09-J2000-74

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Reviewed: 04/11/18

Revised: 05/15/18

Subject: Ergotamine (Ergomar)

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Ergotamine is an ergot alkaloid administered to relieve migraine headaches. It is roughly 70% effective in controlling acute migraine attacks and has been shown to be more effective if taken early in the course of the migraine. Because prolonged use or excessive dosage of ergot alkaloids can lead to ergotism, dependence, and/or rebound headaches, ergotamine should not be used for chronic daily management of migraines or vascular headaches. Ergotamine is available as a single agent (Ergomar) or in combination with caffeine.

The American Academy of Neurology practice parameters for treatment of acute migraine provide recommendations for selecting acute therapies. Agents are grouped according to the level of evidence supporting clinical benefit. Preferred therapies are listed in group 1 due to proven, pronounced statistical and clinical benefit as demonstrated by at least two double-blind, placebo-controlled, studies. Agents in group 1 include triptans, acetaminophen/aspirin plus caffeine, ibuprofen, naproxen, prochlorperazine, and butorphanol. Group 2 agents are those with moderate statistical and clinical benefit as demonstrated by one double-blind, placebo-controlled study. Agents in group 2 include acetaminophen plus codeine, butalbital plus aspirin and caffeine, diclofenac, and chlorpromazine. Agents in group 3 are those that have not been proven clinically or statistically effective and have conflicting or inconsistent evidence. Group 3 agents include ergotamine plus caffeine and single agent ergotamine. Ergotamine plus caffeine is commercially available as Cafergot.

POSITION STATEMENT:

Comparative Effectiveness

The FDA has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility **does not meet the definition of medical necessity**.

Single-agent ergotamine (Ergomar) oral and sublingual therapy is associated with a clinically inferior benefit (compared to ergotamine-caffeine combination products and triptans, or serotonin receptor agonists) and increased risk of adverse events, drug abuse, and psychological dependence; therefore, use **does not meet the definition of medical necessity**.

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- At the first sign of an attack or to relieve symptoms after onset of an attack, one 2 mg tablet is placed under the tongue.
- Another tablet should be taken at half-hour intervals thereafter, if necessary, but dosage must not exceed three tablets in any 24hour period.
- Total weekly dosage should not exceed five tablets (10 mg) in any one week and should not be used for chronic daily administration.

Dose Adjustments

None

Drug Availability

Sublingual Tablet: 2 mg

PRECAUTIONS:

Boxed Warning

Serious and/or life-threatening peripheral ischemia has been associated with the coadministration of ergotamine tartrate with potent CYP 3A4 inhibitors including protease inhibitors and macrolide antibiotics. Because CYP 3A4 inhibition elevates the serum levels of ergotamine tartrate, the risk for vasospasm leading to cerebral ischemia and/or ischemia of the extremities is increased. Hence, concomitant use of these medications is contraindicated.

Contraindications

- Concomitant use with potent CYP3A4 inhibitors (ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin, ketoconazole, itraconazole, protease inhibitors, macrolide antibiotics)
- Coronary heart disease, peripheral vascular disease, or hypertension
- Hypersensitivity to ergotamine tartrate or to any component of the product
- Impaired hepatic or renal function
- Pregnant or may become pregnant
- Sepsis

Precautions/Warnings

- Administration: Chronic daily use is not recommended; fibrotic complications (retroperitoneal and/or pleuropulmonary fibrosis or thickening of the aortic, mitral, tricuspid, and/or pulmonary valves) have been reported with long-term concomitant use with caffeine.
- Addiction potential: Drug abuse and psychological dependence have been reported.
- Cardiovascular: Ergotism may occur, particularly in cases of administration above the recommended dosages .
- Concomitant use: Use with other vasoconstrictors (eg, sympathomimetics, propranolol, nicotine) is not recommended.
- Withdrawal: Withdrawal symptoms (rebound headache) with long-term chronic use have been reported.

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding

J8499	Prescription drug, oral, non-chemotherapeutic, Not Otherwise Specified

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

DEFINITIONS:

None

RELATED GUIDELINES:

None

OTHER:

None

REFERENCES:

1. Clinical Pharmacology [Internet]. Tampa (FL): Gold Standard, Inc.; 2018 [cited 3/30/18]. Available from: http://www.clinicalpharmacology.com/.
2. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine; 2000 Feb 29 - [cited 3/30/18]. Available from: http://clinicaltrials.gov/.
3. DRUGDEX® System [Internet]. Greenwood Village (CO): Thomson Micromedex; Updated periodically [cited 3/30/18]. Available from: http://www.thomsonhc.com/.
4. Orphan Drug Designations and Approval [Internet]. Silver Spring (MD): US Food and Drug Administration; 2018 [cited 3/30/18]. Available from: http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm/.
5. Silberstein SD. Practice parameter: evidence-based guidelines for migraine headache (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2000 Sep 26;55(6):754-62.
6. TerSera Therapeutics. Ergomar sublingual (ergotamine tartrate) tablet. 2018 [cited 3/30/18]. In: DailyMed [Internet]. Bethesda (MD): National Library of Medicine. Available from: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=dac9637f-3326-4f25-b7b9-f9f54b738232/.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 4/11/18.

GUIDELINE UPDATE INFORMATION:

06/15/17	New Medical Coverage Guideline.
5/15/18	Review and revision to guideline; consisting of updating references