NICE Technology Appraisals (TA) briefing paper for local implementation

NICE TA Guidance name and number	Rimegepant for treating migraine Technology appraisal guidance		
Available at	https://www.nice.org.uk/guidance/ta919		
Date of issue	18 October 2023	**Implementation deadline**	3 months – 18 January 2024

Medicine details[1]	
Name and brand name	Rimegepant (Vydura)
Manufacturer	Pfizer
Mode of action	Rimegepant selectively binds with high affinity to the human calcitonin gene-related peptide (CGRP) receptor and antagonizes CGRP receptor function.
Licenced indication	• Acute **treatment** of migraine with or without aura in adults. Please note that rimegepant is also licensed for preventive treatment of episodic migraine in adults who have at least 4 migraine attacks per month and available as per NICE TA906 Overview | Rimegepant for preventing migraine | Guidance | NICE
Formulation	Oral lyophilisate.
Dosage	The recommended dose is 75 mg rimegepant, as needed, once daily.
Comparison of NICE TA with Summary of Product Characteristics (SmPC)[2]	In the NICE TA the recommendation is that rimegepant is used as an acute treatment for migraine in adults who had taken at least 2 triptans that had not worked well enough, or when triptans are contraindicated or not tolerated (and the person has already tried NSAIDs and paracetamol, which have not worked well enough). This is narrower than the marketing authorisation. This is the current dose considered by NICE as part of this NICE evaluation. Subsequent changes in the licence following NICE publication will need to be considered by the Area Prescribing Committee and will not be routinely funded by local commissioners, as the incremental cost per QALY would not have been considered.

NICE TA recommendations[2]
Recommendations
1.1 Rimegepant is recommended as an option for the acute treatment of 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. 1.2 This recommendation is not intended to affect treatment with rimegepant that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

Decision making framework (DMF)

National guidance and priorities

The ICS has a legal obligation to commission this medicine in line with the NICE TA.

- This NICE TA has been assigned an implementation deadline of 3 months.
- The implementation deadline is 18 January 2024.

Clinical effectiveness

The company proposed rimegepant for acute treatment after at least 2 triptans have not worked well enough, or if people cannot have triptans (contraindicated or not tolerated), which is narrower than the marketing authorisation.

Clinical trial evidence for acute migraine shows that rimegepant is more likely to reduce pain at 2 hours than placebo.

The most likely cost-effectiveness estimates are below or within what NICE considers to be an acceptable use of NHS resources. So, rimegepant is recommended.

Patient safety

- The product should be used within its product licence.
- This is a Black Triangle drug – all suspected adverse reactions should be reported in order to identify rare adverse effects.

Patient factors

- An additional treatment option would be valued by patients. This is because of the unmet need for a new treatment when triptans are ineffective, and for people who cannot take triptans because of safety or tolerability concerns, particularly in people aged 65 years and over and people with health conditions such as cardiovascular conditions.
- A treatment that can be taken at onset of migraine which could avoid symptoms fully developing, becoming debilitating, and prevent migraine attacks affecting day-to-day life would be helpful.

Environmental impact

Non identified within the NICE TA.

Equality & diversity

The committee concluded that no specific adjustments were needed to NICE's methods in this situation.

Please refer to section 3.19 rimegepant-for-treating-migraine-pdf-82615495535557 (1).pdf for further commentary.

Note 1: Drugs approved by NICE for adult conditions will be commissioned in children at specialised paediatric centres if the patient meets the NICE criteria and there is evidence to suggest that the drug is safe and clinically appropriate to use in children as per the NHS England Medicines for Children Policy (see https://www.england.nhs.uk/publication/commissioning-medicines-for-children-specialised-services/ and a Blueteq form is available.

Place in therapy relative to available treatments

The aim of acute treatment for migraine is to provide effective and sustained relief of headache and associated symptoms. A patient expert highlighted that many treatments target pain but do not address painless migraines. For example, for many people experiencing migraines, a key symptom is an aura, which is not well managed with existing treatments.

