

# Prior Authorization Requirements for Calcitonin Gene-Related Peptide Antagonists

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**C**alcitonin gene-related peptide (CGRP) antagonists have emerged as important therapeutic options for migraine treatment and prophylaxis. The market for CGRP antagonists is extremely large, as more than 1 billion individuals worldwide experience migraines each year.<sup>1</sup> However, use of these agents may be limited due to a high cost burden.<sup>1</sup> To date, 8 CGRP antagonists have been approved by the FDA, 6 of which have been approved for migraine prophylaxis: erenumab, fremanezumab, galcanezumab, eptinezumab, rimegepant, and, most recently, atogepant.<sup>2-7</sup> The remaining CGRP antagonists, ubrogepant and zavegepant, are indicated only for migraine treatment and share this indication with rimegepant.<sup>8,9</sup>

Prior authorization (PA) is a common tool used by managed care organizations (MCOs) to ensure appropriate and cost-effective medication utilization.<sup>10</sup> The use of PA is common for high-cost medications, therapies that may be used inappropriately (eg, off-label indications), and for medication classes in which various clinically similar options exist. For all these reasons, many MCOs have instituted PA requirements on the CGRP antagonist class. However, PA criteria are not universal and are determined based on each MCO's review of clinical evidence, financial resources and agreements, and/or population demographics.<sup>10,11</sup> Additionally, an MCO's ability to develop new policies or update existing criteria may be hindered by factors outside its control, including regulatory restrictions, logistical challenges, and administrative limitations. Consequently, requirements may differ across MCOs, affecting patients and providers. Providers have described the PA process as a high burden, leading to delays in care, discarded treatment recommendations, and negative health outcomes for patients.<sup>12</sup>

PA policies for different medication classes have been explored in the literature, with a majority focusing on each state's Medicaid policies for the selected drug class.<sup>13-18</sup> Additionally, recent data suggest stark differences in the application of prescriber requirements to coverage decisions.<sup>19</sup> Overall, evidence suggests that wide differences in criteria among policies exist, resulting in discrepancies of clinical appropriateness and restricted access for patients. Despite these available data, research defining the broad types of PA criteria

## ABSTRACT

**OBJECTIVES:** To determine whether broad categories of criteria exist among prior authorization (PA) policies from different managed care organizations (MCOs) and to identify similarities and differences among MCO coverage requirements for medications within the calcitonin gene-related peptide (CGRP) antagonist class.

**STUDY DESIGN:** Quantitative and qualitative descriptive analysis.

**METHODS:** PA policies from different MCOs for erenumab, fremanezumab, galcanezumab, and eptinezumab were identified through a comprehensive online search. Individual criteria from each policy were analyzed and grouped into both broad and specific categories. Descriptive statistics were used to identify and summarize trends among policies.

**RESULTS:** A total of 47 MCOs were included in the analysis. The vast majority of policies applied to galcanezumab (n = 45; 96%), erenumab (n = 44; 94%), and fremanezumab (n = 40; 85%), with fewer policies for eptinezumab (n = 11; 23%). There were 5 broad categories of PA criteria found to be included in coverage policies: prescriber specialization (n = 21; 45%), prerequisite drugs (n = 45; 96%), safety considerations (n = 8; 17%), and response to therapy (n = 43; 91%). The final category, titled appropriate use, included any criteria meant to ensure appropriate medication use and included age requirements (n = 26; 55%), suitable diagnosis (n = 34; 72%), exclusion of other diagnoses (n = 17; 36%), and exclusion of concurrent medications (n = 22; 47%).

**CONCLUSIONS:** This study identified 5 broad categories of PA criteria used by MCOs in the management of CGRP antagonists. However, within these categories, specific criteria from different MCOs varied significantly.

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## TAKEAWAY POINTS

Using calcitonin gene-related peptide antagonists as a case study, this qualitative analysis identified significant differences in prior authorization (PA) criteria across managed care organizations (MCOs), which may contribute to patient and provider confusion.

- ▶ There are 5 broad categories of PA criteria commonly included in coverage policies: prescriber specialization, appropriate use, prerequisite drugs, safety considerations, and response to therapy.
- ▶ Within these categories, the stringency of MCOs' requirements differs significantly.
- ▶ Using these broad categories as a guide may help improve consistency among MCOs and help providers navigate PA requirements more effectively.

used by MCOs is scarce. To address this gap and summarize new information regarding a high-profile medication class, we examined trends in PA requirements for CGRP antagonists among MCOs.

## METHODS

We conducted a qualitative and quantitative descriptive analysis of CGRP antagonist PA policies. Policies were identified through a comprehensive online search using Google in July 2020 using prespecified search terms ([eAppendix Table 1](#)) (eAppendix available at [ajmc.com](#)). As required by the institutional review board, upon locating publicly posted policies online, we attempted to contact each MCO to request permission on an opt-out basis to include the MCO's policy in the analysis. The MCOs were informed that each organization would remain anonymous, results would be shared only in the aggregate, and no exact language from policies would be used.

