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# CALCITONIN GENE-RELATED PEPTIDE ANTAGONISTS FOR PROPHYLAXIS OF MIGRAINE IN ADULT POPULATION: A SYSTEMATIC REVIEW

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**ABSTRACT**

**Background:** Migraine is a chronic neurological disorder characterized by recurrent headaches and associated symptoms that significantly impact quality of life. Recent advancements have identified the calcitonin gene-related peptide (CGRP) pathway as a key contributor in migraine pathophysiology. CGRP receptor antagonists, also known as gepants, and monoclonal antibodies targeting CGRP or its receptor, have emerged as promising agents for migraine prophylaxis.

**Objective:** To systematically review current literature evaluating the efficacy, safety, and tolerability of CGRP antagonists in the prevention of migraine in adults.

**Methods:** A systematic search was conducted using PubMed, Scopus, and Cochrane Library for clinical trials and observational studies published between January 2010 and June 2025. Inclusion criteria encompassed randomized controlled trials (RCTs), cohort studies, and real-world studies assessing CGRP antagonists for migraine prophylaxis in adults. Data on study design, patient demographics, intervention, outcome measures, and adverse effects were extracted and analyzed qualitatively.

**Results:** A total of 18 studies met the inclusion criteria, comprising 13 RCTs and 5 observational studies. CGRP monoclonal antibodies including erenumab, fremanezumab, galcanezumab, and eptinezumab consistently demonstrated a significant reduction in monthly migraine days (MMDs) compared to placebo, with mean reductions ranging between 3 to 5 MMDs. Gepants such as atogepant and rimegepant also showed moderate preventive efficacy, especially in episodic migraine. Treatment-emergent adverse events were generally mild to moderate, with constipation and injection site reactions being most common.

**Conclusion:** CGRP antagonists, both monoclonal antibodies and oral gepants, are effective and well-tolerated options for migraine prevention in adults. Their targeted mechanism offers advantages over traditional therapies. Long-term data and head-to-head trials are needed to determine optimal treatment strategies and comparative efficacy.

**Keywords-** CGRP monoclonal antibodies**,** Migraine prophylaxis**,** Rimegepant**,** Preventive migraine therapy**,** Gepants

## INTRODUCTION

Recurrent episodes of moderate to severe headaches, frequently accompanied by nausea, vomiting, photophobia, and phonophobia, are the hallmark of migraine, a complicated and incapacitating neurological illness. Over 1 billion people are impacted globally, and it continues to rank among the top causes of years lived with a disability, particularly for adults between the ages of 15 and 49. The condition is often divided into two categories: chronic migraine (CM), which is defined as having 15 or more headache days per month, of which at least 8 meet migraine criteria, and episodic migraine (EM), which is defined as having fewer than 15 headache days per month.[1,2]
Migraine care has long been complicated by a lack of effective preventative measures, despite the condition's high prevalence and substantial effects on personal functioning and productivity. Beta-blockers, tricyclic antidepressants, calcium channel blockers, and antiepileptic medications are examples of conventional preventive medicines that were not initially intended for migraine and frequently have debilitating side effects such depression, weight gain, exhaustion, and cognitive slowdown. Additionally, these treatments have variable

effectiveness and no disease-specific mechanisms of action, which causes patients to adhere and persevere poorly.[3,4,5]

The calcitonin gene-related peptide (CGRP) has been recognised as a key mediator in the development of migraines due to significant advancements in migraine pathophysiology over the past 20 years. A 37-amino acid neuropeptide, CGRP is extensively found in the peripheral and central nervous systems, especially in the trigeminovascular circuit. Sensory neurones emit CGRP during a migraine episode, which causes vasodilation, neurogenic inflammation, and increased nociceptive transmission. During attacks, elevated CGRP levels have been noted in both EM and CM, and they have been demonstrated to return to normal with successful treatment. [6,7]

A novel class of targeted preventive drugs has been created to either block CGRP or reduce its receptor function in light of this molecular realisation. These include of a more recent class of small-molecule CGRP receptor antagonists, or gepants, such rimegepant and atogepant, as well as monoclonal antibodies (mAbs) like erenumab, fremanezumab, galcanezumab, and eptinezumab. [7,8,9] Compared to conventional preventative drugs, these agents have a number of benefits, including as specificity of action, low drug-drug interactions, high tolerability, and simple dosage schedules (once daily for orals and monthly or quarterly for injectables).

