Drug and Biologic Coverage Policy

Effective Date **12/15/2022**
Next Review Date… **12/1/2023**
Coverage Policy Number **IP0507**

Ranolazine

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Related Coverage Resources

Quantity Limitations - (1201)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for ranolazine (**Aspruzyo Sprinkle**™).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

The product in the table below is considered medically necessary when the following are met:

Employer Group Non-Covered Products and the Preferred Covered Alternatives:

Non-Covered Product	Criteria
Aspruzyo Sprinkle (ranolazine)	**BOTH** of the following (1 and 2): 1. Individual has inability to swallow tablets 2. **ONE** of the following (A or B):

Non-Covered Product	Criteria
	A. For new starts, documented inadequate response, contraindication or intolerance to **TWO** of the following: i. beta blockers ii. calcium-channel blockers iii. nitrates B. Individual is currently receiving Aspruzyo Sprinkle

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Ranolazine (Aspruzyo Sprinkle is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Background

OVERVIEW
Aspruzyo Sprinkle is an antianginal indicated for the treatment of chronic angina.[1]

Guidelines
In 2012, the Clinical Guidelines Committee of the American College of Physicians published guidelines for the management of stable ischemic heart disease.[2] Long-acting nitrates or calcium channel blockers (CCBs) should be prescribed for relief of symptoms when beta-blockers are contraindicated or cause unacceptable adverse effects in patients with ischemic heart disease. Long-acting nitrates or CCBs in combination with beta-blockers should be given for the relief of symptoms when initial treatment with beta-blockers is not successful in patients with stable ischemic heart disease. If initial treatment with beta blockers leads to intolerable adverse effects or is contraindicated, ranolazine can be useful when used in place of beta blockers for the treatment of symptoms in patients with stable ischemic heart disease.

References

1. Aspruzyo Sprinkle™ [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; February
2. 2022.
3. Qaseem A, Fihn SD, Dallas P, et al, for the Clinical Guidelines Committee of the American College of Physicians. Management of stable ischemic heart disease: summary of a clinical practice guideline from the American College of Physicians/American College of Cardiology Foundation/American Heart Association/American Association of Thoracic Surgery/Preventive Cardiovascular Nurses Association/Society of Thoracic Surgeons. Ann Intern Med. 2012; 157:735-743.