



**BlueCross BlueShield  
of Alabama**

**CGRP  
Prior Authorization with  
Quantity Limit  
Criteria Program Summary**

This prior authorization program applies to Commercial, GenPlus, NetResults A, SourceRx and Health Insurance Marketplace formularies.

**OBJECTIVE**

The intent of the CGRP prior authorization with quantity limit is to encourage appropriate use according to FDA labeling, guidelines, and/or clinical trial data.

**PROGRAM PRIOR AUTHORIZATION AND QUANTITY LIMIT TARGET AGENTS**

<b>Brand (generic)</b>	<b>GPI (NDC)</b>	<b>Multisource Code</b>	<b>Quantity Limit</b>
<b>(Aimovig (erenumab))</b>			
70 mg/mL autoinjector; 1 pack	6770202010D520 (55513-0841-01)	M, N, O, Y	1 autoinjectors / 30 days <sup>a</sup>
70 mg/mL autoinjector; 2 pack	6770202010D520 (55513-0841-02)	M, N, O, Y	2 autoinjectors / 30 days <sup>a</sup>
70 mg/mL prefilled <sup>a</sup> syringe	TBD	M, N, O, Y	2 prefilled syringes / 30 days <sup>a</sup>
<b>(fremanezumab)</b>			
TBD	TBD	M, N, O, Y	TBD based on FDA labeled maximum
<b>(galcanezumab)</b>			
TBD	TBD	M, N, O, Y	TBD based on FDA labeled maximum

a – quantity limit is cumulative to 2 x 70 mg injections per month between dosage forms

**PRIOR AUTHORIZATION AND QUANTITY LIMIT CRITERIA FOR APPROVAL**

**Initial Approval**

**Target Agents** will be approved when ALL of the following are met:

1. ONE of the following:
  - a. The patient has a diagnosis of chronic migraine as defined by BOTH of the following:
    - i. ≥15 headache days per month of migraine-like or tension-like headache for a minimum of 3 months
    - AND**
    - ii. ≥8 migraine headache days per month for a minimum of 3 months
  - OR**
  - b. BOTH of the following:
    - i. The patient has a diagnosis of episodic migraine AND ONE of the following:
      1. The patient has >4 migraine headaches per month
      - OR**
      2. The patient’s migraine headaches last >12 hours
      - OR**
      3. The patient’s migraine attacks cause significant disability or diminished quality of life despite appropriate acute treatment
      - OR**
      4. The patient has contraindications to acute therapies
      - OR**
      5. The patient has tried and received inadequate response to acute therapies

**OR**

6. The patient has serious side effects to acute therapies

**OR**

7. The patient is at risk of medication overuse headache without preventative therapy

**AND**

ii. The request is for Aimovig (erenumab)

**AND**

2. ONE of the following:

a. The patient has failed at least two migraine prophylaxis classes (anticonvulsants [divalproex, valproate, topiramate], beta blockers [atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [amitriptyline, venlafaxine]) after an adequate trial as defined by BOTH of the following:

i. The trial length was at least 6 weeks at generally accepted doses

**AND**

ii. The patient was  $\geq 80\%$  adherent to the prophylaxis agent during the trial

**OR**

b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an anticonvulsant, a beta blocker, AND an antidepressant listed above

**AND**

3. The patient has not received botulinum toxin injection for headache prophylaxis in the past 4 months

**AND**

4. The patient will not be initiating botulinum toxin headache prophylaxis after starting the requested agent

**AND**

5. The patient has been evaluated for and does not have medication overuse headache

**AND**

6. ONE of the following:

a. The patient is not currently taking another CGRP agent

**OR**

b. The other CGRP agent will be discontinued prior to beginning therapy with the requested agent

**AND**

7. The prescriber is a headache specialist (e.g. neurologist, The United Council for Neurologic Subspecialties [UCNS] certified) or has consulted with a headache specialist