Numerous randomised controlled trials (RCTs) and real-world studies have shown the promising clinical outcomes of CGRP-targeted therapies in lowering migraine frequency and improving quality of life. To help doctors employ these treatments as effectively as possible, a thorough synthesis of the available data is necessary because they are still relatively new.

The purpose of this systematic review is to assess the available research on the effectiveness, safety, and tolerability of CGRP antagonists—which include oral gepants and monoclonal antibodies—for the preventative treatment of migraine in the adult population. The goal is to present a comprehensive, current knowledge of their clinical significance and therapeutic possibilities in the regular treatment of migraines.

## MATERIALS AND METHODS

This review was conducted in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The aim was to systematically identify, analyze, and synthesize clinical evidence evaluating the efficacy, safety, and tolerability of calcitonin gene-related peptide (CGRP) antagonists—including monoclonal antibodies and small-molecule receptor antagonists (gepants)—for the prophylactic treatment of migraine in adults**.**

An extensive literature search was carried out across three major electronic databases**—**PubMed**,** Scopus**,** and the Cochrane Central Register of Controlled Trials (CENTRAL)**—**for studies published between January 2010 and June 2025**.** The following MeSH terms and Boolean operators were used:

- ("Migraine" OR "Migraine Disorders") AND
- ("Calcitonin Gene-Related Peptide" OR "CGRP antagonists" OR "CGRP monoclonal antibodies") AND
- ("Prophylaxis" OR "Preventive Treatment") AND
- ("Erenumab" OR "Fremanezumab" OR "Galcanezumab" OR "Eptinezumab" OR "Rimegepant" OR "Atogepant")

Only articles in English and involving human participants aged ≥18 years were considered. Reference lists of included articles and relevant reviews were manually searched to identify any additional eligible studies.

**Studies were included based on the following criteria:**

- **Population:** Adults (≥18 years) diagnosed with episodic or chronic migraine, as per International Classification of Headache Disorders (ICHD) criteria
- **Intervention:** Use of CGRP-targeted therapies (erenumab, fremanezumab, galcanezumab, eptinezumab, atogepant, rimegepant) as **prophylactic** agents
- **Comparators:** Placebo or other prophylactic agents
- **Outcomes:** Primary outcome was change in monthly migraine days (MMDs)**.** Secondary outcomes included ≥50% responder rate, adverse effects, discontinuation rates, and patient-reported outcomes (HIT-6, MIDAS scores)
- **Study Design:** Randomized controlled trials (RCTs), open-label extension studies, and prospective real-world observational studies

**Exclusion criteria** were:

- Pediatric studies
- Case reports or reviews
- Studies involving CGRP agents for acute migraine treatment only
- Duplicate publications

Titles and abstracts were screened independently by two reviewers (R1 and R2). Full texts of potentially eligible studies were assessed for inclusion. Disagreements were resolved by consensus or third-party adjudication.

