



Louisiana

Migraine Medications (Oral, Injectable, Transdermal, and Nasal)

Policy # 00337

Original Effective Date: 01/09/2013

Current Effective Date: 02/21/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

For Patients With "Step Therapy" (generic before brand) ONLY:

Based on a review of the available data, brand name oral, injectable, transdermal, and nasal serotonin 5HT-1 receptor agonist (triptan) products, including, but not limited to Zecuity^{®†} (sumatriptan transdermal system), Zomig^{®‡} (zolmitriptan tablets), Zomig-ZMT^{®‡} (zolmitriptan orally disintegrating tablets), Axert^{®‡} (almotriptan tablets), Onzetra^{®‡} Xsail^{®‡} (sumatriptan nasal powder), Zembrace^{™‡} Symtouch^{™‡} (sumatriptan injection), Imitrex^{®‡} Nasal (sumatriptan nasal spray), and Relpax^{®‡} (eletriptan tablets), as well as the branded non-triptan medication, Cambia^{®‡} (diclofenac), may be considered **eligible for coverage** when one of the below patient selection criteria is met:

Patient Selection Criteria

Coverage eligibility will be considered for brand name oral, injectable, transdermal, and nasal serotonin 5HT-1 receptor agonists (triptans) or brand name Cambia (diclofenac) when one of the following criteria is met:

- The patient has tried and failed a generic oral or injectable triptan medication (e.g., sumatriptan [tablets or injection], naratriptan tablets, eletriptan tablets, rizatriptan [tablets or orally disintegrating tablets], almotriptan tablets, frovatriptan tablets, or zolmitriptan [tablets or orally disintegrating tablets]); or
- There is clinical evidence or patient history that suggests the generically available oral or injectable products will be ineffective or cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand name oral, injectable, transdermal, and nasal serotonin 5HT-1 receptor agonists (triptans) or brand name Cambia (diclofenac) when patient selection criteria are not met or for usage not included in the above patient selection criteria to be **not medically necessary**.**

For Patients With "Prior Authorization" ONLY:

Based on review of the available data, the Company may consider select serotonin 5HT-1 receptor agonist (triptan) products, including, but not limited to Onzetra Xsail (sumatriptan nasal powder) or Zembrace

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Symtouch (sumatriptan injection), to be **eligible for coverage** when the below patient selection criteria are met for the requested drug:

Patient Selection Criteria

Coverage eligibility will be considered for select serotonin 5HT-1 receptor agonist (triptan) products, including, but not limited to Onzetra Xsail (sumatriptan nasal powder) or Zembrace Symtouch (sumatriptan injection), when the following criteria are met for the requested drug:

- For Onzetra Xsail requests: Patient has tried and failed (e.g., intolerance or inadequate response) at least TWO GENERIC serotonin 5HT-1 receptor agonist (triptan) agents [one of which must be **oral** (e.g., sumatriptan tablets, naratriptan tablets, eletriptan tablets, rizatriptan (tablets or orally disintegrating tablets), almotriptan tablets, frovatriptan tablets, or zolmitriptan (tablets or orally disintegrating tablets) AND the other must be **nasal** (e.g., sumatriptan nasal)] unless there is clinical evidence or patient history that suggests the use of TWO GENERIC serotonin 5HT-1 receptor agonist (triptan) agents [one of which must be **oral** (e.g., sumatriptan tablets, naratriptan tablets, eletriptan tablets, rizatriptan (tablets or orally disintegrating tablets), almotriptan tablets, frovatriptan tablets, or zolmitriptan (tablets or orally disintegrating tablets) AND the other must be **nasal** (e.g., sumatriptan nasal)] will be ineffective or cause an adverse reaction to the patient.
- For Zembrace Symtouch requests: Patient has tried and failed (e.g., intolerance or inadequate response) at least TWO GENERIC serotonin 5HT-1 receptor agonist (triptan) agents [one of which must be **oral** (e.g., sumatriptan tablets, naratriptan tablets, eletriptan tablets, rizatriptan (tablets or orally disintegrating tablets), almotriptan tablets, frovatriptan tablets, or zolmitriptan (tablets or orally disintegrating tablets) AND the other must be **injectable** (e.g., sumatriptan injection)] unless there is clinical evidence or patient history that suggests the use of TWO GENERIC serotonin 5HT-1 receptor agonist (triptan) agents [one of which must be **oral** (e.g., sumatriptan tablets, eletriptan tablets, naratriptan tablets, rizatriptan (tablets or orally disintegrating tablets), almotriptan tablets, frovatriptan tablets, or zolmitriptan (tablets or orally disintegrating tablets) AND the other must be **injectable** (e.g., sumatriptan injection)] will be ineffective or cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of select serotonin 5HT-1 receptor agonist (triptan) products, including, but not limited to Onzetra Xsail (sumatriptan nasal powder) or Zembrace Symtouch (sumatriptan injection), when the patient selection criteria for the requested drug are not met to be **not medically necessary**.**

