Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2020**
Policy Number: PA.CP.PHAR.70	**Effective Date: 01/01/2018** **Revision Date: 01/15/2020**
Policy Name: Ivabradine (Corlanor)	

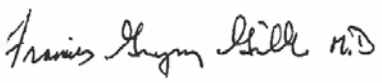
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

1Q 2020 annual review: added recently FDA-approved pediatric indication extension references reviewed and updated.

Name of Authorized Individual (Please type or print):	**Signature of Authorized Individual:**
Francis G. Grillo, MD	

Clinical Policy: Ivabradine (Corlanor)

Reference Number: PA.CP.PMN.70
Effective Date: 01/18
Last Review Date: 01/19

Coding Implications
Revision Log

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 ≤ 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 (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 ≥ 6 months;
4. LVEF ≤ 35% for adults or ≤ 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: bisoprolol, carvedilol (immediate- or extended-release), or metoprolol succinate (extended release) at therapeutic doses, each used for ≥ 30 days, unless all are contraindicated or clinically significant adverse effects are experience;
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. Request does not exceed 15 mg (2 tablets or 15 mL) per day.

Approval duration: Length of Benefit

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 (2 tablets of 15 mL) per day.

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;

Approval duration: Length of Benefit

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)

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/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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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	Adult and pediatric patients ≥ 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.	15 mg/day

Indication	Dosing Regimen	Maximum Dose
	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.	

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.; April 2019. Available at: https://www.corlanor.com/. Accessed May 6, 2019.
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.; 2019. 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	
1Q 2019 annual review: references reviewed and updated.	01.19	
Aligned initiation approval duration and continued approval duration.	05/19	
1Q 2020 annual review: added recently FDA-approved pediatric indication extension references reviewed and updated.	01/2020	