Clinical Policy: Milrinone

Reference Number: IL.ERX.SPA.P37
Effective Date: 06.01.21
Last Review Date: 05.21
Line of Business: Illinois Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Milrinone is a bipyridine inotropic/vasodilator agent with phosphodiesterase inhibitor activity.

FDA Approved Indication(s)
Milrinone is indicated for the short-term intravenous treatment of patients with acute decompensated heart failure.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that milrinone is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Heart Failure (must meet all)**:**

1. Diagnosis of one of the following (a or b):
   a. Acute decompensated heart failure;
   b. Bridge to heart transplantation;
2. Prescribed by or in consultation with a cardiologist;
3. Age ≥ 18 years;
4. Clinical documentation of thorough hemodynamic assessment;
5. Member cannot be weaned from intravenous to oral inotropic therapy despite repeated attempts;
6. Both of the following are met regarding milrinone administration (a and b):
   a. Prescribed for use as a continuous infusion (i.e., intermittent infusions not permitted);
   b. For short-term (< 3 months) palliation for members with end-stage disease who cannot be stabilized with standard medical treatment;
7. Member will have both of the following in place (a and b):
   a. Close observation with appropriate electrocardiographic equipment;
   b. Facility for immediate treatment of potential cardiac events;
8. Member has a negative drug screen;
9. Dose does not exceed either of the following (a or b):
   a. For optional loading dose: 50 mcg/kg;
   b. For continuous dosing: maximum dose of 1.13 mg/kg/day.

Approval duration: 1 month

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Heart Failure (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving milrinone for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1.13 mg/kg/day.

Approval duration: 2 months

B. Other diagnoses/indications:

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication: hypersensitivity to milrinone
- Boxed warning(s): none

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Heart failure	Loading dose: 50 mcg/kg Maintenance dose: 0.375 - 0.75 mcg/kg/min	1.13 mg/kg/day

VI. Product Availability

Single-dose vials: 1.5 mg and 7.5 mg lyophilized powder

VII. References

1. Milrinone Lactate Prescribing Information. Lake Forest, IL: Hospira, Inc; March 2021. Available at: http://labeling.pfizer.com/ShowLabeling.aspx?id=7388. Accessed April 16, 2021.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed April 16, 2021.
3. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA Guideline for the management of heart failure: A report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines. J Am Coll Cardiol. 2013 Oct;62 (16): e147–e239.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created (adopted from MRX P.37)	04.20.21	05.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of

medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.