All lines of business (LOBs) were included (ie, commercial, health care reform, Medicaid, Medicare), and policies for which the LOB could not be identified were categorized as "unspecified." National, regional, and state MCOs were represented. In addition, all MCO types (eg, health plans, pharmacy benefit managers) were included.

To limit the scope of the study, only pharmacy benefit policies for erenumab, fremanezumab, galcanezumab, and eptinezumab for migraine prophylaxis were considered for analysis. Rimegepant and atogepant did not gain FDA approval for migraine prophylaxis until after the analysis was complete. All policies and requirements for ubrogepant, rimegepant, and zavegepant for migraine treatment; criteria for galcanezumab with regard to cluster headache prophylaxis; and medical policies for eptinezumab were excluded.

Policies effective from July 2019 to July 2020 were included to account for a 1-year look-back from the time of analysis. Policies were included only if an effective date could be located. Policies were excluded if a request was received by the MCO to not be included or if no contact information for any individual from the MCO could be found. The most recent version of any MCO's policies was used if multiple versions were found.

The MCOs for which policies were located from multiple LOBs (eg, a commercial policy and a Medicare policy) or for multiple agents (eg, a commercial policy covering erenumab and a second commercial

policy covering fremanezumab) were analyzed for differences among the identified criteria. If the simple majority (ie, greater than 50%) of criteria differed among policies, the MCO was excluded from the study. If fewer than half of the criteria differed, only the stricter of the available criteria were included and analyzed as 1 set of criteria for 1 MCO. See [eAppendix Table 2](#) for examples of these instances and how they were analyzed.

We used descriptive statistics to identify and summarize trends among policies. Policies

were first organized by the medication(s) included and the indications covered. From here, individual criteria from each policy were analyzed and grouped into both broad and specific categories. There were 5 broad categories of PA criteria developed: requirements on prescriber specialization, appropriate use, prerequisite drugs, safety considerations, and response to therapy. Although it is not a PA criterion itself, a sixth category of authorization length was also used. Quantity limits and any other limitations of coverage not explicitly stated in each policy's criteria were not included in the analysis.

Several terms were defined during the analysis to ensure consistency ([eAppendix Table 1](#)). This project was determined to be exempt from review by the Wilkes University Institutional Review Board.

## RESULTS

Policies from 47 MCOs were included in the analysis ([Figure 1](#)). The vast majority of policies applied to galcanezumab (n = 45; 96%), erenumab (n = 44; 94%), and fremanezumab (n = 40; 85%), with fewer policies for eptinezumab (n = 11; 23%). Additional MCO characteristics and full results can be found in [Table 1](#) and [eAppendix Table 3](#), respectively.

## Prescriber Specialization

A prescriber requirement, indicating that the agent must be prescribed by or in consultation with a certain specialist, was included by 21 (45%) MCOs. Of these 21 MCOs, 20 (95%) required the prescription to be written by or in consultation with a specialist, whereas 1 (5%) accepted only prescriptions written by a specialist.

Of the 21 MCOs that required specialist involvement, 20 (95%) considered neurologists as appropriate specialists, with 1 (5%) MCO not stipulating the type of specialist required; 11 (52%) MCOs also accepted pain specialists, whereas 9 (43%) also accepted headache specialists ([Figure 2](#)).

## Appropriate Use

Appropriate use was considered to be any criteria that ensured that the patient was a candidate for the medication based on FDA labeling and/or clinical evidence. The first component of appropriate use, an age requirement, was included by 26 (55%) MCOs. Of these, the

age requirement was listed as 18 years or older by 24 (92%) MCOs, whereas 2 (8%) specified that the patient's age had to be appropriate based on the requested medication's labeling.

Appropriate use also involves a suitable diagnosis or indication, which was required by 34 (72%) MCOs. Of these, 7 (21%) MCOs accepted migraine with or without aura, whereas 24 (71%) accepted episodic or chronic migraine; 21 of the 24 (88%) MCOs accepting episodic or chronic migraine specified a certain number of migraine and/or headache days to define the type of migraine. The defined number of days varied among both diagnoses (eAppendix Table 1), but the most variation was seen in how MCOs defined episodic migraine. Of the 21 MCOs that defined episodic migraine, the most common definition of either "less than 15 headache days per month" or "4 to 14 migraine days per month" was included by only 8 (38%), with added inconsistency related to a required amount of time (eg, 3 months) since symptom onset.

Similarly, 17 (36%) of the 47 MCOs looked for prescribers to exclude diagnoses of medication overuse headache (n = 15; 88%); other headache disorders (n = 4; 24%), such as rebound headache, medication withdrawal headache, cluster headache, and hemiplegic migraine; and other medical conditions that contribute to migraine headache (n = 3; 18%), such as sleep disorders, jaw disorders, and cardiovascular disorders.

Finally, appropriate use involved ensuring that certain medications will not be used concurrently. This was included by 22 (47%) MCOs. In this analysis, the medications restricted from concomitant use with the requested CGRP antagonist were other agents within the same class (n = 19; 86%) or onabotulinumtoxinA (n = 18; 82%).

