Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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

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; **AND**
III. Individual has a left ventricular ejection fraction less than or equal to 35% (McMurray 2014).

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%.

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

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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: December 4, 2019.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
4. 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: April 3, 2019.
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. *Journal of the American College of Cardiology.* 2017;70(6):776-803. Available at: http://www.onlinejacc.org/content/70/6/776. Accessed: April 3, 2019.