Mass General Brigham
Health Plan

Zycubo (copper histidinate)
Effective 09/01/2026

Plan	☐ MassHealth UPPL ☒ Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Zycubo (copper histidinate) is indicated for the treatment of Menkes disease in pediatric patients. Treatment of Zycubo for more than three years has not been studied.

Coverage Guidelines
If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all of the following criteria are met:

1. Submission of medical records (e.g. chart notes) documenting diagnosis of Menkes disease
2. Submission of medical records (e.g., chart notes) documenting molecular genetic testing that confirms pathogenic variants of the ATP7A gene (copper-transporting ATPase) as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)
3. Provider attestation that the member will be closely monitored for copper accumulation and related toxicity throughout therapy
4. Prescribed by or in consultation with one of the following:
    a. Pediatrician
    b. Neurologist
    c. Geneticist

Continuation of Therapy
Requests for reauthorization will be approved when all of the following criteria are met:

1. Submission of medical records (e.g, chart notes) documenting that member demonstrates positive clinical response to therapy
2. Provider attestation that the member will continue to be monitored for copper accumulation and related toxicity throughout therapy
3. Member has not exceeded 3 years duration of treatment with Zycubo
4. Prescribed by or in consultation with one of the following:

a. Pediatrician
b. Neurologist
c. Geneticist

Limitations

1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted for 12 months
3. The following quantity limits apply

Drug Name and Dosage	Quantity Limit
Zycubo 2.9 mg vial	2 vials per day

References

1. Kaler SG. Neurodevelopment and brain growth in classic Menkes disease is influenced by age and symptomatology at initiation of copper treatment. *J Trace Elem Med Biol*. 2014;28(4):427-430. doi:10.1016/j.jtemb.2014.08.008.
2. Liu W, Xue Y, Cao C, Yang L, Zhang L. Copper homeostasis and cuproptosis in neurological disorders. *Drug Des Devel Ther*. 2026;20:580005. doi:10.2147/DDDT.S580005.
3. Maung MT, Carlson A, Olea-Flores M, et al. The molecular and cellular basis of copper dysregulation and its relationship with human pathologies. *FASEB J*. 2021;35:e21810. doi:10.1096/fj.202100273RR.
4. National Organization for Rare Disorders (NORD). Menkes disease. NORD. March 24, 2020. Accessed March 30, 2026. https://rarediseases.org/rare-diseases/menkes-disease/
5. Zycubo (copper histidinate) [prescribing information]. Solana Beach, CA: Sentynl Therapeutics, Inc; January 2026.

Review History

06/10/2026 – Reviewed at June P&T. Effective 09/01/2026.