Copper histidinate (ZYCUBO)

Goal(s):
- Promote appropriate use of copper histidinate based on available evidence.

Length of Authorization:
- Up to 12 months

Requires PA:
- Copper histidinate (ZYCUBO)

Covered Populations: FFS and CCO patients beginning 05/1/26 (pharmacy or provider administered claims)

Covered Alternatives:
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request for a patient with a prior FFS approval for the requested drug?	**Yes**: Go to **Renewal Criteria**	**No:** Go to #3
3. Is this an FDA approved age and indication?	**Yes**: Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Is patient both treatment naïve AND over 3 years of age?	**Yes**: Go to #5	**No:** Go to #6
5. Is there documentation that Occipital Horn Disease has been ruled out?	**Yes**: Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Is the drug prescribed by or in consultation with a specialist with experience treating Menkes disease (e.g., medical geneticist, pediatric neurologist)?	**Yes**: Go to #7	**No:** Pass to RPh. Deny; medical appropriateness
7. Is there documentation of baseline lab work within past 3 months including: serum copper and ceruloplasmin levels, serum electrolytes, kidney and liver function, and complete blood count (CBC)?	**Yes**: Go to #8	**No:** Pass to RPh. Deny; medical appropriateness
8. Is the requested dose/interval appropriate based on FDA labeling?	**Yes:** Go to #9	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
9. Is there documentation of genetic testing indicating severe loss of function variant of *ATP7A* gene (mutation types: deletion/duplication, nonsense, or canonical splice junction variants)?	**Yes**: Pass to RPh; Pend. Refer to DMAP for secondary review. Approve based on age: < 12 months: enough units to reach 1st birthday with twice daily dosing; ≥ 12 months: approve for 6 months enough units for once daily dosing. Note: all vials are single use only.	**No:** Go to #10
10. Is genetic testing pending?	**Yes**: Pass to RPh; Pend. Refer to DMAP for secondary review. Approve for one month while awaiting results. Dose based on age: < 12 months: twice daily dosing; ≥ 12 months: once daily dosing Note: all vials are single use only.	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Is there documentation of appropriate laboratory monitoring based on labeling recommendations and current length of therapy? Note: product labeling recommends serum copper and ceruloplasmin levels, serum electrolytes, kidney and liver function, and CBC every 6 weeks for first 6 months, then every 3 months for 18 months, and then every 6 months thereafter while on treatment.	**Yes**: Go to #2	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
2. Is dosing interval appropriate based on FDA labeling and *current* age? Note: dosing should be adjusted to once daily after 1 year of age.	**Yes:** Pass to RPh; Pend. Refer to DMAP for secondary review. Approval duration: 12 months	**No:** Pass to RPh. Deny; medical appropriateness