Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Entresto (sacubril/valsartan)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***October 2015***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Entresto (sacubril/valsartan).

Entresto (sacubril/valsartan) is indicated 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.

DEFINITIONS

ACE_I- angiotensin converting enzyme inhibitor

ARB- angiotensin receptor blocker

NYHA- New York Heart Association classification of functional capacity

Ejection fraction- Ejection fraction is a measurement of the percentage of blood leaving your heart each time it contracts.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications.

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This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Entresto (sacubril/valsartan), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must have a diagnosis of chronic heart failure (NYHA Class II-IV)
- Must have a left ventricular ejection fraction (LVEF) ≤ 40%
- Must not have any of the following contraindications:
  - Prior history of angioedema with prior ACE-I or ARB therapy
  - Concurrent use of an ACE-I
  - Concurrent use of aliskiren in patients with diabetes

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to duration of member's membership with plan (if indefinite auth)
Quantity Level Limit	
24/26mg	60 tablets per lifetime
49/51mg, 97/103mg	60 tablets per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Entresto [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; July 2015.
2. 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. J Am Coll Cardiol. 2013;62:e147-239.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Criteria revision	1/16
Annual review	2/17, 2/18
Criteria revision	8/16