### Prerequisite Drugs

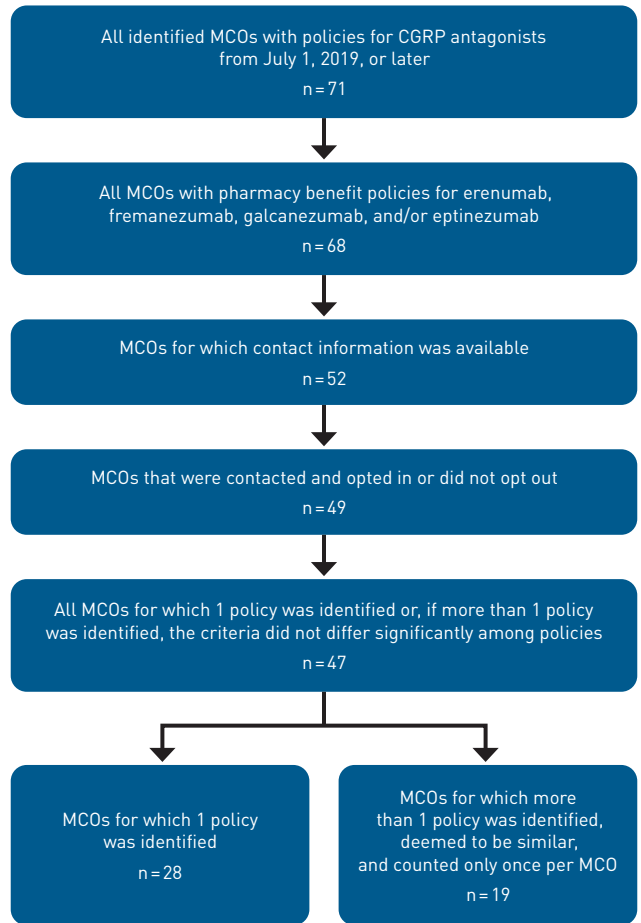
Nearly all MCOs (n = 45; 96%) included criteria requiring a previous trial and failure of at least 1 non-CGRP antagonist medication for migraine prophylaxis, with the majority of these MCOs necessitating a previous trial of 1 (n = 13; 29%) or 2 (n = 25; 56%) alternative medications before the requested agent could be approved. The remaining 7 (16%) MCOs required a previous trial of 3 alternatives (Figure 2).

The MCOs differed with regard to the specificity of the agents tried in the past. Twenty-one (84%) of the 25 MCOs that required a previous trial of 2 alternatives required those alternatives to be from different drug classes, whereas the remaining 4 (16%) also accepted previous therapies from the same class. Similarly, 6 (86%) of the 7 MCOs that required 3 medications to be tried first required all 3 agents to come from different drug classes.

In addition, 28 (62%) of the 45 MCOs requiring a previous trial of a non-CGRP antagonist medication for migraine prophylaxis specified a required length of the trial, although no consensus among MCOs was identified. Of these, 7 (25%) MCOs required each medication to have been tried for a minimum of 4 weeks, 4 (14%) specified at least 6 weeks, 10 (36%) stated at least 8 weeks, and 7 (25%) noted at least 12 weeks.

Of the 45 MCOs that required alternative medications for migraine prophylaxis to be trialed, 44 (98%) listed the alternatives

**FIGURE 1.** Policy Selection for Study Inclusion and Analysis



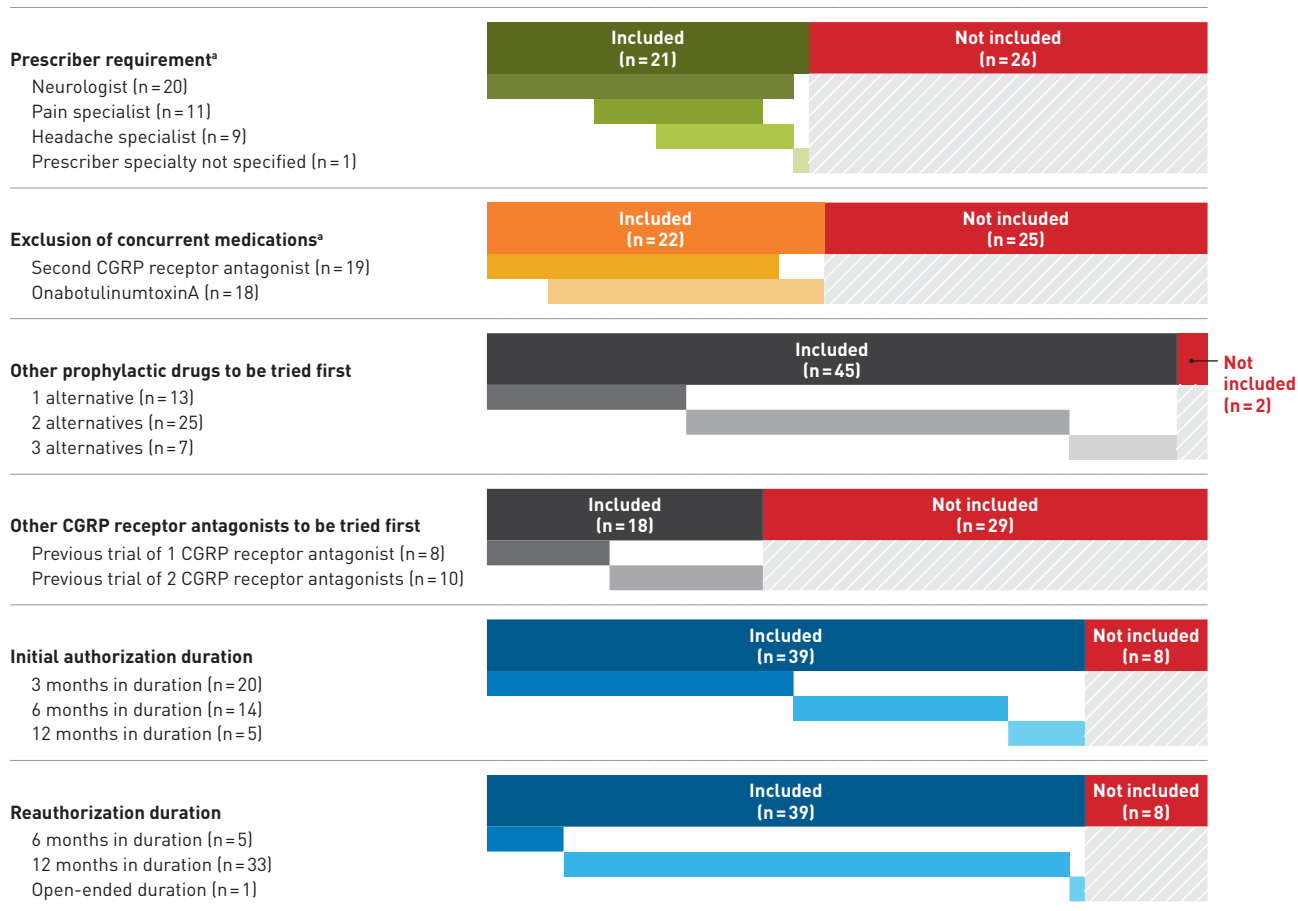
CGRP, calcitonin gene-related peptide; MCO, managed care organization.

**TABLE 1.** Policy Characteristics

Characteristic	n [%]
Line(s) of business covered by policy*	
Commercial	10 [21%]
Health care reform	6 [13%]
Medicaid	10 [21%]
Medicare	13 [28%]
Unspecified	18 [38%]
Drugs covered within identified policies	
Eptinezumab	11 [23%]
Erenumab	44 [94%]
Fremanezumab	40 [85%]
Galcanezumab	45 [96%]

\*Although only 1 combined set of criteria was analyzed for managed care organizations with policies covering multiple lines of business, each line of business covered by a managed care organization was collected to provide characteristic information on the policies.

FIGURE 2. Managed Care Organization Prior Authorization Requirements



CGRP, calcitonin gene-related peptide.

\*Overlap between rows indicates that certain policies included multiple criteria.

as either the names of individual medications (eg, propranolol) or the medications' classes (eg,  $\beta$ -blockers), whereas 1 (2%) did not specify which agents were considered appropriate alternatives. Listing alternatives by class name was done by 37 (84%) of these MCOs, whereas 7 (16%) included medication names without listing classes. See [Table 2](#) for more detail.

Of these 44 MCOs that listed alternatives, the most commonly accepted medications or classes included anticonvulsants (n=44; 100%),  $\beta$ -blockers (n=43; 98%), and antidepressants (n=39; 89%). Less frequently mentioned were angiotensin-converting enzyme inhibitors/angiotensin II receptor blockers (n=9; 20%), calcium channel blockers (n=8; 18%), and onabotulinumtoxinA (n=8; 18%). See [Figure 3](#) for more detail.

Eighteen (40%) MCOs, all of which required prerequisite non-CGRP antagonist therapies, also required a previous trial of 1 (n=8; 44%) or 2 (n=10; 56%) preferred agents within the CGRP antagonist class

before approval (Figure 2). The most commonly preferred agents were galcanezumab (n=13; 72%) and erenumab (n=13; 72%), followed by fremanezumab (n=6; 33%), with none preferring eptinezumab.

### Safety Considerations

Criteria built around safety considerations, such as confirming the absence of adverse events, contraindications, or pregnancy, were included by 8 (17%) MCOs. Of these 8 MCOs, 5 (63%) considered safety in both their initial and reauthorization criteria.

### Duration of Authorization and Response to Therapy

There were 39 (83%) MCOs that specified an authorization duration in their policy for initial and reauthorized approvals (Figure 2). Of these 39 MCOs, 20 (51%) limited initial approval to 3 months, 14 (36%) listed a 6-month duration, and 5 (13%) allowed for a 12-month approval. Reauthorization time frames tended to be

longer in duration, with 5 (13%) MCOs noting a 6-month duration, 33 (85%) citing a 12-month duration, and 1 (3%) having an open-ended reauthorization period.

