

PRIOR AUTHORIZATION POLICY

POLICY: Cardiology – Ivabradine Prior Authorization Policy

- Corlanor® (ivabradine tablets and oral solution – Amgen, generic [tablets only])

REVIEW DATE: 08/14/2024

OVERVIEW

Ivabradine, a hyperpolarization-activated cyclic nucleotide-gated channel blocker, is indicated for the following uses:¹

- **Heart failure, in adults**, to reduce the risk of hospitalization for worsening of the disease in those with stable, symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) $\leq 35\%$, who are in sinus rhythm with a resting heart rate ≥ 70 beats per minute (bpm) and either are receiving maximally tolerated doses of beta blockers or have a contraindication to beta blocker use.
- **Heart failure, in pediatric patients ≥ 6 months and older**, for treatment of stable symptomatic disease due to dilated cardiomyopathy, among those who are in sinus rhythm with an elevated heart rate.

Data are available with ivabradine that note improvement in symptoms and increased exercise performance in patients with inappropriate sinus tachycardia, defined as a sinus heart rate > 100 bpm at rest (with a mean 24-hour heart rate > 90 bpm not due to primary causes) which is generally associated with distressing symptoms such as palpitations, weakness, dizziness and syncope.²⁻⁹ Beta blockers have also been used for this condition. Limited data are available for other treatments that have been used and/or effectiveness have not been established (e.g., beta blockers, fludrocortisone, volume expansion, clonidine, and erythropoietin).

Guidelines

A few guidelines have recommendations that involve ivabradine.

- **Heart Failure:** The American Heart Association/American College of Cardiology/Heart Failure Society of America published guidelines in 2022 for the management of heart failure.¹⁰ For patients with symptomatic (New York Heart Association Class II to III) stable chronic heart failure with reduced ejection fraction (LVEF $\leq 35\%$) who are receiving guideline-directed medical therapy, including a beta blocker at maximum tolerated dose, and who are in sinus rhythm with a heart rate of ≥ 70 beats per minute at rest, ivabradine can be beneficial to reduce heart failure hospitalizations and cardiovascular death.
- **Inappropriate Sinus Tachycardia:** The 2015 Heart Rhythm Society Expert Consensus Statement on the diagnosis and treatment of postural tachycardia syndrome, inappropriate sinus tachycardia, and vasovagal syncope state that ivabradine can be useful for treating patients with inappropriate sinus tachycardia.² Additionally, the 2015 American College of Cardiology, American Heart Association Task Force on Clinical Practice Guidelines, and the Heart Rhythm Society also state that ivabradine is reasonable for ongoing management in patients with symptomatic inappropriate sinus tachycardia (class IIa recommendation).³ Beta blockers may be considered for ongoing management in patients with symptomatic inappropriate sinus tachycardia (class IIb recommendation). Also, the guidelines state that the combination of beta blockers and ivabradine may be considered for the ongoing management of patients with inappropriate sinus tachycardia (class IIb recommendation).

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POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of ivabradine. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with ivabradine as well as the monitoring required for adverse events and long-term efficacy, approval requires ivabradine to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of ivabradine is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Heart Failure.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has a left ventricular ejection fraction (LVEF) $\leq 35\%$ currently or prior to initiation of ivabradine therapy; AND
 - C) Patient is in normal sinus rhythm or sinus tachycardia with a resting heart rate of ≥ 70 beats per minute; AND
 - D) Patient meets ONE of the following (i or ii):
 - i. Patient has tried or is currently receiving one beta blocker for heart failure treatment; OR
Note: Examples of beta blockers are metoprolol succinate sustained-release, carvedilol, bisoprolol, and Coreg CR (carvedilol extended-release capsules).
 - ii. Patient has a contraindication to use of beta blocker therapy; AND
Note: Examples that are contraindications to use of beta blockers are bronchospastic disease such as chronic obstructive pulmonary disease and asthma, severe hypotension or bradycardia.
 - E) The medication is prescribed by or in consultation with a cardiologist.
2. **Heart Failure due to Dilated Cardiomyopathy in Pediatric Patients.** Approve for 1 year if the patient meets BOTH of the following (A and B):
 - A) Patient is < 18 years of age; AND
 - B) The medication is prescribed by or in consultation with a cardiologist.

Other Uses with Supportive Evidence

3. **Inappropriate Sinus Tachycardia.** Approve for 1 year if the patient meets BOTH of the following (A and B):
 - A) Patient meets ONE of the following (i or ii):
 - i. Patient has tried or is currently receiving one beta blocker for inappropriate sinus tachycardia; OR
Note: Examples of beta blockers are metoprolol and bisoprolol.
 - ii. Patient has a contraindication to use of beta blocker therapy; AND
Note: Examples that are contraindications to use of beta blockers are bronchospastic disease such as chronic obstructive pulmonary disease and asthma, severe hypotension or bradycardia.
 - B) The medication is prescribed by or in consultation with a cardiologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of ivabradine is recommended in those who meet the following criteria:

- 1. Stable Angina Pectoris, in Patients Without Chronic Heart Failure.** Ivabradine has been studied as a treatment for stable angina pectoris but further data are needed.¹¹⁻¹³ The 2023 American Heart Association/American College of Cardiology guidelines for chronic coronary disease (CCD) state that in patients with CCD and normal left ventricular function, the addition of ivabradine to standard anti-anginal therapy is potentially harmful.¹⁴
- 2.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

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