UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Entresto

Program	Prior Authorization
Medication	Entresto (valsartan-sacubitril)
Issue Date	5/2015
Pharmacy and Therapeutics Approval Date	2/2018
Effective Date	4/2018

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.

2. Coverage Criteria:

A. Initial Therapy

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

   a. As continuation of therapy initiated during an inpatient stay

   -OR-

   b. **Entresto** will be approved based on **all** of the following

      (1) Diagnosis of heart failure (with or without hypertension)

      -AND-

      (2) Ejection fraction is less than or equal to 40 percent

      -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. <u>Reauthorization</u>

1. **Entresto** will be approved based on **<u>both</u>** 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.

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3. References:

1. Entresto Prescribing Infation. Novartis Pharmaceuticals Corporation. East Hanover, NJ. November 2017.
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. 2016 ACC/AHA/HFS A Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. *Circulation*. 2016; 134:e282-e293.

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%.