



methergine/methylergonovine tablets

Policy # 00636

Original Effective Date: 01/01/2019

Current Effective Date: 10/09/2023

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.*

Based on review of available data, the Company may consider methergine or methylergonovine tablets for quantities greater than 28 tablets per 28 day supply to be **eligible for coverage**** when the patient selection criteria are met.

Note that a quantity of 28 tablets or less used for uterine atony, hemorrhage and subinvolution of the uterus DOES NOT require a prior authorization

Patient Selection Criteria

Coverage eligibility for methergine or methylergonovine tablets in quantities greater than 28 tablets per 28 day supply will be considered when the following criteria are met:

- Patient is 18 years of age or older; AND
 - Patient is using the requested drug for the treatment of acute migraine headache (active migraine headache); AND
 - Patient has tried and failed (i.e. intolerance or inadequate response) at least ONE GENERIC triptan therapy (e.g. sumatriptan) unless there is clinical evidence or patient history that suggests the use of at least ONE GENERIC triptan therapy will be ineffective or cause an adverse reaction to the patient; AND
 - Patient has tried and failed (i.e. intolerance or inadequate response) at least TWO other types of GENERIC abortive therapy, from different classes, (e.g., analgesics [acetaminophen, nonsteroidal anti-inflammatories {NSAIDs}], butalbital-containing products [butalbital-acetaminophen, butalbital-

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acetaminophen-caffeine, butalbital-acetaminophen-caffeine-codeine, butalbital-aspirin-caffeine, butalbital-aspirin-caffeine-codeine], dihydroergotamine) unless there is clinical evidence or patient history that suggests the use of TWO other types of GENERIC abortive therapy (from different classes) will be ineffective or cause an adverse reaction to the patient; AND

- Patient is currently being treated and/or has tried and failed prophylactic therapy for migraine headaches; OR
- Patient is using the requested drug to prevent the future occurrence of migraine headaches (e.g. prophylactic therapy); AND
 - Patient has tried and failed (i.e. intolerance or inadequate response) at least ONE GENERIC triptan therapy (e.g. sumatriptan) unless there is clinical evidence or patient history that suggests the use of at least ONE GENERIC triptan therapy will be ineffective or cause an adverse reaction to the patient; AND
 - Patient has tried and failed (i.e. intolerance or inadequate response) at least THREE standard prophylactic pharmacologic therapies [each from a different class (one of which MUST include a CGRP {calcitonin gene related peptide} antagonist)] unless there is clinical evidence or patient history that suggests the use of THREE standard prophylactic pharmacologic therapies [each from a different class (one of which MUST include a CGRP antagonist)] will be ineffective or cause an adverse reaction to the patient. Note: Prophylactic pharmacologic classes include anticonvulsants (e.g. topiramate, divalproex), beta blockers (e.g. propranolol, metoprolol, nadolol), tricyclic antidepressants (e.g. amitriptyline, nortriptyline), calcium channel blockers (e.g. verapamil), botulinum toxins (e.g. Botox[®]), and CGRP antagonists (e.g. Aimovig[®]).

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

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Based on review of available data, the Company considers requests for methergine or methylergonovine tablets for quantities greater than 28 tablets per 28 day supply when the patient selection criteria are not met to be **investigational**.*

Based on review of available data, the Company considers requests for methergine or methylergonovine tablets for quantities greater than 28 tablets per 28 day supply for use in uterine atony, hemorrhage and subinvolution of the uterus to be **investigational**.*

Background/Overview

Note that methergine and methylergonovine are both generic names for the product methylergonovine. Methergine/methylergonovine is a semi-synthetic ergot alkaloid FDA approved following delivery of the placenta, for routine management of uterine atony, hemorrhage and subinvolution of the uterus. The oral dose for this FDA approved indication is one tablet, 0.2 mg, 3 or 4 times daily in the puerperium for a maximum of 1 week. The National Headache Foundation notes that methylergonovine can cause constriction of the smooth muscles in the blood vessels, which can be helpful in treating migraines. This product has been used for both the prevention and treatment of acute migraine headaches. The dose of methylergonovine used for migraines is 0.2 to 0.4 mg three times a day; a maximum dose of 1.6 mg/day has been reported (eight 0.2 mg tablets per day). Use of these products is recommended for limited periods of time and under careful supervision of a physician. This product is also available in intravenous and intramuscular formulations, however this policy only applies to the oral form.

Options for the treatment of acute migraine headaches include drugs such as triptans (e.g. sumatriptan) and analgesics (e.g. ibuprofen, acetaminophen, butalbital containing products as well as dihydroergotamine products). Options for the prophylaxis of migraine headaches includes drug classes such as anticonvulsants (e.g. topiramate, divalproex), beta blockers (e.g. propranolol, metoprolol, nadolol), tricyclic antidepressants (e.g. amitriptyline, nortriptyline), calcium channel blockers (e.g. verapamil), botulinum toxins (e.g. Botox), and CGRP antagonists (e.g. Aimovig).

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Methergine/methylergonovine is indicated following delivery of the placenta, for routine management of uterine atony, hemorrhage and subinvolution of the uterus.

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration

approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

This policy is in place to ensure that this drug is used for its FDA approved indication at the appropriate dose and to ensure that there is a mechanism for approval of the nationally accepted guideline use (as the dose for migraines is over the dose mentioned in the package insert). However, for migraine utilization, there are more effective and more economical options available than methergine/methylergonovine that should be used prior.

References

1. Methergine [package insert]. Novartis. East Hanover, New Jersey, Updated 2012.
2. Methergine/methylergonovine Prior Authorization Document. Express Scripts. Updated May 2018.
3. Methergine, National Headache Foundation. Available at: <http://www.headaches.org/2007/10/25/methergine/>. Accessed on April 23, 2018.
4. Matchar DB, Young WB, Rosenberg JH, et al. American Academy of Neurology. 2000. Evidence-based guidelines for migraine headache in the primary care setting: pharmacological management of acute attacks. Available at: <https://www.aan.com/Guidelines>. Accessed on February 28, 2016.
5. Marmura MJ, Silberstein SD, Schwedt TJ. The acute treatment of migraine in adults: the American Headache Society evidence assessment of migraine pharmacotherapies. Headache. 2015;3-20.
6. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment of episodic migraine prevention in adults. Neurology. 2012;78:1337-1345.

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09/06/2018	Medical Policy Committee review
09/19/2018	Medical Policy Implementation Committee approval. New policy.
09/05/2019	Medical Policy Committee review
09/11/2019	Medical Policy Implementation Committee approval. No change to coverage.
09/03/2020	Medical Policy Committee review
09/09/2020	Medical Policy Implementation Committee approval. No change to coverage.
09/02/2021	Medical Policy Committee review
09/08/2021	Medical Policy Implementation Committee approval. No change to coverage.
09/01/2022	Medical Policy Committee review
09/14/2022	Medical Policy Implementation Committee approval. No change to coverage.
09/07/2023	Medical Policy Committee review
09/13/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 09/2024

*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 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: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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.

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