BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Migraine Medications (Oral and Injectable)

Policy # 00337
Original Effective Date: 01/09/2013
Current Effective Date: 09/17/2014

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.

Note: This policy addresses the oral and injectable triptan formulations, not the nasal spray triptan formulations. This policy also addresses brand name Cambia (diclofenac).

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.*

Based on a review of the available data, brand name oral and injectable serotonin 5HT-1 receptor agonist (triptan) products, including, but not limited to Zomig® ‡ (zolmitriptan tablets), Zomig-ZMT® ‡ (zolmitriptan orally disintegrating tablets), Axert® ‡ (almotriptan tablets), 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 and injectable 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, sumatriptan injection, naratriptan tablets, rizatriptan (tablets or orally disintegrating tablets), or zolmitriptan (tablets or orally disentigrating tablets); or
- The patient is experiencing an acute migraine attack; or
- There is clinical evidence or patient history that suggests the generically available 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 and injectable 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**.**

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 ≥ 6 years of age. 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. 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 the presence of an acute migraine attack as well as clinical evidence or patient history that suggests a generic 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 caveats, there is no advantage of using a brand name oral or injectable 5HT-1 receptor agonist (triptan) or brand name Cambia (diclofenac) over a generic triptan. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs.

References

1. Express Scripts Triptans Step Therapy Program. 1/11/2012
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.

Policy History

Original Effective Date: 01/09/2013
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01/03/2013	Medical Policy Committee review.
01/09/2013	Medical Policy Implementation Committee approval. New Policy
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.

Next Scheduled Review Date: 09/2015

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

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1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**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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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.