

# **Migraine Stakeholder Meeting Outcome Statement**

**Tuesday 29 October 2024**

## ***Attendees***

Members of the Pharmaceutical Benefits Advisory Committee (PBAC), and consumer and professional representatives from Migraine Australia, the Australian and New Zealand Headache Society (ANZHS), the Brain Foundation, and the Department of Health and Aged Care were in attendance. One university scientist with expertise in the genetics of migraine also attended in their own right.

Non-departmental attendees undertook confidentiality declarations and provided conflict of interest statements.

## **Purpose of meeting**

The PBAC Chair outlined that the objective of the stakeholder meeting was to discuss patient and clinician perspectives on issues with access to migraine medicines.

The following were identified as issues for discussion:

- Differences between current treatment guidelines and contemporary Australian clinical practice and Pharmaceutical Benefits Scheme (PBS) restrictions for migraine medicines.
- PBS restriction eligibility criteria to move through subsidised lines of therapy.
- Definitions of migraine/headache patient groups used in PBS restrictions.
- Patient access to neurologists.
- Estimates of the number of patients accessing non-PBS medicines and potential growth of the market should these medicines become PBS subsidised.
- Medicine supply shortages of calcitonin gene-related peptide (CGRP) therapies.
- Discontinuation of sumatriptan nasal spray and subcutaneous injection formulations.
- Clinical need for access to medicines for patients with specific migraine types.

Representatives from Migraine Australia and the Australian and New Zealand Headache Society provided presentations on the patient and clinician perspective on migraine treatments and issues with access to subsidised therapy.

## ***Meeting discussion***

### Prevalence and burden of disease

- Stakeholders noted research on the prevalence and burden of disease associated with migraine in Australia. According to the World Health Organization (WHO), migraine is the second leading cause of disability globally and the leading cause of disability in women aged 18-49 years. Migraine is more common in people aged 20-50 years, a peak time for productivity.
- Stakeholders noted the greater disease burden of chronic compared with episodic migraine, and the quality of life and economic benefits to be gained from preventing conversion of episodic migraine to chronic migraine.
- Stakeholders noted that the estimated prevalence for migraine in Australia was approximately 15-20%, or 4.9 million Australians, with chronic migraine affecting around 492,000 Australians (approximately 2% of the Australian population).
- Stakeholders noted that there was no high-quality epidemiological data on migraine prevalence in Australia and that estimates were generally based on data from other countries. It was considered unlikely that better data on migraine prevalence in Australia would be available soon. Stakeholders considered that there was a need for Australian epidemiological data on migraine, including the number of people, time to diagnosis, response to medications, and economic impacts of disease.
- Migraine is considered a neurobiological condition associated with structural and functional changes in the brain that may lead to increased pain sensitivity, sleep disorders and neurohormonal conditions. Stakeholders noted that migraine patients had increased rates of several comorbid conditions, including depression, anxiety, obesity, diabetes and cardiovascular conditions.
- Stakeholders considered migraine a spectrum disorder. While pain was a significant contributor to disease burden for many patients, some patients showed less common symptoms, such as vertigo, and difficulties with concentration, speech and vision, that could also be disabling and lead to hospital presentations. Stakeholders noted that chronic migraine is defined in international diagnostic criteria.
- Migraine is associated with increased health care costs and disability payments, lost productivity through reduced engagement in work and schooling, reduced earning capacity, and reduced ability to contribute to family and carer responsibilities.

### Access to subsidised calcitonin gene-related peptide (CRGP) therapy

- Stakeholders noted that several cost-effectiveness studies indicated that CRGP therapy was likely to be cost-effective due to productivity gains.
- Stakeholders noted that CGRPs were recommended as a first-line medication for prevention of chronic migraine by the American Headache Society, European Headache Federation and the International Headache Society. Stakeholders considered that it was inappropriate to require patients to be contraindicated, intolerant or have an inadequate response to three other preventive therapies to access subsidised CGRP therapy. Stakeholders considered that this delayed patients receiving effective preventive therapy, leading to a worsening of disease and development of long-term sequelae.