Forty-three (91%) MCOs included reauthorization criteria, and all required a response to therapy to occur for the requested agent to be reauthorized. Most MCOs (n = 28; 65%) included more than 1 consideration of what constitutes a response to therapy. The most commonly accepted definitions were a reduction from baseline in the number of migraines (n = 38; 88%), in migraine severity (n = 19; 44%), and in the use of acute migraine abortive medications (n = 10; 23%).

## DISCUSSION

When analyzing the PA criteria for CGRP antagonists, we identified significant inconsistencies among requirements, despite successfully defining 5 broad categories of PA criteria.

One area of inconsistency was a difference in prescriber specialty requirements among MCOs that included this criterion. Managed care organizations differ on whether specialists are required to prescribe CGRP antagonists, with more than half of MCOs not including this requirement. When a specialist was required, there was additional inconsistency regarding which specialist(s) are appropriate. However, each MCO's awareness of specialist options within its network may account for some of the differences in prescriber requirements.

We also identified inconsistencies within the broad category of appropriate use, in which some MCOs included an age requirement as a specific age (ie, 18 years or older) as opposed to an appropriate age based on the medication's labeling. If the medication covered by the policy were to receive an expanded age indication from the FDA, requiring a specific age can lead to a potentially inappropriate denial of care for the expanded population. However, many MCOs alleviate this concern by having mechanisms in place to allow for approval of expanded indications prior to formal policy modification.

According to their package inserts, all of the agents included in our study are FDA-approved for the preventive treatment of migraine in adults and were studied in patients with episodic migraine and chronic migraine.<sup>2-5</sup> Although the diagnosis requirement was included in most MCO policies, the definitions of the number of migraine or headache days required to confirm a diagnosis varied significantly, especially for episodic migraine. This difference appears to reflect an inconsistency of each medication's pivotal clinical trial inclusion criteria.<sup>2-5</sup> Different diagnosis definitions among MCOs emphasize that PA criteria is determined by each MCO's clinical review of available literature.<sup>10</sup>

**TABLE 2.** Example Prior Authorization Criteria

Category <sup>a</sup>	Example criteria requiring a previous trial on ...	n (%) <sup>b,c</sup>
Definitive medication classes, example individual medications	"...2 medication classes, including β-blockers (eg, propranolol, etc) and anticonvulsants (eg, valproic acid, etc)."	13 (30%)
Definitive medication classes, definitive individual medications	"...2 medication classes, including β-blockers (ie, propranolol, carvedilol) and anticonvulsants (ie, valproic acid, divalproex)."	10 (23%)
Definitive medication classes, individual medications not listed	"...2 medication classes, including β-blockers and anticonvulsants."	6 (14%)
Example medication classes, example individual medications	"...2 medication classes, such as β-blockers (eg, propranolol, carvedilol), anticonvulsants (eg, valproic acid, divalproex), or antidepressants (eg, amitriptyline, venlafaxine)."	2 (5%)
Example medication classes, definitive individual medications	"...2 medication classes, such as β-blockers (propranolol, carvedilol), anticonvulsants (valproic acid, divalproex), or antidepressants (amitriptyline, venlafaxine)."	0 (0%)
Example medication classes, individual medications not listed	"...2 medication classes, such as β-blockers, anticonvulsants, antidepressants, etc."	6 (14%)
Medication classes not listed, definitive individual medications	"...2 medications, including propranolol and valproic acid."	4 (9%)
Medication classes not listed, example individual medications	"...2 medications, such as propranolol, valproic acid, amitriptyline, etc."	3 (7%)

<sup>a</sup>See eAppendix Table 1 for definitions of "definitive" and "example."

<sup>b</sup>The percentage of the 44 policies that required a previous trial on prophylactic migraine medications and listed alternatives.

<sup>c</sup>The sum of the percentages does not equal 100 due to rounding.

