3-month trial of therapy, prescribing retained by specialist. The correspondence should include clinical details such as the monthly headache/migraine days at baseline. If patient is currently receiving rimegepant for treatment of acute migraine advise the patient and GP on any changes to recommendations for acute treatment.
8	Ensure the patient/carer has agreed to treatment and has been counselled at initiation. Advise the patient to read the patient information leaflet inside the pack when they receive the medication. To contact the specialist if any issues/concerns following initiation.
9	Review the patient after 3 months of treatment to assess efficacy and tolerability of rimegepant. If adequate response has been achieved (i.e. at least a 50% reduction in migraine frequency) and the treatment is to continue, provide the GP with the baseline investigations and efficacy results, rationale of treatment choice, dose to be prescribed and any other information deemed necessary to ensure safe transfer of prescribing responsibility for the patient to the GP. Ensure the patient has sufficient supply of medication to allow the transfer of care to take place.
10	Be available to the GP for advice if the patient's clinical condition changes, (e.g. sustained loss of response/worsening of symptoms, patient develops a new contra-indication to rimegepant), if there are concerns around adherence, tolerability or adverse drug events.

General Practitioner Responsibilities	
1	Prescribe rimegepant at the dose specified by the neurology service, using the generic name so any concomitant prescribing of additional gepant therapy is more readily identified.
2	If the patient is currently prescribed rimegepant for acute treatment of migraine the specialist will advise on whether any changes to therapy are needed.
3	Review ongoing treatment as specified below, seeking support from the specialist team where appropriate.
4	Seek advice and discuss management plan with the specialist team if concerns arise about adherence, tolerability issues and/or contra-indications, efficacy monitoring results, adverse drug events or if the patient's clinical condition has changed.
5	Monitor adherence with therapy and raise concerns with the specialist team as required
6	Review the patient after 9 to 12 months of starting treatment to include assessment of ongoing response (use headache diaries), tolerance/adverse events, new cautions/contraindications, adherence, drug interactions and need for continued therapy.
7	For patients remaining on treatment continue to review annually to include assessment of ongoing response (use headache diaries), tolerance/adverse events, new cautions/contraindications, adherence, drug interactions and need for continued therapy.

CONTRAINDICATIONS[1]

- Hypersensitivity to the active substance or to any of the excipients
- Pregnancy and/or breastfeeding (local specialists have advised that treatment should be stopped for at least 4 weeks before trying to conceive)
- End-stage renal disease (Cl_{cr} <15ml/min)
- Severe hepatic impairment (Child-Pugh C)
- Children (under 18 years of age)
- Concomitant use with strong inhibitors of CYP3A4
- Concomitant use with strong or moderate inducers of CYP3A4
- Medication overuse headache

CAUTIONS[1]

- Severe renal impairment
- Drug interactions (see notable drug interactions section below)
- CGRP is a potent vasodilator and blocking its vasodilatory action may have other effects within the body. Whilst there are no specific cautions or contraindications listed in the SmPC, patients with clinically significant cardiovascular or cerebrovascular disease were excluded from trials (e.g. Myocardial Infarction (MI), Acute Coronary Syndrome (ACS), Percutaneous Coronary Intervention (PCI), cardiac surgery, stroke or Transient Ischemic Attack (TIA) during the 6 months prior to enrolment in the trial). The potential risk of use in these cohorts is therefore uncertain and specialist advice should be sought if needed.
    - If the patient develops a new vascular condition whilst on treatment the risk/benefit should be reassessed, and specialist advice sought if needed.

DOSAGE

- The recommended dose of rimegepant is one 75mg tablet every other day with or without food.
- Rimegepant is available as an oral tablet that melts in the mouth and should be placed on or under the tongue and allowed to dissolve. It will disintegrate in the mouth and can be taken without liquid.
- Patients should be advised to use dry hands when opening the blister and referred to the package leaflet for complete instructions.
- Rimegepant is supplied in packets of 8, repeat prescriptions should not exceed 2 packets (16 tablets) per month.

Dosage modification in renal impairment

Rimegepant should be avoided in patients with end-stage renal disease (CLcr < 15 ml/min).
No dose adjustment is required in patients with mild, moderate, or severe renal impairment.
Caution should be exercised during frequent use in patients with severe renal impairment.

Dosage modification in hepatic impairment

Rimegepant should be avoided in patients with severe hepatic impairment. No dose adjustment is required in patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment.

FOLLOW UP/REVIEW IN PRIMARY CARE

In primary care patients should be reviewed within 9 to 12 months of starting treatment and then annually. Patients should be encouraged to contact their GP if they experience issues between review appointments.

