

Clinical Pharmacy Program Guidelines for Entresto

Program	Prior Authorization
Medication	Entresto (valsartan-sacubitril)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	5/2015
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	1/2021

1. Background:

Entresto (valsartan-sacubitril) is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure patients with chronic heart failure and reduced ejection fraction. 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.

2. Coverage Criteria:

<p>A. <u>Initial Therapy</u></p> <p>1. Entresto will be approved based on <u>one</u> of the following criteria:</p> <p style="padding-left: 40px;">a. As continuation of therapy initiated during an inpatient stay</p> <p style="text-align: center;">-OR-</p> <p style="padding-left: 40px;">b. Both of the following:</p> <p style="padding-left: 80px;">(1) Diagnosis of pediatric heart failure with systemic left ventricular systolic dysfunction which is symptomatic.</p> <p style="padding-left: 80px;">(2) Prescribed by or in consultation with a cardiologist.</p> <p style="text-align: center;">-OR-</p> <p style="padding-left: 40px;">c. <u>All</u> of the following</p> <p style="padding-left: 80px;">(1) Diagnosis of heart failure (with or without hypertension)</p> <p style="text-align: center;">-AND-</p> <p style="padding-left: 80px;">(2) Ejection fraction is less than or equal to 40 percent</p>
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-AND-

- (3) Heart failure is classified as one of the following:
- (a) New York Heart Association Class II
 - (b) New York Heart Association Class III
 - (c) New York Heart Association Class IV

-AND-

- (4) **One** of the following:

- (a) Patient is on a stabilized dose and receiving concomitant therapy with one of the following beta-blockers:
 - i. bisoprolol
 - ii. carvedilol
 - iii. metoprolol

-OR-

- (b) Patient has a contraindication or intolerance to beta-blocker therapy

-AND-

- 5) Patient does not have a history of angioedema

-AND-

- (6) Patient will discontinue any use of concomitant ACE Inhibitor or ARB before initiating treatment with Entresto. ACE inhibitors must be discontinued at least 36 hours prior to initiation of Entresto

-AND-

- (7) Patient is not concomitantly on aliskiren therapy.

-AND-

- (8) Entresto is prescribed by, or in consultation with, a cardiologist.

Authorization will be issued for 12 months.

B. Reauthorization

1. **Entresto** will be approved based on **both** of the following criteria:

- a. The Entresto dose has been titrated to a dose of 97 mg/103 mg twice daily, or to a maximum dose as tolerated by the patient

-AND-

- b. Documentation of positive clinical response to therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Entresto [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2019.
2. McMurray JJ, Desai AS, Gong J. Dual angiotensin receptor and neprilysin inhibition as an alternative to angiotensin-converting enzyme inhibition in patients with chronic systolic heart failure: rationale for and design of the prospective comparison of ARNI with ACEI to determine impact on global mortality and morbidity in heart failure trial (PARADIGM-HF). *European Journal of Heart Failure* 2013; 15: 1062–1073
3. McMurray JJ, Packer M, Desai AS, et al. Angio-tensin-neprilysin inhibition versus enalapril in heart failure. *N Engl J Med* 2014;371:993-1004.
4. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA Guideline for the Management of Heart Failure. *Circulation* 2013; 128:e240-e327.
5. 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. *Circulation*. 2017;136(6):e137-e161

Program	Prior Authorization - Entresto (valsartan-sacubitril)
Change Control	
5/2015	New program.
6/2016	Additional criteria added to align with Employer & Individual Medical Necessity program. Updated policy template.
2/2017	Removed requirement that angioedema must be associated with an ACE inhibitor or ARB, based on the 2016 ACC/AHA/HFSA recommendation that Entresto should not be administered to patients with a history of angioedema. Updated references and

	policy template.
9/2017	Removed BNP requirement.
2/2018	Updated metoprolol to remove specification of metoprolol succinate. Revised ejection fraction from 35% to 40%.
2/2019	Annual review. Updated references.
11/2019	Added criteria for coverage of pediatric heart failure. Updated references.
11/2020	Annual review. Added additional clinical rules section. Updated references.