Pharmacy Medical Necessity Guidelines: Corlanor® (ivabradine)

Effective: April 14, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

Corlanor (ivabradine) is indicated to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) ≤ 35%, who are in sinus rhythm with resting heart rate ≥ 70 beats per minute, and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use. Corlanor is also indicated for the treatment of stable symptomatic heart failure due to dilated cardiomyopathy in pediatric patients 6 months of age and older, who are in sinus rhythm with an elevated heart rate.

SHIFT was a randomized, double-blind, placebo-controlled trial that evaluated Corlanor in adult patients with NYHA class II-IV heart failure, LVEF ≤35% and resting heart beat ≥70 beats per minute. Patients were included if they were clinically stable for at least four weeks on an optimized clinical regimen that included maximally tolerated doses of beta-blockers and, in most cases, ACE inhibitors or ARBs, spironolactone, and diuretics. At the end of the trial there was no statistically significant benefit in cardiovascular death alone, although Corlanor did reduce the risk of the combined endpoint of hospitalization for worsening heart failure or cardiovascular death based on time-to-event analysis.

COVERAGE GUIDELINES

The plan may authorize coverage of **Corlanor** (ivabradine) for Members when **ALL** the following criteria for a particular regimen are met and limitations do not apply:

1. The prescriber is a cardiologist

AND

2. Documented diagnosis of worsening heart failure with stable, symptomatic chronic heart failure with left ventricular ejection fraction ≤ 35%, in sinus rhythm with resting heart rate ≥ 70 beats per minute

AND

The Member is either on a maximally tolerated dose of a beta blocker or has a contraindication to beta-blocker use.

OR

3. The Member is six months of age or older

AND

Documented diagnosis of stable symptomatic heart failure due to dilated cardiomyopathy

AND

Documentation the Member is in sinus rhythm with an elevated heart rate

LIMITATIONS

None

CODES

None

REFERENCES

1. Corlanor (ivabradine) [package insert]. Thousand Oaks, CA: Amgen Inc.; February 2022.
2. Fox K, Ford I, Steg PG et al. Ivabradine for patients with stable coronary artery disease and left-ventricular systolic dysfunction (BEAUTIFUL): a randomised, double-blind, placebo-controlled trial. Lancet. 2008; 372(9641):807-16.
3. Fox K, Ford I, Steg PG et al. Ivabradine in stable coronary artery disease without clinical heart failure. N Engl J Med. 2014; 371(12):1091-9.

4. Komamura K. Similarities and differences between pathogenesis and pathophysiology of diastolic and systolic heart failure. Cardio Res Pract. 2013. URL: http://www.hindawi.com/journals/crp/2013/824135/. Available from Internet. Accessed 2015 May 21.
5. Maddox TM, Januzzi JL, et al. 2021 Update to the 2017 ACC expert consensus decision pathway for optimization of heart failure treatment: answers to 10 pivotal issues about heart failure with reduced ejection fraction. *JACC*. 2021;77(6):772-810.
6. McMurray JJV, Adamopoulos S, Anker SD et al. ESC guidelines for the diagnosis and treatment of acute and chronic heart failure 2012. Eur Heart J. 2012; 33(14):1787-847.
7. Medi-Span® Master Drug Data Base v2.5 (MDDB®), 15 June 2015, Clinical Drug Information, LLC.
8. Mozaffarian D, Benjamin EJ, Go AS et al. Heart disease and stroke statistics-2015 update: a report from the American Heart Association. Circulation. 2015; 131(4):e29-322. URL: http://circ.ahajournals.org/content/131/4/e29.full.pdf+html. Available from Internet. Accessed 2015 April 28.
9. National Institute for Health and Care Excellence. Chronic heart failure: management of chronic heart failure in adults in primary and secondary care. 2010 August. URL: http://www.nice.org.uk/guidance/cg108/resources/guidance-chronic-heart-failure-pdf. Available from Internet. Accessed 2015 April 21.
10. National Institute for Health and Care Excellence. Ivabradine for treating chronic heart failure. 2012 November. URL: http://www.nice.org.uk/guidance/ta267/resources/guidance-ivabradine-for-treating-chronic-heart-failure-pdf. Available from Internet. Accessed 2015 April 21.
11. Pharmaceutical Benefits Scheme. URL: http://www.pbs.gov.au/html/consumer.home. Available from Internet. Accessed 2015 June 1.
12. Swedberg K, Komajda M, Bohm M et al. Ivabradine and outcomes in chronic heart failure (SHIFT): a randomised placebo-controlled study. Lancet. 2010; 376(9744):875-85.
13. Yancy CW, Jessup M, Bozkurt B et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013; 128(16):e240-327. URL: http://circ.ahajournals.org/content/128/16/e240.full.pdf+html. Available from Internet. Accessed 2015 April 27.
14. Zouein FA, de Castro Bras LE, da Costa DV et al. Heart failure with preserved ejection fraction: emerging drug strategies. J Cardiovasc Pharmacol. 2013; 62(1):13-21.
15. Zucker IH, Xiao L, Haack KKV. The central RAS and sympathetic nerve activity in chronic heart failure. Clin Sci. 2014; 126(1):695-706.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. July 11, 2023: No changes.
2. April 9, 2024: Effective May 1, 2024, updated RxUM fax number.
3. April 8, 2025: No changes
4. April 14, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services