SmartPA Criteria Proposal

Drug/Drug Class:	Ranolazine Clinical Edit *(formerly Ranexa Clinical Edit)*
First Implementation Date:	June 13, 2007
Proposed Date:	October 17, 2023
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 7-1-2022 to 6-30-2023			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
ASPRUZYO SPRINKLE ER 500MG PKT	0	-	-
ASPRUZYO SPRINKLE ER 1000MG PK	0	-	-
RANEXA ER 500 MG TABLET	4,156	$ 67,623.08	$ 16.27
RANEXA ER 1,000 MG TABLET	1,599	$ 33,414.86	$ 20.90

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: 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.; March 2022.
- RANEXA® (ranolazine) [package insert]. Foster City, CA: Gilead Sciences, Inc.; October 2019.
- Virani S, Newby L, et al. 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA Guideline for the Management of Patients With Chronic Coronary Disease. J Am Coll Cardiol. 2023 Aug, 82 (9) 833–955. https://doi.org/10.1016/j.jacc.2023.04.003
- Facts & Comparisons. Ranolazine Oral. Accessed August 24, 2023.