

5.40.05

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Cardiovascular Agent	Original Policy Date:	June 26, 2015
Subject:	Corlanor	Page:	1 of 5

Last Review Date: March 12, 2021

Corlanor

Description

Corlanor (ivabradine)

Background

Corlanor (ivabradine) blocks the hyperpolarization-activated cyclic nucleotide-gated channel responsible for the cardiac pacemaker I_f current, which regulates heart rate. The cardiac effects are most pronounced in the sinoatrial (SA) node, but prolongation of the AH interval has occurred as has PR interval prolongation. There is no effect on ventricular repolarization and no effects on myocardial contractility (1).

Regulatory Status

FDA-approved indications: Corlanor is a hyperpolarization-activated cyclic nucleotide-gated channel blocker indicated: (1)

1. 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 ≥ 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.
2. For the treatment of stable symptomatic heart failure due to dilated cardiomyopathy in pediatric patients ages 6 months and older.

Off Label Uses:

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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; clinically significant hypotension; sick sinus syndrome, sinoatrial block or 3rd degree AV block, unless a functioning demand pacemaker is present; clinically significant bradycardia; severe hepatic impairment; pacemaker dependence; 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 of reproductive 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 have not been established in pediatric patients less than 6 months 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** for treatment of heart failure or postural orthostatic tachycardia syndrome (POTS) and if the conditions indicated below are met.

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Corlanor may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

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

1. Stable, symptomatic chronic heart failure
 - a. 18 years of age or older
 - b. Left ventricular ejection fraction $\leq 35\%$
 - c. Normal sinus rhythm with a resting heart rate ≥ 70 beats per minute
2. Postural orthostatic tachycardia syndrome (POTS)
 - a. 18 years of age or older
3. Stable, symptomatic heart failure due to dilated cardiomyopathy
 - a. Age 6 months to 17 years old
 - b. Patient is in sinus rhythm with an elevated heart rate

AND NONE of the following for **ALL** diagnoses:

- a. Clinically significant hypotension
- 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

AND ALL of the following for **ALL** diagnoses:

- a. Prescribed by or recommended by cardiologist

Prior – Approval *Renewal* Requirements

Diagnoses

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

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1. Chronic heart failure
 - a. 18 years of age or older
2. Postural orthostatic tachycardia syndrome (POTS)
 - a. 18 years of age or older
3. Heart failure due to dilated cardiomyopathy
 - a. Age 6 months to 17 years old
 - b. Patient is in sinus rhythm with elevated heart rate

AND ALL of the following for **ALL** diagnoses:

- a. **NO** severe hepatic impairment
- b. Condition has improved or stabilized

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Corlanor (ivabradine) blocks the hyperpolarization-activated cyclic nucleotide-gated channel responsible for the cardiac pacemaker I_f current, which regulates heart rate. The cardiac effects are most pronounced in the sinoatrial (SA) node, but prolongation of the AH interval has occurred as has PR interval prolongation. There is no effect on ventricular repolarization and no effects on myocardial contractility. The safety and efficacy of Corlanor have not been established in pediatric patients less than 6 months of age (1).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Corlanor while maintaining optimal therapeutic outcomes.

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References

1. Corlanor [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2019.
2. McDonald C, Frith J, and Newton J. Single centre experience of ivabradine in postural orthostatic tachycardia syndrome. *Europace*. 2011;13:427–430. Accessed on February 22, 2021.
3. Nwazue VC et al. Postural tachycardia syndrome and inappropriate sinus tachycardia: role of autonomic modulation and sinus node automaticity. *Journal American Heart Assoc*. 2014;3(2):e000700. Accessed on February 22, 2021.

Policy History

Date	Action
June 2015	Addition of Corlanor to PA
September 2015	Annual review
December 2015	Annual editorial review
May 2016	Addition of Postural Tachycardia Syndrome (POTS) Policy number change from 5.16.05 to 5.40.05
June 2016	Annual review
December 2016	Annual editorial review Addition of age to renewal requirements
September 2017	Annual editorial review and reference update
September 2018	Annual review
May 2019	Addition of indication of heart failure due to dilated cardiomyopathy in pediatric patients 6 months and older
June 2019	Annual review
September 2020	Annual review
March 2021	Annual editorial review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.