Effective Date **11/1/2021**
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Coverage Policy Number **IP0050**

Calcitonin Gene-Related Peptide (CGRP) Inhibitors for Employer Group Plans

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Related Coverage Resources

Botulinum Therapy
Rimegepant – (IP0147)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for the following injectable calcitonin gene-related peptide (CGRP) inhibitors:

- **Aimovig**® (erenumab injection for subcutaneous use)
- **Ajovy**® (fremanezumab-vfrm injection for subcutaneous use)
- **Emgality**® (galcanezumab-gnlm injection for subcutaneous use)
- **Vyepti**™ (eptinezumab-jjmr injection for intravenous use)

Medical Necessity Criteria

Calcitonin Gene-Related Peptide (CGRP) Inhibitor products (Aimovig, Ajovy, Emgality, and Vyepti) are considered medically necessary when the following are met:

I. **Aimovig (erenumab-aooe).** Individual meets **ONE** of the following (1 or 2):

1. **Migraine Headache Prevention.** Individual meets **ALL** of the following criteria (A, B, and C):
    A. Individual is 18 years of age or older
    B. Individual has 4 or more migraine headache days per month (prior to initiating a migraine-preventative medication)
    C. Documentation of **ONE** of the following (i or ii):
        i. Individual has had an inadequate response following a minimum 3 month trial of **TWO** different prescription migraine prevention therapies from different classes of migraine prophylaxis medications including the following:
            a. Antiepileptic drugs (divalproex sodium, valproate, topiramate)
            b. Antidepressants (amitriptyline, venlafaxine)
            c. Beta-blockers (metoprolol, propranolol, timolol)
            d. onabotulinumtoxinA (Botox)
        ii. Individual has a contraindication per FDA label, significant intolerance, or is not a candidate* for antiepileptic drugs, antidepressants, beta-blockers, and onabotulinumtoxinA (Botox)

    **Note: Not a candidate due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], or other attributes/conditions or is unable to administer and requires this dosage formulation*

2. **Migraine Headache Prevention, Concurrent Use of Erenumab-aooe (Aimovig) with OnabotulinumtoxinA (Botox).** Individual meets **ALL** of the following criteria (A, B, and C):
    A. Individual is 18 years of age or older
    B. Documentation of **ONE** of the following (i or ii):
        i. Individual has had an inadequate response following a minimum 3 month trial of **TWO** different prescription migraine prevention therapies from different classes of migraine prophylaxis medications including the following:
            a. Antiepileptic drugs (divalproex sodium, valproate, topiramate)
            b. Antidepressants (amitriptyline, venlafaxine)
            c. Beta-blockers (metoprolol, propranolol, timolol)
            d. onabotulinumtoxinA (Botox)
        ii. Individual has a contraindication per FDA label, significant intolerance, or is not a candidate* for antiepileptic drugs, antidepressants, and beta-blockers
    C. Individual is continuing to experience 4 or more migraine headache days per month after therapy with **ONE** of the following preventative treatments for chronic migraine (i or ii):
        i. A minimum 3 month trial of erenumab-aooe (Aimovig)
        ii. A minimum 6 month trial (2 injection cycles) of onabotulinumtoxinA (Botox)

    **Note: Not a candidate due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], or other attributes/conditions or is unable to administer and requires this dosage formulation*

II. Ajovy (fremanezumab-vfrm). Individual meets **ONE** of the following (1 or 2)

1. **Migraine Headache Prevention.** Individual meets **ALL** of the following criteria (A, B, and C):
    A. Individual is 18 years of age or older
    B. Individual has 4 or more migraine headache days per month (prior to initiating a migraine-preventative medication)
    C. Documentation of **ONE** of the following (i or ii):
        i. Individual has had an inadequate response following a minimum 3 month trial of **TWO** different prescription migraine prevention therapies from different classes of migraine prophylaxis medications including the following:
            a. Antiepileptic drugs (divalproex sodium, valproate, topiramate)
            b. Antidepressants (amitriptyline, venlafaxine)
            c. Beta-blockers (metoprolol, propranolol, timolol)

d. onabotulinumtoxinA (Botox)

ii. Individual has a contraindication per FDA label, significant intolerance, or is not a candidate* for antiepileptic drugs, antidepressants, beta-blockers, and onabotulinumtoxinA (Botox)

