Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Corlanor (ivabradine)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: **July 2015**

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Corlanor (ivabradine)

Corlanor (ivabradine) 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 of ≥ 70 bpm and either on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy &

Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Corlanor (ivabradine), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by a cardiologist
- Must have a diagnosis of stable, symptomatic chronic heart failure
- Must have a left ventricular ejection fraction ≤ 35%
- Must have a sinus rhythm with a resting heart rate of ≥ 70 beats per minute
- Must currently be receiving a beta-blocker at target dose for heart failure treatment (i.e. metoprolol succinate, carvedilol, bisoprolol) unless there is an intolerance or contraindication to beta-blocker use
- Must have had a hospitalization for heart failure within the past year
- Must not have any of the following:
    - Blood pressure < 90/50 mmHg
    - Current active decompensated heart failure
        - Must be stabilized on an optimal regimen (maximally tolerated doses of beta-blockers, and in most cases ACE/ARBs, spironolactone, and diuretics) for at least 4 weeks before initiation
    - Sick sinus syndrome, sinoatrial block, or 3rd degree AV block unless a functioning demand pacemaker is present (not set to ≥ 60 bpm)
    - Severe hepatic impairment (Child-Pugh C)
    - Dependence on a pacemaker
        - Ventricular or atrioventricular pacing > 40% of the day
        - Demand pacemakers set to a rate > 60 beats per minute

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to duration of member's membership with plan
Reauthorization	N/A

Quantity Level Limit	
Corlanor	• 60 tablets per 30 days • 90 tablets per 30 days of the 5mg is covered for the 1st month of treatment

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Corlanor [prescribing information]. Thousand Oaks, CA: Amgen, Inc.; April 2015.
2. Swedberg K, Komajda M, Bohm M, et al. Ivabradine and outcomes in chronic heart failure (SHIFT): a randomized placebo-controlled study. *Lancet.* 2010; 376:875-885.
3. Swedberg K, Komajda M, Bohm M, et al. Rationale and design of a randomized, double-bline, placebo-controlled outcome trial of ivabradine in chronic heart failure: the Systolic Heart Failure Treatment with the If Inhibitor Ivabradine Trial (SHIFT). *Eur Heart J* 2010; 12:75-81.
4. McMurray JJ, Adamopoulos S, Anker SD, et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012: The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association (HFA) of the ESC. *Eur Heart J.* 2012; 22:1787-1847.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*