SmartPA Criteria Proposal

Drug/Drug Class:	Ranolazine Clinical Edit *(formerly Ranexa Clinical Edit)*
First Implementation Date:	June 13, 2007
Revised Date:	October 20, 2022
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 ranolazine agents

Why Issue Selected: Ranolazine 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, ranolazine 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 ranolazine 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 ranolazine's antianginal effects has not been determined. First line therapies for chronic angina include nitrates, beta-blockers, and calcium channel blockers; therapy with ranolazine should be reserved as a second line therapy.

Program-Specific Information:

Date Range FFS 4-1-2021 to 3-31-2022			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
ASPRUZYO SPRINKLE ER 500MG PKT	0	-	-
ASPRUZYO SPRINKLE ER 1000MG PK	0	-	-
RANEXA ER 500 MG TABLET	2,140	$65,922.95	$11.40
RANEXA ER 1,000 MG TABLET	937	$43,401.02	$11.79

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: Ranolazine agents
- Age range: All appropriate MO HealthNet participants aged 18 years and older

Approval Criteria

- Participant 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)
- **For Aspruzyo: Clinical Consultant review required for reason why generic ranolazine tablets cannot be utilized**

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Documented history of significant hepatic impairment

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

- ASPRUZYO SPRINKLE™ (ranolazine) [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; February 2022.
- RANEXA® (ranolazine) [package insert]. Foster City, CA: Gilead Sciences, Inc.; October 2019.
- Fihn SD, Gardin JM, Abrams J, et al. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease: executive summary: a report of the American College of Cardiology Foundation/American Heart Association task force on practice guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons [published correction appears in Circulation. 2014 Apr 22;129(16):e462]. Circulation. 2012;126(25):3097-3137. doi:10.1161/CIR.0b013e3182776f83
- Facts & Comparisons. Ranolazine Oral. Accessed May 19, 2022.