ivabradine (Corlanor®)

EOCCO POLICY

Policy Type: NF Pharmacy Coverage Policy: EOCCO040

Description

Ivabradine (Corlanor) is an orally administered direct and selective inhibitor of the hyperpolarization-activated cyclic nucleotide-gated (HCN-gated) channels, or the f-channels that are located in the cardiac sinoatrial node which results in a lowering of the heart rate.

Length of Authorization

- Initial: 12 months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit	DDID
ivabradine (Corlanor)	5 mg tablets	Heart Failure in Adult Patients	60 tablets/30 days	188210
	7.5 mg tablets		60 tablets/30 days	188211
	5 mg/5 mL solution	Heart Failure in Pediatric Patients	450 mL/30 days	Not available yet

Initial Evaluation

I. Ivabradine (Corlanor) may be considered medically necessary when the following criteria below are met:
   A. Prescribed by or in consultation with a cardiologist; **AND**
   B. A diagnosis of one of the following:
      1. **Heart Failure in Adult Patients**; **AND**
         i. Prescribed by or in consultation with a cardiologist; **AND**
         ii. The member have stable, symptomatic chronic heart failure; **AND**
         iii. The member have left ventricular ejection fraction ≤ 35%; **AND**
         iv. The member is in sinus rhythm with resting heart rate ≥ 70 beats per minute; **AND**
         v. Treatment with maximally tolerated beta-blockers have been ineffective, contraindicated, or not tolerated; **AND**
         vi. The member does not have any of the following contraindications:
            a. Acute decompensated heart failure
            b. Blood pressure less than 90/50 mmHg

c. Sick sinus syndrome, sinoatrial block or 3rd degree AV block, unless a functioning demand pacemaker is present
d. Resting heart rate less than 60 bpm prior to treatment
e. Severe hepatic impairment
f. Pacemaker dependence
g. Concomitant use of strong cytochrome CYP3A4 inhibitors (e.g. azole antifungals, macrolide antibiotics, HIV protease inhibitors);

OR

2. **Heart Failure in Pediatric Patients; AND**
   i. Member is ≥ 6 months years of age; **AND**
   ii. The member has stable symptomatic heart failure due to dilated cardiomyopathy; **AND**
   iii. The member is in sinus rhythm with elevated heart rate; **AND**
   iv. The member does not have any of the following contraindications:
      a. Acute decompensated heart failure
      b. Blood pressure less than 90/50 mmHg
      c. Sick sinus syndrome, sinoatrial block or 3rd degree AV block, unless a functioning demand pacemaker is present
      d. Resting heart rate less than 60 bpm prior to treatment
      e. Severe hepatic impairment
      f. Pacemaker dependence
      g. Concomitant use of strong cytochrome CYP3A4 inhibitors (e.g. azole antifungals, macrolide antibiotics, HIV protease inhibitors);

OR

3. **Inappropriate Sinus Tachycardia**; **AND**
   i. The member has inappropriate sinus tachycardia; **AND**
   ii. The member does not have any of the following contraindications:
      a. Acute decompensated heart failure
      b. Blood pressure less than 90/50 mmHg
      c. Sick sinus syndrome, sinoatrial block or 3rd degree AV block, unless a functioning demand pacemaker is present
      d. Resting heart rate less than 60 bpm prior to treatment
      e. Severe hepatic impairment
      f. Pacemaker dependence
      g. Concomitant use of strong cytochrome CYP3A4 inhibitors (e.g. azole antifungals, macrolide antibiotics, HIV protease inhibitors)

II. Ivabradine (Corlanor) is considered not medically necessary when criteria above are not met and/or when used for:
   A. Coronary artery disease with or without heart failure

III. Ivabradine (Corlanor) is considered investigational when used for all other conditions, including but not limited to:
   A. Non-stable, asymptomatic chronic heart failure
   B. Pediatric heart failure not due to dilated cardiomyopathy

Renewal Evaluation

I. **Heart Failure in adults, heart failure in pediatrics, inappropriate sinus tachycardia**; **AND**
   A. Member has previously received treatment with ivabradine (Corlanor); **AND**
   B. Continues to meet criteria identified in section I of the initial Evaluation; **AND**
   C. Provider attest to stabilization of disease (e.g. heart rate reduction, reduction in hospitalization due to worsening heart failure); **AND**
   D. Absence of unacceptable toxicity from the medication

Supporting Evidence

I. Ivabradine (Corlanor) is indicated to reduce the risk of hospitalization for worsening heart failure in adult 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.

II. ACC/AHA 2015 guideline recommends the use of ivabradine (Corlanor) [moderate evidence] over the historical standard treatment of beta-blockers [weak evidence] for the treatment of inappropriate sinus tachycardia.

Investigational or Not Medically Necessary Uses

I. Coronary artery disease
   A. In the BEAUTIFUL and SIGNIFY trials, no benefits were found in patients with stable coronary artery disease with or without stable heart failure, who were given ivabradine (Corlanor).

II. Non-stable, asymptomatic chronic heart failure
    A. Ivabradine (Corlanor) has not been studied in patients with non-stable, asymptomatic chronic heart failure; therefore, it would be considered investigational when Corlanor is requested in that setting.
III. Pediatric heart failure not due to dilated cardiomyopathy
    A. Ivabradine (Corlanor) has not been studied in pediatric patients with heart failure that is not due to dilated cardiomyopathy; therefore, it would be considered investigational when Corlanor is requested in that setting.

References

1. Corlanor [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc. April 2019.
2. Fox K, Ford I, Steg G, et al. Ivabradine for patients with stable coronary artery disease and left-ventricular systolic dysfunction (BEAUTIFUL): a randomised, double-blind, placebo-controlled trial. Lancet. 2008 Sep 6;372(9641):807-16. doi: 10.1016/S0140-6736(08)61170-8.
3. Ferrari R, Fox K. The role of heart rate may differ according to pathophysiology setting: from SHIFT to SIGNIFY. Eur Heart J. 2015;36:2042–2046

Policy Implementation/Update:

Date Created	May 2015
Date Effective	May 2015
Last Updated	August 2015
Last Reviewed	06/2019

Action and Summary of Changes	Date
Transitioned criteria to policy. In this transition, the following updates were made: added new indication for pediatric heart failure due to dilated cardiomyopathy, incorporated the approvable off-label indication of inappropriate sinus tachycardia, and added renewal criteria.	06/2019