

Cardiovascular Agents – valsartan-sacubitril (Entresto®)

Medical policy no. 40.99.20-1

Effective: October 1, 2018

Related medical policies:

- Cardiovascular Agents - Sinus Node Inhibitors

Background:

Heart failure is a term used to describe a weakened heart that cannot deliver enough nutrient-rich blood and oxygen to the body's cells. When the body cannot get the oxygen it needs it can result in fatigue and shortness of breath. Everyday activities such as walking or other activities of daily life can become very difficult.

Medical necessity

Drug	Medical Necessity
valsartan-sacubitril (Entresto®)	Entresto® may be considered medically necessary when: Used 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.

Clinical policy:

Clinical Criteria	
Initial Authorization Criteria	<ol style="list-style-type: none"> 1. Patient has ONE of the following: <ol style="list-style-type: none"> a. Patient is currently on therapy or initiated during an inpatient stay b. Patient has ALL of the following: <ol style="list-style-type: none"> i. Diagnosis of heart failure classified as New York Heart Associate Class II, III, or IV ii. Ejection fraction is less than or equal to (\leq) 40% iii. Patient has a history of trial, contraindication, or intolerance due to adverse reactions to the following first-line agents, used in combination, unless clinically inappropriate: <ol style="list-style-type: none"> 1. Angiotensin-converting enzyme (ACE) inhibitor or an angiotensin receptor blocker (ARB) 2. Beta-blocker 2. Patient does not have a history of angioedema 3. Not to be used in combination with an ACE inhibitor. If patient is currently taking an ACE inhibitor, prescriber states plan to discontinue agent at least 36 hours before starting Entresto

	Approve for 12 months
Reauthorization Criteria	Documentation of positive clinical response to therapy Approve for 12 months

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
valsartan-sacubitril (Entresto [®])	#60 tablets per 30-days

Definitions

Term	Description (Patient symptoms)
NYHA Class I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).
NYHA Class II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).
NYHA Class III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
NYHA Class IV	Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

References

1. Entresto Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. November 2017.
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3. Yancy, CW, Jessup, M, Bozkurt, B, et al. 2016 ACC/AHA/HFSA Focused Update on New Pharmacological Therapy for Heart Failure: An 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. *Journal of the American College of Cardiology*. 2016 May 17. PMID: 27216111
4. Yancy, CW, Jessup, M, Bozkurt, B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines. United States, 2013. p. e240-327.
5. 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
6. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA Guideline for the Management of Heart Failure. *Circulation* 2013; 128:e240-e327.
7. American Heart Association (2017) Classes of Heart Failure. Retrieved from http://www.heart.org/HEARTORG/Conditions/HeartFailure/AboutHeartFailure/Classes-of-Heart-Failure_UCM_306328_Article.jsp#.Wsa_L8KWxPZ