Clinical Policy: Ranolazine (Ranexa)

Reference Number: PA.CP.PMN.34
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

Description
Ranolazine (Ranexa®) is an antianginal agent.

FDA approved indication
Ranexa is indicated for the treatment of chronic angina.

Policy/Criteria
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria **

It is the policy of Pennsylvania Health and Wellness ® that Ranexa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Angina (must meet all)**:**

1. Diagnosis of chronic angina;
2. Prescribed by or in consultation with a cardiologist;
3. Member meets one of the following (a, b, or c):
   a. Failure of concurrent use of a beta-blocker and long-acting nitrate at therapeutic doses for ≥ 30 days;
   b. Failure of concurrent use of a calcium channel blocker and long-acting nitrate at therapeutic doses for ≥ 30 days;
   c. Member experienced clinically significant adverse effects or has contraindications to both calcium channel blockers and beta blockers, or long-acting nitrates.
4. Request does not exceed 2000 mg/day (2 tablets/day).

Approval duration: 12 months

B. Other diagnoses/indications – Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. Chronic Angina (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit, or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 2000 mg/day (2 tablets/day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: 12 months or duration of request (whichever is less)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key
FDA: Food and Drug Administration

V. Dosage and Administration

The recommended starting dosage of Ranexa is 500 mg orally twice daily. Based on clinical symptoms, the dose may be increased up to the maximum dose of 1,000 mg twice daily if needed.

VI. Product Availability

Extended-release tablets: 500 mg, 1000 mg.

VII. References

1. Ranexa Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; January 2016. Available at: https://www.ranexa.com/. Accessed December 12, 2017.
2. Fihn SD, Gardin JM, Abrams J, Berra K, Blankenship JC, Dallas AP, et al. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease: 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. Circulation 2012; 126:e354.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2016. Available at: http://www.clinicalpharmacology-ip.com/.

Reviews, Revisions, and Approvals	Date	Approval Date
References reviewed and updated.	02/18	