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Coverage Policy Number.....**IP0286**

Ivabradine

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for ivabradine (Corlanor®).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Ivabradine (Corlanor) is considered medically necessary when ONE of the following is met (1, 2, or 3):

1. **Heart Failure.** Individual meets **ALL** of the following criteria (A, B, C, and D):
    A. Individual is 18 years of age or older
    B. Individual has a left ventricular ejection fraction (LVEF) less than or equal to 35% prior to initiation of ivabradine (Corlanor) therapy
    C. Individual is in sinus rhythm with a resting heart rate greater than or equal to 70 beats per minute
    D. Documentation of **ONE** of the following (i or ii):
        i. Concurrent treatment with maximally tolerated doses of a beta blocker for heart failure

ii. Individual has a contraindication or intolerance for beta blocker therapy

2. **Heart Failure due to Dilated Cardiomyopathy in Pediatric Individuals.** Individual meets **ALL** of the following criteria (A, B, C, and D):
   A. Individual is less than 18 years of age
   B. Individual has a left ventricular ejection fraction (LVEF) less than or equal to 45% prior to initiation of ivabradine (Corlanor) therapy
   C. Individual is on stable treatment for heart failure
   D. Individual is in sinus rhythm with a resting heart rate greater than or equal to 105 beats per minutes for ages 6 to 12 months; greater than or equal to 95 beats per minute for ages greater than 1 year to less than 3 years; greater than or equal to 75 beats per minute for ages 3 years to less than 5 years; and greater than or equal to 70 beats per minute for ages 5 years to less than 18 years of age

3. **Inappropriate Sinus Tachycardia.** Individual meets **BOTH** of the following criteria (A and B):
   A. Documentation of **ONE** of the following (i or ii)
      i. Individual has had an inadequate response to at least **ONE** beta blocker
      ii. Individual has a contraindication or intolerance for beta blocker therapy
   B. The medication is being prescribed by, or in consultation with, a cardiologist or electrophysiologist

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Ivabradine (Corlanor) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months

Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

1. **Stable Angina Pectoris, in Individuals Without Chronic Heart Failure.**
   Corlanor has been studied as a treatment for stable angina pectoris, but further data are needed.[11-13] US guidelines addressing stable angina do not include Corlanor.[14,15]

Background

OVERVIEW
Corlanor, a hyperpolarization-activated cyclic nucleotide-gated channel blocker, is indicated for the following uses:[1]

- **Heart failure, in adults**, to reduce the risk of hospitalization for worsening of the disease in those with stable, symptomatic chronic heart failure 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.
- **Heart failure, in pediatric patients ≥ 6 months and older**, for treatment of stable symptomatic disease due to dilated cardiomyopathy, among those who are in sinus rhythm with an elevated heart rate.

Data are available with Corlanor that note improvement in symptoms and increased exercise performance in patients with inappropriate sinus tachycardia, defined as a sinus heart rate > 100 bpm at rest (with a mean 24-hour heart rate > 90 bpm not due to primary causes) which is generally is associated with distressing symptoms such as palpitations, weakness, dizziness and syncope.[2-9] Beta blockers have also been used for this condition. Limited data are available for other treatments that have been used and/or effectiveness have not been established (e.g., beta blockers, fludrocortisone, volume expansion, clonidine, and erythropoietin).

Guidelines
A few guidelines have recommendations that involve Corlanor.
- **Heart Failure:** The American Heart Association/American College of Cardiology/Heart Failure Society of America published guidelines in 2022 for the management of heart failure.[10] For patients with symptomatic (New York Heart Association Class II to III) stable chronic heart failure with reduced ejection fraction (LVEF ≤ 35%) who are receiving guideline-directed medical therapy, including a beta blocker at maximum tolerated dose, and who are in sinus rhythm with a heart rate of ≥ 70 beats per minute at rest, Corlanor can be beneficial to reduce heart failure hospitalizations and cardiovascular death.
- **Inappropriate Sinus Tachycardia:** The 2015 Heart Rhythm Society Expert Consensus Statement on the diagnosis and treatment of postural tachycardia syndrome, inappropriate sinus tachycardia, and vasovagal syncope state that Corlanor can be useful for treating patients with inappropriate sinus tachycardia.[2] Additionally, the 2015 American College of Cardiology, American Heart Association Task Force on Clinical Practice Guidelines, and the Heart Rhythm Society also state that Corlanor is reasonable for ongoing management in patients with symptomatic inappropriate sinus tachycardia (class IIa recommendation).[3] Beta blockers may be considered for ongoing management in patients with symptomatic inappropriate sinus tachycardia (class IIb recommendation). Also, the guidelines state that the combination of beta blockers and Corlanor may be considered for the ongoing management of patients with inappropriate sinus tachycardia (class IIb recommendation). Because of the specialized skills required for evaluation and diagnosis of patients treated with Corlanor as well as the monitoring required for adverse events and long-term efficacy, approval requires Corlanor to be prescribed by or in consultation with a physician who specializes in the condition being treated.

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