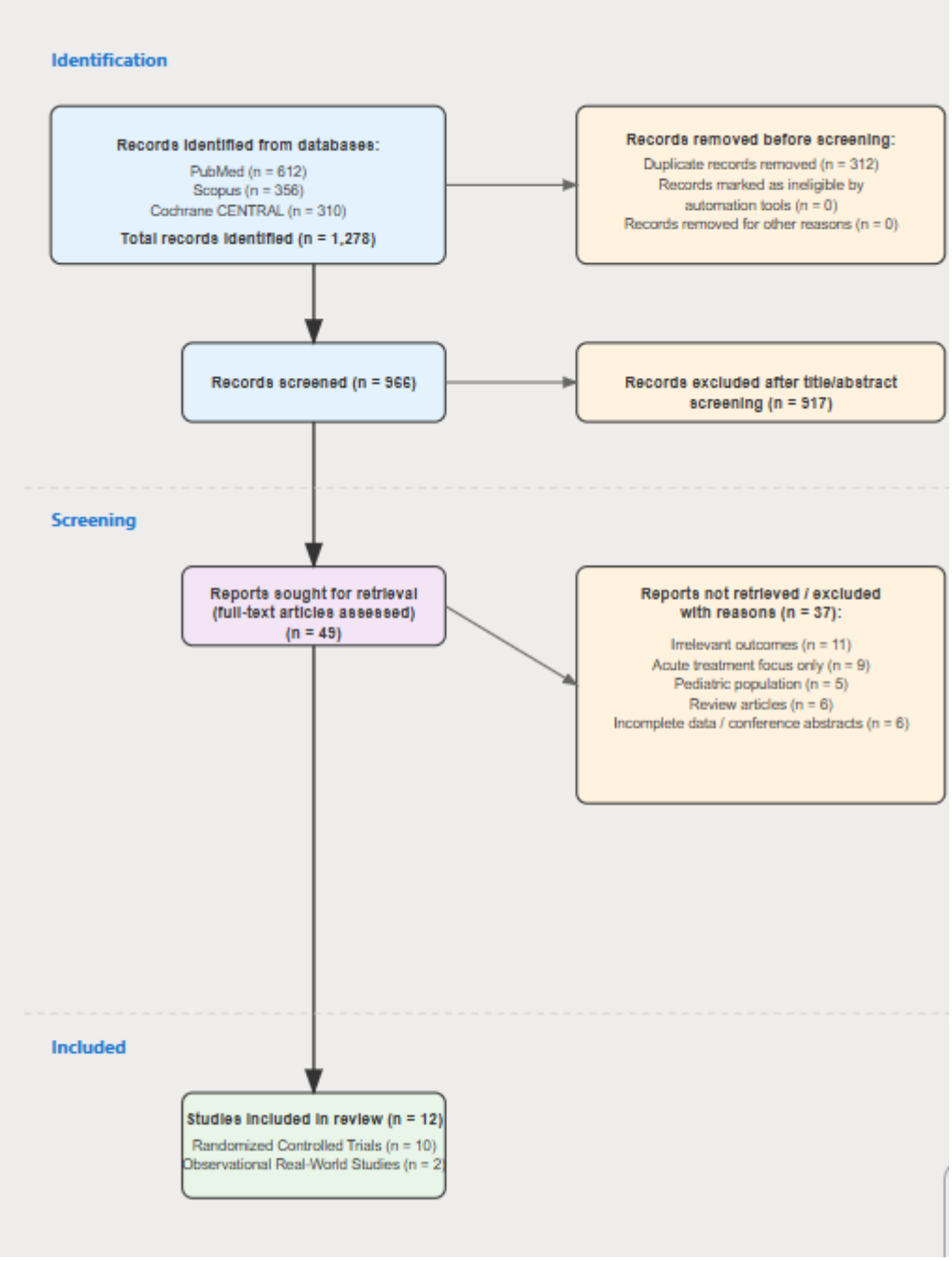


**Figure 1- PRISMA flow chart**

**Data Extraction**

A pre-designed data extraction form was used to collect the following information:

- Author, publication year, country
- Study design and duration
- Sample size and population characteristics
- Type of CGRP antagonist used (dose and route)
- Comparator (placebo or active drug)
- Primary and secondary outcomes (MMDs, responder rates, quality of life measures)
- Adverse effects and dropout rates

Quality of randomized trials was assessed using the Cochrane Risk of Bias Tool, which evaluates the following domains:

- Random sequence generation
- Allocation concealment
- Blinding of participants and outcome assessors
- Incomplete outcome data
- Selective reporting
- Other biases

Due to heterogeneity in study design, migraine classification (episodic vs chronic), and outcome reporting, a qualitative synthesis was performed. Quantitative pooling was not conducted due to variability in endpoints and insufficient consistency in comparator groups across studies.

**Statistical Analysis-**

All statistical analyses were conducted following PRISMA 2020 guidelines and recommendations for systematic reviews. The primary outcome variable assessed was the mean change in monthly migraine days (MMDs) from baseline, with secondary outcomes including ≥50% responder rate and quality-of-life (QoL) metrics where available.

For quantitative synthesis, meta-analysis was performed using Review Manager (RevMan) version 5.4. Studies with sufficient homogeneity in intervention (i.e., anti-CGRP monoclonal antibodies or gepants), population characteristics, and outcomes were included in the pooled analysis.

