PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

ENTRESTO
(sacubitril and valsartan)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Adult Heart Failure

Entresto is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal.

LVEF is a variable measure, so use clinical judgment in deciding whom to treat.

Pediatric Heart Failure

Entresto is indicated for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older. Entresto reduces NT-proBNP and is expected to improve cardiovascular outcomes.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient is 18 years of age or older
  AND
- The requested drug is being prescribed to reduce the risk of cardiovascular death and hospitalization for heart failure
  AND
- The patient has a diagnosis of symptomatic chronic heart failure
  AND
  - The patient has a left ventricular ejection fraction (LVEF) less than or equal to 40 percent. Documentation is required for approval. **AND**
  - The patient will receive concomitant treatment with a maximally tolerated dose of a beta-blocker (e.g., carvedilol, metoprolol succinate, bisoprolol)
    OR
  - The patient has experienced an intolerance to a beta-blocker (e.g., carvedilol, metoprolol succinate, bisoprolol)
    OR
  - The patient has a contraindication that would prohibit a trial of a beta-blocker (e.g., carvedilol, metoprolol succinate, bisoprolol)

  OR
- The patient has structural heart disease (i.e., left atrial enlargement [LAE], left ventricular hypertrophy [LVH]). Documentation is required for approval.

OR

- This request is for a pediatric patient one year of age or older
  AND

- The requested drug is being prescribed for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction

AND

- If the patient has a diagnosis of diabetes, the requested drug will not be used in combination with Tekturna (aliskiren)

  OR
- If the patient has renal impairment (estimated Glomerular Filtration Rate [eGFR] less than 60 milliliters per minute per 1.73 meters squared [mL/min/1.73m^2]), the requested drug will not be used in combination with Tekturna (aliskiren)

REFERENCES

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2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed March 12, 2021.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed March 15, 2021.
4. Maddox TM, Januzzi JL, Allen LA, et al. 2021 Update to the 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction: A Report of the American College of Cardiology Solution Set Oversight Committee. *J Am Coll Cardiol.* Published online January 2021. Available at: https://www.jacc.org/doi/10.1016/j.jacc.2020.11.022?_ga=2.266943758.1073019511.1611765807-2024013049.1611765807
5. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA Guideline for the Management of Heart Failure. *J Am Coll Cardiol*. 2013;62(16):e147-e239.