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/or 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.

Medical Necessity Requirements for HUMATIN (paromomycin sulfate)

Criteria for Initial Therapy:

Prescriber Qualifications
- A physician specializing in the diagnosis or in consultation with a Gastroenterologist or Infectious Disease Physician

Indication
- Intestinal amebiasis in adult or pediatric
- Hepatic coma in adult
- Cryptosporidiosis associated diarrhea in patients with HIV in adult or adolescent

ORIGINAL EFFECTIVE DATE: 11/16/2023 | ARCHIVE DATE: | LAST REVIEW DATE: 11/20/2025 | LAST CRITERIA REVISION DATE: 11/21/2024

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

- Dientamoeba fragilis infection in adult

Alternative Therapies
- Failure, contraindication per FDA label, intolerance, or is not a candidate for **ONE** of the following:
  - For **hepatic coma**: combination of lactulose and neomycin
  - For **Cryptosporidiosis associated diarrhea in patients with HIV**: Nitazoxanide
  - For **Dientamoeba fragilis infection**: Metronidazole

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the United States Food and Drug Administration (FDA) (see Definitions section)

Safety
- Does not have FDA label contraindication of intestinal obstruction
- Does not have ulcerative lesions of the bowel

Documentation Requirements
- Completed request form including:
  - Chart notes
  - Lab results
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration
- Intestinal amebiasis: 7 to 10 days treatment
- Hepatic coma: 6 months OR end of plan year
- Cryptosporidiosis associated diarrhea in patients with HIV: 7 days treatment
- Dientamoeba fragilis infection: 7 days treatment

Criteria for Continuation of Therapy (renewal therapy):
Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualifications
- Continues to be seen by a physician specializing in the diagnosis or in consultation with a Gastroenterologist or Infectious Disease Physician

Clinical Response
- Positive clinical response defined as **ONE** of the following:
  - **Hepatic coma**: documentation of Grade II encephalopathy and requires continued therapy
  - **Cryptosporidiosis associated diarrhea**: diarrhea improved but not resolved and stools continue to have oocysts
  - **Intestinal amebiasis and Dientamoeba fragilis infection**: considered new infections and evaluated using Initial Criteria

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

PHARMACY COVERAGE GUIDELINE

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

Adherence
- Adherence to prescribed therapy regimen has been documented

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- Does not have FDA label contraindication of intestinal obstruction
- Does not have ulcerative lesions of the bowel

Documentation Requirements
- Chart notes
- Supporting clinical documentation with evidence of improvement
- Lab values confirming safe use

Continuation Therapy Criteria Approval Duration
- 12 months OR end of plan year

Criteria for Off-Label Use Requests:

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

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

PHARMACY COVERAGE GUIDELINE

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

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

Resources:

Humatin (paromomycin sulfate) product information, revised by Waylis Therapeutics LLC 01-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed June 27, 2025.

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 2025. Topic last updated May 19, 2025. Accessed September 26, 2025.

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 2025. Topic last updated September 19, 2024. Accessed September 26, 2025.

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 2025. Topic last updated March 19, 2025. Accessed September 26, 2025.

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 2025. Topic last updated June 14, 2024. Accessed September 26, 2025.

ORIGINAL EFFECTIVE DATE: 11/16/2023 | ARCHIVE DATE: | LAST REVIEW DATE: 11/20/2025 | LAST CRITERIA REVISION DATE: 11/21/2024

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.