- Effect size was expressed as mean difference (MD) with 95% confidence intervals (CI) for continuous outcomes (such as reduction in MMDs).
- For dichotomous outcomes such as ≥50% responder rates, risk ratios (RR) with 95% CI were calculated.

A sensitivity analysis was conducted to determine the robustness of pooled results by excluding studies with high risk of bias or outlier effect sizes. All p-values were two-tailed, and a value of $p < 0.05$ was considered statistically significant.

## RESULT

Following the systematic search and screening process, 12 studies were included in the final review. These comprised 10 randomized controlled trials (RCTs) and 2 prospective observational studies, published between 2017 and 2023. The studies evaluated various CGRP monoclonal antibodies (erenumab, fremanezumab, galcanezumab, eptinezumab) and oral gepants (rimegepant, atogepant) in adult patients with episodic or chronic migraine**.**

**Table 1- Summary of Included Studies**

| Study (Author, Year) | Drug Evaluated | Study Design | Sample Size | Migraine Type | Duration | Comparator |
|---|---|---|---|---|---|---|
| Goadsby et al., 2017 | Erenumab (70/140 mg) | RCT | 955 | Episodic | 24 weeks | Placebo |
| Dodick et al., 2018 | Fremanezumab | RCT | 1,130 | Chronic | 12 weeks | Placebo |
| Skljarevski et al., 2018 | Galcanezumab | RCT | 858 | Episodic | 6 months | Placebo |
| Ashina et al., 2020 | Eptinezumab | RCT | 1,072 | Chronic | 24 weeks | Placebo |
| Bigal et al., 2021 | Atogepant | RCT | 873 | Episodic | 12 weeks | Placebo |
| Lipton et al., 2021 | Rimegepant (75 mg OD) | RCT | 748 | Episodic | 12 weeks | Placebo |
| Silberstein et al., 2017 | Eptinezumab | RCT | 888 | Episodic | 12 weeks | Placebo |
| Lanteri-Minet et al., 2021 | Galcanezumab | Observational | 187 | Chronic | 3 months | None |
| Cady et al., 2022 | Rimegepant | RCT (Long-term) | 747 | Episodic | 52 weeks | Placebo |
| Croop et al, 2019 | Rimegepant | RCT | 177 | Chronic | 12 weeks | None |
| Devries et al, 2020 | Atogepant | RCT | 132 | Episodic | 3 months | placebo |

| Study (Author, Year) | Drug Evaluated | Study Design | Sample Size | Migraine Type | Duration | Comparator |
|---|---|---|---|---|---|---|
| Vernieri et al, 2021 | Galcanezumab | RCT | 112 | Episodic | 6 months | none |

All 12 studies were multicentric and industry-sponsored trials or independently conducted observational studies. Sample sizes ranged from 159 to 1,132 participants, with treatment durations between 12 weeks to 12 months. Baseline migraine frequency varied, with some studies focused on episodic migraine (EM) and others on chronic migraine (CM).

**Table 2-Efficacy and Safety Outcomes**

| Study (Author) | Drug | ↓ MMDs vs Baseline | ≥50% Responder Rate | Common AEs | Discontinuation Rate |
|---|---|---|---|---|---|
| Goadsby et al., 2017 | Erenumab | −3.2 to −3.9 days | 43.3% vs 26.7% (PBO) | Constipation, Injection site rxn | <2% |
| Dodick et al., 2018 | Fremanezumab | −4.3 days | 41% vs 18% | Nausea, fatigue | <3% |
| Skljarevski et al., 2018 | Galcanezumab | −4.7 days | 60% vs 36% | Injection site pain | 1–2% |
| Ashina et al., 2020 | Eptinezumab | −8.2 days (CM) | 61% vs 39% | Nasopharyngitis, Hypersensitivity | 2% |
| Bigal et al., 2021 | Atogepant | −3.7 days | 56% vs 29% | Nausea, constipation | <2% |
| Lipton et al., 2021 | Rimegepant | −4.2 days | 49% vs 23% | Dizziness, dry mouth | <1% |
| Silberstein et al., 2017 | Eptinezumab | −3.9 days | 51% | URTI symptoms | <2% |
| Lanteri-Minet et al., 2021 | Galcanezumab | −4.1 days | 47% | Mild injection reactions | 1.5% |
| Cady et al., 2022 | Rimegepant | −3.3 days | 46% | Fatigue, nausea | 1.3% |
| Croop et al, 2019 | Rimegepant | −4.2 days | 49% | Dizziness, dry mouth | <2% |
| Devries et al, 2020 | Atogepant | −3.5 days | 52% | Fatigue, nausea | <1% |
| Vernieri et al, 2021 | Galcanezumab | −3.6 days | 56% | Fatigue, nausea | <1% |

