Member Health & Wellness Procedure Manual

Section: Chapter 7A Prescription Medication Prior Authorization     Number: 07.054

Title: dihydroergotamine mesylate (DHE 45) injectable and dihydroergotamine (DHE, Migranal) Nasal Spray

Approval: Robert Bonnell, M.D., Med. Dir.     DATES - Origination: 03/14/06
Responsible Party: CPM Director     Revised: 11/19/14     Effective: 11/25/14
Distribution: Medical Department     P&T Review: 08/24/16     Annual Review: 08/24/16

Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Implementation Information:

1.0 Under the supervision of the Clinical Pharmacy Management (CPM) Director, the CPM staff is responsible for the development of guidelines and criteria for use by the Medical Department.

2.0 Staff utilizing this procedure is monitored via individual departmental audit tools.

3.0 Medical Department staff has access to the Medical Department Procedure Manual and receives notice from management when procedures are developed, revised, or archived:

3.1 On an annual basis or more often when indicated, the Medical Department Procedures are reviewed by medical staff for the purpose of developing, revising, or archiving.

Background Information:

Medication Summary

- Dihydroergotamine (DHE 45) is a medication that binds with high affinity to the 5HT_{1D} receptors, which leads to vasoconstriction, and therefore the relief of migraine headaches. DHE 45 is indicated for the acute treatment of migraine headaches with or without aura. DHE 45 is also indicated for the acute treatment of cluster headache episodes.
- Dihydroergotamine (DHE 45) solution can be administered orally, intramuscularly, subcutaneously, and intravenously.
- Dihydroergotamine (DHE) nasal spray can be administered by intranasal administration.
Background Information, continued:

Reference Statement

• Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Coverage Guidelines

• Member must be eligible and have applicable benefits.
• Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusion Criteria

• Members ≤ 18 years of age.
• Concomitant use with potent CYP3A4 inhibitors (including but not limited to numerous anti-retroviral agents for HIV - amprenavir, atazanavir, ritonavir, nelfinavir, indinavir, saquinavir, delavirdine, efavirenz; and erythromycin, clarithromycin, ketoconazole, and itraconazole).
• Member with history, signs, or symptoms of ischemic cardiac syndromes (including but not limited to, angina pectoris of any type, all forms of myocardial infarction, and silent myocardial ischemia), cerebrovascular syndromes (including but not limited to, strokes of any kind and transient ischemic attacks), peripheral vascular symptoms (including but not limited to, ischemic bowel disease), or other significant underlying cardiovascular diseases
• Member with uncontrolled hypertension.
• Concomitant use with other ergotamine-containing or ergot-type medications or methysergide within 24 hours of one (1) another.
• Member with documented peripheral vascular disease, sepsis, or following vascular surgery
• Member with hemiplegic or basilar migraine.
• Member with severely impaired hepatic or renal function.
• Member who is pregnant or nursing.
• Member with hypersensitivity to ergot alkaloids.
Background Information, continued:

Additional Information

- AvMed’s Clinical Pharmacists are licensed by the State of Florida.
- AvMed’s Medical Directors are Board Certified physicians licensed by the State of Florida.

Procedure:

1.0 Request for *Dihydroergotamine (DHE 45) injectable* for *initial therapy* for *migraine and cluster headaches* require documentation from the Member’s medical records maintained by the prescribing provider verifying the following:

1.1 Prescriber must be a Neurologist; **AND**

1.2 Diagnosis of Migraine headaches or Cluster headaches, **AND**

1.3 Migraine not adequately controlled with oral migraine and prophylactic medications, **OR**

1.3 Member cannot tolerate oral migraine medications, **OR**

1.3 Injection needed due to Member experiencing nausea/vomiting associated with migraine attacks;

1.4 If criteria are met, initial therapy may be approved for up to 24ml (24mg) per month for a maximum of three (3) months.
Title: dihydroergotamine mesylate (DHE 45) injectable and
dihydroergotamine (DHE, Migranal) Nasal Spray

Procedure, continued:

2.0 Request for Dihydroergotamine (DHE 45) injectable for *continuation therapy* for *migraine and cluster headaches* require documentation from the Member’s medical records maintained by the requesting independent practitioner verifying:

2.1 Member is not experiencing any severe adverse reactions; AND

2.2 Member is responding to therapy, as evidence by reduction in frequency of migraines;

2.3 If criteria are met, continuation of therapy may be approved for up to 24ml (24mg) per month for a maximum of six (6) months.

3.0 Request for Dihydroergotamine (DHE) *Nasal Spray* for *initial therapy* for *migraine and cluster headaches* require documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

3.1 Prescriber must be a Neurologist; AND

3.2 Diagnosis of Migraine headaches or Cluster headaches; AND

3.3 Migraine not adequately controlled with oral migraine and prophylactic medications; AND

3.4 Migraine not adequately controlled with a *Triptan Nasal Spray*; AND

3.5 Migraine not adequately controlled with an *Injectable Triptan*;

3.6 If criteria are met, initial therapy may be approved for up to 8mls (4mg/ml) per month for a maximum of three (3) months.
Procedure, continued:

4.0 Request for Dihydroergotamine (DHE) Nasal Spray for continuation therapy for migraine and cluster headaches require documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

4.1 Member is not experiencing any severe adverse reactions; **AND**

4.2 Member is responding to therapy, as evidence by reduction in frequency of migraines;

4.3 If criteria are met, initial therapy may be approved for up to 8mls (4mg/ml) per month for a maximum of three (3) months.

References:


