

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: 12/13/2023

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.

Automation: A patient with a of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: generic ranolazine extended-release tablets

Step 2: Aspruzyo Sprinkle, Ranexa

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.
3. No other exceptions are recommended.

12/13/2023

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REFERENCES

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