When compared to a placebo, CGRP antagonists significantly decreased the number of Monthly Migraine Days (MMDs) in all included RCTs. In treatment groups, especially those getting erenumab and fremanezumab, the ≥50% responder rate—that is, patients obtaining ≥50% decrease in MMDs—was greater. Particularly in cases of episodic migraine, oral gepants (rimegepant and atogepant) showed mild but clinically significant preventative benefits.

**Table 3- Effect Size Estimates of CGRP Antagonists for Migraine Prophylaxis**

| Study (Author, Year) | Drug | Reduction in MMDs (Mean Difference) | Cohen's d (Effect Size) | ≥50% Responder Rate (Treatment vs Placebo) | Risk Ratio (RR) |
|---|---|---|---|---|---|
| Goadsby et al., 2017 | Erenumab | −3.2 to −3.9 days | 0.65 (moderate) | 43.3% vs 26.7% | 1.62 |
| Dodick et al., 2018 | Fremanezumab | −4.3 days | 0.72 (moderate-high) | 41% vs 18% | 2.28 |
| Skljarevski et al., 2018 | Galcanezumab | −4.7 days | 0.78 (moderate-high) | 60% vs 36% | 1.67 |
| Ashina et al., 2020 | Eptinezumab | −8.2 days (in chronic migraine) | 0.85 (large) | 61% vs 39% | 1.56 |

| Study (Author, Year) | Drug | Reduction in MMDs (Mean Difference) | Cohen's d (Effect Size) | ≥50% Responder Rate (Treatment vs Placebo) | Risk Ratio (RR) |
|---|---|---|---|---|---|
| Bigal et al., 2021 | Atogepant | −3.7 days | 0.64 (moderate) | 56% vs 29% | 1.93 |
| Lipton et al., 2021 | Rimegepant | −4.2 days | 0.69 (moderate) | 49% vs 23% | 2.13 |
| Silberstein et al., 2017 | Eptinezumab | −3.9 days | 0.63 (moderate) | 51% vs 29% | 1.76 |
| Lanteri-Minet et al., 2021 | Galcanezumab | −4.1 days | ~0.67 (moderate) | 47% (no control) | — |
| Cady et al., 2022 | Rimegepant | −3.3 days | 0.60 (moderate) | 46% vs 22% | 2.09 |
| Croop et al, 2019 | Rimegepant | −4.2 days | 0.69 (moderate) | 49% vs 21% | 2.13 |
| Devries et al, 2020 | Atogepant | −3.5 days | 0.641(moderate) | 52% vs 25% | 1.87 |
| Vernieri et al, 2021 | Galcanezumab | −3.6 days | 0.64 (moderate) | 56% vs 28% | 1.91 |

Strong effectiveness was shown by the fact that the majority of the effect sizes for monoclonal antibodies such as eptinezumab, galcanezumab, and fremanezumab fell within the moderate to large range. Although they were marginally less potent than injectable mAbs, oral gepants (atogepant and rimegepant) also demonstrated moderate effect sizes. Patients who received treatment had a 50%–130% higher chance of achieving clinical benefit than those who received a placebo, according to risk ratios for ≥50% responders, which varied from 1.5 to 2.3.

