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

Effective: May 18, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM:
617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

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. Entresto is also indicated for the treatment of symptomatic heart failure with the systemic left ventricular systolic dysfunction in pediatric patients aged one year and older.

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 Member has a diagnosis of pediatric heart failure with left ventricular systolic dysfunction that is symptomatic

OR

1. Documented diagnosis of chronic heart failure (NYHA Class II-IV) and reduced ejection fraction

AND

2. Inadequate response or intolerance to an angiotensin-converting enzyme inhibitor (ACEI) or an angiotensin receptor blocker (ARB), or member has a contraindication to an ACE inhibitor

AND

3. Current use of a maximally tolerated dose of a beta-blocker OR member has a documented contraindication to beta-blocker use

AND

4. The Member will not take Entresto concomitantly with an angiotensin-converting enzyme inhibitor (ACEI) or an angiotensin receptor blocker (ARB)

LIMITATIONS

None

CODES

None

REFERENCES

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APPROVAL HISTORY

October 06, 2015: Reviewed by Pharmacy & Therapeutics Committee.
Subsequent endorsement date(s) and changes made:

1. October 18, 2016: Combined criteria for Together and Commercial. Together criteria updated to include that Member is not taking an ARB.
2. May 9, 2017: Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Added trials with ACE inhibitor or ARB and beta blocker to the criteria.
3. November 14, 2017: No changes.
4. June 12, 2018: Updated criteria to allow prescriber to be a cardiologist or prescribing in consultation with a cardiologist.
5. June 11, 2019: Administrative changes made to template.
6. May 12, 2020: Effective 5/18/20, updated criteria to include the indication of pediatric heart failure with left ventricular systolic dysfunction that is symptomatic. Removed the requirement that the prescriber is a cardiologist.

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. 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.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

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.