Clinical Policy: Ivabradine (Corlanor)

Reference Number: PA.CP.PMN.70
Effective Date: 01/18
Last Review Date: 04/18

Coding Implications
Revision Log

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

FDA approved indication
- To reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction ≤ 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 (including office chart notes and lab results) supporting that member has met all approval criteria**

It is the policy of health plans affiliated with Pennsylvania Health and Wellness® 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. Left ventricular ejection fraction (LVEF) ≤ 35%;
5. Member is in sinus rhythm with resting heart rate ≥ 70 beats per minute;
6. Failure of 2 of the following PDL beta-blockers recommended for heart failure: bisoprolol, carvedilol, carvedilol ER, or metoprolol succinate (extended release) at therapeutic doses, each trialed for ≥ 30 days, unless member experiences clinically significant adverse effects or has contraindication(s) to beta blocker therapy;
7. Member has used one of the aforementioned beta blockers for ≥ 30 days within the past 60 days, unless contraindicated or clinically significant adverse effects are experienced;
8. At the time of request, member has none of the following contraindications:
   a. Concomitant use of strong cytochrome CYP3A4 inhibitors [e.g., azole antifungals (e.g., itraconazole), macrolide antibiotics (e.g., clarithromycin, telithromycin), HIV protease inhibitors (e.g., nelfinavir), nefazodone];
9. Request does not exceed 15 mg/day and health plan approved daily quantity limit.

Approval duration: 12 months

B. Other diagnoses/indications – Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. Heart Failure (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit, or documentation supports that member is currently receiving Corlanor for heart failure, has received this medication for at least 30 days, and is responding positively to therapy or Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 15 mg/day and health plan approved daily quantity limit.

Approval duration: 12 months

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or Continuity of Care Policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: 12 months

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 policy – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key
CYP3A4: cytochrome P450 3A4
LVEF: left ventricular ejection fraction

V. Dosage and Administration

- The recommended starting dose of Corlanor is 5 mg twice daily with meals. After 2 weeks of treatment, adjust dose based on heart rate. The maximum dose is 7.5 mg twice daily.
- In patients with conduction defects or in whom bradycardia could lead to hemodynamic compromise, initiate dosing at 2.5 mg twice daily.

VI. Product Availability

Corlanor is supplied as film-coated tablets in the following strengths: 5 mg and 7.5 mg.

VII. References

1. Corlanor Prescribing Information. Thousand Oaks, CA: Amgen Inc.; January 2017. Available at: https://www.corlanor.com/. Accessed August 7, 2017.
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.; 2017. Available at: http://www.clinicalpharmacology-ip.com/.

Reviews, Revisions, and Approvals	Date	Approval Date
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.	03.04.18	