PRIOR AUTHORIZATION POLICY

POLICY: Cardiology – Ivabradine Prior Authorization Policy
- Corlanor® (ivabradine tablets and oral solution – Amgen, generic [tablets only])

REVIEW DATE: 08/13/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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) ≤ 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 ≤ 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 bpm 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 orthostatic 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).

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.

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

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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) ≤ 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 of contraindications to the 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 of contraindications to the 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 COVERED

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

is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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]

REFERENCES

1. Corlanor® tablets and oral solution [prescribing information]. Thousand Oaks: CA; Amgen; August 2021.
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5. Oliphant CS, Owens RE, Bolorunduro OB, Jha SK. Ivabradine: a review of labeled and off-label uses. *Am J Cardiovasc Drugs*. 2016;16:337-347.
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7. Mathew ST, Po SS, Thadani U. Inappropriate sinus tachycardia – symptoms and heart rate reduction with ivabradine: a pooled analysis of prospective studies. *Heart Rhythm*. 2018;15:240-247.
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10. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022;145(18):e895-e1032.
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13. Glezer M, Vasyuk Y, Karpov Y. Efficacy of ivabradine in combination with beta-blockers versus uptitration of beta-blockers in patients with stable angina (CONTROL-2 Study). *Adv Ther*. 2018;35:341-352.
14. Virani SS, Newby LK, Arnold SV, et al. 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA guideline for the management of patients with chronic coronary disease: a report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2023;82(9):833-955.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	06/14/2023
Annual Revision	No criteria changes.	06/19/2024
Selected Revision	The name of the policy was changed from Cardiology – Corlanor to Cardiology – Ivabradine and it was noted that generic tablets are available. **Heart Failure:** For the criterion that the patient has a left ventricular ejection fraction ≤ 35% prior to initiation of Corlanor therapy, "Corlanor" was changed to "ivabradine".	07/24/2024
Early Annual Revision	**Inappropriate Sinus Tachycardia:** Criteria were added that the patient has tried or is currently receiving one beta blocker for inappropriate sinus tachycardia or the patient has a contraindication to use of beta blocker therapy. Examples of beta blockers are listed in a Note, as well as examples that are contraindications to use of beta blockers.	08/14/2024
Annual Revision	No criteria changes.	08/13/2025