**AND**

8. The patient does not have any FDA labeled contraindication(s) to the requested agent

**AND**

9. ONE of the following:

a. The requested quantity (dose) is NOT greater than the program quantity limit

**OR**

b. ALL of the following:

i. The requested quantity (dose) is greater than the program quantity limit

**AND**

ii. The requested quantity (dose) is less than or equal to the maximum FDA labeled dose

**AND**

iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit

**OR**

c. ALL of the following:

i. The requested quantity (dose) is greater than the program quantity limit

- AND**
- ii. The requested quantity (dose) is greater than the maximum FDA labeled dose
- AND**
- iii. The prescriber has submitted documentation in support of therapy with a higher dose for an accepted diagnosis (must be reviewed by the Clinical Review pharmacist)

**Length of Approval:** 3 months

### **Renewal Approval**

**Target Agents** will be approved when ALL of the following are met:

1. The patient has been approved for the requested agent previously through the Prime Therapeutics Prior Authorization process
- AND**
2. The prescriber has submitted documentation indicating improvement in migraine prevention (e.g. reduced migraine headache days, reduced migraine frequency, reduced use of acute abortive migraine medication) with the requested agent
- AND**
3. The patient has not received botulinum toxin injection for headache prophylaxis in the past 4 months
- AND**
4. The patient will not be initiating botulinum toxin headache prophylaxis while using the requested agent
- AND**
5. The patient has been evaluated for and does not have medication overuse headache
- AND**
6. The prescriber is a headache specialist (e.g. neurologist, The United Council for Neurologic Subspecialties [UCNS] certified) or has consulted with a headache specialist
- AND**
7. The patient does not have any FDA labeled contraindication(s) to the requested agent
- AND**
8. ONE of the following:
  - a. The requested quantity (dose) is NOT greater than the program quantity limit
  - OR**
  - b. ALL of the following:
    - i. The requested quantity (dose) is greater than the program quantity limit
    - AND**
    - ii. The requested quantity (dose) is less than or equal to the maximum FDA labeled dose
    - AND**
    - iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit
  - OR**
  - c. ALL of the following:
    - i. The requested quantity (dose) is greater than the program quantity limit
    - AND**
    - ii. The requested quantity (dose) is greater than the maximum FDA labeled dose
    - AND**
    - iii. The prescriber has submitted documentation in support of therapy with a higher dose for an accepted diagnosis (must be reviewed by the Clinical Review pharmacist)

**Length of Approval:** 12 months

*This pharmacy policy is not an authorization, certification, explanation of benefits or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All pharmacy policies are based on (i) information in FDA approved package inserts (and black box warning, alerts, or other information disseminated by the FDA as applicable); (ii) research of current medical and pharmacy literature; and/or (iii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*The purpose of Blue Cross and Blue Shield of Alabama's pharmacy policies are to provide a guide to coverage. Pharmacy policies are not intended to dictate to physicians how to practice medicine. Physicians should exercise their medical judgment in providing the care they feel is most appropriate for their patients.*

*Neither this policy, nor the successful adjudication of a pharmacy claim, is guarantee of payment.*

**FDA LABELED INDICATIONS<sup>1-3</sup>**

Agent	Indication	Dosage and Administration	Limitation of Use
<b>Aimovig™</b> (erenumab)  subcutaneous autoinjector, subcutaneous prefilled syringe	Preventive treatment of migraine in adults	Recommended dose is 70 mg once monthly  Some patients may benefit from 140 mg once monthly	None
(fremanezumab)	TBD	TBD	TBD
(galcanezumab)	TBD	TBD	TBD

**CLINICAL RATIONALE**

The calcitonin gene-related peptide (CGRP) is a therapeutic target in migraine because of its hypothesized role in mediating trigeminovascular pain transmission and the vasodilatory component of neurogenic inflammation.<sup>4</sup>

The diagnostic criteria for chronic migraine requires the inclusion of all of the following:<sup>10</sup>

- A. Headache (migraine-like or tension-like) on  $\geq 15$  days per month for  $> 3$  months and fulfilling criteria B and C
- B. Occurring in a patient who has had at least five attacks fulfilling of migraine without aura and/or migraine with aura
- C. On  $\geq 8$  days per month for  $> 3$  months, fulfilling any of the following:
  1. Migraine without aura
  2. Migraine with aura
  3. Believed by the patient to be migraine at onset and relieved by a triptan or ergot derivative
- D. Not better accounted for by another ICHD-3 diagnosis.

