STEP THERAPY POLICY

POLICY: Cardiology – Ranolazine Products Step Therapy Policy
- Aspruzyo Sprinkle™ (ranolazine extended-release granules – Sun)
- Ranexa® (ranolazine extended-release tablets – Gilead, generic)

REVIEW DATE: 01/22/2025

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Aspruzyo Sprinkle and ranolazine extended-release tablets are both indicated for the **treatment of chronic angina**.[1,2] The precise mechanism of action of ranolazine, a piperazine derivative, has not been determined, although the agent selectively inhibits the late sodium cardiac current. Ranolazine extended-release tablets are available generically. Aspruzyo Sprinkle was approved through the 505(b)(2) pathway and as such relied upon existing safety and efficacy information for ranolazine extended-release tablets to support approval. Ranolazine extended-release tablets (supplied in strengths of 500 mg and 1,000 mg) must be swallowed whole; do not crush, break or chew. Aspruzyo Sprinkle (supplied in unit-dose sachets in strengths of 500 mg and 1,000 mg) can be sprinkled on one tablespoonful of soft food (applesauce and yogurt) and immediately consumed. Also, this formulation can be administered via nasogastric and gastrostomy/gastric tube.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2

Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Step 1: generic ranolazine extended-release tablets

Step 2: Aspruzyo Sprinkle, Ranexa

Cardiology – Ranolazine Products Step Therapy Policy product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

2. Approve Aspruzyo Sprinkle if the patient meets one of the following criteria (A or B):
   A) Patient requires administration by nasogastric or gastrostomy/gastric tube;
   OR
   B) Patient is unable to swallow or has difficulty swallowing tablets or capsules.

REFERENCES

1. Aspruzyo Sprinkle™ extended-release granules [prescribing information]. Cranbury, NJ: Sun; February 2022.
2. Ranexa® extended-release tablets [prescribing information]. Foster City, CA: Gilead; October 2019.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/13/2023
Annual Revision	No criteria changes.	01/22/2025