NHS
Cheshire and Merseyside

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

NHS Cheshire and Merseyside recommends the prescribing of RIMEGEPANT oral lyophilisate (Vydura® ▼), following specialist initiation, for preventing migraine in accordance with NICE TA906.

AMBER patient retained by specialist.

NICE technology appraisal (TA) 906[1] recommends rimegepant as an option for preventing episodic migraine in adults only if:

- They have at least 4 and fewer than 15 migraine attacks per month **and**
- At least 3 preventative treatments have not worked.

Treatment should be stopped after 12 weeks if the frequency of migraine attacks does not reduce by at least 50%[1].

NICE advise that rimegepant could be initiated by a specialist then later be prescribed by a GP in primary care.

Prescribing is to be continued by the specialist until stabilisation of dose and treatment efficacy is reviewed at week 12. If adequate response is achieved, the specialist may then request the patient's GP to take over prescribing responsibility.

If people with the condition and their clinicians consider rimegepant to be one of a range of suitable treatments, after discussing the advantages and disadvantages of all the options, the least expensive should be used taking into account administration costs, dosage, price per dose and commercial arrangements.[1]

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 acute treatment of migraine with or without aura in adults[2]. However, **rimegepant is not currently recommended for acute treatment of migraine** as NICE will publish a separate technology appraisal for this indication. This statement only applies to the use of rimegepant for preventing migraine.

See separate statement for the Cheshire and Merseyside APG recommendation for the prescribing of rimegepant for the acute treatment of migraine.

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.

The randomised, double-blind, placebo-controlled study included male and female adults with at least a 1-year history of migraine (with or without aura)[3]. The patients had a history of 4-18 migraine attacks of moderate to severe pain intensity. They experienced an average of 10.9 headache days during the 28-day observational period. Patients were randomised to receive rimegepant 75mg (N = 373) or placebo (N=374) for up to 12 weeks, at a dose of one every other day for the 12-week treatment period[3]. Patients were allowed to use other acute treatments for migraine (e.g., triptans, NSAIDs, paracetamol, antiemetics) as needed. Patients were allowed to continue in an open label extension study for an additional 12 months. The primary efficacy endpoint was the change from baseline in the mean number of monthly migraine days during weeks 9 through 12 of the double-blind treatment phase. The results showed a statistically significant reduction in mean monthly migraine days (MMD) from baseline during weeks 9-12 with rimegepant (-4.3) compared with placebo (-3.5)[3]. Secondary endpoints included the achievement of at least 50% reduction from baseline in monthly moderate or severe migraine days during weeks 9-12. 49.1% of patients in the treatment arm compared with 41.5% of patients in the placebo arm experienced at least 50% reduction from baseline[3].

Safety

The most common adverse reaction was nausea, which occurred in 1.4% of patients[1]. 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.

Contraindication – hypersensitivity to the active substance or excipients.

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

Cost

Annual cost of treatment with rimegepant 75mg every other day is £2,360 per patient.[4]

NICE states that there are likely to be resource benefits for the NHS because no training is required to administer the treatment and injection site reactions would be avoided. As there are no commercial arrangements in place for rimegepant, it can be procured and dispensed in primary care and reimbursed at the NHS List price.

NICE expects that 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). This is because rimegepant is a further treatment option. Uptake of Rimegepant would displace other calcitonin gene-related peptide (CGRP) receptor antagonists, and the overall cost of treatment for this patient group will be similar.

Patient factors

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 preventing migraine is 75mg every other day. Dose escalation to 75mg daily is not recommended for preventing migraine and should not be used.**
- Rimegepant is available in pack sizes of 2 and 8 tablets. The cost per tablet is the same for both pack sizes.[4]

Implementation notes

- Rimegepant requires specialist initiation within secondary or tertiary care.
- Patients will be counselled by the specialist centre and advised to keep headache diaries whilst on rimegepant treatment.
- Prescribing is to be continued by the specialist until stabilisation of dose and treatment efficacy is reviewed at week 12. If adequate response is achieved, the specialist may then request the patient's GP to take over prescribing responsibility.
- All rimegepant patients will be retained and reviewed annually by the specialist and will not be discharged.
- The decision to stop or continue treatment should be clearly communicated to the patient's GP after each annual review.

References

1. NICE. Rimegepant For Preventing Migraine. Technology Appraisal Guidance [TA906]. Published: 05 July 2023. Available at https://www.nice.org.uk/guidance/TA906 . Accessed 11 July 2023.
2. Pfizer Limited. Summary of Product Characteristics: Vydrra 75mg oral lyophilizate. Last updated 02 June 2023. Available at https://www.medicines.org.uk/emc/product/13928. Accessed 11 July 2023.
3. Croop R, Lipton RB et al. Oral Rimegepant for Preventative Treatment of Migraine: A Phase 2/3 Randomised, Double-blind, Placebo-controlled Trial. The Lancet. January 02,2021; 397(10268), 51-60.
4. NHS Business Services Authority. Dictionary of medicines and devices (dm+d) browser. Accessed 18 July 2023.