AdvancedHealth
Bridging the Future of Healthcare

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Sacubitril/Valsartan (Entresto) Drug Use Criteria

Created: 7/2024
Reviewed:

Includes:

Brand©	*Generic*
Entresto	*sacubitril/valsartan*

GUIDELINE FOR USE:

Initial Request:

1. Is the request for renewal of a previously approved prior authorization?
    a. If yes, go to renewal criteria.
    b. If no, go to #2

2. Is the member being followed by cardiology or initiated in a hospital setting?
    a. If yes, go to #3
    b. If no, deny as criteria not met. Please consult cardiology.

3. Has the member previously tolerated an ACE-I or ARB with no history of hypersensitivity to any component of Entresto and no known history of angioedema?
    a. If yes, go to #4
    b. If no, deny as not meeting criteria. Entresto is not recommended if member did not tolerate a previous trial of ACE-I or ARB, have a hypersensitivity to any component of Entresto, or has known history of angioedema.

4. Is the request for a member with a confirmed diagnosis of heart failure with preserved ejection fraction and NYHA class II-IV?
    a. If yes, approve for 3 months. Benefits of therapy are most clearly evident in members with left ventricular ejection fraction below normal. Use judiciously with higher baseline ejection fraction.
    b. If no, go to #5

5. Is the request for a member with a confirmed diagnosis of heart failure with reduced ejection fraction (≤40%) and NYHA class II-IV?
    a. If yes, go to #6
    b. If no, deny as not meeting criteria. Entresto is approved for members with chronic heart failure. Off-label use of a medication is not a covered benefit.

6. Is the member on a maximally tolerated dose of carvedilol, sustained-release metoprolol succinate, or bisoprolol or is there a documented intolerance or contraindications to each of these beta-blockers?
    a. If yes, approve for up to 3 months.

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b. If no, deny as not meeting criteria. Members with heart failure with reduced ejection fraction should be a beta blocker to reduce mortality and hospitalizations.

Renewal Request:

1. Is the member currently taking the target dose of 97/103mg two times daily or to a maximum dose as tolerated by the member?
    a. If yes, approve for up to 12 months.
    b. If no, go to #2

2. Is there clinical rationale to why the drug has not been titrated to the target dose?
    a. If yes, document rationale and approve up to 90 days. Prior authorization will be required every 90 days until target dose is achieved or the maximum dose the member can tolerate has been achieved.
    b. If no, deny as not meeting criteria. Please titrate member to target dose or document rationale to why member cannot be titrated.

Rationale:

To ensure access to medication for members with chronic heart failure.

FDA Approved Indications:

Adults:

- 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.

Pediatric

- 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

Dosing:

Adults with heart failure with reduced ejection fraction:

- Patients previously taking a moderate to high dose of an ACE inhibitor (eg, >10 mg/day of enalapril or equivalent) or ARB (eg, >160 mg/day of valsartan or equivalent):
    - Oral: Initial: Sacubitril 49 mg/valsartan 51 mg twice daily. Double the dose as tolerated after 1 to 2 weeks to the target maintenance dose of sacubitril 97 mg/valsartan 103 mg twice daily
- Patients previously taking a low dose of an ACE inhibitor (eg, ≤10 mg/day of enalapril or equivalent) or ARB (eg, ≤160 mg/day of valsartan or equivalent):
    - Oral: Initial: Sacubitril 24 mg/valsartan 26 mg twice daily. Double the dose as tolerated in 1- to 2-week intervals to the target maintenance dose of sacubitril 97 mg/valsartan 103 mg twice daily
- Patients not currently taking an ACE inhibitor or an ARB:

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- Oral: Initial: Sacubitril 24 mg/valsartan 26 mg twice daily. Double the dose as tolerated in 1- to 2-week intervals to the target maintenance dose of sacubitril 97 mg/valsartan 103 mg twice daily

Adults with heart failure with preserved ejection fraction:

- **Oral:** Initial: Sacubitril 24 mg/valsartan 26 mg twice daily **or** sacubitril 49 mg/valsartan 51 mg twice daily, depending on baseline BP. Double the dose as tolerated in ~2- to 4-week intervals to the target maintenance dose of sacubitril 97 mg/valsartan 103 mg twice daily

Pediatrics:

- Please reference product labeling

Dose adjustments:

- Please reference product labeling

Contraindications:

Hypersensitivity to sacubitril, valsartan, or any component of the formulation; history of angioedema related to previous ACE inhibitor or ARB therapy; concomitant use or use within 36 hours of ACE inhibitors; concomitant use of aliskiren in patients with diabetes
Note: According to the ACC/AHA/HFSA guidelines, the use of sacubitril/valsartan is contraindicated in patients with a history of angioedema, regardless of cause (AHA/ACC/HFSA [Heidenreich 2022).

References:

1. 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. Accessed 7/9/2024 https://www.ahajournals.org/doi/pdf/10.1161/CIR.0000000000001063
2. UpToDate: Overview of the management of heart failure with reduced ejection fraction in adults. Accessed 7/9/2024
3. Entresto Prescribing information. Revised: 4/2024