SENTARA HEALTH PLANS

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Zycubo® (copper histidinate)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

Recommended Dosage:

- Infants: 1.45 mg twice daily; doses should be separated by 8 to 12 hours.
- Children and Adolescents < 17 years: 1.45 mg once daily.

Quantity Limit:

- 2 single-dose vials (2.9 mg/vial) per day; Total collective approval duration not to exceed 3 years of therapy.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

❑ **Diagnosis: Menkes Disease**

Initial Authorization: 12 months

❑ Member is <18 years of age

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- ❑ Prescribed by or in consultation with a neurologist, medical geneticist, or other specialist in treatment of Menkes disease
- ❑ Member has a diagnosis of classic Menkes disease confirmed by a severe pathogenic variant of the ATP7A gene (duplication/deletion, nonsense, or a canonical splice junction variant) documented on molecular genetic test results **(please provide test results)**
- ❑ If symptomatic, member has clinical signs and symptoms (including but not limited to characteristic Menkes kinky hair, skin abnormalities, progressive neurologic impairment, growth and developmental delays, and multisystem complications affecting the brain, bones, and connective tissues) that are consistent with Menkes disease
- ❑ Member's baseline serum copper level is < 75 mg/dL and serum ceruloplasmin level is < 20 mg/dL or below normal reference range for age **(please provide current lab test results)**
- ❑ Member's baseline serum electrolytes, kidney and liver function, and complete blood count (CBC) have been assessed **(please provide current documentation)**
- ❑ Member does **NOT** have diagnosis of occipital horn syndrome
- ❑ May be approved for infant members (<1 year of age) for 1 month if according to the prescriber, the member has findings suggestive of Menkes disease and genetic testing is in progress **(resubmission of request with documentation of genetically confirmed diagnosis will be required after 1 month)**

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet diagnostic criteria in initial authorization section above
- ❑ Member has a documented positive response to therapy as evidenced by improvement or stabilization in disease progression **(please provide current supporting lab test results and other documentation that the disease has responded)**
- ❑ Member's serum copper, ceruloplasmin, electrolytes, kidney and liver function, and complete blood count (CBC) continue to be assessed as per guideline recommendations **(please provide current documentation)**
- ❑ Member is **NOT** using Zycubo in combination with other experimental or approved therapies for treatment of Menkes disease
- ❑ If requesting for more than 3 years of therapy, documentation of medical necessity for continued benefit-to-risk must be provided

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Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: **3/26/2026**
REVISED/UPDATED/REFORMATTED: 4/16/2026