

## PHARMACY POLICY – 5.01.503

## Migraine and Cluster Headache Medications

Effective Date: Aug. 1, 2018

Last Revised: July 10, 2018


Replaces: N/A

RELATED MEDICAL POLICIES:

5.01.584 CGRP Inhibitors for Migraine Prophylaxis

Select a hyperlink below to be directed to that section.

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## Introduction

There are many different types of headaches. Tension headaches are the most common form and can be treated with over-the-counter pain relievers, like aspirin or ibuprofen. Migraine and cluster headaches are more severe and may need prescription medication.

Migraine is a debilitating disease, with severe headaches. Some people have other symptoms like seeing auras, experiencing nausea or vomiting, and suffering an inability to tolerate bright light or loud noises. About one in eight Americans has migraines. It's the seventh most disabling disease worldwide. Women are twice as likely as men to suffer from migraine.

Some people have just a few headaches a month. These may be treated with pills like ibuprofen or prescription medications like sumatriptan. These treatments stop the headaches after they've started. However, if people take too much of the headache-stopping medications, over time they may end up with more headaches. This is poor long-term strategy.

Cluster headaches are severe headaches that come on quickly, last 30 to 90 minutes, go away, and then come back a little while later. They are different from migraine headaches. Patients with cluster headaches may need a different approach to treatment, though using many of the same drugs.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## Policy Coverage Criteria

**Note:** The medications addressed in this policy may be considered medically necessary for the FDA- approved ages.

### Medical Necessity

**The medications covered by this policy may be considered medically necessary for the treatment of migraine and cluster headaches when one or more of the following conditions is/are met:**

- The quantity dispensed is in accordance with the table below

**OR**

- The prescription is for an oral or intranasal formulation NOT in excess of 30 doses per 30 day time period, **AND** the patient has unsuccessfully tried at least three categories of prophylactic migraine headache therapies listed in the [Appendix](#) section (unless such are contraindicated).

**Prescriptions to treat headaches not meeting the above criteria may be considered medically necessary based on the clinical circumstances of an individual patient.**

**Brand name oral, injectable, nasal spray, nasal powder, or patch triptan products (other than Treximet®) will be considered medically necessary in quantities not exceeding 18 tablets, 8 injections, 18 nasal sprays, 8 nasal powder inhalations, or 4 patches (respectively) per 30 days when the patient has had a trial and failure of at least two different generic triptan products in any dosage form (ie, oral, injectable, or nasal spray).**

**If the requested medication is a multisource brand and has a generic equivalent, then one of the required generic trials must be the generic version of the brand name medication that is being requested.**

**Note:** For quantities in excess of 18 tablets, 8 injections, 18 nasal sprays, 8 nasal powder inhalations, or 4 patches per 30 days, please see [Criteria for Approving Additional Quantities](#) below.

**Treximet® (sumatriptan/naproxen combination) may be considered medically necessary in quantities not exceeding 18 tablets per 30 days when the patient has failed a trial of generic sumatriptan in combination with two generic NSAIDs, one of which MUST be generic naproxen.**

**Note:** For quantities in excess of 18 tablets per 30 days, please see [Criteria for Approving Additional Quantities](#)



Medical Necessity
below.
<b>All other uses of the medications addressed by this policy are considered not medically necessary.</b>

Criteria for Approving Additional Quantities
<p><b>Criteria for Approving Additional Quantities of Triptans for Migraine</b></p> <ul style="list-style-type: none"> <li>• Patient has failed a trial of a different triptan prior to dose escalation</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Doses are not exceeding FDA labeled maximum daily doses</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Patient is not experiencing medication overuse headache(s)</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Patient has unsuccessfully tried at least three categories of prophylactic migraine headache therapies listed in the <a href="#">Appendix</a> (unless contraindicated)</li> </ul>
<p><b>Criteria for Approving Additional Quantities of Triptans for Cluster Headache</b></p> <ul style="list-style-type: none"> <li>• Patient has unsuccessfully tried at least three categories of other cluster headache therapy relievers from Headache Treatment Overview listed in the <a href="#">Appendix</a></li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Patient has used at least three categories of prophylactic cluster headache therapies (unless contraindicated)</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Doses are not exceeding FDA labeled maximum daily doses</li> </ul>

Maximum standard quantities of the listed medications in a rolling 30-day time period are provided in the following table. These quantities are based on national guidelines<sup>26</sup> and standard of care as indicated by local expert opinion. It is important to note that the American Headache Society recommends the use of triptans not exceeding 10 days/month to prevent the development of medication overuse headache.