Note: Not a candidate due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], or other attributes/conditions or is unable to administer and requires this dosage formulation

2. **Migraine Headache Prevention, Concurrent Use of Fremanezumab-vfrm (Ajovy) with OnabotulinumtoxinA (Botox).** Individual meets **ALL** of the following criteria (A, B, and C):
   A. Individual is 18 years of age or older
   B. Documentation of **ONE** of the following (i or ii):
      i. Individual has had an inadequate response following a minimum 3 month trial of **TWO** different prescription migraine prevention therapies from different classes of migraine prophylaxis medications including the following:
         a. Antiepileptic drugs (divalproex sodium, valproate, topiramate)
         b. Antidepressants (amitriptyline, venlafaxine)
         c. Beta-blockers (metoprolol, propranolol, timolol)
         d. onabotulinumtoxinA (Botox)
      ii. Individual has a contraindication per FDA label, significant intolerance, or is not a candidate* for antiepileptic drugs, antidepressants, and beta-blockers
   C. Individual is continuing to experience 4 or more migraine headache days per month after therapy with **ONE** of the following preventative treatments for chronic migraine (i or ii):
      i. A minimum 3 month trial of fremanezumab-vfrm (Ajovy)
      ii. A minimum 6 month trial (2 injection cycles) of onabotulinumtoxinA (Botox)

Note: Not a candidate due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], or other attributes/conditions or is unable to administer and requires this dosage formulation

III. Emgality (galcanezumab-gnlm). Individual meets **ONE** of the following (1, 2, or 3):

1. **Episodic Cluster Headache Treatment.** Individual meets **ALL** of the following criteria (A, B, and C):
   A. Individual is 18 years of age or older
   B. Individual has between one headache every other day and eight headaches per day
   C. Documentation of **ONE** of the following (i or ii):
      i. Individual has had an inadequate response to **ONE** of the following (a or b)
         a. sumatriptan injectable
         b. zolmitriptan nasal spray[#]

         [#]*Prior authorization may apply*
      ii. Individual has a contraindication per FDA label, significant intolerance, or is not a candidate* for sumatriptan injectable and zolmitriptan nasal spray

Note: Not a candidate due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], or other attributes/conditions or is unable to administer and requires this dosage formulation

2. **Migraine Headache Prevention.** Individual meets **ALL** of the following criteria (A, B, and C):
   A. Individual is 18 years of age or older
   B. Individual has 4 or more migraine headache days per month (prior to initiating a migraine-preventative medication)
   C. Documentation of **ONE** of the following (i or ii):

i. Individual has had an inadequate response following a minimum 3 month trial of **TWO** different prescription migraine prevention therapies from different classes of migraine prophylaxis medications including the following:
    a. Antiepileptic drugs (divalproex sodium, valproate, topiramate)
    b. Antidepressants (amitriptyline, venlafaxine)
    c. Beta-blockers (metoprolol, propranolol, timolol)
    d. onabotulinumtoxinA (Botox)
ii. Individual has a contraindication per FDA label, significant intolerance, or is not a candidate* for antiepileptic drugs, antidepressants, beta-blockers, and onabotulinumtoxinA (Botox)

**Note: Not a candidate due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], or other attributes/conditions or is unable to administer and requires this dosage formulation*

3. **Migraine Headache Prevention, Concurrent Use of Galcanezumab-gnlm (Emgality) with OnabotulinumtoxinA (Botox).** Individual meets **ALL** of the following criteria (A, B, and C):
    A. Individual is 18 years of age or older
    B. Documentation of **ONE** of the following (i or ii):
        i. Individual has had an inadequate response following a minimum 3 month trial of **TWO** different prescription migraine prevention therapies from different classes of migraine prophylaxis medications including the following:
            a. Antiepileptic drugs (divalproex sodium, valproate, topiramate)
            b. Antidepressants (amitriptyline, venlafaxine)
            c. Beta-blockers (metoprolol, propranolol, timolol)
            d. onabotulinumtoxinA (Botox)
        ii. Individual has a contraindication per FDA label, significant intolerance, or is not a candidate* for antiepileptic drugs, antidepressants, and beta-blockers
    C. Individual is continuing to experience 4 or more migraine headache days per month after therapy with **ONE** of the following preventative treatments for chronic migraine (i or ii):
        i. A minimum 3 month trial of galcanezumab-gnlm (Emgality)
        ii. A minimum 6 month trial (2 injection cycles) of onabotulinumtoxinA (Botox)

