SmartPA Criteria Proposal

Drug/Drug Class:	Entresto Clinical Edit
First Implementation Date:	December 3, 2018
Proposed Date:	October 17, 2023
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 (ARNI) containing sacubitril, a neprilysin inhibitor, and valsartan, an angiotensin II receptor blocker (ARB). Entresto was first FDA approved in July 2015 and was indicated for adults with chronic heart failure (NYHA Class II – IV) and reduced ejection fraction (HFrEF). In October 2019 Entresto gained approval for pediatric patients aged 1 year and older with symptomatic heart failure with left ventricular systolic dysfunction; approval was based on demonstrated reductions in the cardiac biomarker N-terminal pro-B-type natriuretic peptide (NT-proBNP). In February 2021 Entresto gained FDA approval for a broader indication of chronic heart failure in adults, which covers heart failure patients with both reduced and preserved left ventricular ejection fractions (HFrEF/HFpEF). The 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure recommends ARNIs as first-line therapy to reduce morbidity and mortality in HFrEF. Entresto is commonly prescribed with other heart failure medications including evidence-based beta-blockers, aldosterone antagonists, SGLT2 inhibitors, and diuretics.

Due to the high cost and specific approved indications, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Entresto.

Program-Specific Information:

Date Range FFS 7-1-2022 to 6-30-2023			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
ENTRESTO 24 MG-26 MG TABLET	9,454	$ 5,295,372.21	$ 560.12
ENTRESTO 49 MG-51 MG TABLET	5,012	$ 2,889,604.27	$ 576.54
ENTRESTO 97 MG-103 MG TABLET	3,074	$ 1,821,004.54	$ 592.39

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

Approval Criteria

- Documented diagnosis of heart failure

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; February 2021.
- IPD Analytics. Cardiovascular: Heart Failure. Accessed July 14, 2023.
- 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. Circulation. 2022;145:e895–e1032. 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 | Circulation (ahajournals.org)