BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

HUMATIN™ (paromomycin sulfate) oral
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

➢ **Criteria for initial therapy:** Humatin (paromomycin sulfate) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Gastroenterologist or Infectious Disease Physician

2. Individual has a confirmed diagnosis of **ONE** of the following:
    a. Intestinal amebiasis in an adult or pediatric individual

    b. Hepatic coma in an adult

c. Cryptosporidiosis-associated diarrhea in patients with HIV in an adult or adolescent individual

d. Dientamoeba fragilis infection in an adult

3. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

4. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for **ONE** of the following:
   a. For hepatic coma: combination of lactulose and neomycin
   b. Cryptosporidiosis-associated diarrhea in patients with HIV: Nitazoxanide
   c. Dientamoeba fragilis infection: Metronidazole

5. Individual **DOES NOT** have the FDA-label contraindication of intestinal obstruction

6. Individual **DOES NOT** have ulcerative lesions of the bowel

Initial approval duration:
   a. For Intestinal amebiasis: 7-10 days treatment
   b. For Hepatic coma: 6 months
   c. For Cryptosporidiosis-associated diarrhea in patients with HIV: 7 days treatment
   d. For Dientamoeba fragilis infection: 7 days treatment

- **Criteria for continuation of coverage (renewal request):** Humatin (paromomycin sulfate) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Gastroenterologist or Infectious Disease Physician

2. Individual's condition has responded while on therapy with response defined as **ONE** of the following:
   a. **For hepatic coma** there is documentation of Grade II encephalopathy and requires continued therapy
   b. **For Cryptosporidiosis-associated diarrhea** there is documentation diarrhea has improved but has not resolved and stools continue to have oocysts
   c. **For Intestinal amebiasis and Dientamoeba fragilis infection:** Request for continuation will be considered new infections and will be evaluated using the Initial Criteria above

3. Individual has been adherent with the medication

4. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

5. Individual **DOES NOT** have the FDA-label contraindication of intestinal obstruction

6. Individual **DOES NOT** have ulcerative lesions of the bowel

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**
2. **Off-Label Use of Cancer Medications**

Description:

Humatin (paromomycin sulfate) is indicated for acute and chronic intestinal amebiasis in adults and pediatric individuals. It is not effective in extraintestinal amebiasis. Humatin (paromomycin sulfate) is also indicated for the management of hepatic coma in adults as adjunctive therapy.

Paromomycin sulfate is a broad-spectrum antibiotic, the *in-vitro* and *in-vivo* antibacterial action of paromomycin closely parallels that of neomycin. It is poorly absorbed after oral administration, with almost 100% of the drug recoverable in the stool.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Grading system for hepatic encephalopathy			
Grade	Mental Status	Asterixis	EEG
I	Euphoria/Depression	Yes/No	Usually normal
	Mild confusion		
	Slurred speech		
	Disordered sleep		
II	Lethargy	Yes	Abnormal
	Moderate confusion		
III	Marked confusion	Yes	Abnormal
	Incoherent		
	Sleeping but arousable		
IV	Coma	No	Abnormal

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Resources:

Humatin (paromomycin sulfate) product information, revised by Waylis Therapeutics LLC 01-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed August 14, 2024.

Leder K, Weller PF. Intestinal entamoeba histolytica amebiasis. In: UpToDate, Ryan ET, Bogorodskaya (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through August 2024. Topic last updated June 14, 2024. Accessed October 01, 2024.

Ridola L, Riggio O. Hepatic encephalopathy in adults: treatment. In: UpToDate, Tapper E, Robson KM (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through August 2024. Topic last updated September 19, 2024. Accessed October 01, 2024.

Weller PF, Leder K. Dientamoeba fragilis. In: UpToDate, Ryan ET, Bogorodskaya (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through August 2024. Topic last updated April 26, 2023. Accessed October 01, 2024.

Leder K, Weller PF. Cryptosporidiosis: Treatment and prevention. In: UpToDate, Ryan ET, Bogorodskaya (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through August 2024. Topic last updated June 14, 2024. Accessed October 01, 2024.

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