Corlanor (ivabradine)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

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 Corlanor (ivabradine) drug 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 ≤ 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.

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 Use
Treatment of Inappropriate Sinus Tachycardia in adults.

POLICY

Criteria for Approval
The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is for an adult patient

AND

- 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
  AND
- The patient has a left ventricular ejection fraction (LVEF) less than or equal to 35 percent. Documentation is required for approval.
  AND
- The patient 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])
  AND
- The patient is receiving treatment with a maximally tolerated dose of a beta-blocker OR the patient has an intolerance or contraindication to beta-blocker use
  AND
- The patient is in sinus rhythm
  AND
- If the request is not for continuation of therapy, the patient has a resting heart rate greater than or equal to 70 beats per minute [BPM]

OR

- The requested drug is being prescribed for the management of symptomatic inappropriate sinus tachycardia (IST)

OR

- The request is for a pediatric patient 6 months of age or older
  AND
- The requested drug is being prescribed for the treatment of stable, symptomatic heart failure due to dilated cardiomyopathy (DCM)
  AND
- The patient is in sinus rhythm
  AND
- If the request is not for continuation of therapy, the patient has an elevated heart rate

Approval will be for **12 months.**

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
Corlanor oral solution: 450 mL/30 days
Corlanor tablets: 2 tablets per day

CLINICAL RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. 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 ≤ 35%, who are in sinus rhythm with a resting heart rate ≥ 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.1-3 Corlanor also has compendial support for use in the management of inappropriate sinus tachycardia in adults.[3,5]

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 ≤ 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, uptitration 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 ≤ 35%), who are receiving GDMT, including a beta-blocker at maximum tolerated dose, and who are in sinus rhythm with a heart of ≥ 70 bpm at rest to reduce HF hospitalizations and cardiovascular death.[4] 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 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.1 Due to the reduction in heart rate that's targeted during therapy, the following are only required for initial approval: resting heart rate ≥ 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.[5]

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.; April 2019.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed February 16, 2021.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed February 16, 2021.
4. Maddox TM, Januzzi JL, Allen LA, 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: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. Published online January 2021. Available at: https://www.jacc.org/doi/10.1016/j.jacc.2020.11.022?_ga=2.266943758.1073019511.1611765807-2024013049.1611765807

POLICY HISTORY

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