    **Note: Not a candidate due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], or other attributes/conditions or is unable to administer and requires this dosage formulation*

IV. Vyepti (eptinezumab-jjmr). Individual meets **ONE** of the following (1 or 2):

1. **Migraine Headache Prevention.** Individual meets **ALL** of the following criteria (A, B, C, and D):
    A. Individual is 18 years of age or older
    B. Individual has 4 or more migraine headache days per month (prior to initiating a migraine-preventative medication)
    C. Documentation of **ONE** of the following (i or ii):
        i. Individual has had an inadequate response to at least **ONE** triptan (for example, almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan)
        ii. Individual has a contraindication per FDA label, significant intolerance, or is not a candidate* for triptans.
    D. Documentation of **ONE** of the following (i or ii):
        i. Individual has had an inadequate response following a minimum 3 month trial of **TWO** different prescription migraine prevention therapies from different classes of migraine prophylaxis medications including the following:
            a. Antiepileptic drugs (divalproex sodium, valproate, topiramate)
            b. Antidepressants (amitriptyline, venlafaxine)
            c. Beta-blockers (metoprolol, propranolol, timolol)

d. onabotulinumtoxinA (Botox)

ii. Individual has a contraindication per FDA label, significant intolerance, or is not a candidate* for antiepileptic drugs, antidepressants, beta-blockers, and onabotulinumtoxinA (Botox)

**Note: Not a candidate due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], or other attributes/conditions or is unable to administer and requires this dosage formulation*

2. **Migraine Headache Prevention, Concurrent Use of Eptinezumab-jjmr (Vyepti) with OnabotulinumtoxinA (Botox).** Individual meets **ALL** of the following criteria (A, B, C, and D):
   A. Individual is 18 years of age or older
   B. Documentation of **ONE** of the following (i or ii):
      i. Individual has had an inadequate response to at least **ONE** triptan (for example, almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan)
      ii. Individual has a contraindication per FDA label, significant intolerance, or is not a candidate* for triptans.
   C. Documentation of **ONE** of the following (i or ii):
      i. Individual has had an inadequate response following a minimum 3 month trial of **TWO** different prescription migraine prevention therapies from different classes of migraine prophylaxis medications including the following:
         a. Antiepileptic drugs (divalproex sodium, valproate, topiramate)
         b. Antidepressants (amitriptyline, venlafaxine)
         c. Beta-blockers (metoprolol, propranolol, timolol)
         d. onabotulinumtoxinA (Botox)
      ii. Individual has a contraindication per FDA label, significant intolerance, or is not a candidate* for antiepileptic drugs, antidepressants, and beta-blockers
   D. Individual is continuing to experience 4 or more migraine headache days per month after therapy with **ONE** of the following preventative treatments for chronic migraine (i or ii):
      i. A minimum 3 month trial of eptinezumab-jjmr (Vyepti)
      ii. A minimum 6 month trial (2 injection cycles) of onabotulinumtoxinA (Botox)

      **Note: Not a candidate due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], or other attributes/conditions or is unable to administer and requires this dosage formulation*

Coverage for calcitonin gene-related peptide (CGRP) inhibitors varies across plans and may require the use of preferred products in addition to the medical necessity criteria listed above. Refer to the customer's benefit plan document for coverage details.

When coverage requires the use of preferred products, there is documentation of **ONE** of the following:

A. The individual has had inadequate efficacy (following a minimum 3 month trial) to the number of covered alternatives according to the table below

OR

B. The individual has a contraindication according to FDA label, significant intolerance, or is not a candidate* for the covered alternatives according to the table below
**Note: Not a candidate due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], other attributes/conditions, or is unable to administer and requires this dosage formulation)*

Employer Group Non-Covered Products and Preferred Covered Alternatives by Drug List:

Non-Covered Product	Standard / Performance	Value / Advantage	Cigna Total Savings	Legacy
Aimovig (erenumab-aooe)	**Preferred product**			
Ajovy (fremanezumab-vfrm)	**Preferred product**			
Emgality (galcanezumab-gnlm)	**Preferred product**			
Vyepti (eptinezumab-jjmr)	**TWO** of the following: • erenumab-aooe (Aimovig)[#] • fremanezumab-vfrm (Ajovy)[#] • galcanezumab-gnlm (Emgality)[#]			

