Pharmacy Medical Necessity Guidelines: Corlanor® (ivabradine)

Effective: May 18, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM:
617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

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 (LVEF) ≤ 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. Corlanor is also indicated for the treatment of stable symptomatic heart failure due to dilated cardiomyopathy in pediatric patients 6 months of age and older, who are in sinus rhythm with an elevated heart rate.

SHIFT was a randomized, double-blind, placebo-controlled trial that evaluated Corlanor in adult patients with NYHA class II-IV heart failure, LVEF ≤35% and resting heart beat ≥70 beats per minute. Patients were included if they were clinically stable for at least four weeks on an optimized clinical regimen that included maximally tolerated doses of beta-blockers and, in most cases, ACE inhibitors or ARBs, spironolactone, and diuretics. At the end of the trial there was no statistically significant benefit in cardiovascular death alone, although Corlanor did reduce the risk of the combined endpoint of hospitalization for worsening heart failure or cardiovascular death based on time-to-event analysis.

COVERAGE GUIDELINES

The plan may authorize coverage of Corlanor (ivabradine) for Members when **all** the following criteria for a particular regimen are met and limitations do not apply:

1. The prescriber is a cardiologist

AND

2. Documented diagnosis of worsening heart failure 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

The Member is either on a maximally tolerated dose of a beta blocker or has a contraindication to beta-blocker use.

AND

The Member has received stand of care therapy with an ACE inhibitor (ACEI) or angiotensin receptor blocker (ARB), or has an intolerance or contraindication to an ACEI or ARB

OR

3. The Member is six months of age or older

AND

Documented diagnosis of stable symptomatic heart failure due to dilated cardiomyopathy

AND

Documentation the Member is in sinus rhythm with an elevated heart rate

LIMITATIONS

None

CODES

None

REFERENCES

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APPROVAL HISTORY

August 11, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. January 1, 2016: Administrative change to rebranded template.
2. August 9, 2016: Effective January 1, 2017, Medical Necessity Guideline applies to Tufts Health Together. Criteria for all plans requires prescriber is a cardiologist.

3. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Updated criteria to require a trial with an ACE inhibitor or ARB.
4. June 12, 2018: Updated criteria for ACEI/ARB trial
5. April 9, 2019: Administrative changes made to template.
6. May 12, 2020: Effective 5/18/20, updated the criteria to include the diagnosis of stable symptomatic heart failure due to dilated cardiomyopathy.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.