CVS Caremark®

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| Reference number(s) |
| 1277-A, 1276-A |

# Initial Prior Authorization Entresto

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
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| Entresto | sacubitril and valsartan |

## Indications

### 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

### Adult Heart Failure

Authorization may be granted when the requested drug is being prescribed to reduce the risk of cardiovascular death and hospitalization for heart failure when ALL of the following criteria are met:

* The patient is 18 years of age or older
* The patient has a diagnosis of symptomatic chronic heart failure and ONE of the following criteria are met:
  + The patient has ANY of the following: left ventricular ejection fraction less than or equal to 40 percent (i.e., Heart Failure with reduced Ejection Fraction [HFrEF]), previous left ventricular ejection fraction less than or equal to 40 percent and a follow-up left ventricular ejection fraction measurement of greater than 40 percent (i.e., Heart Failure with improved Ejection Fraction [HFimpEF]). [ACTION REQUIRED: Documentation is required for approval]. In addition, the patient meets ONE of the following criteria:
    - The patient will receive concomitant treatment with a maximally tolerated dose of a beta-blocker (e.g., carvedilol, metoprolol succinate, bisoprolol)
    - The patient has experienced an intolerance to a beta-blocker (e.g., carvedilol, metoprolol succinate, bisoprolol)
    - The patient has a contraindication that would prohibit a trial of a beta-blocker (e.g., carvedilol, metoprolol succinate, bisoprolol)
  + The patient has ANY of the following: left ventricular ejection fraction of 41 to 49 percent (i.e., Heart Failure with mildly reduced Ejection Fraction [HFmrEF]), left ventricular ejection fraction greater than or equal to 50 percent (i.e., Heart Failure with preserved Ejection Fraction [HFpEF]). In addition, the patient meets the following criteria:
    - The patient has evidence or history of spontaneous or provokable increased left ventricular filling pressures (e.g., elevated natriuretic peptide, noninvasive and invasive hemodynamic measurement). [ACTION REQUIRED: Documentation is required for approval].
* If the patient has a diagnosis of diabetes, the requested drug will NOT be used in combination with Tekturna (aliskiren)
* If the patient has renal impairment (estimated Glomerular Filtration Rate [eGFR] less than 60 milliliters per minute per 1.73 meters squared [mL/min/1.73m2]), the requested drug will NOT be used in combination with Tekturna (aliskiren)

### Pediatric Heart Failure

Authorization may be granted when the requested drug is being prescribed for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction when ALL of the following criteria are met:

* This request is for a pediatric patient one year of age or older
* If the patient has a diagnosis of diabetes, the requested drug will NOT be used in combination with Tekturna (aliskiren)
* If the patient has renal impairment (estimated Glomerular Filtration Rate [eGFR] less than 60 milliliters per minute per 1.73 meters squared [mL/min/1.73m2]), the requested drug will NOT be used in combination with Tekturna (aliskiren)

## Duration of Approval (DOA)

* 1277-A: DOA: 36 months
* 1276-A: DOA: 12 months

## References

1. Entresto [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2021.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed April 2, 2024.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 04/02/2024).
4. Heidenreich PA, Bozkurt B, Aguilar D et. al. 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. J Am Coll Cardiol. 2022; 79:e263-e421.
5. Kittleson MM, Panjrath GS, Amancherla K et. al. 2023 ACC expert consensus decision pathway on management of heart failure with preserved ejection fraction: a report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2023;81(18):1835-1878.
6. Maddox TM, Januzzi JL Jr, Allen LA, et. al. 2024 ACC expert consensus decision pathway for treatment of heart failure with reduced ejection fraction: a report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol 2024;XX:XXX-XX.

## Document History

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