Hyperpolarization-Activated Cyclic Nucleotide-Gated (HCN) Channel Blocker (Corlanor) Prior Authorization with Quantity Limit Criteria Program Summary

This prior authorization program applies to Commercial, NetResults A series, SourceRx and Health Insurance Marketplace formularies.

OBJECTIVE

The intent of the Hyperpolarization-Activated Cyclic Nucleotide-Gated (HCN) prior authorization (PA) with Quantity Limit (QL) program is to appropriately select patients for therapy according to product labeling and/or clinical guidelines and according to dosing recommended in product labeling. Corlanor will be approved for use in patients with stable, symptomatic chronic heart failure; who have a baseline or current left ventricular ejection fraction of ≤35%; who are in sinus rhythm with a resting heart rate of ≥70 beats per minute; who is on maximally tolerated dose of beta blocker or the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to beta blockers. The program will approve for doses within the set limit. Doses above the set limit will be approved if the requested quantity is below the FDA limit and cannot be dose optimized or when the quantity is above the FDA limit and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis. Requests for an HCN agent will be reviewed when patient specific documentation is provided.

TARGET DRUG

Corlanor® (ivabradine)

Brand (generic)	GPI	Multisource Code	Quantity Limit Per Day
Corlanor (ivabradine)			
5 mg tablet	40700035100320	M, N, O, or Y	2 tablets
7.5 mg tablet	40700035100330	M, N, O, or Y	2 tablets

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Corlanor will be approved when ALL of the following are met:

1. ONE of the following:
    a. ALL of the following:
        i. The patient has stable, symptomatic chronic heart failure (e.g. NYHA Class II, III, IV; ACCF/AHA Class C, D)
        AND
        ii. The patient has a baseline OR current left ventricular ejection fraction of ≤35%
        AND
        iii. Prior to initiating therapy with the requested agent, the patient is in sinus rhythm with a resting heart rate of ≥70 beats per minute
        AND
        iv. ONE of the following:
            1. The patient is on a maximally tolerated dose of beta blocker (e.g. atenolol, bisoprolol, carvedilol, metoprolol)
            OR
            2. The patient has a history of a documented intolerance, FDA labeled contraindication, or hypersensitivity to a beta blocker (e.g. atenolol, bisoprolol, carvedilol, metoprolol)

    AND
2. The patient does NOT have any FDA labeled contraindication(s) to the requested agent

AND

3. ONE of the following:
    a. The quantity requested is less than or equal to the program quantity limit
    OR
    b. The quantity (dose) requested is above the program limit, less than or equal to the maximum dose recommended in FDA approved labeling and the prescribed dose cannot be achieved using a lesser quantity of a higher strength
    OR
    c. The quantity (dose) requested is greater than the maximum dose recommended in FDA approved labeling and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Length of Approval: 12 months

FDA APPROVED INDICATIONS AND DOSAGE[1]

	Indication	Dosage & Administration
Corlanor® (ivabradine)	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	Starting dose is 5 mg twice daily. 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

CLINICAL RATIONALE

Heart Failure

The ACCF/AHA/HFSA (Heart Failure Society of America) state that ivabradine can be beneficial to reduce HF hospitalization for patients with symptomatic (NYHA class II-III) stable chronic HFrEF (LVEF ≤35%) who are receiving guideline directed evaluation and management (GDEM), including a beta blocker at maximum tolerated dose, and who are in sinus rhythm with a heart rate of 70 bpm or greater at rest.[5]

The ACCF/AHA guideline classifies heart failure by the following in relation to New York Heart Association (NYHA) Functional Classification:[2]

ACCF/AHA Stages of HF	ACCF/AHA Stage Description	NYHA Functional Classification	NYHA Functional Classification Description
A	At high risk for HF but without structural heart disease or symptoms of HF	None	None
B	Structural heart disease but without signs or symptoms of HF	I	No limitation of physical activity. Ordinary physical activity does not cause symptoms of HF
C	Structural heart disease with prior or current symptoms of HF	I	No limitation of physical activity. Ordinary physical activity does not cause symptoms of HF
		II	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in symptoms of HF

ACCF/AHA Stages of HF	ACCF/AHA Stage Description	NYHA Functional Classification	NYHA Functional Classification Description
		III	Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes symptoms of HF
		IV	Unable to carry on any physical activity without symptoms of HF, or symptoms of HF at rest
D	Refractory HF requiring specialized interventions	IV	Unable to carry on any physical activity without symptoms of HF, or symptoms of HF at rest

The ACCF/AHA guideline recommends the following algorithm for the treatment of heart failure with reduced ejection fraction (HFrEF) (≤40%) ACCF/AHA Class C and NYHA Class I-IV:[2]

- All patients should receive an angiotensin converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) in addition to a beta blocker
- For volume overloaded NYHA Class II-IV patients, a loop diuretic should be added
- For persistently symptomatic African American NYHA class III-IV patients, hydralazine and isosorbide dinitrate should be added
- For NYHA Class II-IV patients with estimated creatinine >30 mL/min and potassium <5.0 mEq/dL, an aldosterone antagonist should be added

Safety[1]

Ivabradine is contraindicated in patients with:

- 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

REFERENCES

1. Corlanor prescribing information. Amgen Inc. January 2017.
2. 2013 ACCF/AHA Guideline for the Management of Heart Failure. Accessed at http://circ.ahajournals.org/. April 24, 2017.
3. 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. Accessed at http://circ.ahajournals.org. April 24, 2017

The purpose of Blue Cross and Blue Shield of Alabama's pharmacy policies are to provide a guide to coverage. Pharmacy policies are not intended to dictate to physicians how to practice medicine. Physicians should exercise their medical judgment in providing the care they feel is most appropriate for their patients.

Neither this policy, nor the successful adjudication of a pharmacy claim, is guarantee of payment.