Prior Authorization Review Panel
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: Aetna Better Health	**Submission Date:** **11**/1/2020
Policy Number:	**Effective Date:** 1/1/2020 **Revision Date:** 2/2020
Policy Name: Corlanor (Non-PDL)	
Type of Submission – Check all that apply: ☐ **New Policy** **X Revised Policy** ☐ **Annual Review – No Revisions**	
***All revisions to the policy must be highlighted using track changes throughout the document.** **Please provide any clarifying information for the policy below:** Thank you.	
Name of Authorized Individual (Please type or print): **Natalie Nkurunziza, Pharm.D.**	**Signature of Authorized Individual:** 

Last Review: 2/2020
Previous PARP Approval: 2/2019
Current PARP Approval: 11/2020

AETNA BETTER HEALTH®

Non-Formulary Prior Authorization guideline for Corlanor (Non-PDL)

Authorization guidelines:

May be authorized for patients at least 18 years old when the following criteria are met:

A. Diagnosis of stable symptomatic chronic heart failure (NYHA Class II-III) with a left ventricular ejection fraction less than or equal to 35%
B. Member is in sinus rhythm
C. Resting heart rate ≥ 70 beats per minute (bpm)
D. Member will continue therapy with maximally tolerated beta-blocker or member has an intolerance or contraindication to beta-blockers
E. Member will continue therapy with an angiotensin converting enzyme inhibitor (ACEI)/angiotensin receptor blocker (ARB) or Entresto or member has an intolerance or contraindication to ACEI/ARB. (Note: *Entresto requires Prior Authorization*)
F. Provider attestation that member does not have any of the following contraindications to treatment:
    a. Acute decompensated heart failure
    b. Blood pressure < 90/50 mmHg
    c. Pacemaker dependent (i.e. heart rate maintained exclusively by pacemaker)
    d. Sick sinus syndrome, sinoatrial block of third degree AV block (unless a functioning demand pacemaker is present)
    e. Severe hepatic impairment (Child-Pugh class C)

May be authorized for pediatric members 6 months of age or older when the following criteria are met:

A. Diagnosis of heart failure due to dilated cardiomyopathy (DCM) where:
    a. Member is in sinus rhythm with a resting heart rate of greater than or equal to 70 beats per minute
    b. Provider attestation that no contraindications to treatment exist:

Last Review: 2/2020
Previous PARP Approval: 2/2019
Current PARP Approval: 11/2020

i. Acute decompensated heart failure
ii. Blood pressure less than 90/50 mmHg
iii. Pacemaker dependent (for example, heart rate maintained exclusively by pacemaker)
iv. Sick sinus syndrome, sinoatrial block of third-degree AV block (unless functioning demand pacemaker is present)
v. Severe hepatic impairment (Child-Pugh class C)

Additional Information

Quantity Limit: 2 tablets per day (Adults and Pediatrics)

Oral solution for pediatrics: 120 ampules per 30 days

Corlanor is NOT covered for members with the following criteria:

- Use not approved by the FDA; **AND**
- The use is unapproved and not supported by the literature or evidence as an accepted off-label use.

Approval Duration

Initial Approval: 6 months

Renewals: 1 year

Criteria for renewal:

A. Member is responding to treatment
B. HR is within the recommended range for continuation of the maintenance dose (i.e., 50-60 bpm) or dose is adjusted accordingly to achieve goal

Medically Necessary — A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

Last Review: 2/2020
Previous PARP Approval: 2/2019
Current PARP Approval: 11/2020

- The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

Determination of Medical Necessity for covered care and services, whether made on a Prior Authorization, Concurrent Review, Retrospective Review, or exception basis, must be documented in writing.

The determination is based on medical information provided by the Member, the Member's family/caretaker and the Primary Care Practitioner, as well as any other Providers, programs, agencies that have evaluated the Member.

All such determinations must be made by qualified and trained Health Care Providers. A Health Care Provider who makes such determinations of Medical Necessity is not considered to be providing a health care service under this Agreement.

References:

1. Yancy CW et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure Circulation: 2017. http://www.onlinejacc.org/content/accj/70/6/776.full.pdf?_ga=2.179733604.1964533065.1574204551-936785029.1560984365 Accessed November 19, 2019.
2. Corlanor (ivabradine) [package insert]. Thousand Oaks, CA; Amgen Inc.; Revised April, 2019. Retrieved from https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/corlanor/corlanor_pi.pdf . Accessed November 19, 2019.
3. Corlanor. Clinical Pharmacology [Internet]. Tampa (FL): Elsevier.c2018 [cited 2018 October 29] Available from: http://www.clinicalpharmacology.com

Last Review: 2/2020
Previous PARP Approval: 2/2019
Current PARP Approval: 11/2020