[#]*Prior authorization may apply*

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Calcitonin gene-related peptide (CGRP) inhibitors (Aimovig, Ajovy, Emgality and Vyepti) are considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response (for example, reduction in monthly migraine days or hours or reduction in days requiring acute migraine-specific treatment)

Authorization Duration

Aimovig (erenumab-aooe)

Migraine Headache Prevention (at a dose of either 70 mg OR 140 mg once monthly):

- Initial approval duration: up to 6 months
- Reauthorization approval duration: up to 12 months

Ajovy (fremanezumab-vfrm)

Migraine Headache Prevention (at a dose of either 225 mg monthly OR 675 mg every 3 months):

- Initial approval duration: up to 6 months
- Reauthorization approval duration: up to 12 months

Emgality (galcanezumab-gnlm)

Episodic Cluster Headache Treatment [at a dose of 300 mg (3 consecutive subcutaneous injections of 100 mg each) at the onset of the cluster period, and then monthly until the end of the cluster period]:

- Initial approval duration: up to 3 months
- Reauthorization approval duration: up to 6 months

Migraine Headache Prevention (loading dose of 240 mg (month 1), followed by monthly doses of 120 mg):

- Initial approval duration: up to 6 months
- Reauthorization approval duration: up to 12 months

Vyepti (eptinezumab-jjmr)
Migraine Headache Prevention (at a dose of either 100 mg or 300 mg every 3 months)
- Initial approval duration: up to 6 months
- Reauthorization approval duration: up to 12 months

Conditions Not Covered

Aimovig, Ajovy, Emgality and Vyepti are considered experimental, investigational or unproven for **ANY** other use including the following (this list may not be all inclusive):

1. **Acute Treatment of Migraine.**
   Aimovig, Ajovy, Emgality and Vyepti have not been studied for the acute treatment of migraine.

2. **Cluster Headache, Treatment or Prevention (Aimovig, Ajovy and Vyepti only).**
   Aimovig has not been studied in patients with cluster headache. The pivotal trials of Aimovig excluded patients with this condition.[7,8] Ajovy has not been found to be effective in in patients with chronic or episodic cluster headache.[12] Vyepti has not been studied in patients with cluster headache. The pivotal trials of Vyepti excluded patients with this condition.[13,14]

3. **Concurrent use (for example, during the same time period) of two CGRP inhibitors indicated for the preventative treatment of migraine (for example, Aimovig, Ajovy, Emgality, Nurtec ODT, Vyepti)**

4. **Hemiplegic Migraine, Treatment or Prevention.**
   Aimovig has not been studied in patients with hemiplegic migraine. The pivotal trials of Aimovig excluded patients with this condition.[7,8]

Background

Overview
Aimovig, a calcitonin gene-related peptide (CGRP) receptor antagonist, is indicated for the preventive treatment of migraine in adults.[1] Aimovig is a human monoclonal antibody that binds to the CGRP receptor and antagonizes CGRP receptor function. The recommended dosage of Aimovig is 70 mg injected subcutaneously (SC) once monthly. Some patients may benefit from a dosage of 140 mg SC once monthly.

Ajovy, a calcitonin gene-related peptide (CGRP) antagonist, is indicated for the preventive treatment of migraine in adults.[9] Ajovy is a human monoclonal antibody that binds to the CGRP ligand and blocks its binding to the receptor. The recommended dosage of Ajovy is 225 mg injected subcutaneously (SC) once monthly or 675 mg every 3 months (quarterly), which is administered as three consecutive SC injections of 225 mg each. A healthcare professional, patient, and/or caregiver may administer Ajovy.

Emgality, a calcitonin gene-related peptide (CGRP) antagonist, is indicated for the preventive treatment of migraine in adults and for the treatment of episodic cluster headache in adults.[10] Emgality is a human monoclonal antibody that binds to the CGRP ligand and blocks its binding to the receptor. The recommended dosage of Emgality for the prevention of migraine is 240 mg (two consecutive subcutaneous [SC] injections of 120 mg each) once as a loading dose, followed by monthly doses of 120 mg injected subcutaneously. For cluster headache, Emgality is dosed as 300 mg SC (administered as three consecutive injections of 100 mg each) at the onset of the cluster period, and then monthly until the end of the cluster period. Emgality is intended for patient self-administration.

