penicillamine (Cuprimine®) / trientine (Syprine®)

Policy #  00531
Original Effective Date: 01/01/2017
Current Effective Date: 01/01/2017

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider penicillamine (Cuprimine®) and trientine (Syprine®) to be eligible for coverage.

Patient Selection Criteria
Coverage eligibility for penicillamine (Cuprimine) or trientine (Syprine) will be considered when the following criteria are met for the requested drug:

- If the requested drug is penicillamine (Cuprimine): There is clinical evidence or patient history that suggests the use of penicillamine (Depen) will be/was ineffective or will/did cause an adverse reaction to the patient.
  (Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)
- If the requested drug is trientine (Syprine): Patient has a diagnosis of Wilson’s disease AND the patient is intolerant of a penicillamine product.

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of penicillamine (Cuprimine) WITHOUT clinical evidence or patient history that suggests the use of penicillamine (Depen) will be/was ineffective or will/did cause an adverse reaction to the patient to be not medically necessary.**

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of trientine (Syprine) for any indication other than its respective FDA approved indication to be investigational.*

Background/Overview
Cuprimine and Depen, which both contain 200mg of penicillamine, are both indicated for the treatment of Wilson’s disease, cystinuria, and in patients with severe, active rheumatoid arthritis who have failed to respond to an adequate trial of conventional therapy. The main difference between the two is that Depen is a tablet while Cuprimine is a capsule. There is also a vast difference in price, making Depen the more economical option with equal clinical efficacy as Cuprimine. Syprine is indicated for the treatment of
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Wilson’s disease in those that are intolerant to penicillamine. Syprine is a drug that has a very specific FDA approval and should be managed as such.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
Cuprimine and Depen, which both contain 200mg of penicillamine, are both indicated for the treatment of Wilson’s disease, cystinuria, and in patients with severe, active rheumatoid arthritis who have failed to respond to an adequate trial of conventional therapy. Syprine is indicated for the treatment of Wilson’s disease in those that are intolerant to penicillamine.

Rationale/Source
The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the use of penicillamine (Depen) will be/was ineffective or will/did cause an adverse reaction to the patient. Based on a review of the available data and in the absence of the above mentioned caveat, there is no advantage of using Cuprimine over Depen. This policy is also meant to ensure that Syprine is being used for its labeled indication.

References

Policy History
Original Effective Date: 01/01/2017
Current Effective Date: 01/01/2017
09/08/2016 Medical Policy Committee review
09/21/2016 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 09/2017

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
   1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
   2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
   3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

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A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.