FDA INDICATIONS AND USAGE[1]

Corlanor™ (ivabradine) is a hyperpolarization-activated cyclic nucleotide-gated channel blocker indicated:

- To reduce risk of hospitalization for worsening heart failure in adult patients with stable, symptomatic chronic heart failure with reduced left ventricular ejection fraction.
- For the treatment of stabler symptomatic heart failure due to dilated cardiomyopathy in pediatric patients ages 6 months and older.

APPROVAL CRITERIA[1,2,3]

Heart Failure

1. Patient has a worsening heart failure diagnosis of stable, symptomatic heart failure **AND;**
2. Medication is being prescribed by or in consultation with a cardiologist **AND;**
3. If the patient is 18 years of age or older, all the following criteria must be met:
    a. Patient has a left ejection fraction ≤35 % **AND;**
    b. Patient is in normal sinus rhythm **AND;**
    c. Patient's heart rate is ≥ 70 beats per minute **AND;**
    d. Patient has tried and failed or has a contraindication to beta blockers at maximally tolerated dose.
4. If the patient is 6 months to 17 years of age, all the following criteria must be met:
    a. Patient has stable symptomatic heart failure due to dilated cardiomyopathy **AND;**
    b. Patient is in normal sinus rhythm with an elevated heart rate.

Inappropriate Sinus Tachycardia (IST)

1. Patient has a diagnosis of inappropriate sinus tachycardia (IST) **AND;**
2. Medication is being prescribed by or in consultation with a cardiologist **AND;**
3. Patient is in normal sinus rhythm **AND;**
4. Patient has had a trial of a beta blocker and failed to achieve an adequate response **OR;**
5. Patient has a contraindication to or a documented intolerance of a beta blocker.

DENIAL CRITERIA[1,2]

1. Patient has clinically significant hypotension **OR;**
2. Patient has sick sinus syndrome, sino-atrial block, or third degree atrioventricular block, unless a functioning demand pacemaker is present **OR;**
3. Demand pacemakers set to rates ≥ 60 beats per minute **OR**;
4. Severe hepatic impairment **OR;**
5. Acute decompensated heart failure.

CAUTIONS[1]

- Females should use effective contraception due to fetal toxicity.
- Patients should be monitored for atrial fibrillation.
- Not recommended in patients with second degree AV block.
- Heart rate should be monitored throughout therapy.

DURATION OF APPROVAL

- Approval: Up to 3 months
- Reauthorization: Up to 12 months

QUANTITY LIMITS

- 60 – 5mg tablets
- 60 – 7.5mg tablets
- 450ml – 5mg/5ml oral solution

REFERENCES / FOOTNOTES:

1. Corlanor [Package Insert]. Thousand Oaks, CA. Amgen Inc.; 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/209964lbl.pdf Accessed: September 17, 2019.
2. Sheldon, RS, Grubb, BP, et al. 2015 Heart Rhythm Society Expert Consensus Statement on the Diagnosis and Treatment of Postural Tachycardia Syndrome, Inappropriate Sinus Tachycardia, and Vasovagal Syncope. Heart Rhythm, 2015, 12(6), e41-e63.
3. Yancy CW, Jessup M, Bozkurt B, Butler J, Casey Jr DE, 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/HFSAFocused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure, Journal of the American College of Cardiology (2016), doi: 10.1016/j.jacc.2016.05.011.