Clinical Policy: Ivabradine (Corlanor)

Reference Number: CP.PMN.70
Effective Date: 11.01.15
Last Review Date: 02.19
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 patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) ≤ 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.

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 ≥ 18 years;
4. LVEF ≤ 35%;
5. Member is in sinus rhythm with resting heart rate ≥ 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 ≥ 30 days, unless all are contraindicated or clinically significant adverse effects are experienced;
7. Member has used one of the aforementioned beta blockers for ≥ 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:
HIM – 12 months
Medicaid/Commercial – 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, HIM.PHAR.21 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) per day.

Approval duration:
HIM – 12 months
Medicaid/Commercial – 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, HIM.PHAR.21 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.PHAR.21 for health insurance marketplace 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** Immediate-release: 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. Extended-release: 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
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	08.16	11.16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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.		
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 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	

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members 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.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103