Dosage and Quantity Limits	
Drug Name, Strength and Dosage Form(s)	Maximum Quantity of Medication in a 30 Day Time Period
<b>All oral triptans (including oral dissolving tablet dosage form)</b>	<ul style="list-style-type: none"> <li>• 18 tablets</li> </ul>
<b>Butorphanol NS 10 mg/mL nasal spray</b>	<ul style="list-style-type: none"> <li>• 2 canisters</li> </ul>



Dosage and Quantity Limits	
Drug Name, Strength and Dosage Form(s)	Maximum Quantity of Medication in a 30 Day Time Period
<b>Migranal® (Dihydroergotamine) Nasal Spray</b>	<ul style="list-style-type: none"> <li>8 ampules</li> </ul>
<b>Zomig 2.5mg and 5 mg Nasal Spray</b>	<ul style="list-style-type: none"> <li>18 nasal sprays</li> </ul>
<b>Sumatriptan injection</b>	<ul style="list-style-type: none"> <li>4 injectable kits (8 injections)</li> <li>8 single-dose vials (8 injections)</li> <li>8 needle-free delivery devices (8 injections)</li> </ul>
<b>Sumatriptan nasal spray</b>	<ul style="list-style-type: none"> <li>18 nasal sprays</li> </ul>
<b>Sumatriptan patch</b>	<ul style="list-style-type: none"> <li>1 carton (4 patches)</li> </ul>
<b>Sumatriptan nasal powder</b>	<ul style="list-style-type: none"> <li>8 doses (16 capsules for inhalation; 1 per each nostril)</li> </ul>

## Coding

Code	Description
<b>CPT</b>	
J3030	Injection, sumatriptan succinate, 6 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)

## Related Information

### Benefit Application

This policy is managed through the Pharmacy benefit.

The limitation of migraine headache therapies in a rolling 30-day period is in conformance to member contracts, which state quantities may be limited based on medical necessity. Exceptions to pharmacy prior authorization duration/quantity limitations will be made on a case-by-case basis after review of patient medical records.



This policy is applicable to enrollees who are managed by the Company's Pharmacy Formulary. It does not apply to enrollees managed under the Express Scripts Formulary.

## Evidence Review

### Description

Migraine headache is a common disorder seen in clinical practice. According to the U.S. National Center for Health Statistics, the overall age-adjusted 3-month prevalence of migraine is 19.1% in women and 9.0% in men in the United States, almost half of whom are undiagnosed or undertreated. Most headaches are caused by the primary headache disorders, which include migraine, cluster, and tension-type headaches. Secondary headaches, which are those with underlying pathologic causes, are far less common. Migraine is a chronic condition with recurrent acute attacks whose characteristics vary among patients and often even among attacks within a single patient. Migraine is a syndrome with a wide variety of neurologic and non-neurologic manifestations. The International Headache Society has developed diagnostic criteria for migraine with and without aura. Clinicians should bear in mind that a patient may suffer from headaches arising from multiple etiologies. Most recently, attention has been focused on possible confusion between sinus headache and migraine, which often mimics sinus symptoms (congestion, rhinorrhea, etc.).

Appropriate management of the headache patient includes several components:

- Accurate diagnosis of the patient's condition.
- Effective pharmacological management of acute attacks, including a rescue strategy designed to minimize emergency department utilization.
- Prophylactic strategies to reduce attack frequency and mitigate their effect on function and quality of life. These should include trigger avoidance when possible, as well as maintenance pharmacotherapy in patients with more frequent headaches.
- Patients with frequent and severely disabling headaches may benefit from referral to a multidisciplinary headache specialty service where a holistic approach is applied to optimize the patient's functional status.

Patient self-management is an important strategy in migraine treatment. Numerous tools are available to the patient and primary care practitioner to facilitate this approach.



The "triptan" medications, including almotriptan (Axert®), eletriptan (Relpax®), frovatriptan (Frova®), naratriptan (Amerge), rizatriptan (Maxalt®), sumatriptan (Imitrex®), sumatriptan 85mg/naproxen 500mg (Treximet®), and zolmitriptan (Zomig®), are specific 5-hydroxytryptamine (5-HT<sub>1B/1D</sub>) receptor agonists used in the abortive treatment of acute migraine or cluster headaches with or without aura. Triptans selectively bind to the 5-HT<sub>1D</sub> receptors on T<sub>6</sub> sensory afferent neurons and 5-HT<sub>1B</sub> receptors on meningeal vasculature. While the etiology of migraine is still not completely understood, the use of 5-HT agonists results in cranial vasoconstriction and inhibition of pro-inflammatory neuropeptide release, which correlates with the relief of migraine.