For Patients With BOTH “Prior Authorization” AND “Step Therapy”:

Based on a review of the available data, brand name oral, injectable, transdermal, and nasal serotonin 5HT-1 receptor agonist (triptan) products, including, but not limited to Zecuity^{®†} (sumatriptan transdermal system) Zomig^{®†} (zolmitriptan tablets), Zomig-ZMT^{®†} (zolmitriptan orally disintegrating tablets), Axert^{®†} (almotriptan tablets), Onzetra^{®†} Xsail^{®†} (sumatriptan nasal powder), Zembrace^{™‡} Symtouch^{™‡} (sumatriptan injection), Imitrex^{®‡} Nasal (sumatriptan nasal spray), and Relpax^{®‡} (eletriptan tablets) as well

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as the branded non-triptan medication, Cambia^{®†} (diclofenac), may be considered **eligible for coverage** when one of the below patient selection criteria is met:

Patient Selection Criteria

Coverage eligibility will be considered for brand name oral, injectable, transdermal, and nasal serotonin 5HT-1 receptor agonists (triptans) or brand name Cambia (diclofenac) when one of the following criteria is met:

- For Onzetra Xsail requests: Patient has tried and failed (e.g., intolerance or inadequate response) at least TWO GENERIC serotonin 5HT-1 receptor agonist (triptan) agents [one of which must be **oral** (e.g., sumatriptan tablets, naratriptan tablets, eletriptan tablets, rizatriptan (tablets or orally disintegrating tablets), almotriptan tablets, frovatriptan tablets, or zolmitriptan (tablets or orally disintegrating tablets) AND the other must be **nasal** (e.g., sumatriptan nasal)] unless there is clinical evidence or patient history that suggests the use of TWO GENERIC serotonin 5HT-1 receptor agonist (triptan) agents [one of which must be **oral** (e.g., sumatriptan tablets, naratriptan tablets, eletriptan tablets, rizatriptan (tablets or orally disintegrating tablets), almotriptan tablets, frovatriptan tablets, or zolmitriptan (tablets or orally disintegrating tablets) AND the other must be **nasal** (e.g., sumatriptan nasal)] will be ineffective or cause an adverse reaction to the patient.
- For Zembrace Symtouch requests: Patient has tried and failed (e.g., intolerance or inadequate response) at least TWO GENERIC serotonin 5HT-1 receptor agonist (triptan) agents [one of which must be **oral** (e.g., sumatriptan tablets, naratriptan tablets, eletriptan tablets, rizatriptan (tablets or orally disintegrating tablets), almotriptan tablets, frovatriptan tablets, or zolmitriptan (tablets or orally disintegrating tablets) AND the other must be **injectable** (e.g., sumatriptan injection)] unless there is clinical evidence or patient history that suggests the use of TWO GENERIC serotonin 5HT-1 receptor agonist (triptan) agents [one of which must be **oral** (e.g., sumatriptan tablets, naratriptan tablets, eletriptan tablets, rizatriptan (tablets or orally disintegrating tablets), almotriptan tablets, frovatriptan tablets, or zolmitriptan (tablets or orally disintegrating tablets) AND the other must be **injectable** (e.g., sumatriptan injection)] will be ineffective or cause an adverse reaction to the patient.
- For ALL other requests: The patient has tried and failed a generic oral or injectable triptan medication (e.g., sumatriptan tablets, sumatriptan injection, naratriptan tablets, eletriptan tablets, rizatriptan (tablets or orally disintegrating tablets), almotriptan tablets, frovatriptan tablets, or zolmitriptan (tablets or orally disintegrating tablets) OR there is clinical evidence or patient history that suggests the generically available oral or injectable products will be ineffective or cause an adverse reaction to the patient

