



ICER CASE STUDY: MIGRAINE

A cost-effectiveness evaluation of CGRP inhibitors for episodic or chronic migraine headaches exemplifies many of ICER's limitations.

Treating Migraine

Migraine is one of the most prevalent neurological disorders worldwide, associated with substantial health, sociological, and economic consequences.ⁱ The current treatment options for migraine are medicines that were developed for other diseases, such as hypertension, depression, and epilepsy.

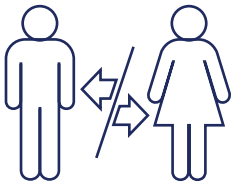
During the last decade, however, new medicines have been developed to explicitly target the causes of migraine. They are known as CGRP inhibitors, because they block the small protein calcitonin gene-related peptide, preventing the onset of a migraine headache.ⁱⁱ

Are Preventive Therapies Cost Effective?

Evaluating the benefits of CGRP inhibitors will culminate in ICER's estimated value-based price. This price will, by necessity, assume that these medicines' value to each individual patient can be evaluated based on the medicine's average value to the entire migraine population.

That is not the reality.

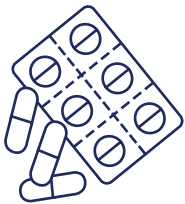
Value Considerations



CGRP inhibitors' effectiveness will likely vary from patient to patient. Similarly, individual patients' clinical response to current migraine therapies also varies. Thus, the relief provided by CGRP inhibitors, relative to current medicines, will meaningfully differ across patients.



The severity of patients' migraines will also vary. Some patients will experience severe migraine headaches on a regular basis; other patients will experience less severe migraine headaches, yet still on a regular basis; while other patients may experience severe migraine headaches, but only periodically. These clinical issues will directly inform how much patients value CGRP inhibitors.



Further complicating an assessment of value, **migraine and its treatments provide no real biomarkers for comparison.** Patients' anecdotal experiences and descriptions of symptoms to their physician are often the best indicator of their condition.



Moreover, the majority of migraine patients experience co-morbid conditions. These include depression, anxiety, arthritis, and others, in addition to the symptoms associated with migraine. Since the number, type, and severity of co-morbid conditions varies across patients, the subjective value of CGRP inhibitors will also vary.



Finally, as an "invisible disease," **migraine is often misunderstood, its impact underestimated.** The societal impact of the disease is at once both multifaceted and difficult to objectively calculate. Factors include cost and impact on employers, patients themselves, their caregivers, their families and their communities.

ICER's Limitations

The Fallacy of the Cost-Effective Price

Due to these important patient-specific considerations, it is not possible to calculate a single price for CGRP inhibitors that reflects its value to all patients living with migraine. Further, to the extent such estimates impact insurers' coverage decisions, wide-sweeping judgments can hurt individual patients.

Timing Issues

As is typical with the drugs ICER evaluates, CGRP inhibitors will be newly available to patients around the same time that ICER releases its report findings. This timing severely restricts the amount that is known about these drugs, which introduces significant uncertainty about the benefits and risks of CGRP inhibitors.

Metrics

ICER's scoping document confirms that the evaluation will use the QALY metric to gauge the cost-effectiveness of the CGRP inhibitors. Evidence suggests that the QALY metric is flawed, particularly for medicines, such as CGRP inhibitors, that improve patients' quality of life and whose value is not easily quantified.

ICER's metrics also fall short in another important way. Due to lack of effective treatment options, some patients with migraine and headache disorders are prescribed opioids for their headache pain. A valuable benefit of new therapies is that they provide an alternative to opioids, limiting patients' and their families' exposure to potentially addictive drugs. ICER's metrics, however, are ill equipped to quantify the significant value of avoiding opioid exposure.

What it Means for Patients

Based on the information provided in ICER's scoping document, the evidence report on CGRP inhibitors will suffer from many of the limitations that have plagued previous reports.

This poses serious concerns for migraine and headache disorders patients. If ICER's flawed calculations produce an unrealistic "value-based price," health plans may adopt less-than-desirable coverage policies for CGRP inhibitors.

Men and women who have suffered with few effective treatment options may discover that, despite years of anticipation, preventive treatment is still out of reach.



i. Dua, T. et al. "Neurological Disorders: Public Health Challenges." 2006. http://www.who.int/mental_health/neurology/neurological_disorders_report_web.pdf.

ii. Deen, M. et al. (2017) "Blocking CGRP in migraine patients – a review of pros and cons." *The Journal of Headache Pain*, December, 18:96; <https://link.springer.com/article/10.1186/s10194-017-0807-1>.