UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2290-3
Program	Prior Authorization/Medical Necessity
Medication	Corlanor® (ivabradine)
P&T Approval Date	10/2022, 8/2023, 9/2024
Effective Date	12/1/2024

1. Background:

Corlanor (ivabradine) is a hyperpolarization-activated cycle nucleotide-gated channel blocker indicated to reduce the risk of hospitalization for worsening of 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. It is also indicated to treat 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. Also, although not an FDA-approved indication, Corlanor has also shown to have efficacy in treating inappropriate sinus tachycardia (IST).

2. Coverage Criteria[a]:

A. **Initial Authorization**

1. **Corlanor** will be approved based on **one** of the following criteria:

a. **All** of the following:

(1) Worsening heart failure in a diagnosis of stable, symptomatic chronic [e.g. New York Heart Association (NYHA) class II, III or IV] heart failure

-AND-

(2) Patient has a left ventricular ejection fraction (EF) ≤ 35%

-AND-

(3) The patient is in sinus rhythm

-AND-

(4) Patient has a resting heart rate ≥ 70 beats per minute

-AND-

(5) **One** of the following[b]:

i. Patient is on a stabilized dose and receiving concomitant therapy with a maximally tolerated beta-blocker (e.g., carvedilol, metoprolol succinate, bisoprolol)
ii. Patient has a contraindication or intolerance to beta-blocker therapy

-AND-

(6) **One** of the following:

i. Patient is on a stabilized dose and receiving concomitant therapy with Jardiance or Farxiga* (includes combination products containing empagliflozin and dapagliflozin*)
ii. Patient has a contraindication or intolerance to SGLT2 inhibitor therapy

-AND-

(7) **One** of the following:

i. Patient is on a stabilized dose and receiving concomitant therapy with one of the following:

(1) angiotensin-converting enzyme (ACE) inhibitor (e.g. captopril, enalapril)
(2) angiotensin II receptor blocker (ARB) (e.g. candesartan, valsartan)
(3) angiotensin receptor-neprilysin inhibitor (ARNI) (e.g. Entresto)

-OR-

ii. Patient has a contraindication or intolerance to ACE inhibitors, ARBs, and ARNIs

-AND-

(8) **One** of the following:

i. Patient is on a stabilized dose and receiving concomitant therapy with a maximally tolerated aldosterone antagonist (e.g. eplerenone, spironolactone)
ii. Patient has a contraindication or intolerance to aldosterone antagonist therapy

-AND-

(9) Prescribed by or in consultation with a cardiologist

-OR-

b. **All** of the following:

(1) Diagnosis of stable symptomatic heart failure due to dilated cardiomyopathy (DCM)

-AND-

(2) Patient is in sinus rhythm

-AND-

(3) Patient has an elevated heart rate

-AND-

(4) Prescribed by or in consultation with a cardiologist

-OR-

c. **All** of the following:

(1) Diagnosis of inappropriate sinus tachycardia (IST)

-AND-

(2) Patient is in sinus rhythm

-AND-

(3) **One** of the following:

i. Patient has tried and failed or had an inadequate response to a beta-blocker (e.g., carvedilol, metoprolol succinate, bisoprolol)
ii. Patient has a contraindication or intolerance to beta-blocker therapy

-AND-

(4) Prescribed by or in consultation with a cardiologist

-OR-

d. Patient is currently established on Corlanor therapy

Authorization will be issued for 12 months.

B. **Reauthorization**

1. **Corlanor** will be approved based on the following criterion:

a. Documentation of positive clinical response to Corlanor therapy

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
[b] Tried/failed alternatives are supported by FDA labeling

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply Limits may be in place.
- *Typically excluded from coverage

4. References:

1. Corlanor [Package Insert] Thousand Oaks, CA: Amgen Inc.; August 2021
2. Heidenreich, P. A., Bozkurt, B., Aguilar, D., et al. 2022 ACC/AHA/HFSA guideline for the management of heart failure. *Journal of Cardiac Failure*, 2022 28(5), e1-e167.
3. Sheldon, R.S., Grubb, B.P., et al. 2015 Heart Rhythm Society Expert Consensus Statement on the Diagnosis and Treatment of Postural Tachycardia Syndrome, Inappropriate Sinus Tachycardia, and Vasovagal Syncope. Heart Rhythm, 2015, 12(6), e41-e63.

Program	Prior Authorization/Medical Necessity – Corlanor® (ivabradine)
Change Control	
10/2022	New program.
8/2023	Updated background and added criteria for use in inappropriate sinus tachycardia.
9/2024	Annual review. No changes.