Vyepti, a calcitonin gene-related peptide (CGRP) inhibitor, is indicated for the preventive treatment of migraine in adults.[11] Vyepti is a humanized monoclonal antibody produced in *Pichia pastoris* yeast cells by recombinant DNA technology. Vyepti binds to the CGRP ligand and blocks its binding to the CGRP receptor. The recommended dosage is 100 mg administered by intravenous (IV) infusion over approximately 30 minutes once every 3 months; however, some patients may benefit from a dosage of 300 mg IV once every 3 months. Vyepti must be administered by a healthcare provider.

Disease Overview
Migraine is a common, chronic condition marked by paroxysmal, unilateral attacks of moderate-to-severe throbbing headache which is aggravated by routine physical activity (e.g., walking or climbing stairs) and associated with nausea, vomiting, and/or photophobia and phonophobia.[2] Migraine headache episodes typically last 4 to 72 hours if untreated. Migraine affects approximately 15% of US adults.[3] Migraines have been defined as chronic or episodic. Chronic migraine is described by the International Headache Society as headache occurring on ≥ 15 days/month for > 3 months and has the features of migraine headache on ≥ 8 days/month.[2] Episodic migraine is characterized by headaches that occur < 15 days/month.[4] Patients with episodic migraine may transform to chronic migraine over time at a rate of about 2.5% of episodic-migraine patients/year. Potential strategies for preventing migraine transformation include preventing and treating headaches, lifestyle modifications, or effective management of comorbidities (e.g., obesity, obstructive sleep apnea, depression, anxiety). Episodic migraine is more common than chronic migraine; however, chronic migraine is associated with a markedly greater personal and societal burden.

Guidelines
An updated assessment of the **preventive and acute treatment of migraine** by the **American Headache Society** (2018) reaffirms previous migraine guidelines.[5] Patients with migraine should be considered for preventive treatment when attacks significantly interfere with patients' daily routines despite acute treatment; frequent attacks (≥ 4 monthly headache days); contraindication to, failure, overuse, or adverse events with acute treatments; or patient preference. Before developing a preventive treatment plan, the appropriate use (e.g., drug type, route and timing of administration, frequency) of acute treatments should be initiated and coupled with education and lifestyle modifications. All patients with migraine should be offered a trial of acute treatment. Based on the level of evidence for efficacy and the American Academy of Neurology (AAN) scheme for classification of evidence, the following oral treatments have established efficacy and should be offered for migraine prevention: antiepileptic drugs (divalproex sodium, valproate sodium, topiramate [not for women of childbearing potential without a reliable method of birth control]); beta-blockers (metoprolol, propranolol, timolol); and frovatriptan (for short-term preventive treatment of menstrual migraine).[6] The following treatments are probably effective and should be considered for migraine prevention: antidepressants (amitriptyline, venlafaxine); beta-blockers (atenolol, nadolol); and angiotensin receptor blockers (candesartan).

Four injectable preventive therapies for migraine are mentioned in the AHS consensus statement: Botox® (onabotulinumtoxinA injection) and three monoclonal antibodies targeting CGRP (Aimovig, Ajovy® [fremanezumab-vfrm injection], and Emgality® [galcanezumab-gnlm injection]).[5] The update notes that a CGRP inhibitor should only be initiated in patients who are diagnosed with migraine, have ≥ 4 migraine headache days per month, and have intolerance or inadequate response to 6-week trials of at least two traditional oral migraine preventive medications. Additional criteria apply depending on the number and severity of monthly headache days. Clinical judgment may result in an emerging treatment being added to one or more established treatments. If initiating treatment with a CGRP inhibitor in a patient already on a preventive treatment, it is appropriate to add the CGRP inhibitor to the existing regimen and make no other changes until the effectiveness of the CGRP inhibitor is determined since the risk of interactions between traditional oral migraine preventive medications and the CGRP inhibitors is minimal or nonexistent. Making a decision regarding continuation of therapy for a CGRP inhibitor requires a trial of the medication for at least 3 months, and treatment should be continued only if benefits can be documented during that time (e.g., reduction in mean monthly headache days of ≥ 50% relative to the pretreatment baseline). Since migraine may improve or remit over time, it is important to reevaluate therapeutic response and, if possible, taper or discontinue treatment if patients no longer meet the criteria for offering preventive treatment. However, once control is established, the decision to discontinue or taper treatment should be a shared decision between patient and clinician.

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