MEDICAL MUTUAL®

# Drug Policy

| Policy: | Corlanor (ivabradine) | Annual Review Date: 07/18/2024<br>Last Revised Date: 07/18/2024 |
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## OVERVIEW

Corlanor, a hyperpolarization-activated cyclic nucleotide-gated channel blocker, is indicated to reduce the risk of hospitalization for worsening heart failure (HF) in adult patients with stable, symptomatic chronic HF with left ventricular ejection fraction (LVEF) ≤ 35%, who are in sinus rhythm with a resting heart rate ≥ 70 beats per minute (bpm) and either are receiving maximally tolerated doses of beta blockers or have a contraindication to beta blocker use. It is also indicated for the treatment of stable, symptomatic heart failure due to dilate cardiomyopathy (DCM) in pediatric patients aged 6 months or older, who are in sinus rhythm with an elevated heart rate. Corlanor is an inhibitor of the $I_f$ current in the sinoatrial node, which slows heart rate (HR). Corlanor has several contraindications including: use in patients with acute decompensated HF, blood pressure < 90/50 mmHg, sinus sick syndrome, sinoatrial block, third degree atrioventricular block (unless a functioning demand pacemaker is present), resting HR < 60 bpm, severe hepatic impairment and patients whose heart rate is maintained exclusively by the pacemaker. Corlanor is also contraindicated in patients receiving strong cytochrome P450 (CYP) 3A4 inhibitors (e.g., azole antifungals, macrolide antibiotics).

## POLICY STATEMENT

This policy involves the use of Corlanor. Prior authorization is recommended for pharmacy benefit coverage of Corlanor. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

**Automation**: When available, 1) ICD-10 codes for Heart Failure (ICD-10: **I50.2***) AND 2) history of beta-blocker use within the previous 720 days prior to or while using Corlanor will be used for automation to allow approval for Corlanor for patients at least 18 years of age.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Corlanor is recommended in those who meet the following criteria:

1. **Chronic Heart Failure (HF)**
   **Criteria.** *Patient must meet the following criteria*
   **A.** The patient has a left ventricular ejection fraction (LVEF) ≤ 35% at baseline; AND

**B.** The patient is in normal sinus rhythm with a resting heart rate of ≥ 70 beats per minute (bpm) at baseline; AND
**C.** The patient meets one of the following:
  **a.** The patient has tried or is currently receiving one beta-blocker at the maximally tolerated dose for heart failure treatment (for example: metoprolol succinate sustained-release, carvedilol, bisoprolol, Coreg CR); OR
  **b.** The patient has a documented contraindication to use of beta-blocker therapy (for example: bronchospastic disease such as chronic obstructive pulmonary disease [COPD] or asthma, severe hypotension, bradycardia); AND
**D.** The patient is 18 years of age or older; AND
**E.** Medication is prescribed by, or in consultation with, a cardiologist.

**2. <u>Symptomatic Heart Failure due to Dilated Cardiomyopathy (DCM)</u>**
**Criteria.** *Patient must meet the following criteria*

**A.** The patient is a pediatric patient aged 6 months or older to less than 18 years; AND
**B.** The patient is in normal sinus rhythm with an elevated heart rate; AND
**C.** Medication is prescribed by or in consultation with, a cardiologist.

**3. <u>Inappropriate Sinus Tachycardia</u>**
**Criteria.** *Patient must meet the following criteria*
**A.** Medication is prescribed by, or in consultation with, a cardiologist.

**Initial Approval/ Extended Approval.**
**A)** *Initial Approval:* 6 months
**B)** *Extended Approval:* 1 year

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Corlanor has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Stable Angina Pectoris, in Patients Without Chronic Heart Failure.** Corlanor has been studied as a treatment for stable angina pectoris, but further data are needed. US guidelines addressing stable angina do not include Corlanor.

2. **Pacemaker Dependency.** Corlanor is contraindicated in patients whose heart rate is maintained exclusively by a pacemaker.

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

**Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

## REFERENCES

1. Corlanor® tablets [prescribing information]. Thousand Oaks: CA; Amgen; April 2019.
2. Swedberg K, Komajda M, Böhm M, et al, on behalf of the SHIFT Investigators. Ivabradine and outcomes in chronic heart failure (SHIFT): a randomised, placebo-controlled study. *Lancet*. 2010;376:875-885.
3. Heidenreich, P, 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. JACC. 2022 May, 79 (17) e263–e421. https://doi.org/10.1016/j.jacc.2021.12.012
4. Yancy CW, Jessup M, Bozkurt B, et al. Report of the American College of Cardiology/American Heart Association task force on clinical practice guidelines and the Heart Failure Society of America [published May 20, 2016]. *J Am Coll Cardiol*. 2016; doi:10.1016/j.jacc.2016.05.011
5. Abed HS, Fulcher J, Kilborn NJ, Keech AC. Inappropriate sinus tachycardia: focus on ivabradine. *Intern Med J*. 2016 Apr 5. [Epub ahead of print].
6. Ivabradine. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 27 June 2019. Accessed on 19 July 2019.
7. Page R, Joglar J, Caldwell M. et al. 2015 ACC/AHA/HRS Guideline for the Management of Adult Patients With Supraventricular Tachycardia: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. JACC. 2016 Apr, 67 (13) e27–e115. https://doi.org/10.1016/j.jacc.2015.08.856
8. Sheldon RS, Grubb BP 2nd, Olshansky B, et al. 2015 heart rhythm society expert consensus statement on the diagnosis and treatment of postural tachycardia syndrome, inappropriate sinus tachycardia, and vasovagal syncope. Heart Rhythm. 2015;12(6):e41-e63. doi:10.1016/j.hrthm.2015.03.029