

## DRUG POLICY

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# Corlanor® (ivabradine)

## BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

## DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-Approved Indications

#### **Heart Failure in Adult Patients**

Corlanor is indicated to reduce the risk of hospitalization for worsening heart failure in adult patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction  $\leq 35\%$ , who are in sinus rhythm with resting heart rate  $\geq 70$  beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.

#### **Heart Failure in Pediatric Patients**

Corlanor is indicated for the 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.

### Compendial Uses

1. Treatment of Inappropriate Sinus Tachycardia in adults.

## POLICY

### Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. Chart notes or medical records documenting left ventricular ejection fraction (LVEF)

## Criteria for Approval

### **Chronic Heart Failure**

Authorization may be granted when the requested drug is being prescribed to reduce the risk of hospitalization for worsening heart failure in a patient with stable, symptomatic chronic heart failure when ALL of the following criteria are met:

1. The requested drug is being prescribed for an adult
2. The member has a left ventricular ejection fraction (LVEF) less than or equal to 35 percent
3. The member is currently receiving optimal therapy for heart failure management (e.g., angiotensin-converting enzyme inhibitor [ACEI], angiotensin II receptor blocker [ARB], angiotensin receptor-neprilysin inhibitor [ARNI], beta-blocker, sodium-glucose co-transporter-2 inhibitor [SGLT2I], mineralocorticoid receptor antagonist [MRA])
4. The member meets ONE of the following:
  - A. Member is receiving treatment with a maximally tolerated dose of a beta-blocker
  - B. Member has an intolerance or contraindication to beta-blocker use
5. Member is in sinus rhythm

### **Heart Failure Due to Dilated Cardiomyopathy (DCM)**

Authorization may be granted when the requested drug is being prescribed for the treatment of stable, symptomatic heart failure due to dilated cardiomyopathy (DCM) when ALL of the following criteria are met:

1. The requested drug is being prescribed for a pediatric member 6 months of age or older
2. The member is in sinus rhythm
3. The member has an elevated heart rate

### **Inappropriate Sinus Tachycardia (IST)**

Authorization may be granted when the requested drug is being prescribed for the management of symptomatic inappropriate sinus tachycardia (IST) when the following criteria is met:

1. The requested drug is being prescribed for an adult

**Approval will be for 12 months.**

## Other

Corlanor (ivabradine) is considered **not medically necessary** for members who do not meet the criteria set forth above.

## Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

## Quantity Limits Apply

Corlanor oral solution: 450 mL/30 days

Corlanor (ivabradine) tablets: 2 tablets per day

## **CLINICAL RATIONALE**

Corlanor is indicated to reduce the risk of hospitalization for worsening heart failure in adult patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction  $\leq 35\%$ , who are in sinus rhythm with a resting heart rate  $\geq 70$  beats per minute (BPM) 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 (DCM) in pediatric patients aged 6

months and older, who are in sinus rhythm with an elevated heart rate. Corlanor also has compendial support for use in the management of inappropriate sinus tachycardia in adults.

