NHS
Cheshire and Merseyside

RIMEGEPANT oral lyophilisate (Vydura® ▼) for treating migraine in adults

The Cheshire and Merseyside Area Prescribing Group recommends the prescribing of RIMEGEPANT oral lyophilisate (Vydura® ▼) for treating migraine in accordance with NICE TA919.

AMBER following specialist recommendation

TEMPORARY STATEMENT PENDING PRESCRIBING SUPPORT INFORMATION*

NICE technology appraisal (TA919)[1] recommends rimegepant as an option for acute treatment of migraine (both episodic and chronic migraine) with or without aura in adults, only if for previous migraines:

- at least 2 triptans were tried and they did not work well enough or
- triptans were contraindicated or not tolerated, and nonsteroidal anti-inflammatory drugs (NSAIDs) and paracetamol were tried but did not work well enough.

Treatment should be started on the advice of a migraine specialist.

Clinicians and people with the condition should consider stopping rimegepant if there is no response after 2 to 3 attacks[1]. However, there is no formal stopping criteria.

For further information on the management of migraine, please refer to the following national and local guidance:

- NICE Clinical Guideline [CG150] Headaches in over 12s: diagnosis and management, last updated 17 December 2021
- British Association for the Study of Headache National Headache Management System for Adults, 2019
- Pan Mersey Area Prescribing Committee Headache pathway (adults), last updated 28 September 2022.
- Cheshire Area Prescribing Group Headache Pathway (Adults), last updated December 2020

Rimegepant is also licensed for the prevention of episodic migraine in adults. However, this his policy statement applies only to the use of rimegepant for acute treatment of migraine and doesn't extend to the prevention of migraine. There is a separate statement for the use of rimegepant for the prevention of episodic migraine in adults.

*The Cheshire and Merseyside APG agreed that this drug for this indication should be Amber Recommended until the appropriate pathway and additional information to support prescribing is available.

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

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Effectiveness

Rimegepant selectively binds with high affinity to the human calcitonin gene-related peptide (CGRP) receptor and antagonises CGRP receptor function[2].

There are 3 double-blind, randomised controlled trials (BHV3000-301, BHV3000-302 and BHV3000-303) that evaluated rimegepant in adults aged 18 years and over, with 2-8 moderate-to-severe migraine attached per month and fewer than 15 monthly migraine days (MDDs)[2]. A single dose of rimegepant (75mg) was taken as a tablet in BHV3000-301 (n=1,084), a tablet in BHV3000-302 (n=1,072) and an oral dispersible tablet in BHV3000-303 (n=1,351)[2]. The 3 trials compared rimegepant with placebo for 11 weeks[2]. The primary outcomes were freedom from pain at 2 hours, and freedom from the person's most bothersome symptoms (MBS) (for example, aura) at 2 hours. A secondary outcome was pain relief at 2 hours. Rescue medication (i.e., NSAIDs, paracetamol, and/or antiemetic) was allowed 2 hours after initial treatment and triptans were not allowed within 48 hours of initial treatment[2]. Approximately 14% of patients were taking preventive medicinal products for migraine at baseline[2]. None of the patients in BHV3000-301 were on concomitant preventive medicinal products that act on the calcitonin gene-related peptide pathway[2].

In BHV3000-301, the percentage of patients achieving headache pain freedom and MBS freedom at 2 hours after a single dose was statistically significantly greater in patients who received rimegepant compared to those who received placebo. In addition, statistically significant effects of rimegepant compared to placebo were demonstrated for the additional efficacy endpoints of pain relief at 2 hours, sustained pain freedom from 2 to 48 hours, use of rescue medication within 24 hours, and ability to function normally at 2 hours after dosing[2]. In BHV3000-303 (similar dosage form to the UK licensed product), results showed that rimegepant provided increased freedom from pain and freedom from patients' MBS within 2 hours of treatment compared with placebo (36% versus 27%)[2].

Safety

The most common adverse reaction was nausea, which occurred in 1.2% of patients[2]. Most of the reactions were mild or moderate in severity. Hypersensitivity, including dyspnoea and severe rash, occurred in less than 1% of patients treated. These reactions can occur days after administration, and delayed serious hypersensitivity has occurred.

Rimegepant is not recommended for concomitant use with strong inhibitors of CYP3A4 and strong or moderate inducers of CYP3A4[2].

Contraindication – hypersensitivity to the active substance or excipients.

For further details on safety, drug interactions, cautions and contraindications, please see SPC.

Cost

Based on NICE assumptions of 3.5 migraine episodes per month (one tablet for each episode)[4], the annual cost of treatment with rimegepant 75mg, as needed, once daily is £542 per patient.[3]

NICE expect the resource impact of implementing the recommendations in England will be less than £5 million per year (or approximately £8,800 per 100,000 population)[4]. Given there is current use of rimegepant and its position in the pathway, it is not anticipated there will be a significant resource impact as a result of this guidance.[4]

Patient factors[2]

There is limited experience with rimegepant in patients aged 65 years or older. No dose adjustment is required as the pharmacokinetics of rimegepant are not affected by age.

No dose adjustment is required in patients with mild, moderate or severe renal impairment. Rimegepant has not been studied in patients with end-stage renal disease and patients on dialysis.

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

As a precautionary measure, rimegepant should be avoided during pregnancy. There are no data on the effects on milk production. The mother's clinical need for rimegepant whilst breastfeeding should be weighed against any potential adverse reactions on the breastfed infant.

Prescribing information

- The recommended dose of rimegepant for the acute treatment of migraine is 75mg as needed, up to a maximum of once daily. The dose of rimegepant for the prevention of episodic migraine is different to acute treatment, please see separate statement.
- Rimegepant is also recommended for **prevention** of migraine and NICE have published a separate technology appraisal.
- Rimegepant is available in pack sizes of 2 and 8 tablets. The cost per tablet is the same for both pack sizes.[3]

Implementation notes

- Rimegepant for the acute treatment of migraine should be started on the advice of a migraine specialist. The specialist should advise on the appropriate follow up required and review period for treatment.
- Patients should be counselled on the appropriate dosing for acute treatment of migraine.
- There are no formal stopping criteria for this indication but consideration to stop should be made if there is no response after 2-3 attacks.

References

1. National Institute for Health and Care Excellence. NICE technology appraisal 919. Rimegepant for treating migraine, 18 October 2023. Accessed 06 November 2023.
2. Pfizer Limited. Summary of Product Characteristics: Vydura 75mg oral lyophilizate, 13 July 2023. Accessed 06 November 2023.
3. NHS Business Services Authority. Dictionary of medicines and devices (dm+d) browser. Accessed 05 December 2023.
4. National Institute for Health and Care Excellence. NICE technology appraisal 919. Resource impact statement: Rimegepant for treating migraine, updated 30 November 2023. Accessed 05 December 2023.