Migraine prevention may be of benefit in those with the following:<sup>4,9,13</sup>

- Frequent or long lasting migraine headaches ( $> 4$  headaches/month or headaches lasting  $> 12$  hours)
- Migraine attacks that cause significant disability or diminished quality of life despite appropriate acute treatment
- Contraindication to acute therapies
- Failure of acute therapies
- Serious adverse effects of acute therapies
- Risk of medication overuse headache
- Menstrual migraine (when acute abortive therapies are incomplete or unsatisfactory)<sup>12</sup>

Preventative pharmacotherapy for chronic migraine is less well studied than for episodic migraine. However, use of recommended episodic prevention agents is also recommended in chronic migraine. Clinical trials suggest efficacy is often first noted at four weeks and can continue to increase for three months.<sup>4</sup>

The American Headache Society and the American Academy of Neurology suggest the following agents for the prevention of migraine:<sup>9</sup>

- Established as effective
  - Antiepileptic drugs (AEDs)
    - Divalproex
    - Valproate
    - Topiramate

- Beta blockers
  - Metoprolol
  - Propranolol
  - Timolol
- Triptans
  - Frovatriptan for short term menstrually associated migraines (MAMs) prevention
- Probably effective
  - Antidepressants
    - Amitriptyline
    - Venlafaxine
  - Beta blockers
    - Atenolol
    - Nadolol
  - Triptans
    - Naratriptan, zolmitriptan for short term MAMs prevention

### **Erenumab**

Erenumab was studied in chronic migraine in a randomized, double-blind, placebo-controlled, phase 2 study. 656 men and women aged 18-65 years with a history of chronic migraine (with or without aura) were enrolled. In each of the 3 months before screening, patients had to have had 15 or more headache days per month, of which 8 or more of those days were migraine days. Patients were also required to be 80% compliant with their headache logs. Patients were excluded if they were older than 50 years at migraine onset and if they had a history of cluster headache or hemiplegic migraine, or chronic migraine with continuous pain. Patients were also excluded from the study if they had no therapeutic response (reduction in frequency, duration, or severity of headache) with prophylaxis of more than three treatment categories after an adequate trial (at least 6 weeks of treatment at generally accepted doses). Migraine preventive drugs were prohibited during the study and 2 months before the start of the baseline phase. Botulinum toxin injections in the head or neck region were prohibited during the study and for at least 4 months before the start of the baseline phase. At baseline, the monthly migraine days was 18.2 (SD 4.7) for the placebo group, 17.9 (SD 4.4) for the erenumab 70 mg group, and 17.8 (SD 4.7) for the 140 mg erenumab group. Monthly headache days was 21.1 (SD 3.9) for placebo, 20.5 (SD 3.8) for 70 mg erenumab group, and 20.7 (SD 3.8) mg for 140 erenumab group. Monthly acute migraine-specific drug use days was 9.6 (SD 7.6) for placebo, 8.8 (SD 7.2) for erenumab 70 mg, and 9.7 (SD 7.0) for erenumab 140 mg. Study outcomes were assessed after 12 weeks:<sup>5</sup>

- Monthly migraine days reduction was -4.2 (SE 0.4) days for placebo, 6.6 (SE 0.4) days for erenumab 70 mg and 140 mg.
- Both doses of erenumab showed a statistically significant difference in reduction of -2.5 (CI -3.5 to -1.4) days in monthly migraine days vs. placebo.
- Erenumab also exhibited statistically significant higher number of patients who were 50% responders (decrease of at least 50% migraine days vs. baseline) vs placebo. However, the percentage of 50% responders in both dosage strengths was in the minority (40% for 70 mg, 41% for 140 mg, 23% for placebo).
- There was a statistically significant difference in reduction of monthly acute migraine-specific drug treatment days for erenumab vs. placebo (-1.9 days vs placebo for 70 mg, -2.6 days vs placebo for 140 mg).
- There was not a statistically significant difference in cumulative monthly headache hours vs. placebo.

