# PRIOR AUTHORIZATION CRITERIA

**BRAND NAME***
**(generic)**

**ENTRESTO**
**(sacubitril and valsartan)**

***Status: CVS Caremark Criteria*** ***Ref # 1277-A***
***Type: Initial Prior Authorization*** ***Ref # MDC-2 1276-A***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

**FDA-APPROVED INDICATIONS**

Entresto is 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 usually administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other ARB.

**COVERAGE CRITERIA**

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

- The patient has the diagnosis of chronic heart failure (New York Heart Association [NYHA] Class II-IV) and reduced ejection fraction less than or equal to 40 percent

**RATIONALE**

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Entresto (sacubitril and valsartan) is a combination of a neprilysin inhibitor and an angiotensin II receptor blocker. Entresto is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (New York Heart Association [NYHA] Class II-IV) and reduced ejection fraction. PARADIGM-HF was a randomized, double-blind trial comparing Entresto and enalapril in 8,442 adult patients with symptomatic chronic heart failure (NYHA class II–IV) and systolic dysfunction (left ventricular ejection fraction ≤ 40%).[2] Entresto is usually administered in conjunction with other heart failure therapies, in place of an angiotensin-converting-enzyme (ACE) inhibitor or another angiotensin II receptor blocker (ARB).

Entresto is available as tablets, containing sacubitril 24 mg/valsartan 26 mg; sacubitril 49 mg /valsartan 51 mg; and sacubitril 97 mg /valsartan 103 mg. The recommended starting dose of Entresto is 49 mg/51 mg twice-daily. The prescriber should double the dose of Entresto after 2 weeks to 4 weeks to the target maintenance dose of 97 mg/103 mg twice daily, as tolerated by the patient.

**REFERENCES**


1. Entresto [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; November 2018.
2. McMurray JV, Packer M, Desai AS, et al. Angiotensin-neprilysin inhibition versus enalapril in heart failure. *N Engl J Med*. 2014;371(11):993-1004.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed March 2019.

4. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed March 2019.

Written by: UM Development (MS/SE)
Date Written: 07/2015
Revised: (LN) 08/2015 (added reduced ejection fraction); (MS) 03/2016 (no clinical changes), 03/2016 (editorial changes for readability); (MS) 03/2017, (ME) 03/2018 (no clinical changes); (KC) 03/2019 (no clinical changes)
Reviewed: Medical Affairs (KU) 07/2015; (LS) 03/2017
External Review: 08/2015, 06/2016, 06/2017, 06/2018, 06/2019

**CRITERIA FOR APPROVAL**

| | | | |
|---|---|---|---|
| 1 | Does the patient have the diagnosis of chronic heart failure (New York Heart Association [NYHA] Class II-IV) and reduced ejection fraction less than or equal to 40 percent? | Yes | No |

| Guidelines for Approval MDC-2 1276-A | |
|---|---|
| **Duration of Approval** | **12 Months** |
| **Set 1** | |
| **Yes to question(s)** | **No to question(s)** |
| 1 | None |

| Mapping Instructions MDC-2 1276-A | | | |
|---|---|---|---|
| | **Yes** | **No** | **DENIAL REASONS – DO NOT USE FOR MEDICARE PART D** |
| 1. | Approve, 12 months | Deny | You do not meet the requirements of your plan.<br>Your plan covers this drug when you meet all of these conditions:<br>- You have chronic heart failure (New York Heart Association [NYHA] Class II-IV)<br>- You have reduced ejection fraction less than or equal to 40 percent.<br>Your request has been denied based on the information we have.<br>[Short Description: No approvable diagnosis] |

| Mapping Instructions 1277-A | | | |
|---|---|---|---|
| | **Yes** | **No** | **DENIAL REASONS – DO NOT USE FOR MEDICARE PART D** |
| 1. | Approve, 36 months | Deny | You do not meet the requirements of your plan.<br>Your plan covers this drug when you meet all of these conditions:<br>- You have chronic heart failure (New York Heart Association [NYHA] Class II-IV)<br>- You have reduced ejection fraction less than or equal to 40 percent<br>Your request has been denied based on the information we have.<br>[Short Description: No approvable diagnosis] |