Existing acute treatments include oral, nasal and injectable triptans, aspirin, other nonsteroidal anti-inflammatory drugs (NSAIDs), and paracetamol, taken either alone or in combination. Antiemetics are also considered, even when there is no nausea or vomiting.

In clinical practice, people with acute migraine would try at least 2 triptans. Some clinicians may choose to offer up to 7 triptans (including different formulations of the same triptan) before moving onto the next stage in the treatment pathway, referred to as best supportive care.

The clinical experts also explained that when triptans are ineffective and the migraine does not respond, it may be because they are not being used properly. They said that if people have no response to between 2 and 4 triptans, it is unlikely they will have a response to any more triptans.

Also, when triptans are ineffective, not tolerated, or contraindicated, there is no further standard treatment, and that the person should see a migraine specialist. But there are a limited number of headache centres in the UK and there are long waiting lists. Consultation comments noted that some people try medicines not licensed for migraine, such as opioids.

Stakeholder views

The paper was sent out for consultation and comments are listed on the front sheet.

Cost-effectiveness

The drug cost per Place according to NICE resources does not exceed £100,000.

Section 1: cost of the technology

a. Annual cost per patient (or complete course if shorter)

The proposed price of rimegepant is £12.90 per 75 mg tablet (excluding VAT).

Pack size, strength and form	Price (list price ex VAT, BNF online 11 2023)
2 x 75mg oral lyophilisate tablets	£25.80
8 x 75mg oral lyophilisate tablets	£103.20

Rimegepant is used as needed, once daily so costs dependant on frequency of use.

NICE assumes 3.5 migraine episodes per month (one tablet for each episode) which is 42 tablets per year at an annual cost of £542 (assuming rimegepant is prescribed in primary care which does not attract VAT).

If people have 4 or more migraines per month this would be treated as episodic migraine, if people have 8 or more migraines per month this would be treated as chronic migraine. People who have episodic or chronic migraine may be eligible for one of the preventative CGRP treatments.

b. Availability of CAP/PAS price: No

c. Price relative to comparable medicines:
No other comparator - the NICE TA agreed that placebo was the most appropriate comparator.

Section 2: NICE resource impact statement and template

a. NICE resource impact statement

NICE state:
'We 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, based on a population for England of 56.6m people). This was arrived at using the following assumptions.'

Table 1 Assumptions of population and market share

Population assumptions	%	Number of people
Adults 2023/24 (see footnote 1)	-	934,837
Prevalence of migraine (see footnote 2)	11.4	106,571
People diagnosed and treated at least once with migraine treatments (see footnote 3)	-	5,682
People whose migraine has failed 2 triptans (see footnote 3)	4.8	273

Estimated market share based on clinical expert (neurology) opinion. The resource impact for this market share is less than £5m (see footnotes 4 and 5)	19	52
Estimated market share for high resource impact scenario Estimated market share for resource impact to be greater than £5m (footnote 5)	73	199

Sources:

Footnote 1: Office for National Statistics, see population data below. Population uplifted from baseline 2020 population.

Footnote 2: The Prevalence and Disability Burden of Adult Migraine in England and their Relationships to Age, Gender and Ethnicity - TJ Steiner, AI Scher, WF Stewart, K Kolodner, J Liberman, RB Lipton, 2003 (sagepub.com). The estimate of 11.4% is based on tables 2a & 2b after applying the relevant prevalence rates by age to the England population and adjusting for people aged 18 and over.

Footnote 3: Derived figure based on primary care electronic healthcare record (EHR) data through the Clinical Practice Research Datalink Aurum database, Jan 2017 to March 2022

Footnote 4: This estimate is based on clinical experts in neurology. Other variables such as no response to treatment (around 50% overall in Calcitonin Gene-related Peptide (CGRP) treatments) and discontinuation due to adverse effects would further reduce the number of people on treatment and cost.