Erenumab's efficacy in episodic migraines was examined in two studies. Study 1 included 955 patients with episodic migraines. Patients were randomly assigned to either placebo, 70 mg of erenumab, or 140 mg erenumab. Patients had to have at least 4 and fewer than 15 migraine

days per month and fewer than 15 headache days per month on average during the 3 month screening period. Exclusion criteria included having received botulinum toxin within 4 months before or during the baseline phase, used devices or procedures for migraine prevention within 2 months before the baseline phase, or had had no therapeutic response to more than two migraine-preventive treatment categories. The study allowed enrollment of patients with concomitant use of 1 migraine preventative medication at a stable dose. Study outcomes were assessed after 24 weeks. Baseline and outcomes results are presented in Table 1 below.<sup>6</sup>

Table 1.

	Placebo	Erenumab 70 mg	Erenumab 140 mg
Baseline migraine days per month	8.2 (SD 2.5)	8.3 (SD 2.5)	8.3 mg (SD 2.5)
Baseline days of acute migraine-specific medication per month	3.4 (SD 3.4)	3.2 (SD 3.4)	3.4 (SD 3.5)
Monthly MPFID score	13.7 (SD 9.1)	14.0 (SD 8.9)	13.1 (SD 8.3)
Monthly MPFID physical-impairment score	12.2 (SD 9.4)	12.6 (SD 9.6)	12.0 (SD 9.0)
Primary endpoint - reduction from baseline in migraine days per month	-1.8 (SE 0.2)	-3.2 (SE 0.2)	-3.7 (SE 0.2)
Difference in reduction from baseline in migraine days per month vs. placebo	NA	-1.4 (95% CI -1.9 to -0.9)	-1.9 (95% CI -2.3 to -1.4)
Change from baseline in days of use of acute migraine-specific medication per month	-0.2 (SE 0.1)	-1.1 (SE 0.1)	-1.6 (SE 0.1)
Difference in reduction from baseline in days of use of acute migraine-specific medication vs. placebo	NA	-0.9 (95% CI -1.2 to -0.6)	-1.4 (95% CI -1.7 to -1.1)
Change in monthly MPFID everyday-activities score	-3.3 (SE 0.4)	-5.5 (SE 0.4)	-5.9 (SE 0.4)
Difference in reduction in monthly MPFID everyday-activities score vs. placebo	NA	-2.2 (95% CI -3.3 to -1.2)	-2.6 (95% CI -3.6 to -1.5)
Change in monthly MPFID physical-impairment score	-2.4 (SE 0.4)	-4.2 (SE 0.4)	-4.8 (SE 0.4)
Difference in reduction in monthly MPFID physical-impairment score vs. placebo	NA	-1.9 (95% CI -3.0 to -0.8)	-2.4 (95% CI -3.5 to -1.4)

MPFID - Migraine Physical Function

Study 2 was a randomized, multi-center, 3-month, placebo-controlled, double-blind study evaluating erenumab for the preventive treatment of episodic migraine. A total of 577 patients with a history of episodic migraine were randomized to receive either erenumab 70 mg (N = 286) or placebo (N = 291) by subcutaneous injection once monthly for 3 months. Exclusion criteria included use of botulinum toxin, patients with no response to >2 prophylactic treatments for migraine, and patients with medication overuse headache. Patients were allowed use of only 1 prophylactic medication during the study if the dosing for the prophylactic medication was stable within 2 months prior to the start of therapy. Results of the study are summarized in table 2 below:<sup>11</sup>

Table 2.

