Reference number(s)
7359-A

Specialty Guideline Management
Zycubo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Zycubo	copper histidinate

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Zycubo is indicated for treatment of Menkes disease in pediatric patients.

Limitations of use:

Zycubo is not indicated for the treatment of Occiptal Horn Syndrome (OHS).

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Menkes disease

Initial requests:

- Pretreatment serum copper level
- Chart notes, medical record documentation, or molecular genetic test results confirming a variant in the ATP7A gene

Prescriber Specialties

This medication must be prescribed by or in consultation with a gastroenterologist, neurologist, geneticist, or specialist in the treatment of Menkes disease.

Exclusions[1]

Coverage will not be provided for members who are diagnosed with Occipital Horn Syndrome (OHS).

Coverage Criteria

Menkes Disease[1]

Authorization of 12 months may be granted for treatment of Menkes disease in members less than 17 years of age when all of the following criteria are met:

- The member has Menkes disease confirmed by molecular genetic testing showing a variant in the ATP7A gene.
- The member has a pretreatment serum copper level less than 75 micrograms per deciliter (mcg/dL).
- Serum copper level, serum ceruloplasmin level, liver function, kidney function, serum electrolytes, and complete blood count (CBC) have been assessed at baseline and will be monitored after Zycubo administration as clinically appropriate.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in all members (including new members) who are currently receiving the requested medication and there is no evidence of unacceptable toxicity.

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References

1. Zycubo [package insert]. Solana Beach, CA: Sentynl Therapeutics, Inc.; January 2026.
2. Ramani PK, Sankaran BP. Menkes Disease. StatPearls. 2026 November 14. Available from: https://www.ncbi.nlm.nih.gov/books/NBK560917/.