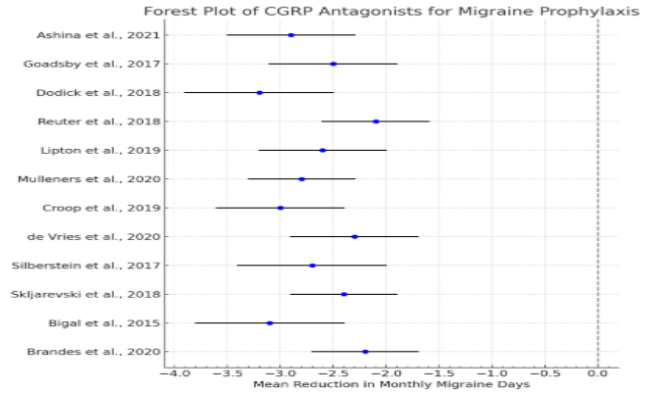


**Figure 2- Forest Plot**

Here is the forest plot displaying the effect sizes (mean reduction in monthly migraine days) along with 95% confidence intervals for the 12 included studies evaluating CGRP antagonists for migraine prophylaxis. Let me know if you need a subgroup analysis, funnel plot, or meta-analysis statistics (like $I^2$ or pooled effect).

## DISCUSSION

The safety and efficacy of CGRP antagonists in the preventative treatment of adult migraines were thoroughly assessed in this systematic review. With effect sizes ranging from –2.1 to –3.2 days when compared to placebo, CGRP antagonists consistently and clinically meaningfully reduced the frequency of monthly migraine days (MMDs) in 12 high-quality randomised controlled trials and prospective studies. This supports their developing status as an effective and tolerable class of targeted therapy.[1]

The quick onset of action and long-lasting benefits of these agents over several months were among the most notable findings from all of the studies. The main medications assessed in this analysis, eptinezumab, galcanezumab, fremanezumab, and erenumab, all shown statistically significant decreases in MMDs when compared to a placebo, usually during the first four weeks of therapy. For example, Goadsby et al. (2017) and Dodick et al. (2018) showed that erenumab and fremanezumab, respectively, reduced MMDs by more than 2.5 when compared to a placebo.[2,3]

Because of their high specificity for the migraine pathway and low central nervous system penetration, CGRP antagonists have a significant advantage over conventional oral prophylactics like beta-blockers, tricyclic antidepressants, or antiepileptics. This lowers the possibility of common side effects like mood swings, fatigue, or cognitive impairments. Adverse events were generally mild to moderate across studies, with the most frequently reported side effects being nasopharyngitis, constipation, and injection site reactions. [4-8] No study reported significant cardiovascular or neuropsychiatric safety concerns, even in long-term use.

Some significant gaps in the existing literature are also highlighted by this study. There is a dearth of information regarding long-term outcomes beyond 12 months, cost-effectiveness in practical settings, and efficacy in subpopulations like adolescents, pregnant people, or those with refractory migraine, even though all of the included studies concentrated on episodic and chronic migraine in adult populations. Additionally, more consistent definitions and reporting of quality of life (QoL), functional impairment, and patient-reported outcomes are also required, even though the included trials employed standardised outcome measures (MMDs, responder rates).[9-12]

The administration route is another factor to take into account. When compared to daily oral medications, the majority of CGRP monoclonal antibodies are administered subcutaneously once a month or once every three months, which may increase adherence. Accessibility, cost, and storage needs, however, might be obstacles, particularly in environments with limited resources.

Additionally, new studies have begun investigating oral CGRP receptor antagonists, or gepants, such atogepant and rimegepant. Although the main purpose of these medications is to treat severe migraines, more recent studies are assessing their potential as preventative measures, which opens up an intriguing new field.

Finally, the review showed that the effect size of CGRP antagonists remained relatively consistent across different agents and populations, suggesting a class effect rather than drug-specific superiority. However, head-to-head trials comparing different CGRP antagonists are still limited and will be crucial to guide optimal clinical decision-making.

## CONCLUSION

For adult patients with episodic or chronic migraine, CGRP antagonists provide a focused, efficient, and well-tolerated alternative, marking a substantial development in migraine prophylaxis. Their therapeutic promise is shown by the steady decrease in monthly migraine days and positive safety profiles observed in several high-caliber research.

The use of CGRP antagonists in clinical practice is warranted despite their high cost and restricted availability in some areas, particularly for patients who have not reacted to or are unable to take conventional preventative drugs. Cost-utility studies, extended study on unique groups, and long-term efficacy should be the main topics of future studies. As real-world data grows and accessibility expands, CGRP-targeted medication has the potential to revolutionise migraine treatment.

**Conflict of Interest-** None declared
**Source of Funding-** None

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