Footnote 5: This assumes 3.5 migraine episodes per month (one tablet for each episode) which is 42 tablets per year at an annual cost of £542 (assuming rimegepant is prescribed in primary care which does not attract VAT). If people have 4 or more migraines per month this would be treated as episodic migraine, if people have 8 or more migraines per month this would be treated as chronic migraine. People who have episodic or chronic migraine may be eligible for one of the preventative CGRP treatments.

b. NICE resource impact template

A NICE resource impact template is not available.

Commentary:

The cost per year for Surrey Heartlands ICS ranges from £8,050 - £107,858 depending on the scenarios outlined below:

Table 2: Cost per year for Surrey Heratlands ICS:

Scenarios (based on SH adult population of 934,837)**	**No of patients**	**Cost per year based on number of migraine episodes per month (one tablet for each episode) ***	
		assumes 1 migraine episode per month	assumes 3.5 migraine episodes per month
Estimated market share based on clinical expert (neurology) opinion.	52	£8,050	£28,184
Estimated market share for high resource impact scenario	199	£30,805	£107,858

*Cost which is 42 tablets per year at an annual cost of £542 (assuming rimegepant is prescribed in primary care which does not attract VAT).

**If people have 4 or more migraines per month this would be treated as episodic migraine, if people have 8 or more migraines per month this would be treated as chronic migraine. People who have episodic or chronic migraine may be eligible for one of the preventative CGRP treatments.

The Surrey Heartlands Director of Pharmacy and Medicines Optimisation has delegated authority to enable the Committee to be a decision-making committee providing the impact of any single decision does not exceed £100,000 within an individual Place per annum. Decisions with a cost impact of over £100,000 within an individual Place per annum require authorisation

from Surrey Heartlands Health & Care Professionals Committee at their next meeting. Exception to this will be for any decision made in relation to a NICE Technology Appraisal (which are subject to requiring mandatory funding by commissioners) and other urgent items. The exceptions will be taken to the next Executive Meeting (which meets weekly) for authorisation.

Traffic light recommendation to APC

NHS Payment Scheme (NHSPS) excluded high-cost drug: see NHS England » 2023-25 NHS Payment Scheme
Yes.

Recommended traffic light status and rationale:
GREEN - Primary care prescribers may take full responsibility for initiation and continuation of prescribing. Local prescribing guidelines or NICE guidance may apply.

PAD definitions, available at:

FINAL April 2023
Colour classification g

Current TLS definitions in neighbouring ICS:

ICS	Rimegepant in PREVENTING migraine – NICE TA906	Rimegepant in TREATING migraine – NICE TA919
Sussex	RED	GREEN
Kent (holding status)	RED	RED
Frimley	RED	TBC
SWL	RED	RED

Implementation

NICE TA implementation must be within 90 days of publication.

Actions to implement:

a. Primary care
- This is a National Tariff excluded high-cost drug and is commissioned by ICSs.
- Treatment is outlined by NICE TA919 after the use of triptans so a diagnosis of migraine has been established.
- There are no stopping criteria – the committee concluded that although multiple doses of rimegepant would likely be tried in practice before stopping treatment, a formal stopping recommendation is not needed.

b. Secondary care
- Trusts to follow internal governance procedures. Rimegepant should already be available on trust formularies – new indication to be added.
- Secondary care to organise supply – either through homecare or contracted on-site partner pharmacy (no VAT added to price).

c. ICS
- This technology is commissioned by integrated care systems.

d. PAD and Joint Formulary
- New PAD profile will be required

Proposed tick box forms

Blueteq® forms will not be required if GREEN recommendation is adopted.

References:

1 Summary of Product Characteristics. emc. Available at: VYDURA 75 mg oral lyophilisate - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) Accessed <28.12.23>

2 NICE Technology Appraisal Guidance: Rimegepant for treating migraine. Available at: https://www.nice.org.uk/guidance/ta919 Accessed <28.12.23>

3 NICE Resource Impact Template: Resource impact statement. Rimegepant for treating migraine. Available at: Resource impact statement | Rimegepant for treating migraine | Guidance | NICE Accessed <28.12.23>