Pharmacy Medical Necessity Guidelines

Carbaglu® (carglumic acid)

Effective: 8/27/14

Clinical Documentation and Prior Authorization Required: √

Type of Review – Case Management

Not Covered: √

Type of Review – Clinical Review
Fax: 617-673-0956

Pharmacy (RX) or Medical (MED) Benefit: RX
Department to Review: RxUM

OVERVIEW

FDA-APPROVED INDICATIONS

Carbaglu® (carglumic acid) is the first FDA-approved pharmacological agent indicated for the specific treatment of hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency, a rare urea cycle disorder (UCD). NAGS deficiency is an inherited autosomal recessive metabolic disorder that is one of the most severe and rarest of the urea cycle disorders. The five year survival rate for hyperammonemic patients with a UCD, including NAGS deficiency, is 22% for neonatal onset and 41% for late onset. Despite improvements in prognosis from a better understanding of the disease state, 50% of patients with severe UCDs will die by four years of age.

PHARMACY COVERAGE GUIDELINES

Tufts Health Plan – Network Health may authorize coverage of Carbaglu (carglumic acid) for members when the following criterion is met:

- There is a documented diagnosis of hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency.

LIMITATIONS

None

CODES

None

REFERENCES


APPROVAL HISTORY

- June 12, 2014: Reviewed by the Pharmacy and Therapeutics Committee
BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medical Necessity Guidelines apply to all fully insured Tufts Health Plan – Network Health offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable product formulary in the Pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines, when applicable, and adherence to plan policies and procedures and claims editing logic.