

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2026 P 2418-1
Program	Prior Authorization/Medical Necessity
Medication	Zycubo® (copper histidinate)
P&T Approval Date	5/2026
Effective Date	7/1/2026

**1. Background:**

Zycubo® (copper histidinate) is a copper replacement product indicated for the treatment of Menkes disease in pediatric patients.

Limitations of Use:

Zycubo is not indicated for the treatment of Occipital Horn Syndrome.

**2. Coverage Criteria<sup>a</sup>:**

**A. Initial Authorization**

1. **Zycubo** will be approved based upon **all** of the following criteria:

a. Patient is < 18 years old

-AND-

b. Diagnosis of Menkes disease

-AND-

c. Diagnosis confirmed by molecular genetic test demonstrating a pathogenic or likely pathogenic variant in the *ATP7A* gene

-AND-

d. Patient does not have a diagnosis of Occipital Horn Syndrome

-AND-

e. Prescribed by, or in consultation with **one** of the following:

(1) Geneticist

(2) Pediatric neurologist

(3) A specialist with expertise in the treatment of Menkes disease

**Authorization will be issued for 12 months.**

**B. Reauthorization**

1. **Zycubo** will be approved based on **all** the following criteria:

a. Documentation of positive clinical response to Zycubo therapy

**-AND-**

b. Patient has not exceeded 3 years duration of treatment with Zycubo

**-AND-**

c. Prescribed by, or in consultation with **one** of the following:

- (1) Geneticist
- (2) Pediatric neurologist
- (3) A specialist with expertise in the treatment of Menkes disease

**Authorization will be issued for 12 months.**

<sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

### 3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

### 4. Reference:

1. Zycubo [package insert]. Solana Beach, CA: Sentyln Therapeutics, Inc.; January 2026.
2. Menkes Disease. National organization for rare disorders NORD. Updated March 24, 2020. Available at: <https://rarediseases.org/rare-diseases/menkes-disease/>. Accessed on April 1, 2026.
3. Vairo FPE, Chwal BC, Perini S, Ferreira MAP, de Freitas Lopes AC, Saute JAM. A systematic review and evidence-based guideline for diagnosis and treatment of Menkes disease. *Mol Genet Metab.* 2019;126(1):6-13.

Program	Prior Authorization/Medical Necessity - Zycubo (copper histidinate)
<b>Change Control</b>	
5/2026	New program.