Effective Date: 08/01/2026
Reviewed: 05/2026 Scope: Medicaid

Zycubo (Copper Histidinate)

POLICY

I. CRITERIA FOR APPROVAL

An authorization may be granted when all the following criteria are met:

A. Member is less than 17 years of age
B. Medication is prescribed by, or in consultation with gastroenterologist, neurologist, geneticist, or specialist in the treatment of Menkes disease (MD)
C. Member has documented diagnosis of Menkes disease through one of the following:
    a. Genetic confirmation of an ATP7A mutation consistent with severe MD phenotype
    b. Biochemical plasma catecholamine analysis showing elevated DOPAC:DHPG and dopamine:norepinephrine ratios
    c. Clinical signs and symptoms (including but not limited to characteristic Menkes kinky hair, skin abnormalities, progressive neurologic impairment, growth and development delays, and multisystem complications affecting the brain, bones, and connective tissues) that are strongly consistent with MD when genetic results are pending, and delay would result in harm
D. Documentation that the member does not have Occipital Horn Syndrome (OHS)
E. Documentation that the member has a pretreatment serum copper level less than 75 micrograms per deciliter (mcg/dL)
F. Documentation that the member's 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.

II. CONTINUATION OF THERAPY

An authorization may be granted for all members when all of the following criteria are met:

A. If member has not been approved for this drug by Neighborhood in the past, clinician must submit documentation that initial criteria is met.
B. Documentation that the member is tolerating treatment and is experiencing a positive clinical response (e.g., improved survival, attaining developmental milestones, physical gains, and normalization of copper-related biomarkers)
C. Documentation that the member's diagnosis is confirmed with genetic testing if not confirmed initially
D. Documentation supporting that an additional 6 months of treatment would result in a total treatment duration of 3 years or less.

III. QUANTITY LIMIT

Zycubo 2.9mg/vial: 2 single-dose vials per day or 60 single-dose vials per 30 days

IV. COVERAGE DURATION

- Initial with genetic testing confirmation: 6 months

- Initial with clinical documentation and pending genetic testing: 3 months
- Renewal with genetic testing confirmation: 6 months

V. REFERENCES

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