Pharmacy Policy Bulletin: J-0638 Corlanor (ivabradine) - Commercial and Healthcare Reform	
Number: J-0638	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.)**: **1.** Other Managed Prior Authorization = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0638-019	**Original Date:** 06/03/2015
Effective Date: 10/08/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Corlanor (ivabradine) tablet • Corlanor (ivabradine) oral solution
FDA-Approved Indication(s):	• To reduce the risk of hospitalization for worsening heart failure in adult 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 • Treatment of stable symptomatic heart failure due to dilated cardiomyopathy (DCM) in pediatric patients aged 6 months and older, who are in sinus rhythm with an elevated heart rate

Background:	• Corlanor (ivabradine) is a hyperpolarization-activated cyclic nucleotide-gated channel blocker that slows heart rate by blocking the hyperpolarization-activated cyclic nucleotide-gated (HCN) channel responsible for cardiac pacemaker current. • Heart failure (HF) is a clinical syndrome resulting from any structural or functional impairment of ventricular filling or ejection of blood. The manifestations of HF are dyspnea and fatigue, which may limit exercise tolerance and cause fluid retention. Fluid retention can progress to pulmonary congestion, splanchnic congestion, and peripheral edema. • Heart failure with reduced ejection fraction (HFrEF) occurs when the left ventricular ejection fraction (LVEF) is 40% or less and is accompanied by progressive left ventricular dilatation and adverse cardiac remodeling. • Heart failure affects an estimated 6.5 million United States adults; it accounts for an estimated 1 million hospitalizations per year. Approximately 50% of these hospitalizations are caused by HFrEF. • Dilated cardiomyopathy is characterized by ventricular stretching and thinning. This causes the heart to pump blood less effectively. Dilated cardiomyopathy is a common cause of heart failure and can also contribute to irregular heartbeats. • Step therapy contains criteria for prior utilization or contraindication to beta-blockers recommended for heart failure. Beta-blockers recommended for heart

	failure include bisoprolol (target dose: 10 mg once daily), carvedilol (target dose: 25-50 mg twice daily), and metoprolol succinate (target dose: 200 mg once daily). Common causes of intolerance or contraindication for beta-blockers that are not shared with Corlanor include asthma and hypoglycemia. • Prescribing Considerations: o The maximum dose in adults and pediatrics is 7.5 mg twice daily. o Females should use effective contraception due to fetal toxicity. o Monitor heart rate decreases and bradycardia symptoms during treatment. o Corlanor is contraindicated in sick sinus syndrome, sinoatrial block, or 3rd degree AV block, unless a functioning demand pacemaker is present. o Patients should be monitored for atrial fibrillation. o Corlanor is not recommended in patients with 2nd degree atrioventricular (AV) block.

Approval Criteria

I. Initial Authorization

A. Symptomatic Chronic Heart Failure in Adults

When a benefit, coverage of Corlanor (ivabradine) may be approved when all of the following criteria are met **(1. through 8.)**:

1. The member is 18 years of age or older.
2. The member has a diagnosis of stable, symptomatic chronic heart failure (ICD-10: I50).
3. The member is in normal sinus rhythm.
4. The member has a left ventricular ejection fraction (LVEF) ≤ 35%.
5. The member has a resting heart rate ≥ 70 beats per minute.
6. The member meets one (1) of the following criteria **(a. or b.)**:
  a. The member is concurrently taking one (1) of the following beta-blockers recommended for heart failure **(i., ii., or iii.)**:
    i. Bisoprolol
    ii. Carvedilol
    iii. Metoprolol succinate
  b. The member has experienced therapeutic failure, contraindication, or intolerance to the maximum tolerated dose of all of the following beta-blockers recommended for heart failure **(i., ii., and iii.)**:
    i. Bisoprolol
    ii. Carvedilol
    iii. Metoprolol succinate
7. If the request is for Corlanor oral solution, the member has an inability to swallow tablets.
8. If the request is for brand Corlanor tablets, the member has experienced therapeutic failure or intolerance to generic ivabradine.

B. Symptomatic Heart Failure due to Dilated Cardiomyopathy in Pediatrics

When a benefit, coverage of Corlanor (ivabradine) may be approved when all of the following criteria are met **(1. through 5.)**:

1. The member is 6 months to 17 years of age.
2. The member has a diagnosis of stable symptomatic heart failure (ICD-10: I50) due to dilated cardiomyopathy.
3. The member is in normal sinus rhythm.
4. The member has a resting heart rate ≥ 70 beats per minute.
5. If the request is for Corlanor oral solution, the member has an inability to swallow tablets.

II. Reauthorization

When a benefit, reauthorization of Corlanor (ivabradine) may be approved when all of the following criteria are met **(A., B., and C.)**:

A. The prescriber attests that the member has experienced positive clinical response to therapy.

B. If the request is for Corlanor oral solution, the member meets all of the following criteria **(1. and 2.)**:

1. The prescriber attests that the member continues to have an inability to swallow tablets.

2. If the request is for symptomatic heart failure due to dilated cardiomyopathy, the member is 6 months to 17 years of age.

C. If the request is for brand Corlanor tablets and the member is at least 18 years of age, the member has experienced therapeutic failure or intolerance to generic ivabradine.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None.

References:

1. Corlanor [package insert]. Thousand Oaks, CA: Amgen Inc.; August 2021.
2. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022; 145(18); e895-e1032.
3. Murphy SP, Ibrahim NE, Januzzi JL Jr. Heart Failure With Reduced Ejection Fraction: A Review. *JAMA*. 2020;324(5):488-504.
4. Desai AS, Stevenson LW. Rehospitalization for Heart Failure: Predict or Prevent? *Circulation*. 2012;126(4):501-506.