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand name oral, injectable, transdermal, and nasal serotonin 5HT-1 receptor agonist (triptan) products when the patient selection criteria for the requested drug are not met to be **not medically necessary**.**

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Background/Overview

Serotonin 5-HT₁ receptor agonists (triptans) are used in the treatment of migraines. All of the triptan medications are indicated for the treatment of migraine headache with or without aura and are not intended to be used as prophylactic migraine therapy or to manage hemiplegic or basilar migraine. Axert is approved for the treatment of migraine headache pain in adolescent patients 12 to 17 years of age with a history of migraine attacks with or without aura usually lasting 4 hours or more (when untreated). Maxalt and Maxalt-MLT are approved for the acute treatment of migraine with or without aura in patients \geq 6 years of age. Zecuity is a transdermal system containing sumatriptan that is indicated for the treatment of acute migraines with or without aura. There are data with other select triptan agents in adolescent patients showing them to be well tolerated, but not always statistically different in efficacy from placebo. Zembrace Symtouch is another injectable form of sumatriptan, while Onzetra Xsail is controlled via a novel delivery method that is powered by the patient's breath and delivers the sumatriptan into their nose. Cambia is a non-steroidal anti-inflammatory drug (NSAID) that is indicated for the acute treatment of migraine attacks with or without aura in adult patients.

Rationale/Source

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests a generic oral or injectable triptan drug will be ineffective or cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above mentioned caveat, there is no advantage of using a brand name oral, injectable, transdermal, or nasal 5HT-1 receptor agonist (triptan) or brand name Cambia (diclofenac) over a generic triptan. There are various routes of administration available generically so as not to go directly to a branded medication. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs.

References

1. Express Scripts Triptans Step Therapy Program. 8/15/2017
2. Loder E. Triptan therapy in migraine. *N Engl J Med.* 2010;363:63-70.
3. Damen L, Bruijn JKJ, Verhagen AP, Berger MY, Passchier J, Koes BW. Symptomatic treatment of migraine in children: a systematic review of medication trials. *Pediatrics.* 2005;116(2):e295-302.
4. Callenbach PM, Pels LP, Mulder PG, et al. Sumatriptan nasal spray in the acute treatment of migraine in adolescents and children. *Eur J Paediatr Neurol.* 2007;11:325-330.
5. Lewis D, Winner P, Hershey A, et al. Efficacy of zolmitriptan nasal spray in adolescent migraine. *Pediatrics.* 2007; 120:390–396.
6. Silver S, Gano D, Gerretsen P. Acute treatment of paediatric migraine: a meta-analysis of efficacy. *J Paediatr Child Health.* 2008;44:3-9.
7. Cambia. [package insert]. Nautilus Neurosciences, Inc. Bedminster, New Jersey.
8. Zecuity. [package insert]. NuPathe, Incorporated. West Caldwell, New Jersey 07006.
9. Onzetra Xsail [package insert]. Avanir Pharmaceuticals, inc. Aliso Viejo, California.
10. Zembrace Symtouch [package insert]. Dr. Reddy's. San Diego, California.

Policy History

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01/03/2013 Medical Policy Committee review.

01/09/2013 Medical Policy Implementation Committee approval. New Policy

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02/19/2013	Format revision. Coding section removed
09/05/2013	Medical Policy Committee review.
09/18/2013	Medical Policy Implementation Committee approval. Changed title. Added Cambia to policy. Removed the criteria regarding being unable to chew/swallow as well as age criteria because generics are now available for those special circumstances.
09/04/2014	Medical Policy Committee review
09/17/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/03/2015	Medical Policy Committee review
09/23/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/05/2016	Medical Policy Committee review
05/18/2016	Medical Policy Implementation Committee approval. Changed title to reflect new transdermal system on the market (Zecuity). Updated all sections of the policy to reflect new route of administration for this policy (transdermal).
02/02/2017	Medical Policy Committee review
02/15/2017	Medical Policy Implementation Committee approval. Added new branded products to the policy. Criteria added for step therapy and prior authorization. Title change adding transdermal and nasal.
02/01/2018	Medical Policy Committee review
02/21/2018	Medical Policy Implementation Committee approval. Added the generic drug eletriptan to the policy.
Next Scheduled Review Date:	02/2019

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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