According to the 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure, left ventricular ejection fraction (LVEF) is considered important in the classification of patients with heart failure (HF) because of differing prognosis and response to treatments. In this guideline, heart failure with reduced ejection fraction (HFrEF) is defined as  $LVEF \leq 40\%$ . According to the guideline, step 1 medications may be started simultaneously at initial (low) doses recommended for HFrEF or they may be started sequentially. Step 1 medications include sodium-glucose cotransporter 2 inhibitors (SGLT2I), mineralocorticoid receptor antagonists (MRA), beta-blockers, angiotensin receptor-neprilysin inhibitor (ARNI), angiotensin-converting enzyme inhibitors (ACEI), angiotensin receptor blockers (ARB) and diuretics as needed. Inhibition of the renin-angiotensin system is recommended to reduce morbidity and mortality for patients with HFrEF, and ANRI, ACEI or ARB are recommended as first-line therapy. Treatment with beta blockers reduces the risk of death and the combined risk of death or hospitalization in patients with HFrEF and can improve LVEF, lessen the symptoms of HF and improve clinical status. Mineralocorticoid receptor antagonists show consistent improvements in all-cause mortality and HF hospitalization. Sodium-glucose cotransporter 2 inhibitors are recommended to reduce hospitalizations for HF and cardiovascular mortality, irrespective of the presence of type 2 diabetes. The use of these specific medications for HFrEF should involve initiation at low-starting doses, up titration at specified intervals as tolerated, and achieving-maintaining the target doses shown to be effective in major clinical trials. The treatment goal of diuretic use is to eliminate clinical evidence of fluid retention, using the lowest dose possible to maintain euvolemia. Since the effects of diuretics on morbidity and mortality (with the exception of MRAs) are uncertain, diuretics should always be combined with other guideline-directed medical therapy (GDMT) for HF. Addition of Ivabradine can be considered for patients with symptomatic (NYHA class II to III) stable chronic HFrEF ( $LVEF \leq 35\%$ ), who are receiving GDMT, including a beta-blocker at maximum tolerated dose, and who are in sinus rhythm with a heart rate of  $\geq 70$  bpm at rest to reduce HF hospitalizations and cardiovascular death. Therefore, patients requesting Ivabradine must also be receiving optimal therapy for heart failure management and receiving treatment with a maximally tolerated dose of a beta blocker or have an intolerance or contraindication to beta blocker use.

For use in adults with heart failure, the recommended starting dose of Corlanor is 5 mg twice daily with food. Assess the patient after two weeks and adjust the dose to achieve a resting heart rate between 50 and 60 BPM. Thereafter, adjust the dose as needed based on resting heart rate and tolerability. The maximum dose is 7.5 mg twice daily. The recommended starting dose of Corlanor oral solution in pediatric patients 6 months of age and older and weighing less than 40 kg is 0.05 mg/kg twice daily with food. Assess the patient at two-week intervals and adjust the dose by 0.05 mg/kg to target a heart rate reduction of at least 20%, based on tolerability. The maximum dose is 0.2 mg/kg twice daily for patients 6 months to less than 1 year old, and 0.3 mg/kg twice daily for patients 1 years old and older, up to a total of 7.5 mg twice daily. The recommended starting dose of Corlanor tablets in pediatric patients weighing more than 40 kg is 2.5 mg twice daily with food. Assess the patient at two-week intervals and adjust the dose by 2.5 mg to target a heart rate reduction of at least 20%, based on tolerability. The maximum dose is 7.5 mg twice daily. Due to the reduction in heart rate that's targeted during therapy, the following are only required for initial approval: resting heart rate  $\geq 70$  BPM for an adult patient or elevated heart rate for a pediatric patient.

Inappropriate sinus tachycardia (IST) is defined as sinus tachycardia that is unexplained by physiological demands at rest, with minimal exertion, or during recovery from exercise. Crucial to this definition is the presence of associated, sometimes debilitating, symptoms that include weakness, fatigue, lightheadedness and uncomfortable sensations, such as heart racing. The ACC/AHA/HRS Guideline for the Management of Adult Patients with Supraventricular Tachycardia states that there are no specific recommendations for acute treatment of IST. Because the prognosis of IST is generally benign, treatment is for symptom

reduction and may not be necessary; however, use of ivabradine is reasonable for ongoing management in patients with symptomatic IST.

## PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT\* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

## REFERENCES

1. Corlanor [package insert]. Thousand Oaks, CA: Amgen Inc.; August 2021.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed June 15, 2022.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed June 15, 2022.
4. 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. *J Am Coll Cardiol*. 2022;79:e263-e421.
5. Page PL, Joglar JA, Caldwell MA 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. *Circulation*. 2016;133:e506-e574.

## POLICY HISTORY

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