Dihydroergotamines (Migranal® Nasal Spray and DHE 45 injection) are thought to relieve migraine headaches by constricting peripheral and cranial blood vessels and depressing central vasomotor centers. Dihydroergotamine (DHE) is an alpha-adrenergic blocking agent with a direct stimulating effect on the smooth muscle of peripheral and cranial blood vessels, which produces depression of the central vasomotor centers. DHE is a mixed serotonin agonist/antagonist, and is thought primarily to compensate for insufficient plasma serotonin levels. DHE has a high affinity to 5-HT<sub>1B/1D</sub>, 1A, 2A, 2C as well as to Alpha<sub>1</sub> 2a, 2b and Dopamine D<sub>2</sub>, D<sub>3</sub> receptors. Therapeutic activity is thought to be due to binding at the 5-HT<sub>1D</sub> receptor, preventing neuropeptide release from the trigeminal afferent terminals and blocking neurogenic inflammation. 5-HT<sub>1D</sub> activity leads to vasoconstriction that is more prolonged than that of the triptan class, due to a relatively longer T<sub>1/2</sub> = 10 hours. In addition, the serotonin-stimulating effect of DHE at the 5-HT<sub>1D</sub> and 5-HT<sub>1A</sub> receptor sites counteracts the loss of tone of the extracranial vascular musculature seen in migraine headaches.

Charles and von Dohn reported results of a study of 31 patients with chronic daily headache treated with outpatient home-based continuous intravenous dihydroergotamine for 3 days. They administered 3 mg dihydroergotamine given continuously at a rate of 42 ml/hour on day 1 and 2, and administered 1.5 mg on day 3 at the rate of 21 ml/hour. Patients reported an average of 63.4% reduction in pain intensity at the end of the 3-day infusion (11-point VAS). Side effects were minimal and no serious adverse effects occurred. Approximately one-third of patients became completely headache-free after day 3, and 1 patient had no improvement. An average 86% reduction in headache frequency was observed on follow up and all but one patient converted to episodic migraine. The authors concluded that efficacy and safety of this home-based IV dihydroergotamine withdrawal protocol compared favorably to established inpatient protocols and provides an effective, safe and less expensive outpatient alternative.

Butorphanol NS is a potent analgesic with mixed opioid agonist/antagonist effects, but it is not for migraine-specific treatment. While this agent may be appropriately self-administered as a rescue medication in occasional cases where the patient's other medications have failed, overuse



carries a significant risk of developing tolerance and dependence. It should be prescribed for self-administration with extreme caution. This information in no way supports butorphanol NS for the treatment of migraine.

## Medication overuse

Medication overuse continues to be a concern. Prophylaxis with an expanding variety of drugs, eg, valproate, topiramate and levetiracetam, is reported. The traditional pharmacologic classes of beta-blockers, calcium channel blockers and antidepressants continue to be popular. Calcitonin gene-related peptide receptor antagonists are a new pharmacologic class that appears promising and is being investigated for migraine prophylaxis. Overuse of abortive treatments is worrisome because it creates feedback increasing headache frequency, which in turn increases the amount of medication used. The net result is decrease in control, function and quality of life, along with major increase in medication cost.

## Prophylaxis

Some patients are able to reduce headache frequency by trigger identification and avoidance, but this strategy is of limited usefulness. Over the years a variety of small molecule drugs have been used in attempts to reduce migraine frequency. A Cochrane review found that **anticonvulsants**, specifically topiramate, sodium valproate and divalproex are effective prophylactic treatments for episodic migraine in adults. In contrast to previous reports, the authors found insufficient evidence to further support the use of gabapentin as a migraine prophylactic agent. **Antidepressants**, **beta blockers** and **calcium channel blockers** have been used with benefit to some patients, but a significant proportion of migraine patients do not achieve adequate control with these measures

**Botulinum toxin** products may benefit some patients. BOTOX® (onabotulinumtoxinA) is now FDA-approved to prevent headaches in adults with chronic migraine (headache lasting  $\geq 4$  hours on  $\geq 15$  days/month). BOTOX was evaluated in two randomized, multi-center, 24-week, 2 injection cycle, placebo-controlled double-blind studies in chronic migraine adults not using concurrent prophylaxis. Patients were randomized to receive placebo or 155 Units to 195 Units BOTOX injections every 12 weeks for the 2-cycle, double-blind phase. Patients were allowed to use acute headache treatments during the study. BOTOX treatment demonstrated statistically significant and clinically meaningful improvements from baseline compared to placebo;



however, this treatment requires an office procedure that is unpleasant and must be repeated four times a year.

**Calcitonin gene-related peptide (CGRP) antagonists** are monoclonal antibodies that represent the latest approach to migraine prevention. The first two agents in this class, erenumab (Aimovig) and fremanezumab, are pending final FDA approval in mid-2018. They represent a new option for patients that have failed other means of prophylaxis.

## 2018 Update

A literature search was conducted, and expert opinion of a practicing headache specialist in the area was consulted. As a result, the policy was updated and simplified, consolidating previous updates. The discussion of prophylaxis was updated to include the calcitonin gene-related peptide inhibitor class, including erenumab and fremanezumab, which are currently pending final FDA approval. Outdated references were deleted and replaced with recent guidance from AHS/AAN and other relevant organizations.

