Corlanor

Description

Corlanor (ivabradine)

Background

Corlanor is approved for use in a limited population of cardiac patients who have long-lasting (chronic) heart failure caused by the lower-left part of their heart not contracting well. The drug is indicated for patients who have symptoms of heart failure that are stable, a normal heartbeat with a resting heart rate of at least 70 beats per minute and are also taking beta blockers at the highest dose they can tolerate or who have a contraindication to beta-blocker use (1).

Regulatory Status

FDA-approved indication: Corlanor is a hyperpolarization-activated cyclic nucleotide-gated channel blocker indicated to reduce the risk of hospitalization for worsening heart failure in 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 (1).

Off Label Uses:
Recent studies have described a dramatic improvement in heart rate and postural orthostatic tachycardia syndrome (POTS)-related symptoms with Corlanor. Corlanor is a selective sinus node blocker, reducing firing rate without affecting blood pressure (2-3).

Corlanor must be titrated and adjustments are based upon resting heart rate and tolerability (1). Corlanor is contraindicated in patients with acute decompensated heart failure, blood pressure less than 90/50 mmHg, sick sinus syndrome or 3rd degree AV block unless a functioning
demand pacemaker is present, resting heart rate less than 60 beats per minute prior to treatment, severe hepatic impairment, pacemaker dependent or concomitant use of strong cytochrome P450 3A4 inhibitors (1).

Corlanor may cause fetal toxicity when administered to a pregnant woman based on findings in animal studies. Advise females with child-bearing potential to use effective contraception when taking Corlanor (1).

Corlanor increases the risk of atrial fibrillation. Regularly monitor cardiac rhythm. Discontinue Corlanor if atrial fibrillation develops. Bradycardia, sinus arrest and heart block have occurred with Corlanor. Risk factors for bradycardia include sinus node dysfunction, conduction defects (e.g., 1st or 2nd degree atrioventricular block, bundle branch block), ventricular dyssynchrony and use of other negative chronotropes (e.g., digoxin, diltiazem, verapamil, amiodarone). Concurrent use of verapamil or diltiazem will increase Corlanor exposure, may themselves contribute to heart rate lowering and should be avoided. Assess patient after two weeks and adjust dose to achieve a resting heart rate between 50 and 60 beats per minute. Corlanor is not recommended for use in patients with demand pacemakers set to rates of ≥ 60 beats per minutes (1).

The safety and efficacy of Corlanor has not been established in patients younger than 18 years of age (1).

**Related policies**

Entresto

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Corlanor may be considered **medically necessary** in patients 18 years and older for treatment of stable, symptomatic chronic heart failure with an ejection fraction ≤ 35 and a heart rate ≥ 70 beats per minute, prescribed by or recommended by cardiologist, who are either on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use; patient must not have the following: blood pressure less than 90/50mmHg, sick sinus syndrome, sino-atrial (SA) block, or 3rd degree atrioventricular (AV) block, unless a functioning demand pacemaker is present, demand pacemakers set to rates ≥ 60 beats per minute, or severe hepatic impairment.

Corlanor may be considered **medically necessary** in patients 18 years and older for treatment
of postural orthostatic tachycardia syndrome (POTS) in patients with no severe hepatic impairment.

Corlanor is considered investigational in patients under the age of 18 years and in patients with all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have ONE of the following:

1. Stable, symptomatic chronic heart failure

   AND ALL of the following:
   a. Left ventricular ejection fraction ≤35%
   b. Normal sinus rhythm with a resting heart rate ≥ 70 beats per minute
   c. Prescribed by or recommended by cardiologist

   AND ONE of the following:
   a. Using maximally tolerated doses of beta-blockers
   b. Contraindication to beta-blocker use

   AND NONE of the following:
   a. Blood Pressure less than 90/50mmHg
   b. Sick sinus syndrome, sino-atrial (SA) block, or 3rd degree atrioventricular (AV) block, unless a functioning demand pacemaker is present
   c. Demand pacemakers set to rates ≥ 60 beats per minute
   d. Severe hepatic impairment

2. Postural orthostatic tachycardia syndrome (POTS)
   a. NO severe hepatic impairment

Prior – Approval Renewal Requirements

Diagnosis
Patient must have **ONE** of the following:

1. Chronic heart failure
2. Postural orthostatic tachycardia syndrome (POTS)

**AND ALL** of the following:
   a. Condition has improved or stabilized
   b. **NO** severe hepatic impairment

**Policy Guidelines**

**Pre - PA Allowance**
None

**Prior - Approval Limits**

**Duration**  12 months

**Prior – Approval Renewal Limits**

**Duration**  12 months

**Rationale**

**Summary**
Corlanor is a hyperpolarization-activated cyclic nucleotide-gated (HCN) channel blocker, which affects heart rate. It is indicated to reduce the risk of hospitalization for worsening heart failure in 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. Recent studies have described a dramatic improvement in heart rate and postural orthostatic tachycardia syndrome (POTS) related symptoms with Corlanor. Corlanor is a selective sinus node blocker, reducing firing rate without affecting blood pressure. Corlanor may cause fetal toxicity when administered to a pregnant woman based on findings in animal studies. Advise females of child-bearing potential to use effective contraception when taking Corlanor. Corlanor increases the risk of atrial fibrillation and bradycardia (1-3).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Corlanor while maintaining optimal therapeutic outcomes.
Section: Prescription Drugs
Subsection: Cardiovascular Agent
Subject: Corlanor

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Page: 5 of 5

References

Policy History
Date Action/Reason
June 2015 Addition of Corlanor to PA
September 2015 Annual review
December 2015 Annual editorial review
May 2016 Addition of Postural Tachycardia Syndrome (POTS)
June 2016 Policy number change from 5.16.05 to 5.40.05

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 24, 2016 and is effective on July 1, 2016.

Deborah M. Smith, MD, MPH