Updated: 11/2017
PARP Approved: 03/2017

Gateway Health
Prior Authorization Criteria
Entresto (sacubitril/valsartan)

All requests for EntrestoTM (sacubitril/valsartan) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below. Drug Name

Coverage may be provided when the diagnosis is **chronic heart failure (New York Heart Association Class II-IV)** and the following criteria is met:

- The member is 18 years of age or older
- Treatment is prescribed by or in consultation with a cardiologist
- The member has a New York Heart Association (NYHA) Classification of II-IV
    - NYHA Class II: Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath)
    - NYHA Class III: Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea
    - NYHA Class IV: Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases
- The member is receiving concomitant therapy with both of the following, unless the member was unable to tolerate or has a contraindication to therapy:
    - Beta blocker (bisoprolol, carvedilol, or extended-release metoprolol succinate)
    - Aldosterone antagonist
- The member has an ejection fraction of $\leq$ 40%
- The member is not pregnant
- The member does not have any of the following contraindications to therapy:
    - History of angioedema related to previous ACE inhibitor or ARB therapy
    - Concomitant use with ACE inhibitors
    - Concomitant use with aliskiren (Tekturna) in members with diabetes
- Dosing is within the following prescribing-supported parameter(s):
    - Initial dose: 49/51 mg twice-daily
    - Maintenance dose: 97/103 mg twice-daily, as tolerated
    - Dose adjustments: for members not currently taking an ACE inhibitor or ARB or previously taking a low dose of these agents, for members with severe renal impairment, or for members with moderate hepatic impairment: Reduce initial dose to 24/26mg twice-daily. Double the dose every 2-4 weeks to the target maintenance dose of 97/103 mg twice daily, as tolerated.

- **Initial Duration of Approval**: 12 months.

- **Reauthorization criteria**:

  - There is documentation demonstrating the patient is tolerating and obtaining clinical benefit from treatment
  - Member is not pregnant
  - Member has no contraindications to Entresto™ (sacubitril/valsartan) (as listed in the above criteria)

- **Reauthorization Duration of Approval**: 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.