## References

1. Product information for the various agents described; data on file with the manufacturers.
2. Diamond ML. The role of concomitant headache types and non-headache co-morbidities in the under diagnosis of migraine. *Neurology* 2002; 58:S3-S8.
3. Cady RK and Schreiber CP. Sinus headache or migraine? Considerations in making a differential diagnosis. *Neurology* 2002; 58:S10-S14.
4. Gaist D et al. Misuse of Sumatriptan. *The Lancet*, Vol 344, p. 1090, October 15, 1994.
5. Silberstein SD, Silberstein JR. Chronic daily headache: Long-term prognosis following inpatient treatment with repetitive IV DHE; *Headache* 32:439-445, 1992.
6. Raskin NH. Repetitive intravenous dihydroergotamine as therapy for intractable migraine. *Neurology* 35:995-997, 1986.
7. Ferrari MD, Goadsby PJ, Roon KI et al. Triptans (serotonin. 5-HT<sub>1B/1D</sub> agonists) in migraine: detailed results and methods of a meta-analysis of 53 trials. *Cephalgia* 2002; 22:633-58.
8. National Headache Foundation. Migraine Prevention Summit Proceedings. Impact of a Migraine: Evaluating Patient Disability. Part 3 of a 4-part Program. (June 2006). Available at: <https://migraine.com/infographic/the-impact-of-migraine/> Accessed July 2018.
9. Stewart WF, Ricci JA, Chee E et al. Lost productive time and cost due to common pain conditions in the US workforce. *JAMA*. 2003 Nov 12;290(18):2443-54.





10. Early dosing and efficacy of triptans in acute migraine treatment: the TEMPO study. *Cephalalgia*. 2012 Feb;32(3):226-35. <http://www.ncbi.nlm.nih.gov/pubmed/11015163> Accessed July 2018.
11. Rapoport AM. The therapeutic future in headache. *Neurol Sci*. 2012;33(suppl 1):S119-S125.
12. Silberstein SD. Emerging target-based paradigms to prevent and treat migraine. *Clin Pharmacol Ther*. 2013;93(1):78-85.
13. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults. Report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology*. 2012;78:1337-45.
14. Pringsheim T, Davenport WJ, Mackie G, et al for the Canadian Headache Society Prophylactic Guidelines Development Group. Canadian Headache Society guideline for migraine prophylaxis. *Can J Neurol Sci*. 2012;39(2 suppl 2):S1-S62.
15. Loder E, Burch R, Rizzoli P. The 2012 AHS/AAN guidelines for the prevention of episodic migraine: a summary and comparison with other recent clinical practice guidelines. *Headache*. 2012;52:930-45.
16. Raschi E, Piccinni R, Conti V, et al. Adverse cardiovascular events associated with triptans and ergotamines for treatment of migraine: Systematic review of observational studies. *Cephalalgia*. 2014 Sep 22. pii: 0333102414550416. [Epub ahead of print]. Accessed 10/22/14.
17. Peroutka SJ. What turns on a migraine? A systematic review of precipitating factors. *Curr Pain Headache Rep*. 2014 Oct;18(10):454.
18. Mulleners WM, McCrory DC, Linde M. Antiepileptics in migraine prophylaxis: An updated Cochrane review. *Cephalalgia*. 2014 Aug 12. pii: 0333102414534325. [Epub ahead of print]. Accessed 10/22/14.
19. Powers SW, Kashikar-Zuck SM, Allen JR, et al. Cognitive behavioral therapy plus amitriptyline for chronic migraine in children and adolescents: a randomized clinical trial. *JAMA*. 2013 Dec 25;310(24):2622-30.
20. Onzetra Xsail ( ) [package insert]. Aliso Viejo, CA. Avanir Pharmaceuticals, Inc; Published January, 2016. Available at: <https://www.onzetra.com/prescribing-information> Accessed July 2018.
21. Burch RC, Loder S, Loder E, Smitherman TA. The prevalence and burden of migraine and severe headache in the United States: updated statistics from government health surveillance studies. *Headache*. 2015 Jan; 55(1): 21-34.
22. Goadsby PJ, Reuter U, Hallström Y, et al. A Controlled Trial of Erenumab for Episodic Migraine. *New England Journal of Medicine*. 2017;377(22):2123-2132.
23. Tepper S, Ashina M, Reuter U, et al. Safety and efficacy of erenumab for preventive treatment of chronic migraine: a randomised, double-blind, placebo-controlled phase 2 trial. *The Lancet Neurology*. 2017;16(6):425-434. Loder E, Burch R, Rizzoli P. The 2012 AHS/AAN guidelines for prevention of episodic migraine: a summary and comparison with other recent clinical practice guidelines. *Headache*. 2012; 52(6): 930-945.
24. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016; 86(19): 1818-1826.
25. Management of migraine (with or without aura): Prophylactic treatment. National Institute for Health and Care Excellence Pathways website. Available at: <https://pathways.nice.org.uk/pathways/headaches/management-of-migraine-with-or-without-aura> Accessed July 2018.
26. Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders, 3rd edition. *Cephalalgia*. 2018; 38(1): 1-211.
27. Adams AM, Serrano D, Buse DC, et al. The impact of chronic migraine: The Chronic Migraine Epidemiology and Outcomes (CaMEO) Study methods and baseline results. *Cephalalgia*. 2015; 35(7): 563-578.
28. Yang M, Rendas-Baum R, Varon SF, Kosinski M. Validation of the Headache Impact Test (HIT-6TM) across episodic and chronic migraine. *Cephalalgia*. 2011; 31(3): 357-367.



