PRIOR AUTHORIZATION POLICY

POLICY: Cardiology – Corlanor Prior Authorization Policy
- Corlanor® (ivabradine tablets and oral solution – Amgen)

REVIEW DATE: 06/19/2024

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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

Corlanor, 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 Corlanor 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 Corlanor.

- **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 beats per minute at rest, Corlanor 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 Corlanor 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 Corlanor 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 Corlanor may be considered for the ongoing management of patients with inappropriate sinus tachycardia (class IIb recommendation). Because of the specialized skills required for evaluation and diagnosis of patients treated with Corlanor as well as the monitoring required for adverse events and long-term efficacy, approval requires Corlanor to be prescribed by or in consultation with a physician who specializes in the condition being treated.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Corlanor. All approvals are provided for the duration noted below.

- **Corlanor® (ivabradine tablets and oral solution (Amgen)**

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 Corlanor 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) 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) 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 medication is prescribed by, or in consultation with, a cardiologist.

CONDITIONS NOT COVERED

- **Corlanor® (ivabradine tablets and oral solution (Amgen)**

is(are) considered experimental, investigational or unproven 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.** Corlanor 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 Corlanor to standard anti-anginal therapy is potentially harmful.[14]

REFERENCES

1. Corlanor® tablets and oral solution [prescribing information]. Thousand Oaks: CA; Amgen; August 2021.
2. Sheldon RS, Grubb BP, Olshansky B, 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.

3. Page RL, Caldwell MA, Calkins H, et al. 2015 ACC/AHA/HRS guideline for the management of adult patients with supraventricular tachycardia. A report of the American College of Cardiology/American Heart Association Task Force on clinical practice guidelines, and the Heart Rhythm Society. *Circulation*. 2016;133:e506-e574.
4. Abed HS, Fulcher J, Kilborn NJ, Keech AC. Inappropriate sinus tachycardia: focus on ivabradine. *Intern Med J*. 2016;46(8):875-883.
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.
6. Ruzieh M, Moustafa A, Sabbagh E, et al. Challenges in treatment of inappropriate sinus tachycardia. *Curr Cardiol Rev*. 2018;14:42-44.
7. Mathew ST, Po SS, Thadani U. Inappropriate sinus tachycardiac – symptoms and heart rate reduction with ivabradine: a pooled analysis of prospective studies. *Heart Rhythm*. 2018;15:240-247.
8. Koruth JS, Lala A, Pinne S, et al. The clinical use of ivabradine. *J Am Coll Cardiol*. 2017;70(14):1777-1784.
9. Bonnet D, Berger F, Jokinen E, et al. Ivabradine in children with dilated cardiomyopathy and symptomatic chronic heart failure. *J Am Coll Cardiol*. 2017;70:1262-1272.
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.
11. Werdan K, Ebelt H, Nuding S, et al. Ivabradine in combination with beta-blocker improves symptoms and quality of life in patients with stable angina pectoris: results from the ADDITIONS study. *Clin Res Cardiol*. 2012;101(5):365-373.
12. Perings S, Stockl G, Kelm M, et al, on behalf of the RESPONSIVE study investigators. Effectiveness and tolerability of ivabradine with or without concomitant beta-blocker therapy in patients with chronic stable angina in routine clinical practice. *Adv Ther*. 2016;33:1550-1564.
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