At the appointments:

- Review headache diary and discuss frequency of attacks, effectiveness of treatment, adherence, adverse effects, new cautions/contra-indications, drug interactions and lifestyle improvements. It is important to also evaluate the most bothersome symptom of migraine as this may not be well captured on a pain diary and can sometimes reflect the mismatch between reporting of significant benefit but pain diaries seemingly not reflecting this.
- Reassess lifestyle advice, check correct usage of treatment and reiterate advice on avoidance of MOH (i.e. restriction of use of acute medications to a max of 2 days per week)
- While preventative migraine therapies aim to achieve a clinically meaningful reduction in migraine attacks, the majority of patients will use acute medications to manage breakthrough events.
    - a 50% reduction in severity and frequency of attacks is considered a good response in episodic migraine
- If rimegepant has been effective and the patient is now experiencing fewer than 4 migraine days per month consider a trial withdrawal, (the medication can just be stopped there is no need to taper).
- If rimegepant has been effective but the patient is still having more than 4 migraine days a month, continue rimegepant (with appropriate medication reviews).
- Ask the patient to reconsult if they experience problems in the future (for example increasing severity or frequency of migraine or side effects of medication).

Patient reports worsening of symptoms outside of annual reviews:

- Review headache diaries, treatment history and any lifestyle factors that could be contributing.
- Check correct usage of rimegepant.
- If there has been a sustained loss of response over a 3-month period seek advice from the specialist.

SIDE EFFECTS

The most common adverse reaction for migraine prophylaxis was nausea (1.4%). Most of the reactions were mild or moderate in severity. Hypersensitivity, including dyspnoea and severe rash, occurred in less than 1% of patients treated.
Hypersensitivity reactions, including serious hypersensitivity, can occur days after administration. If a hypersensitivity reaction occurs, rimegepant should be discontinued and appropriate therapy should be initiated.

Rimegepant has no or negligible influence on the ability to drive and use machines.

For a detailed list of side effects, please refer to the summary of product characteristics (SmPC)

Rimegepant is a ▼ drug - report adverse effects directly to the MHRA via the Yellow Card Scheme

NOTABLE DRUG INTERACTIONS (for a comprehensive list, please see BNF or SmPC)

Drug / Drug class		Recommendation
Strong CYP3A4 inhibitors	• Clarithromycin • Itraconazole • Ritonavir	• Rimegepant not recommended
Strong or moderate CYP3A4 inducers	• Phenobarbital • Rifampicin • St John's Wort (Hypericum perforatum) • Bosentan • Efavirenz • Modafinil	• Rimegepant not recommended
Grapefruit/ grapefruit juice		• Regular consumption may increase rimegepant levels and increase the risk of side effects

HEADACHE DIARIES

Patients should be asked to keep a headache diary to record details of their migraine attacks or headache. This can help to confirm the diagnosis and can be used to assess whether acute or preventative medication is working. It can also help the patient to recognise any triggers and warning signs and to show any patterns to attacks.

A headache diary should be simple and record basic information which should include:
Date / day of the week / duration (how long the attack lasted) / severity (how bad the attack was using a severity scale of 0-10 where 0 is no pain and 10 is the worst possible and patient is bed-bound) / other symptoms (e.g., dizziness, vertigo, sensitivity to light, sound, smells) / medication taken / any side effects from medication / any potential triggers.

Example headache diary template: Keeping a headache diary - The Migraine Trust

INFORMATION FOR PATIENTS

- Migraine from Patient Info UK: Migraine leaflet
- Treatment of migraine from Patient Info UK: Migraine treatment-medication and prevention
- NHS Health A-Z: Migraine
- The Migraine Trust: Migraine
- British Association for the Study of Headache Guidelines (BASH): For headache sufferers

VERSION CONTROL

Version	1.0
Prepared by	Pharmacy and Medicines Optimisation Team, Hertfordshire and West Essex (HWE) ICB with relevant HWE ICS stakeholders
Approved by	HWE Area Prescribing committee, November 2024
Review date	The recommendation is based upon the evidence available at the time of publication. This recommendation will be reviewed upon request in the light of new evidence becoming available.

REFERENCES

1. Vydura 75mg oral lyophilisate. Summary of medicinal Product characteristics. Last updated July 2023. https://www.medicines.org.uk/emc/product/13928 Accessed 23/07/24
2. HWE ICS Treatment of migraine in adults in primary care. November 2024.
3. NICE TA 919 Rimegepant for treating migraine. Published date 18th October 2023. https://www.nice.org.uk/guidance/ta919. Accessed 23/07/24
4. NICE TA 906 Rimegepant for preventing migraine. Published date 5th July 2023. https://www.nice.org.uk/guidance/ta906. Accessed 23/07/24