29. Coeytaux RR, Kaufman JS, Chao R, et al. Four methods of estimating the minimal important difference score were compared to establish a clinically significant change in Headache Impact Test. *J Clin Epidemiol.* 2006; 59: 374–380.
30. Lipton RB, Varon SF, Grosberg B, et al. OnabotulinumtoxinA improves quality of life and reduces impact of chronic migraine. *Neurology.* 2011; 77: 1465–1472.
31. Policy was reviewed by a board certified practicing neurologist with specialty in headache management. Approved by the independent P&T Committee May 30, 2018.

## Appendix

### Headache Treatment Overview: Summary of Migraine and Cluster Headache Management

#### *Migraine*

##### **Abortive Therapy**

Aspirin, Acetaminophen, Ergotamine preparations, NSAIDs, Midrin, Triptans, Dihydroergotamine IV/IM, SC, Butorphanol nasal spray, Others (chlorpromazine, prochlorperazine, metoclopramide)

##### **Prophylactic Therapy**

Antidepressants, Beta blockers, Calcium channel blockers, Naproxen, Ergotamine preparations, Divalproex sodium, Topiramate, Botulinum toxin (Botox®), Calcitonin gene-related peptide (CGRP) antagonists, Others (cyproheptadine, clonidine, other anticonvulsants)

#### *Cluster Headaches*

##### **Abortive Therapy**

Ergotamine preparations, Local anesthetic agents, Oxygen, Triptans, Butorphanol nasal spray

##### **Prophylactic Therapy**

Calcium channel blockers, Corticosteroids, Ergotamine preparations, Lithium, Neurostabilizers, Methysergide, Others (capsaicin, leuprolide)



## History

Date	Comments
11/05/97	New Policy – Add to Prescription Drug section.
12/07/99	Replace policy – Policy revised and updated.
12/21/00	Replace policy – Policy reviewed and revised to incorporate P5.01.107, DHE-45.
02/12/02	Replace policy – Policy reviewed and policy statement unchanged; added Frova <sup>®</sup> as acceptable triptan.
01/13/03	Replace policy – Policy revised; references updated.
02/10/04	Replace policy – Policy reviewed; policy statement unchanged.
09/01/04	Replace policy – Policy renumbered from 5.01.103 to 5.01.503; no other changes.
05/10/05	Replace policy – Policy reviewed by P&T 3/22/05; policy statement remains unchanged.
02/14/06	Replace policy – Policy reviewed by P&T 1/31/06; policy statement remains unchanged.
06/16/06	Update Scope and Disclaimer; no other changes.
10/10/06	Replace policy – Policy updated with literature review. Policy statement remains unchanged.
03/13/07	Replace policy – Policy updated with literature review; references added. No change in policy statement.
02/02/08	Replace policy – Policy updated with literature search. Policy statement updated to include: The medications covered by this policy may be considered medically necessary for the treatment of migraine and cluster headache in accordance with the policy guidelines. References and codes updated. Policy was review by P&T and recommended for adoption on January 22, 2008.
05/13/08	Replace policy – Policy updated with literature search; no change to the policy statement. Description and Policy guidelines were updated to include sumatriptan 85mg/naproxen 500mg (Treximet <sup>®</sup> ).
05/12/09	Replace policy – References added; no change in policy statement.
07/29/09	Update Benefit Application; no other changes.
03/09/10	Replace policy – Policy updated with literature search; references added. Reviewed by P&T January 26, 2010. No change to the policy statement.
11/09/10	Replace policy – Policy updated with current names for brand-name drugs



