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); it is usually given with other heart failure therapies in place of an ACE inhibitor or other ARB. The 2016 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). There are 5.7 million people living with heart failure in the United States, with about 670,000 people diagnosed each year. By 2030, the prevalence is expected to exceed 8 million. Children diagnosed with systolic HF face a poor prognosis; it has been estimated that half require a heart transplant before the age of five and almost one-third die or require a transplant within 1 year.

Program-Specific Information:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Claims</th>
<th>Spend</th>
<th>Cost per unit (NADAC)</th>
<th>Cost per month (NADAC)</th>
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</thead>
<tbody>
<tr>
<td>Entresto® 24mg-26mg tab</td>
<td>1,105</td>
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<td>Entresto® 49mg-51mg tab</td>
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</table>

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 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 no approval criteria are met

Required Documentation

<table>
<thead>
<tr>
<th>Laboratory Results:</th>
<th>Progress Notes:</th>
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<tbody>
<tr>
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<table>
<thead>
<tr>
<th>MedWatch Form:</th>
<th>Other:</th>
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<tbody>
<tr>
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</table>

Disposition of Edit

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

Default Approval Period

1 year

References