Pharmacy Medical Necessity Guidelines:
Entresto™ (sacubitril/valsartan)

Effective: June 1, 2017

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<th>Prior Authorization Required</th>
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<th>Type of Review – Care Management</th>
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This Pharmacy Medical Necessity Guideline applies to the following:

Tufts Health Plan Commercial Plans
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

Tufts Health Public Plans
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan

Tufts Health Freedom Plan products
- Tufts Health Freedom Plan – large group plans
- Tufts Health Freedom Plan – small group plans

Fax Numbers:
RXUM: 617.673.0988

Note: For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

OVERVIEW
FDA-APPROVED INDICATIONS
Entresto is a combination of sacubitril, a neprilysin inhibitor, and valsartan, an angiotensin II receptor blocker (ARB), indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction.

The 2016 American College of Cardiology/American Heart Association/Heart Failure Society of American (ACC/AHA/HFSA) heart failure guidelines recommend combining evidence-based beta blockers with an angiotensin converting enzyme (ACE) inhibitor, ARB, or an angiotensin receptor-neprilysin inhibitor (ARNI) in patients with chronic heart failure with reduced ejection fraction (HFrEF) to reduce morbidity and mortality.

COVERAGE GUIDELINES
The plan may authorize coverage of Entresto (sacubitril/valsartan) for Members when all of the following criteria are met:
1. The prescriber is a cardiologist
   AND
2. Documented diagnosis of chronic heart failure (NYHA Class II-IV) and reduced ejection fraction
   AND
3. The Member is not concomitantly taking an angiotensin-converting enzyme inhibitor (ACEI) or an angiotensin receptor blocker (ARB)

LIMITATIONS
None

CODES
None

REFERENCES

**APPROVAL HISTORY**

October 06, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- October 18, 2016: Combined criteria for Together and Commercial. Together criteria updated to include that Member is not taking an ARB.

**BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION**

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage...
decisions are made. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member’s health care needs. 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 service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.