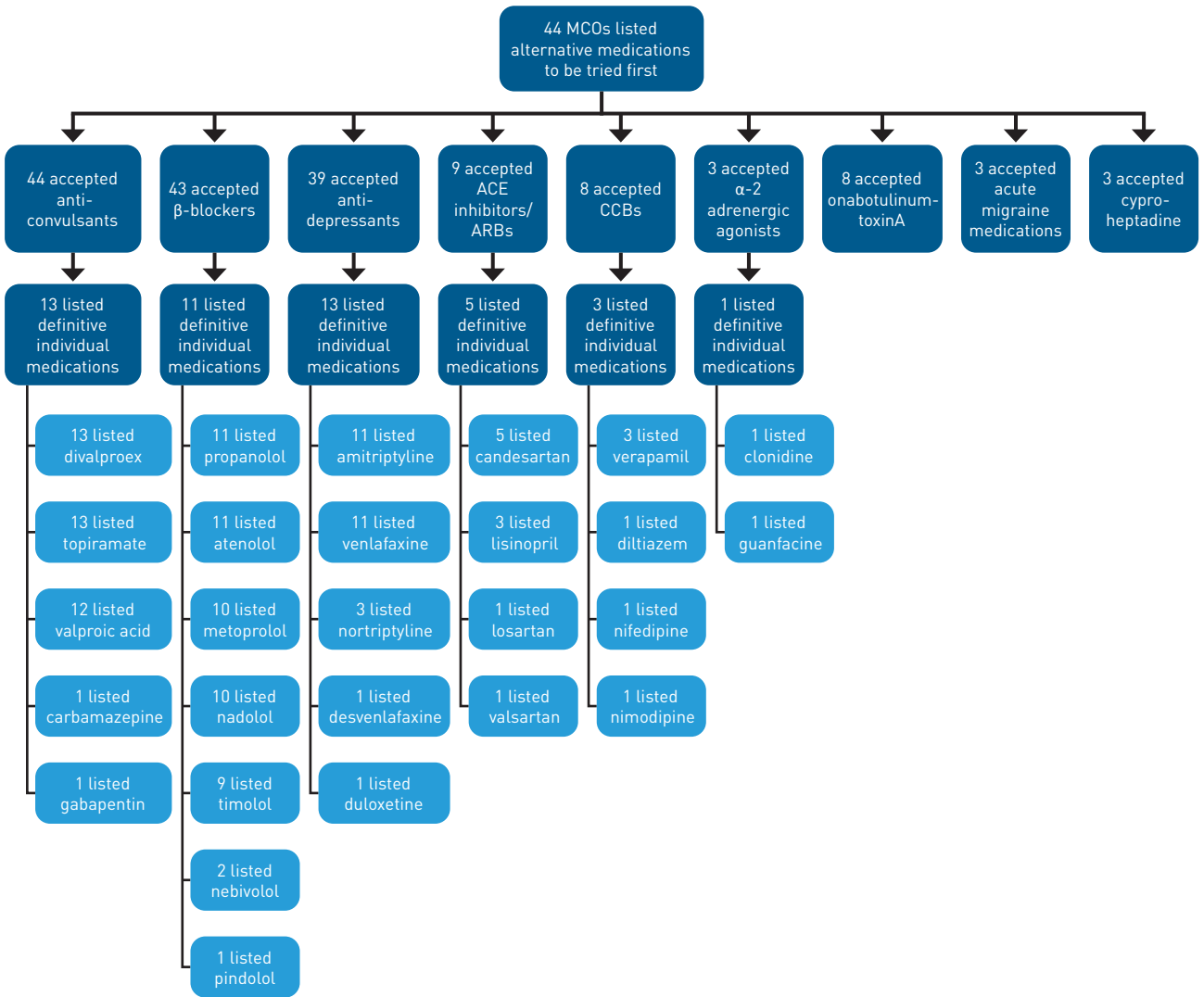
One of the few consistent areas among MCOs was requiring prerequisite drugs. However, the chosen verbiage used by MCOs differed, and this creates ambiguity for patients, providers, and possibly even those reviewing the medication requests from within each MCO. Choosing to list only individual drug names or classes, using definitive or example language, and employing various numbers of classes and trial lengths increases the complexity of coverage requirements among MCOs. Based on their interpretation of existing evidence, guidelines, and clinical compendia, certain MCOs may consider more migraine prophylaxis medications "appropriate" compared with other MCOs, leading to additional patient choice.<sup>20-22</sup>

Response to therapy as a reauthorization criterion was included by nearly all MCOs, but what was considered a positive response to therapy varied. Some MCOs were more particular with their requirements (eg, a decrease by a specific number of headache days), whereas some were more open ended and accepted any measure of improvement. The wide variety of reauthorization criteria identified through this analysis emphasizes differing opinions about appropriate disease control measures and their role in confirming medication efficacy. PA requirements, including reauthorization criteria, must strike a balance among provider autonomy, appropriate medication use, and cost containment.

Our study contributes to the existing literature on the topic of coverage differences among MCOs.<sup>13-18</sup> The number of PA policies analyzed in our study and the inclusion of all LOBs add to the current



**FIGURE 3.** Specific Medications Required in Calcitonin Gene-Related Peptide Antagonist Prior Authorization Policies



ACE, angiotensin-converting enzyme; ARB, angiotensin receptor blocker; CCB, calcium channel blocker; MCO, managed care organization.

literature, reinforcing the idea that variation in PA criteria exists across multiple LOBs.<sup>17</sup> Although PA is an effective cost-management tool and helps ensure appropriate medication utilization, our findings support previous conclusions that inconsistencies in PA requirements among MCOs can lead to an administrative burden for providers and delayed care for patients. Providers and patients should consider an MCO's formulary and utilization management options when recommending treatment or choosing coverage, as a disruption in medication access can affect the patient's condition.<sup>11</sup> Although consistency with clinical evidence is ideal, some degree of variation may be inevitable due to MCO-specific factors. Still, this variation may be desired, as it can create choice in benefit design for patients.

