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**5.40.005**

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2025
<b>Subsection:</b>	Cardiovascular Agent	<b>Original Policy Date:</b>	June 26, 2015
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**Last Review Date:** March 7, 2025

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## Corlanor

### Description

#### Corlanor (ivabradine)

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#### 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  $\geq 70$  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 3<sup>rd</sup> 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., 1<sup>st</sup> or 2<sup>nd</sup> 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  $\geq 60$  beats per minutes (1).

The safety and efficacy of Corlanor have not been established in pediatric patients less than 6 months of age (1).

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## Related policies

Inpefa, Verquvo

## 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** 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  $\geq 70$  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 3<sup>rd</sup> degree atrioventricular (AV) block, unless a functioning demand pacemaker is present
- c. Demand pacemakers set to rates  $\geq 60$  beats per minute
- d. Severe hepatic impairment

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

- a. Prescribed by or recommended by cardiologist

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## 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

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### 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.; August 2021.
2. McDonald C, Frith J, and Newton J. Single centre experience of ivabradine in postural orthostatic tachycardia syndrome. *Europace*. 2011;13:427–430.
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.

**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
June 2021	Annual review
March 2022	Annual review and reference update
June 2022	Annual review
March 2023	Annual review. Changed policy number to 5.40.005
September 2023	Annual review
March 2024	Annual review
March 2025	Annual review

**Keywords**

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.**