- The Department advised that on 1 November 2024, the PBS restrictions for eptinezumab, galcanezumab and fremanezumab will change to allow therapy initiation by a neurologist or a GP in consultation with a neurologist, implementing PBAC's recommendation from its July 2024 meeting.
- Noting long wait times for neurologist appointments, stakeholders considered that it may be appropriate to have different PBS restriction requirements for GP and neurologist initiation, with neurologists being provided more flexibility in determining patients appropriate for subsidised access, such as patients with atypical symptoms or comorbidities that place them at risk of adverse events, and patients who respond to treatment but do not meet the criteria for reduction in the number of migraine headache days. Stakeholders considered that it was important to account for measures of disability other than number of headache or migraine days, such as frequency of hospitalisation.
- Stakeholders considered that ideally GPs prescribing CGRPs would specialise in migraine management through additional training or a credentialing system but noted that this would need to be part of a broader, long-term plan.
- Stakeholders noted real-world evidence that indicated that some patients show a response to therapy but do not meet the requirements of the PBS criteria for continuation, a 50% reduction in migraine headache days, until 6-12 months following initiation. Stakeholders considered that the PBS-subsidised initial therapy period of 3 months may be insufficient.
- Stakeholders considered that non-response to one CRGP was not predictive of non-response to other CRGPs. Therefore, it was important for the PBS restrictions to allow patients to trial other CRGPs if they were non-responders.

#### Access to other subsidised migraine therapies

- Stakeholders considered that combination therapy of CGRPs with botulinum toxin type A (botox) may be appropriate for some patients, particularly short-term use. Stakeholders considered it was biologically plausible that there was an additive benefit from combination therapy due to these drugs affecting different pain receptors and that 'real-world' studies showed an incremental benefit from combination therapy.
- Stakeholders considered that subsidised access to gepants would be particularly useful for intermittent prevention in the management of menstrual migraine, to address wear-off at the end of botox cycles, and for women in the pre-conception phase. Gepants can be used as abortive treatments for migraine and unlike triptans are not associated with medication overuse headache. Stakeholders considered gepants would be useful as acute treatment for patients who are contraindicated, intolerant, or do not respond to nonsteroidal anti-inflammatory drugs (NSAIDs) and triptans, and for those with prolonged acute attacks, or medication overuse headaches.
- CGRPs should generally be stopped 6 months prior to conception but gepants are cleared from the body more rapidly and can be used until close to conception. Stakeholders provided anecdotal evidence of patients continuing to use CGRPs during pre-conception and the first trimester of pregnancy.
- Stakeholders noted that there is no longer a parenteral form of triptan for acute treatment available in Australia following the discontinuation of sumatriptan nasal spray and subcutaneous injection. Stakeholders noted that some patients, such as those with cluster headache, may only respond to triptans in injectable or nasal spray forms, and that

patients with significant early nausea/vomiting and refractory attacks may also be impacted by these discontinuations.

- Stakeholders noted that many medications were used off-label and were not subsidised through the PBS for preventing or managing migraine symptoms. For example, some anti-emetics (e.g. ondansetron), anti-depressants (e.g. nortriptyline, venlafaxine, fluoxetine, duloxetine), and NSAIDs (e.g. indomethacin, naproxen) are not subsidised for use in migraine prevention or management. Stakeholders considered that the PBS-listed quantities of some medicines, or lack of repeats, may increase costs of care for migraine patients, e.g. anti-emetics such as metoclopramide and prochlorperazine.

#### Other issues

- Stakeholders considered it was important for Australia to remain an attractive pharmaceutical market internationally to ensure that a range of migraine therapies are supplied and to avoid supply shortages. The recent CGRP supply shortages caused significant distress to patients and increased physician workloads.
- Stakeholders noted other issues affecting migraine care including the need for: a national strategy, improved health literacy, earlier diagnosis, and access to allied health services.

#### **Conclusion**

The PBAC Chair thanked participants for their time in attending the stakeholder meeting and the advice provided.

The PBAC Chair requested that stakeholders provide consensus advice on the PBS restrictions, including appropriate patient groups for access and how these should be defined, and any continuation, stopping, switching and re-starting rules.

The President of the ANZHS agreed to consult with relevant prescriber and consumer groups, including GPs and pain physicians, on the appropriate PBS restriction criteria for CGRPs to reach a consensus view that could be provided to the PBAC.