	Aimovig 70 mg once monthly	Placebo
Monthly Migraine Days (MMD)		
Change from baseline	-2.9	-1.8
Difference from placebo	-1.0	
p-value	<0.001	
≥50% MMD responders		
% Responders	39.7%	29.5%
Difference from placebo	10.2%	
Odds ratio relative to placebo	1.6	
p-value	0.01	
Monthly acute migraine-specific medication days		
Change from baseline	-1.2	-0.6
Difference from placebo	-0.6	
p-value	0.002	

In the episodic studies, 10-20% of patients on erenumab either did not see a reduction or saw an increase in migraine days per month vs. 25-30% for placebo.<sup>6,11</sup>

### Fremanezumab

Fremanezumab was studied in a double-blind, randomized, placebo-controlled, phase 3 trial with 1130 patients. Individuals were randomized to receive placebo, fremanezumab quarterly, or fremanezumab monthly. Inclusion criteria included an age of 18-70 years, a history of migraine for at least 12 months, history of chronic migraine (headache of any duration or severity on ≥15 days and migraine headache on ≥8 days) during the 28 days prior to intervention. Up to 30% of patients using a stable dose of one migraine-preventive medication for at least 2 months were allowed to continue these medications. Key exclusion criteria were the use of onabotulinum toxin A during the 4 months before screening, the use of interventions or devices for migraine such as nerve blocks and transcranial magnetic stimulation during the 2 months before screening, the use of opioids or barbiturates on more than 4 days prior to intervention, and lack of efficacy of at least two or four clusters of preventative medications after an adequate therapeutic trial. Study outcomes were assessed after 12 weeks:<sup>7</sup>

- The primary endpoint of least squares mean change from baseline of average number of headache days per month was -4.3 (SE0.3) for fremanezumab administered quarterly, -4.6 (SE 0.3) for fremanezumab administered monthly, and -2.5 (SE 0.3) for placebo. The difference between placebo and the two fremanezumab arms were statistically significant.
- The least squares mean change from baseline in average number of migraine headache days per month was -4.9 (SE 0.4) for fremanezumab administered quarterly, -5.0 (SE 0.4) for fremanezumab administered monthly, and -3.2 (SE0.4) for placebo. The difference between placebo and the two fremanezumab arms were statistically significant.
- The percentage of patients with ≥50% reduction in average number of headache days per month was 38% for fremanezumab administered quarterly, 41% for fremanezumab administered monthly, and 18% for placebo
- The least squares mean change from baseline in average number of days of use of any acute headache medication per month was -3.7 (SE 0.3) for fremanezumab administered quarterly, -4.2 (SE 0.3) for fremanezumab administered monthly, and -1.9 (SE 0.3) for placebo. The difference between placebo and the two fremanezumab arms were statistically significant
- 79% of the fremanezumab administered quarterly, 77% of the fremanezumab administered monthly, and 79% of placebo arms were not receiving concomitant preventative medications. The least squares mean change from baseline in average



number of headache days per month for these patients was -4.6 (SE 0.3) for fremanezumab administered quarterly, -4.8 (SE0.3) for fremanezumab administered monthly, and 2.6 (SE 0.3) for placebo. The difference between placebo and the two fremanezumab arms were statistically significant.

- The average number of headache days per month showed statistically significant differences between the two fremanezumab arms and placebo during the 4 weeks period after the first dose.

