MEDICAL MUTUAL®

# Drug Policy

| Policy: | Entresto (sacubitril and valsartan) | Annual Review Date: 06/20/2024<br>Last Revised Date: 06/20/2024 |
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## OVERVIEW

Entresto is a combination of sacubitril, a neprilysin inhibitor, and valsartan, an angiotensin II receptor blocker, 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 in adult patients. It is also indicated for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older.

## POLICY STATEMENT

This policy involves the use of Entresto. Prior authorization is recommended for pharmacy benefit coverage of Entresto. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Entresto as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Entresto be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

**Automation:** When available, ICD-10 codes for Heart Failure (ICD-10: **I50.1*, I50.2*)** will be used for automation to allow approval for Entresto for patients at least 18 years of age.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Entresto is recommended in those who meet the following criteria:

**1. Heart Failure (HF), Adults – initial therapy**

**Criteria.** *Patient must meet the following criteria*

- **A.** Heart failure staged as NYHA Class II or greater; AND
- **B.** Prescribed by or in consultation with a cardiologist; AND
- **C.** Entresto will not be used concomitantly with ACE inhibitors, ARBs, or with aliskiren (Tekturna) in patients with diabetes; AND
- **D.** The dose of Entresto will not exceed 97/103 mg twice daily

2. **Chronic Heart Failure (HF), Adults – continuation of therapy**
**Criteria.** *Patient must meet the following criteria*

**A.** Provider attests that patient achieving clinical benefit while taking Entresto (i.e. decreased hospitalizations, improved heart failure symptoms, improved quality of life, etc); AND
**B.** Entresto is prescribed by or in consultation with a cardiologist; AND
**C.** Entresto is not being used in combination with an ACE inhibitor, an ARB, or aliskiren (Tekturna) in patients with diabetes

3. **Heart Failure (HF), Pediatric Patients – initial therapy**
**Criteria.** *Patient must meet the following criteria*
**A.** The patient is ≥ 1 year of age; AND
**B.** Entresto is being used for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction
**C.** Prescribed by or in consultation with a cardiologist; AND
**D.** Entresto will not be used concomitantly with ACE inhibitors, ARBs, or with aliskiren (Tekturna) in patients with diabetes; AND
**E.** The dose of Entresto will not exceed 97/103 mg twice daily.

4. **Heart Failure (HF), Pediatric Patients – continuation of therapy**
**Criteria.** *Patient must meet the following criteria*
**A.** The patient is ≥ 1 year of age; AND
**B.** Entresto is being used for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction
**C.** Prescribed by or in consultation with a cardiologist; AND
**D.** Entresto will not be used concomitantly with ACE inhibitors, ARBs, or with aliskiren (Tekturna) in patients with diabetes.
**E.** Provider attests the patient is achieving clinical benefit while taking Entresto (i.e. decreased hospitalizations, improved heart failure symptoms, improved quality of life, etc)

**Initial Approval/ Extended Approval.**
**A)** *Initial Approval:* 1 year
**B)** *Extended Approval:* 1 year

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Entresto has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

**Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

## REFERENCES

1. Entresto™ tablets [prescribing information]. East Hanover, NJ: Novartis; November 2018
2. McMurray JJV, Packer M, Desai AS, et al, for the PARADIGM-HF Investigators and Committees. Angiotensin-neprilysin inhibition versus enalapril in heart failure. *N Engl J Med.* 2014;371(11):993-1004.
3. Yancy CW, Jessup M, Bozkurt B, et al. Report of the American College of Cardiology/American Heart Association task force on clinical practice guidelines and the Heart Failure Society of America [published May 20, 2016]. *J Am Coll Cardiol*. 2016; doi:10.1016/j.jacc.2016.05.011
4. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure: a Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. J Am Coll Cardiol. 2017 April 2017. [Epub ahead of print].
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6. Sacubitril/valsartan. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 23 August 2018. Accessed on 21 July 2019.
7. Heidenreich PA, Bozkurt B. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. April 2022