

Clinical Policy: Ivabradine (Corlanor)

Reference Number: CP.PMN.70

Effective Date: 11.01.15

Last Review Date: 11.22

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Ivabradine (Corlanor[®]) is a hyperpolarization-activated cyclic nucleotide-gated channel blocker.

FDA Approved Indication(s)

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 (LVEF) $\leq 35\%$, 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;
- For the treatment of 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.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Corlanor is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Heart Failure (must meet all):

1. Diagnosis of chronic heart failure;
2. Prescribed by or in consultation with a cardiologist;
3. Age ≥ 6 months;
4. LVEF $\leq 35\%$ for adults or $\leq 45\%$ for pediatrics;
5. Member is in sinus rhythm with a resting heart rate of one of the following (a, b, c, or d):
 - a. Age 6 to 12 months: ≥ 105 beats per minute;
 - b. Age 1 to 3 years: ≥ 95 beats per minute;
 - c. Age 3 to 5 years: ≥ 75 beats per minute;
 - d. Age 5 years and older: ≥ 70 beats per minute;
6. Failure of two of the following beta-blockers recommended for heart failure at up to maximally indicated doses, each used for ≥ 30 days, unless clinically significant adverse effects are experienced or all are contraindicated: bisoprolol, carvedilol (immediate- or extended-release), extended-release metoprolol succinate;

7. Member has used one of the aforementioned beta blockers for ≥ 30 days within the past 60 days, unless clinically significant adverse effects are experienced or all are contraindicated;
8. Dose does not exceed 15 mg (2 tablets or 15 mL) per day.

Approval duration:

HIM – 12 months

Medicaid/Commercial – 12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Heart Failure (must meet all):

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Corlanor for heart failure and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 15 mg (2 tablets or 15 mL) per day.

Approval duration:

HIM – 12 months

Medicaid/Commercial – 12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

- b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
- 2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DCM: dilated cardiomyopathy
 FDA: Food and Drug Administration
 LVEF: left ventricular ejection fraction

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Beta-Blockers Recommended for Heart Failure		
bisoprolol (Zebeta [®])	Heart Failure[†] Initially, 1.25 mg PO QD for 48 hours, then 2.5 mg QD for the first month, then 5 mg QD.	10 mg/day
carvedilol (Coreg [®] , Coreg CR [®])	Heart Failure <u>Immediate-release:</u> Initially, 3.125 mg PO BID for 2 weeks. Dosage may be subsequently increased to 6.25, 12.5, and then 25 mg PO BID over successive intervals of at least 2 weeks. <u>Extended-release:</u> Initially, 10 mg PO QD for 2 weeks. Dosage may be subsequently increased to 20, 40, and then 80 mg PO QD over successive intervals of at least 2 weeks.	Immediate-release: 100 mg/day Extended-release: 80 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
metoprolol succinate extended release (Toprol XL [®])	Heart Failure 25 mg PO QD for 2 weeks in patients with NYHA class II heart failure, or 12.5 mg PO QD in patients with more severe heart failure. Double the dose every 2 weeks as tolerated, up to the target dosage of 200 mg PO QD.	200 mg/day

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

†Off-label indication

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
 - Acute decompensated heart failure
 - Clinically significant hypotension
 - Sick sinus syndrome, sinoatrial block, or 3rd degree AV block, unless a functioning demand pacemaker is present
 - Clinically significant bradycardia
 - Severe hepatic impairment
 - Pacemaker dependence (heart rate maintained exclusively by the pacemaker)
 - Concomitant use of strong cytochrome P450 3A4 (CYP3A4) inhibitors
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Heart failure	Adult and pediatric patients \geq 40 kg: Initially 2.5 mg (pediatrics and vulnerable adults) or 5 mg PO BID. After 2 weeks of treatment, adjust dose based on heart rate. The maximum dose is 7.5 mg BID. Pediatric patients < 40 kg: Initially 0.05 mg/kg PO BID. Adjust dose at 2-week intervals by 0.05 mg/kg based on heart rate.	15 mg/day

VI. Product Availability

- Tablets: 5 mg, 7.5 mg
- Oral solution: 5 mg/5 mL

VII. References

1. Corlanor Prescribing Information. Thousand Oaks, CA: Amgen Inc.; August 2021. Available at: <https://www.corlanor.com>. Accessed September 21, 2021.

2. Yancy CW, Jessup M, Bozkurt B, Butler J, et al. American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines. *Circulation*. 2013 Oct 15;128(16):e240-327.
3. Yancy CW, Jessup M, Bozkurt B, et al. 2016 ACC/AHA/HFSA focused update on new pharmacological therapy for heart failure: an update of the 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. *Circulation*. 2016;134: 000-000.
4. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. *Circulation*. 2017;136:e137-e161.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: <http://www.clinicalpharmacology-ip.com/>

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2018 annual review: policies combined for Commercial and Medicaid lines of business; Commercial: added prescriber, age, LVEF, and sinus rhythm; modified requirement related to failure of 2 generic beta-blockers to include only beta-blockers which have been shown to be effective in reducing mortality (bisoprolol, carvedilol, and metoprolol succinate) in patients with chronic heart failure per 2013 ACCF/AHA guideline for the management of heart failure and duration of trial; Medicaid: removed contraindication requirement related to drug-drug interaction and incorporated the information in Appendix C; references reviewed and updated.	04.11.18	08.18
1Q 2019 annual review: no significant changes; references reviewed and updated.	10.30.18	02.19
Added HIM line of business due to addition of agent(s) to the HIM formulary with PA	03.15.19	
RT4: Added recently FDA-approved pediatric indication extension.	05.06.19	
1Q 2020 annual review: no significant changes; references reviewed and updated.	11.26.19	02.20
1Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	10.16.20	02.21
1Q 2022 annual review: no significant changes; references reviewed and updated.	09.21.21	02.22
Revised approval duration for Medicaid and Commercial line of business from length of benefit to 12 months or duration of request, whichever is less. Template changes applied to other diagnoses/indications.	06.23.22	11.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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