PRIOR AUTHORIZATION POLICY

POLICY: Methergine® (methylergonovine maleate tablets, USP – Lupin Pharma, generics)

DATE REVIEWED: 05/27/2020

OVERVIEW

Methylergonovine is a semi-synthetic ergot alkaloid used for the prevention and control of postpartum hemorrhage.[1] Methylergonovine is indicated for management of uterine atony, hemorrhage and subinvolution of the uterus following delivery of the placenta.

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.[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]

Disease Overview, Migraine

Migraine, a chronic neurologic disease, is characterized by attacks of throbbing headache with sensitivities to light and sound.[4] The treatment of migraines is individualized and choice of therapy is based on many factors, including: patient preference; severity and frequency of attacks; the presence, type, and severity of associated symptoms; treatment response to prior therapies; presence of comorbid and coexistent illness; contraindications (e.g., cardiovascular disease); and use of concomitant medications.

Guidelines/Recommendations

An updated assessment of the preventive and acute treatment of migraine by the American Headache Society (2018) reaffirms previous migraine guidelines. The current update lists the triptans and dihydroergotamine (DHE) as effective treatments for moderate or severe acute migraine attacks and mild to moderate attacks that respond poorly to nonsteroidal anti-inflammatory drugs (NSAIDs) or caffeinated combinations (e.g., aspirin + acetaminophen + caffeine). Opioid medications are probably effective; however, they are not recommended for regular use. The recommendation remains that clinicians must consider medication efficacy, potential side effects, and potential medication-related adverse events when prescribing acute medications for migraines. Treatment at the first sign of pain improves the probability of achieving freedom from pain and reduces attack-related disability. Migraine patients who need to use acute treatments on a regular basis should limit treatment to an average of two headache days per week, and patients who exceed this limit should be offered preventive treatment. Therapies that are used for migraine prevention include antiepileptics (divalproex sodium, valproate sodium, topiramate), beta-blockers (metoprolol, propranolol, timolol), onabotulinumtoxin A, and frovatriptan (for short-term preventive treatment of menstrual migraine).

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of methylergonovine 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). 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. All approvals are provided for 1 year in duration unless otherwise noted below.

Automation: Methylergonovine prescriptions for 28 tablets (0.2 mg strength) per 30 days are excluded from Prior Authorization (PA). The PA policy will only apply to methylergonovine prescriptions with quantities exceeding 28 tablets per 30 days.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of methylergonovine is recommended in those who meet the following criteria:

FDA-Approved Indications

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 methylergonovine for 1 year if the patient meets ONE of the following criteria (A or B):
   - **A)** Patient is already receiving methylergonovine therapy; OR
   - **B)** The patient meets all of the following criteria (i, ii, and iii):
     - **i.** Patient has tried and had inadequate efficacy and/or unacceptable side effects to at least one triptan therapy.
       Note: Examples of triptans: almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, and zolmitriptan); AND
     - **ii.** Patient has tried and had inadequate efficacy and/or unacceptable side effects to at least one other type of abortive therapy.
       Note: Examples of abortive therapies include analgesics [acetaminophen, nonsteroidal anti-inflammatories {NSAIDs}], butalbital-containing products [butalbital-acetaminophen, butalbital-acetaminophen-caffeine, butalbital-acetaminophen-caffeine-codeine, butalbital-aspirin-caffeine, butalbital-aspirin-caffeine-codeine], dihydroergotamine [DHE, Migranal®, generics]); AND
     - **iii.** The medication is prescribed by, or in consultation with, a neurologist or headache specialist.

3. **Migraine Headaches (Prophylaxis).** Approve methylergonovine for 1 year if the patient meets both of the following criteria (A and B):
   - **A)** Patient has tried at least two other prophylactic pharmacologic therapies, each from a different pharmacologic class.
     Note: Examples of prophylactic pharmacologic therapies include angiotensin receptor blocker [e.g., candesartan], angiotensin converting enzyme inhibitor [e.g., lisinopril], anticonvulsant [e.g., divalproex sodium, sodium valproate, topiramate], beta-blocker [e.g., atenolol, metoprolol, nadolol, propranolol, timolol], calcium channel blocker [e.g., diltiazem, verapamil], tricyclic antidepressant [e.g., amitriptyline], other antidepressant [e.g., venlafaxine]); AND
   - **B)** The medication is prescribed by, or in consultation with, a neurologist or headache specialist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Methylergonovine has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below.

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Methergine® [prescribing information]. Baltimore, MD: Lupin Pharma; January 2016.
2. Methergine, National Headache Foundation. Available at: http://www.headaches.org/2007/10/25/methergine/. Accessed on May 22, 2019.
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