### **Galcanezumab**

Galcanezumab was studied in a phase 2b trial in patients with episodic migraine. 936 patients were randomized to 1 of 5 treatment groups (2:1:1:1:1 ratio) to receive either placebo or 1 galcanezumab dose level (5, 50, 120, or 300mg), respectively. The study was separated into 4 study periods (SP). SP 1 (4-45 days) was for screening and washout. SP 2 (28-38 days) was the prospective baseline period for evaluating the frequency of migraine headache days (MHDs). SP 3 (3 months) was the double-blinded treatment period. And SP 4 (3 months) was the post-treatment period. Galcanezumab or placebo was administered by subcutaneous (SC) injection once monthly during office visits. Patients were required to track daily headache information starting in SP2. During the study, acute migraine treatments were allowed as needed (opioids or barbiturates were not permitted). Concomitant medications allowed included acetaminophen, nonsteroidal anti-inflammatory drugs, aspirin, triptans, corticosteroids (periodic topical or inhaled but not oral or injected), and ergotamines and their derivatives. Preventive treatments were permitted only during SP 4 at the discretion of the investigator. Patients were men and women 18 to 65 years of age with a history of migraine, with or without aura, for at least 1 year prior to enrollment. For inclusion, patients had to experience a frequency of 4 to 14 MHDs and at least 2 migraine attacks in a 28-day period during SP 2. Migraine onset must have occurred prior to age 50 years. Use of botulinum toxin A and B administered in the head or neck area must have been discontinued at least 4 months prior to SP 2. Patients were excluded from study participation for any of the following reasons: currently enrolled in or discontinued within the last 30 days from a clinical trial using any investigational drug or device; any current or previous exposure to a CGRP or nerve growth factor antibody; history of hemiplegic, ophthalmoplegic, or basilar-type migraine; history or presence of other medical illness indicating a medical problem that would preclude study participation; failure to respond to more than 2 effective migraine preventive treatments; evidence of significant active psychiatric disease; and pregnancy or lactation. Patients should have completed at least 80% of daily headache log entries during SP 2. The mean (SD) MHDs per month at baseline was 6.6 (2.7) and 6.7 (2.6) for placebo and galcanezumab respectively. The mean (SD) migraine attacks per month was 4.7 (1.5) and 4.7 (1.6) for placebo and galcanezumab respectively. The primary objective was to assess whether at least 1 dose of galcanezumab was superior to placebo in the prevention of migraine. The posterior probability of greater improvement in MHDs with galcanezumab, 120 mg (99.6%; -4.8 MHDs, 90% BCI, -5.4 to -4.2 MHDs) compared with placebo (-3.7 MHDs, 90% BCI, -4.1 to -3.2 MHDs) was greater than the specified threshold (95%) for the mean change from baseline in the number of MHDs at month 3. Least square (LS) mean change from baseline for secondary outcomes was statistically significantly different between galcanezumab, 120mg, and placebo at month 3 except for headache days: migraine plus probable MHDs (-5.9; 95% CI, -6.7 to -5.1; P < .001) vs placebo (-4.0; 95% CI, -4.6 to -3.4), probable MHD (-0.9; 95% CI, -1.3 to -0.6; P = .049) vs placebo (-0.5; 95% CI, -0.8 to -0.3), migraine attacks (-3.5; 95% CI, -3.9 to -3.0; P = .003) vs placebo (-2.7; 95% CI, -3.0 to -2.3), 50% response rate (47/62 [75.8%]; P = .03) vs placebo (78/126 [61.9%]), and 100% response rate (22/62 [35.5%]; P = 0.04) vs. placebo (29/126 [23.0%]).<sup>8</sup>

### **Safety**

Erenumab has no FDA labeled contraindications or black box warnings.<sup>1</sup>

Contraindications to fremanezumab include:<sup>2</sup>

- TBD

Fremanezumab contains the following black box warnings:<sup>2</sup>

- TBD

Contraindications to galcanezumab include:<sup>3</sup>

- TBD

Galcanezumab contains the following black box warnings:<sup>3</sup>

- TBD

## References:

1. Aimovig prescribing information. Amgen, Inc. May 2018.
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13. Silberstein SD. Practice parameter: Evidence-based guidelines for migraine headache (an evidence-based review) Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. September 26, 2000; 55 (6).

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