

External Infusion Pump (EIP) - Response to Comment Summary

October 2015

The public comment period for the draft local coverage determination for External Infusion Pump (EIP) closed on August 31, 2015. A public meeting was held on August 26, 2015.

1. Five commenters suggested a liberalization of the prescribing provider (APP/NP/PA or MD).

Response: The medical directors agree, and language in the final policy is reflective of that suggestion. However, since coverage encompasses “Bridge” therapy for patients eligible for and awaiting mechanical circulatory support (MCS)/cardiac transplantation, it is the judgment of the medical directors that a cardiologist with training in the management of advanced heart failure must perform the initial evaluation.

2. Two commenters inquired about a diagnosis code (ICD-10) cross-walk.

Response: The parenteral inotropic therapy section of the draft policy does not contain any ICD-9 diagnoses codes which require a cross-walk to ICD-10 codes. Moreover, the draft policy defines coverage based on the severity of heart failure (Class IV or Stage D) and not on the diagnosis code(s).

3. Two commenters inquired as to what specific documentation will be required to document “improvement in beneficiary symptoms of heart failure while on the selected inotropic drug at the time of discharge from an inpatient or skilled nursing care facility.”

Response: This is not a new requirement. Under the existing policy, it must be clear from the documentation in the beneficiary's medical record that their symptoms of heart failure improved while on the selected drug at the time of discharge from the inpatient or skilled nursing facility. As a reminder, the Centers for Medicare & Medicaid Services (CMS) provides guidance to contractors and providers in the *Program Integrity Manual* (Internet-only Manual 100-08, Chapter 5, §5.7) with respect to documentation in medical records. The PIM §5.7 states (in pertinent part):

For any DMEPOS item to be covered by Medicare, the patient’s medical record must contain sufficient documentation of the patient’s medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the patient’s diagnosis and other pertinent information including, but not limited to, duration of the patient’s condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc.

The patient’s medical record is not limited to the physician’s office records. It may include hospital, nursing home, or HHA records and records from other health care professionals.

4. Four commenters suggested coverage expansion to include patients with New York Heart Association (NYHA) Class IIIb/ACC Stage C heart failure.

Response: Current ACCF/AHA heart failure guidelines are not supportive¹, and the final policy will not expand coverage. One commenter submitted one reference to support their contention that inotropes do not increase mortality in this sub-group of patients. The citation was a review article, which did not specifically address patients with NYHA Class IIIb/ACC Stage C heart failure.² Three commenters did not submit any literature in support of their recommendation.

5. One commenter requested clarification on the credentials of the “prescribing practitioner”.

Response: The policy requires that the initial evaluation be performed by a cardiologist with training in the management of advanced heart failure.

6. One commenter suggested modifying the draft language regarding “continued need”, in order to accommodate beneficiaries in rural areas.

Response: The medical directors agree that some health care facilities in rural areas may not have structured heart failure teams, and language in the final policy is reflective of that suggestion.

7. One commenter suggested clarifying the language regarding Guideline Directed Medical Therapy (GDMT).

Response: The draft policy GDMT language requires documentation of the use of **appropriate**, primarily Class I ACCF/AHA guideline recommended therapies for this group of patients; prior to a trial of parenteral inotropic therapy.

¹ 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. Clyde W. Yancy, MD, MSc, FACC, FAHA; Mariell Jessup, MD, FACC, FAHA; Biykem Bozkurt, MD, PhD, FACC, FAHA; et al. J Am Coll Cardiol. 2013;62(16):e147-e239.

² Guglin M, Kaufman M. International Journal of General Medicine 2014;7 237–251