By electronic mail to: DMAC_Draft_LCD_Comments@anthem.com

August 31, 2015

Stacey V. Brennan, M.D., FAAFP
Medical Director, DME MAC, Jurisdiction B
National Government Services
8115 Knue Rd
Indianapolis, IN 46250-1936

Re: **PROPOSED/DRAFT Local Coverage Determination (LCD): External Infusion Pump Draft Revisions to Inotropic Coverage Criteria**

Dear Dr. Brennan:

The American Association for Homecare (AAHomecare) submits the following comments on the proposed/draft LCD for External Infusion Pumps that was published on July 16, 2015.

AAHomecare represents durable medical equipment, infusion therapy, prosthetics, orthotics, and supplies (DMEPOS) suppliers, manufacturers, and others in the homecare community. Members operate more than 3,000 homecare locations in all 50 states. In light of our members' expertise and experience, AAHomecare is uniquely qualified to comment on the proposed/draft policy.

AAH concurs with NHIA in supports of the proposed changes to the External Infusion Pump coverage, reiterating the following concerns:

1. Qualifying Criteria #3 states that inotropic therapy will qualify only if "Prescribed by a cardiologist with training in the management of advanced heart failure."

   Requests that you broaden the scope regarding who can prescribe inotropic therapy to include palliative care physicians , in addition the Association asks that you also allow advanced registered nurse practitioners {ARNP) with independent practices to order inotropic therapy in states that they are qualified to do so. These clinicians are extremely skilled and experienced in managing end-stage heart failure patients, and often meet a real clinic need in states with rural and hard-to-access locations.

If the determination is made to stay with the draft language, AAH requests that you clarify what board certification is required to prescribe home inotropic drug therapy. It should not be the burden of the supplier to interpret if the level of "training in the management of advanced heart failure" meets the intent of the Local Coverage Determination.

2. Qualifying Criteria #5 states: "An evaluation every three months by a heart failure team with oversight by the prescribing cardiologist which documents the beneficiary's cardiac symptoms and the continuing response and need for therapy.

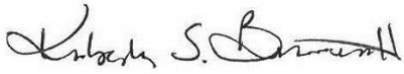
   Since some health care facilities in rural areas may not have structured heart failure teams, the Association requests that the policy be modified slightly to state: "An evaluation every three months by the qualified prescriber or a heart failure team with oversight by the qualified prescriber, which documents the beneficiary's cardiac symptoms and the continuing response on the need for therapy.

3. With the transition to ICD-10 five weeks away, the Association request that you clearly define which ICD-10 code(s) will be acceptable for qualifying beneficiaries. The policy requires that the patient have a Congestive Heart Failure (CHF) diagnosis. However, there is no ICD-10 that directly maps to the ICD-9 428.0 (Congestive Heart Failure, Unspecified). Thus, would ICD-10 150.9_ (Heart Failure, Unspecified) be an acceptable code?

4. AAH has concerns with limiting the coverage of inotropes for only American College of Cardiology Foundation/ American Heart Association (ACCF/AHA) defined Stage D heart failure (HF) patients. This limitation will eliminate access to cardiac transplants for candidates that may be categorized as late New York Heart Association (NYHA) defined Class 3 (3b) HF patients. These patients may be listed for cardiac transplant prior to progression into ACCF/ AHA Stage D. Inotropes benefit these patients by helping them stay as active as possible and ready for transplantation.

Thank you for the opportunity to submit these comments. We look forward to working with you on developing a more reasonable policy that considers the needs of the patient while also maintaining the integrity of the Medicare program.

Sincerely,



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