The intention of this study is not to identify or propose a "correct" set of PA requirements for CGRP antagonists. Instead, we aimed to identify similarities and differences among existing criteria to highlight trends and improve consistency among MCOs. Additionally, as providers desire a greater sense of transparency with regard to MCOs' PA criteria, we looked to offer providers a broad sense of the types of criteria commonly used by plans. Armed with this knowledge, health care providers may more effectively navigate the PA process, despite not knowing an individual MCO's specific criteria.

**Limitations**

Our study has several limitations. Although we were able to conduct a thorough analysis of each policy identified through our

comprehensive online search, whether all relevant policies were found is undeterminable. Still, the qualitative analysis reached a point of data saturation well before the full data set was evaluated.<sup>23</sup>

The structure of each MCO's PA policy differed, with some including criteria, such as an appropriate indication or the exclusion of concomitant medications, under alternate sections (eg, "Covered Uses," "Background," "Limitations of Coverage"). Because it is unclear how these are used by MCOs, we chose to exclude these sections, which may have affected our analysis. For example, whereas 34 MCOs required an appropriate diagnosis as part of their criteria, the remaining 13 mentioned the diagnosis elsewhere in their policies. That said, these sections consistently contained similar requirements to other approval criteria, so the defined categories of criteria would have not been affected.

Our decision to incorporate only the more restrictive criteria when more than 1 policy was identified for a given MCO may introduce bias. Although it is possible that stricter criteria are more specific and would inherently lead to a greater degree of variation in our findings, this applied to a small number of MCOs and did not impact the overall findings in a meaningful way.

Finally, we did not report any criterion that was incorporated by an MCO if it could not be appropriately reworded to maintain anonymity. However, unreported unique criteria represented rare circumstances that would not have affected the overall findings. To further protect anonymity, we did not detail inconsistencies in criteria by different LOBs, MCO types, or geographical locations. Due to the random distribution of the identified policies within these categories, regulatory factors were unlikely to influence the overall findings.

## CONCLUSIONS

This study identified 5 broad categories of PA criteria used by MCOs in the management of CGRP antagonists. However, within these categories, specific criteria from different MCOs varied significantly. ■

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(LM, SK); critical revision of the manuscript for important intellectual content (LM, SK); statistical analysis (LM, SK); provision of patients or study materials (LM, SK); administrative, technical, or logistic support (LM, SK); and supervision (LM, SK).

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**eAppendix Table 1.** Commonly Encountered Terms in Calcitonin Gene-Related Peptide Receptor Antagonist Prior Authorization Criteria

<b>General Definitions</b>	
Managed Care Organization	Includes health plans, pharmacy benefit managers, or other payers.
Search terms used to identify policies	The brand or generic name of each medication included in the study or “CGRP” AND keywords of “prior authorization,” “prior authorization criteria,” or “prior authorization policy.” For example, “erenumab prior authorization,” “CGRP prior authorization policy,” etc.
<b>Prescriber Specialization</b>	
Headache specialist	Includes any criteria that mention headache specialists, regardless if the specific certification requirement is included. Certification requirements may include the Certificate of Added Qualification in Headache Medicine from the National Headache Foundation, United Council for Neurologic Specialties Headache Board Certification, or others.
<b>Appropriate Use</b>	
Diagnosis/Indication	Includes any policy that requires the patient to have migraine with or without aura, episodic migraine, or chronic migraine and/or requires the medication to be used for migraine prophylaxis or an FDA or medically acceptable indication.
Episodic migraine	Definitions varied from one policy to the next, and included: $\geq 4$ migraine days per month, $\geq 5$ migraine days per month, 4-14 migraine days per month, 4-14 headache days per month, and/or $< 15$ headache days per month. In addition, some policies specified the number of headache or migraine days listed must have occurred for at least 3 months, whereas others did not.
Chronic migraine	Definitions varied from one policy to the next, and included: $\geq 8$ migraine days per month, $> 8$ migraine days per month, and/or $\geq 15$ headache days per month. In addition, some policies specified the number of headache or migraine days listed must have occurred for at least 3 months, whereas others did not.
<b>Alternative Medications to be Tried First</b>	
Example alternatives	Defined as any policy that did not strictly specify which alternatives must have been tried, but instead provided examples of other medications that could have been tried to meet the criteria. Terms used to identify these policies include, “e.g.,” “such as,” “not limited to,” and “etc.”
Definitive alternatives	Defined as any policy that strictly specified which alternatives must have been tried to meet the criteria. Definitive alternatives were identified in the absence of terms used to note example alternatives or if the term “i.e.” was used.
<b>Duration of Authorization and Response to Therapy</b>	
Authorization duration	A specified length of time for which the approval of the requested medication is granted.



