Entresto (sacubitril/valsartan)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Entresto (sacubitril/valsartan)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Entresto (sacubitril/valsartan) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual is using for the treatment of New York Heart Association (NYHA) class II, III, or IV heart failure symptoms (McMurray 2014; Solomon 2019); **AND**
III. Individual has a left ventricular ejection fraction less than or equal to 57% (McMurray 2014; Solomon 2019);

OR

IV. Individual is less than 18 years of age; **AND**
V. Individual is using for the treatment of New York Heart Association (NYHA) class II, III or IV heart failure symptoms; **AND**
VI. Individual has a left ventricular ejection fraction less than or equal to 40%.

Continuation requests for Entresto (sacubitril/valsartan) may be approved if the following criteria are met:

I. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in heart failure symptoms, reduction in heart failure related physical limitations, reduction in hospitalization).

Entresto (sacubitril/valsartan) may **not** be approved for any of the following:

I. Individual is pregnant or wishing to become pregnant; **OR**
II. Individual is breastfeeding; **OR**
III. Individual will be utilizing an angiotensin-converting enzyme (ACE) inhibitor **OR** angiotensin receptor blocker (ARB) in combination with Entresto (sacubitril/valsartan); **OR**
IV. Individual will be utilizing in combination with Tekturna (aliskiren)/Tekturna HCT (aliskiren/hydrochlorothiazide) and has a diagnosis of:

A. Diabetes; **OR**
B. Renal impairment (eGFR < 60 mL/min/1.73 m^2);

OR

V. Individual has a history of hereditary angioedema or angioedema related to previous ACE inhibitor or ARB therapy; **OR**
VI. Individual has severe hepatic impairment (Child-Pugh C)

Note:
Entresto has a black box warning for fetal toxicity. Drugs that act directly on the renin-angiotensin system can cause injury and death to a developing fetus. When pregnancy is detected, Entresto should be discontinued and alternative treatments considered. If Entresto is considered lifesaving for the mother, she should be advised of the potential risk to the fetus.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: May 11, 2022.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Heidenreich P, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure. *J Am Coll Cardiol.* 2022 May;79(17):e263–e421.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. McMurray JJV, Packer M, Desai AS, et al. Angiotensin–Neprilysin Inhibition versus Enalapril in Heart Failure. *N Engl J Med*. 2014; 371:993-1004. Available from: http://www.nejm.org/doi/full/10.1056/NEJMoa1409077. Accessed on: May 11, 2022.
6. Solomon SD, McMurray JJV, Anand IS, et. al. Angiotensin-Neprilysin Inhibition in Heart Failure with Preserved Ejection Fraction. *N Engl J Med*. 2019; 381:1609-1620. Available from: https://www.nejm.org/doi/pdf/10.1056/NEJMoa1908655?articleTools=true. Accessed on: May 11, 2022.