

SmartPA Criteria Proposal

Drug/Drug Class:	Entresto Clinical Edit
First Implementation Date:	December 3, 2018
Proposed Date:	September 15, 2022
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> 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 7-1-2021 to 6-30-2022			
Drug	Claims	Spend	Avg Spend per Claim
ENTRESTO 24 MG-26 MG TABLET	5,407	\$2,793,453.96	\$516.64
ENTRESTO 49 MG-51 MG TABLET	2,915	\$1,581,854.76	\$542.66
ENTRESTO 97 MG-103 MG TABLET	1,810	\$980,847.04	\$541.90

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

SmartPA Clinical Proposal Form

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Approval Criteria

- Documented diagnosis of heart failure

Denial Criteria

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

Required Documentation

Laboratory Results:
MedWatch Form:

Progress Notes:
Other:

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 August 15, 2022.
- 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 \(ahajournals.org\)](#)