Date	Comments
04/08/11	Replace policy – Policy J7335 added to policy.
05/17/11	Coding updated; J7335 removed from policy.
11/10/11	Replace policy – Policy updated with literature review; reference 35 added. No change in policy statement. Reviewed by P&T September 27, 2011. Codes J0585 – J0587 removed; not applicable to policy.
11/13/12	Replace policy - Policy updated with literature review; reference 37 added. No change in policy statement.
07/08/13	Minor Update – Clarification was added to the policy that it is managed through the member's pharmacy benefit; this is now listed in the header and within the coding section.
12/09/13	Replace policy. Sumatriptan patch added to the list of drugs considered medically necessary for treating migraine headaches; Policy Guidelines and Appendix updated to align with this addition.
11/20/14	Annual Review. Policy updated with literature review; no change in policy statements. References 47-50 added.
06/09/15	Annual Review. Policy updated with literature review. Medically necessary policy statement updated with clarifying criteria and specific indications for appropriate agents addressed. Approved by P&T, May 2015.
05/01/16	Annual Review, approved April 12, 2016. Change of the criteria for brand name triptan products (requiring 2 step therapies). Addition of 2 new agents: Zembrace® and Onzetra® Xsail®. Edited quantity limit table for Zomig.
03/01/17	Updated Related Policies. Removed 5.01.512 as it was archived.
07/04/17	Policy moved into new format, no changes to policy statement.
01/01/18	Annual Review, approved December 20, 2017. A literature search was conducted, and an expert opinion of a practicing headache specialist in the area was consulted. Zecuity was deleted from the table due to discontinuation. Age specific dosing was added to each triptan. Note added that the age criteria for the drugs addressed in this policy are based on the FDA-approved ages. Added HCPCS code J3030.
08/01/18	Annual Review, approved July 10, 2018. Literature search and expert consultation with a practicing headache specialist. Policy was updated and simplified, consolidating previous updates and discussion of prophylaxis was updated to include CGRP inhibitors. Bibliography was updated to reflect current guideline sources.

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.



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**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.



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**This Notice has Important Information.** This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

**አማርኛ (Amharic):**

ይህ ማስታወቂያ አስፈላጊ መረጃ ይዟል። ይህ ማስታወቂያ ስለ ማመልከቻዎ ወይም የ Premera Blue Cross ሽፋን አስፈላጊ መረጃ ሊኖረው ይችላል። በዚህ ማስታወቂያ ውስጥ ቁልፍ ቀናት ሊኖሩ ይችላሉ። የጤና ሽፋንዎን ለማመጠን በአስፈላጊ እርዳታ ለማግኘት በተውሰኑ የጊዜ ገደቦች እርምጃ መውሰድ ይገባዎት ይሆናል። ይህን መረጃ እንዲያገኙ እና የለምንም ክፍያ በቋንቋዎ እርዳታ እንዲያገኙ መሰብሰብ አለዎት። በስልክ ቁጥር 800-722-1471 (TTY: 800-842-5357) ይደውሉ።

**العربية (Arabic):**

يحتوي هذا الإشعار على معلومات هامة. قد يحوي هذا الإشعار معلومات مهمة بخصوص طلبك أو التغطية التي تزيد الحصول عليها من خلال Premera Blue Cross. قد تكون هناك تواريخ مهمة في هذا الإشعار. وقد تحتاج لاتخاذ إجراء في تاريخ معينة للحفاظ على تغطيتك الصحية أو للمساعدة في دفع التكاليف. يحق لك الحصول على هذه المعلومات والمساعدة بلغتك دون تكبد أية تكلفة. اتصل بـ 800-722-1471 (TTY: 800-842-5357)

**中文 (Chinese):**

**本通知有重要的訊息。**本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或者費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357)。

**Oromoo (Cushite):**

**Beeksisni kun odeeffannoo barbaachisaa qaba.** Beeksisti kun sagantaa yookan karaa Premera Blue Cross tiin tajaajila keessan ilaalchisee odeeffannoo barbaachisaa qabaachuu danda'a. Guyyaawwan murteessaa ta'an beeksisa kana keessatti ilaalaa. Tarii kaffaltiidhaan deeggaramuuf yookan tajaajila fayyaa keessaniif guyyaa dhumaa irratti wanti raawwattan jiraachuu danda'a. Kaffaltii irraa bilisa haala ta'een afaan keessaniin odeeffannoo argachuu fi deeggarsa argachuuf mirga ni qabaattu. Lakkoofsa bilbilaa 800-722-1471 (TTY: 800-842-5357) tii bilbilaa.

**Français (French):**

**Cet avis a d'importantes informations.** Cet avis peut avoir d'importantes informations sur votre demande ou la couverture par l'intermédiaire de Premera Blue Cross. Le présent avis peut contenir des dates clés. Vous devez peut-être prendre des mesures par certains délais pour maintenir votre couverture de santé ou d'aide avec les coûts. Vous avez le droit d'obtenir cette information et de l'aide dans votre langue à aucun coût. Appelez le 800-722-1471 (TTY: 800-842-5357).

