



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIENTINE

Generic	Brand	HICL	GCN	Exception/Other
TRIENTINE	SYPRINE, CLOVIQUE	01109		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a known family history of Wilson's disease or physical examination consistent with Wilson's disease and meet **ONE** of the following criteria?
 - Plasma copper-protein ceruloplasmin less than 20mg/dL
 - Liver biopsy positive for an abnormally high concentration of copper (greater than 250mcg/g dry weight) **OR** the presence of Kayser-Fleischer rings
 - Diagnosis has been confirmed by genetic testing for ATP7B mutations

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
 - The patient has maintained a reduced copper dietary intake (less than 2mg copper per day)
 - The medication is prescribed by or given in consultation with a hepatologist
 - The patient has had a previous trial of or contraindication to Depen (penicillamine)

If yes, **approve for 12 months by HICL with a quantity limit of #8 capsules per day.**

APPROVAL TEXT: Renewal requires that the patient has achieved a free serum copper of less than 10 mcg/dL.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **TRIENTINE (Syprine, Clovique)** will allow for approval for patients with a known family history of Wilson's disease or physical examination consistent with Wilson's disease and who meet **ONE** of the following criteria:

- Plasma copper-protein ceruloplasmin less than 20mg/dL
- Liver biopsy positive for an abnormally high concentration of copper (greater than 250mcg/g dry weight) **OR** the presence of Kayser-Fleischer rings
- Diagnosis has been confirmed by genetic testing for ATP7B mutations

In addition, the following criteria must also be met:

- The patient has maintained a reduced copper dietary intake (less than 2mg copper per day)
- The medication is prescribed by or given in consultation with a hepatologist
- The patient has had a previous trial of or contraindication to Depen (penicillamine)

CONTINUED ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIENTINE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Wilson's disease **AND** meet the following criterion?
 - The patient has achieved a free serum copper of less than 10 mcg/dL

If yes, **approve for lifetime by HICL with a quantity limit of #8 capsules per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **TRIENTINE (Syprine, Clovique)** requires a diagnosis of Wilson's disease AND the patient has achieved a free serum copper of less than 10 mcg/dL.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Syprine.

REFERENCES

- Syprine [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals; December 2016.
- Clovique [Prescribing Information]. Warrendale, PA: Kadmon Pharmaceuticals, LLC; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/20

Created: 08/16

Client Approval: 11/19

P&T Approval: 10/19