PRIOR AUTHORIZATION POLICY

POLICY: Methylergonovine Prior Authorization Policy
- Methergine® (methylergonovine maleate tablets – Lupin, generic)

REVIEW DATE: 06/07/2023

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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Methylergonovine, a semi-synthetic ergot alkaloid, is indicated for management of **uterine atony, hemorrhage, and subinvolution of the uterus following delivery of the placenta;** and for control of **uterine hemorrhage** in the second stage of labor following delivery of the anterior shoulder.[1]

Other Uses with Supportive Evidence

The National Headache Foundation notes that methylergonovine can cause constriction of the smooth muscles in the blood vessels and this effect can be helpful in treating vascular headaches, such as migraines or cluster headaches.[2] Although methylergonovine is more commonly used for prevention of migraine headaches, it can be taken for acute attacks. However, methylergonovine should only be used for limited periods of time in most patients and only under careful supervision of a physician. 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).[3]

Guidelines/Recommendations

An updated assessment of the **preventive and acute treatment of migraine** by the **American Headache Society** (AHS) [2018; update 2021] reaffirms previous migraine guidelines.[4,5] Methylergonovine is not addressed in the update.

Prevention. Patients with migraine should be considered for preventive treatment in the following situations: 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 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). 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). ***Treatment.*** Triptans (e.g., almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, and zolmitriptan) are considered the gold standard for acute treatment of moderate to severe migraine headaches or mild to moderate migraine headaches that respond poorly to over-the-counter analgesics. Nonsteroidal anti-inflammatory drugs (NSAIDs) as a class are mentioned as an option for acute treatment of mild to moderate migraine attacks; celecoxib is not specifically addressed. The potential for cardiovascular and gastrointestinal adverse events with NSAID use is noted. Other treatment options in the mild to moderate setting include nonopioid analgesics, acetaminophen, or caffeinated analgesic combinations. For moderate to severe attacks or attacks which respond poorly to NSAIDs or caffeinated combinations, the update lists the triptans, dihydroergotamine, the oral calcitonin gene-related peptide (CGRP) receptor antagonists (Nurtec® ODT [rimegepant orally disintegrating tablets,] and Ubrelvy® [ubrogepant tablets]), and Reyvow™ (lasmiditan tablet) as effective treatments. The recommendation remains that clinicians must consider medication efficacy and potential medication-related adverse events when prescribing acute medications for migraine.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of methylergonovine, for prescriptions with quantities exceeding 28 tablets per 30 days. Twenty-eight (28) tablets per month will be sufficient to treat uterine atony, hemorrhage, and subinvolution of the uterus following the delivery of the placenta (FDA-approved indication). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients with migraines who are treated with methylergonovine as well as the monitoring required for adverse events and long-term efficacy, approval requires methylergonovine to be prescribed by or in consultation with a physician who specializes in the condition being treated.

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is(are) covered as medically necessary when the following criteria is(are) met for fda-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Uterine Atony, Hemorrhage, and Subinvolution of the Uterus.** Do not approve. The initial quantity of 28 tablets is sufficient to treat this condition; quantities > 28 tablets for this indication will not be approved.

Other Uses with Supportive Evidence

2. **Migraine Headaches – Acute Treatment.** Approve for 1 year if the patient meets BOTH of the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets one of the following (i or ii):
     - **i.** Patient is already receiving methylergonovine therapy; OR
     - **ii.** Patient meets the following criteria (a, b, and c):
       - **a)** Patient has tried and had inadequate efficacy and/or unacceptable side effects to at least one triptan therapy; AND
         Note: Examples of triptans are almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, and zolmitriptan.
       - **b)** Patient has tried and had inadequate efficacy and/or unacceptable side effects to at least one other type of abortive therapy; AND
         Note: Examples of abortive therapies include analgesics (acetaminophen, nonsteroidal anti-inflammatory drugs [NSAIDs]), butalbital-containing products (butalbital-acetaminophen, butalbital-acetaminophen-caffeine, butalbital-acetaminophen-caffeine-codeine, butalbital-aspirin-caffeine, butalbital-aspirin-caffeine-codeine), dihydroergotamine (DHE, Migranal, generic), oral calcitonin gene-related peptide (CGRP) receptor antagonists (Nurtec ODT [rimegepant orally disintegrating tablets], Ubrelvy [ubrogepant tablets], Reyvow [lasmiditan tablet]).
       - **c)** The medication is prescribed by or in consultation with a neurologist or headache specialist.

3. **Migraine Headaches – Prevention.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   - **A)** Patient is ≥ 18 years of age: AND
   - **B)** Patient has tried at least two standard prophylactic pharmacologic therapies, each from a different pharmacologic class; AND
     Note: Examples of prophylactic pharmacologic therapies include angiotensin receptor blocker, angiotensin converting enzyme inhibitor, anticonvulsant, beta-blocker, calcium channel blocker, tricyclic antidepressant, other antidepressant.

C) The medication is prescribed by or in consultation with a neurologist or headache specialist.

CONDITIONS NOT COVERED

- **Methergine® (methylergonovine maleate tablets – Lupin, generic) is(are) considered experimental, investigational or unproven for ANY other use(s).**

REFERENCES

1. Methergine® tablets [prescribing information]. Baltimore, MD: Lupin; January 2016.
2. Methergine, National Headache Foundation. Available at: http://www.headaches.org/2007/10/25/methergine/. Accessed on June 5, 2023.
3. Saper JR, Evans RW. Oral methylergonovine maleate for refractory migraine and cluster headache prevention. *Headache.* 2013 Feb;53(2):378-81.
4. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. *Headache*. 2019;59:1-18.
5. Ailani J, Burch RC, Robbins MS, on behalf of the Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. *Headache*. 2021;00:1–19.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Migraine Headaches – Acute Treatment:** Added requirement that patient is ≥ 18 years of age. **Migraine Headaches – Prevention:** Added requirement that patient is ≥ 18 years of age. **Policy name:** Changed from Methylergonovine (Methergine) PA to Methylergonovine PA.	06/08/2022
Annual Revision	No criteria changes.	06/07/2023