**Kreyòl ayisyen (Creole):**

**Avi sila a gen Enfòmasyon Enpòtan ladann.** Avi sila a kapab genyen enfòmasyon enpòtan konsènan aplikasyon w lan oswa konsènan kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kèk aksyon avan sèten dat limit pou ka kenbe kouvèti asirans sante w la oswa pou yo ka ede w avèk depans yo. Se dwa w pou resewva enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rele nan 800-722-1471 (TTY: 800-842-5357).

**Deutsche (German):**

**Diese Benachrichtigung enthält wichtige Informationen.** Diese Benachrichtigung enthält unter Umständen wichtige Informationen bezüglich Ihres Antrags auf Krankenversicherungsschutz durch Premera Blue Cross. Suchen Sie nach eventuellen wichtigen Terminen in dieser Benachrichtigung. Sie könnten bis zu bestimmten Stichtagen handeln müssen, um Ihren Krankenversicherungsschutz oder Hilfe mit den Kosten zu behalten. Sie haben das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Rufen Sie an unter 800-722-1471 (TTY: 800-842-5357).

**Hmoob (Hmong):**

**Tsab ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb.** Tej zaum tsab ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb txog koj daim ntawv thov kev pab los yog koj qhov kev pab cuam hnuv ntawm Premera Blue Cross. Tej zaum muaj cov hnuv tseem ceeb uas sau rau hauv daim ntawv no. Tej zaum koj kuj yuav tau ua qee yam uas peb kom koj ua tsis pub dhau cov caij nyuog uas teev tseg rau hauv daim ntawv no mas koj thiaj yuav tau txais kev pab cuam kho mob los yog kev pab them tej nqi kho mob ntawd. Koj muaj cai kom lawv muab cov ntshiab lus no uas tau muab sau ua koj hom lus pub dawb rau koj. Hu rau 800-722-1471 (TTY: 800-842-5357).

**Iloko (Ilocano):**

**Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion.** Daytoy a pakdaar mabalin nga adda ket naglaon iti napateg nga impormasion maipanggep iti aplikasyonyo wenna coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a petsa iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramidenyo nga addang sakbay dagiti partikular a naituding nga aldaw tapno mapagtalinaedyo ti coverage ti salun-atyto wenna tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodyo a pagsasao nga awan ti bayadanyo. Tumawag iti numero nga 800-722-1471 (TTY: 800-842-5357).

**Italiano (Italian):**

**Questo avviso contiene informazioni importanti.** Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross. Potrebbero esserci date chiave in questo avviso. Potrebbe essere necessario un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza nella tua lingua gratuitamente. Chiama 800-722-1471 (TTY: 800-842-5357).

**日本語 (Japanese):**

この通知には重要な情報が含まれています。この通知には、Premera Blue Cross の申請または補償範囲に関する重要な情報が含まれている場合があります。この通知に記載されている可能性がある重要な日付をご確認ください。健康保険や有料サポートを維持するには、特定の期日までに行動を取らなければならない場合があります。ご希望の言語による情報とサポートが無料で提供されます。800-722-1471 (TTY: 800-842-5357)までお電話ください。

**한국어 (Korean):**

본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross 를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하의 이러한 정보와 도움을 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357) 로 전화하십시오.

**ລາວ (Lao):**

ແຈງການນີ້ມີຂໍ້ມູນສໍາຄັນ. ແຈງການນີ້ອາດຈະມີຂໍ້ມູນສໍາຄັນກ່ຽວກັບຄໍາຮ້ອງສະໝັກ ຫຼື ຄວາມຄົມຄອງປະກັນໄພຂອງທ່ານຜ່ານ Premera Blue Cross. ອາດຈະມີວັນທີ່ສໍາຄັນໃນແຈງການນີ້. ທ່ານອາດຈະຈໍາເປັນຕ້ອງດໍາເນີນການຕາມກຳນົດ ເວລາສະເພາະເພື່ອຮັກສາຄວາມຄົມຄອງປະກັນສະພາບ ຫຼື ຄວາມຊ່ວຍເຫຼືອເວັ້ນເວົ້ອງຄ່າໃຊ້ຈ່າຍຂອງທ່ານໄວ້. ທ່ານມີສິດໄດ້ຮັບຂໍ້ມູນນີ້ ແລະ ຄວາມຊ່ວຍເຫຼືອເປັນພາສາຂອງທ່ານໂດຍບໍ່ເສຍຄ່າ. ໃຫ້ໃບທາ 800-722-1471 (TTY: 800-842-5357).

