I. Description

Heart failure is a clinical syndrome characterized by dyspnea, fatigue and fluid retention. Therapeutic interventions may include treatment of exacerbating conditions and co-morbidities, surgical procedures, pharmacologic management (such as diuretics, beta-blockers, angiotensin converting enzyme inhibitors or angiotensin receptor blockers, digitalis and aldosterone blockers), mechanical interventions, pacemaker insertion for resynchronization therapy and cardiac transplant. Intravenous administration of sympathomimetic agents (e.g., dobutamine, dopamine) or phosphodiesterase inhibitors (e.g., milrinone) may elicit positive inotropic effects that improve cardiac output and provide symptomatic relief in patients with acutely decompensated heart failure.

II. Criteria/Guidelines

Home continuous inotropic infusion therapy is covered (subject to Limitations and Administrative Guidelines) when all of the following criteria are met:

A. The patient is in the process of being evaluated for or is awaiting mechanical circulatory support or cardiac transplantation.

B. The patient has symptoms of congestive heart failure (e.g., dyspnea at rest) despite treatment with maximum or near maximum tolerated doses of loop diuretic, aldosterone antagonist, beta-blocker-and angiotensin-converting enzyme inhibitor/angiotensin receptor blocker, or another vasodilator used simultaneously (unless patient is allergic or intolerant).

C. The doses are within the following ranges (lower doses are covered only as part of a weaning or tapering protocol from higher dose levels):
   1. Dobutamine 2.5-10 mcg/kg/min
   2. Dopamine 2-5 mcg/kg/min
   3. Milrinone 0.375-0.750 mcg/kg/min

D. The patient must be maintained on the lowest practical drug dose and efforts to decrease the dose or the frequency/duration of the infusion are documented during the first three months of therapy.
E. Hemodynamic studies (which may include inpatient bioimpedance studies) performed within six months prior to initiation of home therapy demonstrate both of the following:
   1. Cardiac index less than or equal to 2.2 L/min/m² and/or pulmonary capillary wedge pressure (PCWP) is greater than or equal to 20 mm Hg before inotropic infusion on maximum medical management.
   2. Increase in cardiac index of at least 20 percent increase and/or decrease in PCWP at least 20 percent during inotropic infusion at the dose initially prescribed for home infusion.
F. The patient’s condition is stable at the time of discharge with documentation of a positive response to inpatient inotropic therapy (e.g., absence of dyspnea at rest, stable cardiac symptoms, vital signs, weight, and laboratory values).
G. There is deterioration in clinical status when the drug is tapered or has been discontinued under observation in the hospital.
H. The patient does not require routine electrocardiographic monitoring at home.
I. The patient is capable of maintaining at least monthly physician follow-up evaluations to assess and document the patient’s cardiac symptoms, vital signs, weight, laboratory values, and response to therapy.
J. Patient is homebound as defined in the Glossary.

III. Limitations

A. Home continuous inotropic infusion therapy is not covered when:
   1. The patient is noncompliant with treatment and follow-up with the prescribing physician.
   2. Evaluation of clinical data, tests, and symptoms indicate that inotropic infusion therapy is no longer required or effective.
   3. The patient can be weaned from inotropic infusion therapy and is responsive to standard oral medications.
   4. Hospitalization is indicated for an unstable patient with significant arrhythmias and/or other medical complications requiring acute care and treatment.
B. Intermittent inotropic therapy is not covered as it has not been shown to improve health outcomes.

IV. Administrative Guidelines

A. Precertification is not required. HMSA reserves the right to perform retrospective review using the above criteria to validate if services rendered met payment determination criteria.
B. For administrative information, including billing instructions, examples and code information, see Home Inotropic Infusion Therapy - Administrative Information.

V. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.
This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VI. References

1. Noridian Administrative Services. LCD for External Infusion Pumps (L11570). Revision effective date 01/01/2015.