Mass General Brigham
Health Plan

Entresto (sacubitril and valsartan)
Effective 01/01/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview

FDA-Approved Indications

1. Adult Heart Failure
   Entresto is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal.
2. Pediatric Heart Failure
   Entresto is indicated for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older. Entresto reduces NT-proBNP and is expected to improve cardiovascular outcomes.

Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Adult Heart Failure

Authorization may be granted when the following criteria is met:

1. The member is 18 years of age or older.
2. The requested drug is being prescribed to reduce the risk of cardiovascular death and hospitalization for heart failure.
3. The member has a diagnosis of symptomatic chronic heart failure and ONE of the following:
   a. The member meets both of the following:
      i. The member has ONE of the following: A) Left ventricular ejection fraction less than or equal to 40 percent (i.e., Heart Failure with reduced Ejection Fraction [HFrEF]), B) Previous left ventricular ejection fraction less than or equal to 40 percent and a follow-up left ventricular ejection fraction measurement of greater than 40 percent (i.e., Heart Failure with improved Ejection Fraction [HFimpEF]).

ii. The member meets ONE of the following:
    1. The member will receive concomitant treatment with a maximally tolerated dose of a beta blocker (e.g., carvedilol, metoprolol succinate, bisoprolol).
    2. The member has experienced an intolerance to a beta-blocker (e.g., carvedilol, metoprolol succinate, bisoprolol).
    3. The member has a contraindication that would prohibit a trial of a beta-blocker (e.g., carvedilol, metoprolol succinate, bisoprolol).

b. The member has any of the following: A) left ventricular ejection fraction less than or equal to 40 percent (i.e., Heart Failure with reduced Ejection Fraction [HFrEF]), B) previous left ventricular ejection fraction less than or equal to 40 percent and a follow-up left ventricular ejection fraction measurement of greater than 40 percent (i.e., Heart Failure with improved Ejection Fraction [HFimpEF]).

4. Submission of chart notes or other documentation supporting ONE of the following:
    a. A current or previous left ventricular ejection fraction percentage less than or equal to 40 percent.
    b. Evidence or history of spontaneous or provokable increased left ventricular filling pressures.
5. If the member has a diagnosis of diabetes, the requested drug will not be used in combination with Tekturna (aliskiren).
6. If the patient has renal impairment (estimated Glomerular Filtration Rate [eGFR] less than 60 milliliters per minute per 1.73 meters squared [mL/min/1.73m2]), the requested drug will not be used in combination with Tekturna (aliskiren).

Pediatric Heart Failure

Authorization may be granted when the following criteria is met:

1. The requested medication is for a pediatric patient one year of age or older.
2. The requested medication is being prescribed for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction.
7. If the member has a diagnosis of diabetes, the requested drug will not be used in combination with Tekturna (aliskiren).
8. If the patient has renal impairment (estimated Glomerular Filtration Rate [eGFR] less than 60 milliliters per minute per 1.73 meters squared [mL/min/1.73m2]), the requested drug will not be used in combination with Tekturna (aliskiren).

Limitations

1. Approvals will be granted for:
    a. 12 months for members under 18 years of age
    b. 36 months for members 18 years of age or older

References

1. Entresto [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2021.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2022; Accessed June 20, 2022.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed June 20, 2022.

4. Heidenreich PA, Bozkurt B, Aguilar D et. al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol.* 2022; 79:e263-e421.

Review History

12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024