**ភាសាខ្មែរ (Khmer):**

សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរៀបចំរបស់អ្នកកាមរយ: Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ជាក់សមត្ថភាព ដល់កិច្ចការច្នៃផ្ទះធានា ដើម្បីនឹងរក្សាទុកការធានារ៉ាប់រងអនាគតរបស់អ្នក ឬប្រាក់ដុល្លារចេញថ្លៃ។ អ្នកមានសិទ្ធិទទួលបានព័ត៌មាននេះ និងដុល្លារនៅក្នុងភាសារបស់អ្នកដោយមិនអស់លុយឡើយ។ សូមទូរស័ព្ទ 800-722-1471 (TTY: 800-842-5357)។

**ਪੰਜਾਬੀ (Punjabi):**

ਇਸ ਨੋਟਿਸ ਵਿਚ ਖਾਸ ਜਾਣਕਾਰੀ ਹੈ. ਇਸ ਨੋਟਿਸ ਵਿਚ Premera Blue Cross ਵਲੋਂ ਤੁਹਾਡੀ ਕਵਰੇਜ ਅਤੇ ਅਰਜੀ ਬਾਰੇ ਮਹੱਤਵਪੂਰਨ ਜਾਣਕਾਰੀ ਹੋ ਸਕਦੀ ਹੈ . ਇਸ ਨੋਟਿਸ ਨਵ ਖਾਸ ਤਾਰੀਖਾਂ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀਂ ਜਸਰਤ ਕਵਰੇਜ ਰਿੱਖਣੀ ਹੋਵੇ ਜਾਂ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਛੁੱਕ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ ਤੋਂ ਪਹਿਲਾਂ ਢੁੱਝ ਖਾਸ ਕਦਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫਤ ਵਿੱਚ ਤੋਂ ਅਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਜਾਣਕਾਰੀ ਅਤੇ ਮਦਦ ਪ੍ਰਾਪਤ ਕਰਨ ਦਾ ਅਧਿਕਾਰ ਹੈ ,ਕਾਲ 800-722-1471 (TTY: 800-842-5357).

**فارسی (Farsi):**

این اعلامیه حاوی اطلاعات مهم میباشد. این اعلامیه ممکن است حاوی اطلاعات مهم درباره فرم تقاضا و یا پوشش بیمه ای شما از طریق Premera Blue Cross باشد. به تاریخ های مهم در این اعلامیه توجه نمایید. شما ممکن است برای حفظ پوشش بیمه تان یا کمک در پرداخت هزینه های درمانی تان، به تاریخ های مشخصی برای انجام کارهای خاصی احتیاج داشته باشید. شما حق این را دارید که این اطلاعات و کمک را به زبان خود به طور رایگان دریافت نمایید. برای کسب اطلاعات با شماره 800-722-1471 (کلیر بران TTY تماس باشماره 800-842-5357) تماس برقرار نمایید.

**Polskie (Polish):**

To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwońcie pod 800-722-1471 (TTY: 800-842-5357).

**Português (Portuguese):**

Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

**Română (Romanian):**

Prezenta notificare conține informații importante privind cererea sau acoperirea asigurării dumneavoastră de sănătate prin Premera Blue Cross. Pot exista date cheie în această notificare. Este posibil să fie nevoie să acționați până la anumite termene limită pentru a vă menține acoperirea asigurării de sănătate sau asistența provizorie la costuri. Aveți dreptul de a obține gratuit aceste informații și ajutor în limba dumneavoastră. Sunați la 800-722-1471 (TTY: 800-842-5357).

**Русский (Russian):**

Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

**Fa'asamoa (Samoan):**

Atonu ua iai i lenei fa'asilasilaga ni fa'amatalaga e sili ona taua e tatau ona e malamalama i ai. O lenei fa'asilasilaga o se fesoasoani e fa'amatala atili i ai i le tulaga o le polokalame, Premera Blue Cross, ua e tau fia maua atu i ai. Fa'amolemole, ia e iloilo fa'alelei i aso fa'apitoa olo'o iai i lenei fa'asilasilaga taua. Masalo o le'a iai ni feau e tatau ona e faia ao le'i aulia le aso ua ta'ua i lenei fa'asilasilaga ina ia e iai pea ma maua fesoasoani mai ai i le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua atu i lenei fa'asilasilaga ma lenei fa'matalaga i legagana e te malamalama i ai aunoa ma se togiga tupe. Vili atu i le telefoni 800-722-1471 (TTY: 800-842-5357).

**Español (Spanish):**

Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

**Tagalog (Tagalog):**

Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring mangailangan ka na magsagawa ng hakbang sa ilang mga itinakdang panahon upang mapanatili ang iyong pagsakop sa kalusugan o tulong na walang gastos. May karapatan ka na makakuha ng ganiitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

**ไทย (Thai):**

ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับกาการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และอาจมีกำหนดการในประกาศนี้ คุณอาจจะต้องดำเนินการภายในกำหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่มีค่าใช้จ่าย คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือนี้ในภาษาของคุณโดยไม่มีค่าใช้จ่าย โทร 800-722-1471 (TTY: 800-842-5357)

**Український (Ukrainian):**

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

**Tiếng Việt (Vietnamese):**

Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện theo thông báo đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357).