SmartPA Criteria Proposal

Drug/Drug Class:	Entresto Clinical Edit
First Implementation Date:	December 3, 2018
Revised Date:	October 21, 2021
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 2021 Update to the 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment lists ARNIs as the preferred agents for treatment of heart failure with reduced ejection fraction, with or without prior aldosterone antagonist or ACEI/ARB therapy. 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 4-1-2020 to 3-31-2021			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
ENTRESTO 24 MG-26 MG TABLET	2,498	$1,243,418.75	$497.76
ENTRESTO 49 MG-51 MG TABLET	1,505	$765,258.09	$508.47
ENTRESTO 97 MG-103 MG TABLET	995	$489,074.24	$491.53

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

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.
- 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 May 21, 2021.
- Maddox T, Januzzi J, Allen L, et al. 2021 Update to the 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2021 Feb, 77 (6) 772-810