

Cardiovascular Agents – Sinus Node Inhibitors

Medical policy no. 40.70.00-1

Effective: October 1, 2018

Related medical policies:

- Cardiovascular Agents - valsartan-sacubitril (ENTRESTO®)

Background:

Sinus node inhibitors reduce heart rate by reducing the frequency of impulses from the sinus node, which is the place in the right atrium of the heart that controls the heart rate. It is a self-administered hyperpolarization-activated cyclic nucleotide-gated channel blocker indicated to reduce the risk of hospitalization for worsening heart failure (HF) in patients with stable, symptomatic HF with reduced ejection fraction (HFrEF).

Medical necessity

Drug	Medical Necessity
Ivabradine (CORLANOR®)	Corlanor may be considered medically necessary when: Used to reduce the risk of hospitalization for worsening heart failure (HF) in patients with stable, symptomatic chronic HF with left ventricular ejection fraction \leq 35%, who are in sinus rhythm with resting heart rate \geq 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
Ivabradine (CORLANOR®)	Corlanor may be covered when ALL of the following are met: <ol style="list-style-type: none"> ALL of the following: <ol style="list-style-type: none"> To prevent worsening heart failure in a diagnosis of stable, symptomatic chronic heart failure (New York Heart Association (NYHA) class II to IV heart failure) Left ventricular ejection fraction less than or equal to (\leq) 35% Currently in sinus rhythm Resting heart rate greater than or equal to (\geq) 70 beats per minute ONE of the following: <ol style="list-style-type: none"> Currently taking maximum tolerated doses of beta blockers (e.g. carvedilol, metoprolol succinate, bisoprolol) Contraindication or intolerance to beta blockers NONE of the following: <ol style="list-style-type: none"> 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

	<ul style="list-style-type: none"> d. Resting heart rate less than (<) 70 bpm prior to treatment e. Severe hepatic impairment f. Pacemaker dependence (heart rate maintained exclusively by the pacemaker) g. In combination with strong cytochrome CYP3A4 inhibitors (e.g. azole antifungals, macrolide antibiotics, HIV protease inhibitors) <p>4. Prescribed by or in consultation with a cardiologist or cardiac specialist</p> <p>Approve for 12 months</p>
	Criteria (Reauthorization)
	<p>Documentation of positive clinical benefit</p> <p>Approve for 12 months</p>

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
Ivabradine (CORLANOR [®])	#60 tablets per 30-days

References

1. Corlanor[®] [Prescribing Information]. Thousand Oaks, CA: Amgen; January 2017.
2. Swedberg, K, Komajda, M, Bohm, M, et al. Ivabradine and outcomes in chronic heart failure (SHIFT): a randomised placebo-controlled study. *Lancet*. 2010;376:875-85. PMID: 20801500
3. Yancy, CW, Jessup, M, Bozkurt, B, et al. 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/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. *Journal of the American College of Cardiology*. 2016 May 17. PMID: 27216111
4. Fox, K, Ford, I, Steg, PG, Tendera, M, Ferrari, R. Ivabradine for patients with stable coronary artery disease and left-ventricular systolic dysfunction (BEAUTIFUL): a randomised, double-blind, placebo-controlled trial. *Lancet*. 2008;372:807-16. PMID: 18757088
5. Fox, K, Ford, I, Steg, PG, Tardif, JC, Tendera, M, Ferrari, R. Ivabradine in stable coronary artery disease without clinical heart failure. *The New England journal of medicine*. 2014 Sep 18;371(12):1091-9. PMID: 25176136