

Drug and Biologic Coverage Policy



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Coverage Policy Number IP0520

Paromomycin

Table of Contents

Overview	1
Initial Approval Criteria.....	1
Continuation of Therapy	2
Authorization Duration	2
Conditions Not Covered.....	2
Background.....	2
References	2

Related Coverage Resources

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for paromomycin (Humatin™).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Initial Approval Criteria

Paromomycin (Humatin) is considered medically necessary for the treatment of ONE of the following:

1. Intestinal amebiasis
2. Hepatic coma
3. Cryptosporidiosis-associated diarrhea in patients with HIV
4. Dientamoeba fragilis infection

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Continuation of Therapy

Continuation of paromomycin (Humatin) is considered medically necessary when initial criteria are met AND beneficial response is demonstrated.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

OVERVIEW

Humatin, a broad spectrum antibiotic, is indicated for the treatment of intestinal amebiasis, acute and chronic, and for the management of hepatic coma, as adjunctive therapy.¹

Guidelines

The US Department of Health and Human Services (HHS) Guidelines for Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV state paromomycin is effective and recommended in the management of diarrhea caused by *Cryptosporidium* in adolescent and adult patients with HIV. The HHS recommend paromomycin be used in combination with optimized ART, electrolyte replacement, symptomatic treatment, and rehydration.²

The Centers for Disease Control and Prevention: Parasites – *Dientamoeba fragilis* guidelines, state paromomycin is effective and recommended for the management of *Dientamoeba fragilis*.³

References

1. Humatin™ capsules [prescribing information]. Wixom, MI: Waylis Therapeutics LLC; January, 2021.
2. US Department of Health and Human Services (HHS) Panel on Opportunistic Infections in Adults and Adolescents with HIV. Guidelines for the prevention and treatment of opportunistic infections in adults and adolescents with HIV: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. http://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf. Accessed May 4, 2020.
3. Centers for Disease Control and Prevention: Parasites—*Dientamoeba fragilis*. Resources for health professionals. http://www.cdc.gov/parasites/dientamoeba/health_professionals/index.html. Updated December 17, 2012. Accessed October 27, 2022.

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