SmartPA Criteria Proposal

Drug/Drug Class:	Entresto Clinical Edit
First Implementation Date:	December 3, 2018
Proposed Date:	December 17, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Entresto® (sacubitril/valsartan)

Why Issue Selected: Entresto® is a combination product containing sacubitril, a neprilysin inhibitor, and valsartan, an angiotensin II receptor blocker (ARB). First FDA approved in July 2015, Entresto is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure (NYHA Class II – IV) and reduced ejection fraction (HFrEF). Entresto is usually given with other heart failure therapies in place of an ACE inhibitor or other ARB. The 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure states that in patients with chronic symptomatic heart failure with HFrEF NYHA Class II or III who tolerate an ACE inhibitor or ARB, replacement with Entresto is recommended to further reduce morbidity and mortality. In October 2019, Entresto received a further FDA indication for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged 1 year and older; approval was based on demonstrated reductions in the cardiac biomarker N-terminal pro-B-type natriuretic peptide (NT-proBNP).

Program-Specific Information:

Date Range FFS 10-01-2019 to 9-30-2020			
Drug	**Claims**	**Spend**	**Average Spend per Claim**
ENTRESTO 24 MG-26 MG TABLET	2,007	$960,849.50	$478.74
ENTRESTO 49 MG-51 MG TABLET	1,286	$622,089.80	$483.74
ENTRESTO 97 MG-103 MG TABLET	836	$396,377.40	$474.13

Type of Criteria:
☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **Clinical Edit**

Data Sources:
☐ **Only Administrative Databases**
☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Entresto® (sacubitril/valsartan)
- Age range: All appropriate MO HealthNet participants aged 1 year and older

Approval Criteria

- Documented history of previous therapy with Entresto in the past 60 days **OR**
- Documented diagnosis of heart failure, NYHA class II – IV, with systolic dysfunction **AND**
- Documented ejection fraction ≤ 40% **AND**
- Documented therapy with an ACE inhibitor or ARB for 60 of the past 90 days

Denial Criteria

- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results:		Progress Notes:	
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)
Rule Type: CE

Default Approval Period

1 year

References

- ENTRESTO® (sacubitril and valsartan) tablets, [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2019.
- 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 J Am Coll Cardiol. 2017 Aug, 70 (6) 776-803. DOI: 10.1016/j.jacc.2017.04.025
- IPD Analytics. Cardiovascular: Heart Failure. Accessed October 27, 2020.