STEP THERAPY CRITERIA

BRAND NAME*
(generic)

RANEXA
(ranolazine extended-release)

Status: CVS Caremark® Criteria
Type: Initial Step Therapy; Post Step Therapy Prior Authorization ***Ref # 658-D***

**Drugs that are listed in the target drug box include both brand and generic and all dosages forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

Ranexa is indicated for the treatment of chronic angina.

Ranexa may be used with beta-blockers, nitrates, calcium channel blockers, anti-platelet therapy, lipid-lowering therapy, ACE inhibitors, and angiotensin receptor blockers.

INITIAL STEP THERAPY

If the patient has filled a prescription for at least a 30-day supply of any two of the following: beta blocker, calcium channel blocker, long-acting nitrate within the past 365 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

Chronic Angina
Authorization may be granted when the requested drug is being prescribed for the treatment of chronic angina when ONE of the following criteria are met:

- The patient has experienced an inadequate treatment response to a combination of TWO of the following: beta blocker, calcium channel blocker, long-acting nitrate
- The patient has experienced an intolerance to a combination of TWO of the following: beta blocker, calcium channel blocker, long-acting nitrate
- The patient has a contraindication to a combination of TWO of the following: beta blocker, calcium channel blocker, long-acting nitrate

CONTINUATION OF THERAPY

Chronic Angina
Authorization may be granted when the requested drug is being prescribed for the treatment of chronic angina when the following criteria is met:

- The patient has achieved or maintained a positive clinical response to treatment from baseline

DURATION OF APPROVAL (DOA)

- 658-D: Initial therapy DOA: 12 months; Continuation of therapy DOA: 36 months

REFERENCES

Ranexa ST, Post PA 658-D UDR 05-2024.docx

1. Ranexa [package insert]. Foster City, CA: Gilead Sciences, Inc.; October 2019.
2. Ranolazine [package insert]. East Brunswick, NJ: Unichem Pharmaceuticals (USA), Inc.; November 2023.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 20234 https://online.lexi.com. Accessed April 4, 2024.
4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: *04/04/2024*).
5. Virani SS, Newby LK, Arnold SV, et al. 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA Guideline for the Management of Patients With Chronic Coronary Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *Circulation*. 2023;148(9):e9-e119.

Written by: UM Development (CT)
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Reviewed: Medical Affairs (KP) 06/2011, 10/2011; (LMS) 10/2012; (DNC) 09/2013; (LMS) 05/2014; (LMS) 04/2015; (EPA) 04/2018; (AN) 4/2019, (CHART) 04/30/20, 04/22/2021, 04/28/2022, 04/27/2023, 04/25/2024
External Review: 08/2011, 12/2011, 12/2012, 12/2013, 08/2014, 08/2015, 08/2016, 08/2017, 08/2018, 08/2019, 08/2020, 08/2021, 08/2022, 08/2023, 09/2024

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for the treatment of chronic angina? [If Yes, then go to 2. If No, then no further questions.]	Yes	No
2	Is this request for continuation of therapy? [If Yes, then go to 3. If No, then go to 4.]	Yes	No
3	Has the patient achieved or maintained a positive clinical response to treatment from baseline? [No further questions]	Yes	No
4	Has the patient experienced an inadequate treatment response to a combination of TWO of the following: beta blocker, calcium channel blocker, long-acting nitrate? [If Yes, then no further questions. If No, then go to 5.]	Yes	No
5	Has the patient experienced an intolerance to a combination of TWO of the following: beta blocker, calcium channel blocker, long-acting nitrate? [If Yes, then no further questions. If No, then go to 6.]	Yes	No
6	Does the patient have a contraindication to a combination of TWO of the following: beta blocker, calcium channel blocker, long-acting nitrate? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for chronic angina. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us

			any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
2.	Go to 3	Go to 4	
3.	Approve, 36 Months	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation: Efficacy]
4.	Approve, 12 Months	Go to 5	
5.	Approve, 12 Months	Go to 6	
6.	Approve, 12 Months	Deny	Your plan only covers this drug if you have tried other drugs and they did not work well for you. We have denied your request because: A) You have not tried two of the following together - a beta blocker, a calcium channel blocker, a long-acting nitrate; and B) You do not have a medical reason not to take them. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step therapy]