SmartPA Criteria Proposal

**Drug/Drug Class:** Ranexa® Clinical Edit

**First Implementation Date:** June 13, 2007

**Revised Date:** February 20, 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 Ranexa® (ranolazine)

**Why was this Issue Selected:** Ranexa® (ranolazine) was initially FDA approved in 2006; however a new generic formulation of Ranexa was approved in 2019. Ranexa is indicated for the treatment of chronic angina. According to the 2012 American College of Cardiology Foundation/American Heart Association guidelines for patients with stable ischemic heart disease, Ranexa may be useful when prescribed as a substitute for beta-blockers for relief of symptoms if initial treatment with beta-blockers leads to unacceptable side effects, is less effective, or if initial treatment with beta-blockers is contraindicated. The guidelines also state Ranexa may be used in combination with beta-blockers for relief of symptoms when initial treatment with beta-blockers is not successful. The mechanism of action of Ranexa's antianginal effects has not been determined. First line therapies for chronic angina include nitrates, beta-blockers, and calcium channel blockers; therapy with Ranexa should be reserved as a second line therapy.

**Program-specific information:**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Date Range FFS 1-1-2019 to 6-30-2019</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Drug</td>
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<tr>
<td>RANEXA ER 500 MG TABLET</td>
<td>627</td>
</tr>
<tr>
<td>RANOLAZINE ER 500 MG TABLET</td>
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<tr>
<td>RANEXA ER 1,000 MG TABLET</td>
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</tr>
<tr>
<td>RANOLAZINE ER 1,000 MG TABLET</td>
<td>101</td>
</tr>
</tbody>
</table>

**Type of Criteria:**
- ☒ Increased risk of ADE
- ☒ Preferred Drug List
- ☒ Appropriate Indications
- ☒ Clinical Edit
- ☐ Databases + Prescriber-Supplied

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

- Drug class for review: Ranexa® (ranolazine)
- Age range: All appropriate MO HealthNet participants aged 18 years and older

Approval Criteria

- Aged 18 years or older AND
- Documented compliance to previous ranolazine therapy (defined as 90 days in the past 120 days) OR
- Documented trial of a nitrate, beta-blocker, or calcium channel blocker (defined as 30 days in the past year)

Denial Criteria

- Therapy will be denied if no approval criteria are met
- Documented history of significant hepatic impairment in the past 2 years

Required Documentation

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

Disposition of Edit

Denial: Exception code “682” (Clinical Edit)
Rule Type: CE

Default Approval Period

1 year

References