**eAppendix Table 2.** Examples of a Managed Care Organization Applying Different Prior Authorization Criteria to Different Medications or Among Different Lines of Business

<b>Drug</b>	<b>Line of Business</b>	<b>Prior Authorization Criteria</b>	<b>Criteria Used in Analysis</b>
<i>Erenumab</i>	Commercial	Previous trial of <i>three</i> prophylactic agents	Trial of <i>three</i> prophylactic agents; and previous trial of one CGRP antagonist prior to approval
<i>Fremanezumab</i>	Commercial	Previous trial of <i>two</i> prophylactic agents; and previous trial of one CGRP antagonist	
Erenumab	<i>Commercial</i>	3 month initial approval, 12 month reauthorization period	3 month initial approval, 6 month reauthorization period
Erenumab	<i>Medicare</i>	6 month initial approval, 6 month reauthorization period	

**eAppendix Table 3.** Prior Authorization Requirements for Calcitonin Gene-Related Peptide Receptor Antagonist in Analyzed Managed Care Organization

<b>Prior Authorization Requirement Category</b>	<b>N (%)<sup>a,b</sup></b>
Prescriber Requirement	21 (45%)
“Prescribed by” a specialist	21 (100%)
Neurologist	20 (95%)
Pain specialist	11 (52%)
Headache specialist	9 (43%)
“In consultation with” a specialist	20 (95%)
Appropriate Use Requirements	-
Age Requirement	26 (55%)
18 years of age or older	24 (92%)
Appropriate age based on labeling	2 (8%)
Diagnosis	34 (72%)
Migraine with or without aura	7 (21%)
Episodic migraine	24 (71%)
Definition included	21 (88%)
Both < 15 headache days/month and 4-14 migraine days/month	8 (38%)
Only < 15 headache days/month	1 (5%)
Only 4-14 migraine days/month	1 (5%)
≥ 4 migraine days/month	7 (33%)
≥ 5 migraine days/month	1 (5%)
≥ 8 migraine days/month	1 (5%)
4-14 headache days/month	2 (10%)
Chronic migraine	24 (71%)
Definition included	21 (88%)
Both ≥ 15 headache days/month and 8 migraine days/month	15 (71%)
Only ≥ 15 headache days/month	2 (10%)
≥ 4 migraine days/month	4 (19%)
Exclusion of Other Diagnoses	17 (36%)
Medication overuse headache	15 (88%)
Other headache disorders	4 (24%)
Other medical conditions	3 (18%)
Exclusion of Concurrent Medications	22 (47%)
Second CGRP antagonist	19 (86%)
OnabotulinumtoxinA	18 (82%)
Prerequisite drugs	45 (96%)
1 alternative	13 (29%)
2 alternatives	25 (56%)
From different drug classes	21 (84%)
From “same or different” drug class	4 (16%)
3 alternatives	7 (16%)
From 3 different drug classes	6 (86%)
From 2 different drug classes	1 (14%)

Trial length	28 (62%)
4 weeks	7 (25%)
6 weeks	4 (14%)
8 weeks	10 (36%)
12 weeks	7 (25%)
Required adherence	5 (18%)
Alternative medications	44 (98%)
Anticonvulsants	44 (100%)
Beta-blockers	43 (98%)
Antidepressants	39 (89%)
ACE inhibitors/ARBs	9 (20%)
Calcium channel blockers	8 (18%)
OnabotulinumtoxinA	8 (18%)
Alpha-2 adrenergic agonists	3 (7%)
Cyproheptadine	3 (7%)
Acute migraine abortive medications	3 (7%)
Required trial on CGRP antagonist	18 (40%)
Listed one preferred CGRP antagonist in policy	4 (22%)
Listed two preferred CGRP antagonists in policy	14 (78%)
Previous trial of 1 CGRP antagonist	4 (29%)
Previous trial of 2 CGRP antagonists	10 (71%)
Preferred CGRP antagonist	18 (40%)
Galcanezumab	13 (72%)
Erenumab	13 (72%)
Fremanezumab	6 (33%)
Safety Requirements	8 (17%)
Included in both initial and reauthorization criteria	5 (63%)
Initial Authorization Duration	39 (83%)
3 months	20 (51%)
6 months	14 (36%)
12 months	5 (13%)
Reauthorization Duration	39 (83%)
6 months	5 (13%)
12 months	33 (85%)
Open-ended	1 (3%)
Response to Therapy	43 (91%)
Included 1 consideration of what constitutes response to therapy	15 (35%)
Included > 1 consideration of what constitutes response to therapy	28 (65%)
Reduction in number of migraines	38 (88%)
By a certain number or percentage	11 (29%)
Reduction in severity of migraines	19 (44%)
Reduction in the use of acute migraine medications	10 (23%)
Reduction in duration of migraines	6 (14%)
Improvement in function/productivity/quality of life	5 (12%)
Reduction in or no emergency or urgent care visits related to migraine	2 (5%)

Positive response to therapy	5 (12%)
Adherence required	3 (7%)

<sup>a</sup> Percentages do not sum to 100% as MCOs may have included multiple criteria within a single category and/or due to rounding.

<sup>b</sup> Percentages should be interpreted as a percent of the N in the broader category above each subcategory.

ACE – Angiotensin Converting Enzyme; ARB – Angiotensin Receptor Blocker; CGRP – Calcitonin Gene-Related Peptide; FDA – United States Food and Drug Administration