

Clinical Policy: Ivabradine (Corlanor)

Reference Number: CP.PMN.70

Effective Date: 11.01.15

Last Review Date: 02.19

Line of Business: Commercial, 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 patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) \leq 35%, who are in sinus rhythm with resting heart rate \geq 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.

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 \geq 18 years;
4. LVEF \leq 35%;
5. Member is in sinus rhythm with resting heart rate \geq 70 beats per minute;
6. Failure of two of the following beta-blockers recommended for heart failure: bisoprolol, carvedilol (immediate- or extended-release), or extended-release metoprolol succinate at therapeutic doses, each used for \geq 30 days, unless all are contraindicated or clinically significant adverse effects are experienced;
7. Member has used one of the aforementioned beta blockers for \geq 30 days within the past 60 days, unless all are contraindicated or clinically significant adverse effects are experienced;
8. Dose does not exceed 15 mg (2 tablets) per day

Approval duration: Length of Benefit**B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial 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) per day.

Approval duration: Length of Benefit

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial 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 and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

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.	Immediate-release: 100 mg/day Extended-release: 80 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	<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.	
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
 - Blood pressure less than 90/50 mmHg
 - Sick sinus syndrome, sinoatrial block, or 3rd degree AV block, unless a functioning demand pacemaker is present
 - Resting heart rate less than 60 bpm prior to treatment
 - 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	Initially, 5 mg PO BID. After 2 weeks of treatment, adjust dose based on heart rate. The maximum dose is 7.5 mg BID.	15 mg/day

VI. Product Availability

Tablets: 5 mg, 7.5 mg

VII. References

1. Corlanor Prescribing Information. Thousand Oaks, CA: Amgen Inc.; January 2017. Available at: <https://www.corlanor.com/>. Accessed October 30, 2018.
2. 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. J Am Coll Cardiol. 2017.

3. Yancy CW, Jessup M, Bozkurt B, Butler J, Casey DE Jr, Colvin MM, Drazner MH, Filippatos G, Fonarow GC, Givertz MM, Hollenberg SM, Lindenfeld J, Masoudi FA, McBride PE, Peterson PN, Stevenson LW, Westlake C. 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, Butler J, Casey DE Jr, Drazner MH, Fonarow GC, Geraci SA, Horwich T, Januzzi JL, Johnson MR, Kasper EK, Levy WC, Masoudi FA, McBride PE, McMurray JJ, Mitchell JE, Peterson PN, Riegel B, Sam F, Stevenson LW, Tang WH, Tsai EJ, Wilkoff BL; 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.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: <http://www.clinicalpharmacology-ip.com/>

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New guideline created	09.15	11.15
Converted to new integrated template. Removed age requirement since not referenced in indications section per PI; Added prescriber specialty; Modified requirement related to failure of 2 PDL beta-blockers to include a) 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 b) duration of trial; Modified specific max quantity limit to FDA max recommended dose and health plan approved QL statement. Updated continuation criteria to include continuity of care Updated references to reflect current literature search.	08.16	11.16
Converted to new template. Added age restriction and DDI contraindication as the interactions are severe per PI/safety approach; Modified max dose requirement to include specific quantity limit. Updated references.	08.07.17	11.17
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	04.11.18	08.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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.		
1Q 2019 annual review: no significant changes; references reviewed and updated.	10.30.18	02.19

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.

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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.

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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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