March 9, 2017

Via Electronic Mail Only
First Coast Service Options, Inc.
Medical Policy
532 Riverside Ave.
ROC 19T
Jacksonville, FL 32202

Re: Non-Coverage of Disposable NPWT codes 97607 and 97608 in DL37166

Dear Medical Director:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we are writing regarding First Coast Service Options, Inc. (First Coast) proposal to non-cover disposable Negative Pressure Wound Therapy CPT codes 97607 and 97608 in proposed Wound Care LCD DL35125.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.

Disposable NPWT technologies have been covered by First Coast for many years. Therefore, the proposal to non-cover these technologies came as a shock - especially given the absence of explanation regarding First Coast’s findings on lack of medical necessity. As such AdvaMed is writing to seek clarification regarding First Coast’s rationale for proposing to non-cover disposable NPWT products billed with CPT codes 97607 and 97608.

Several NPWT manufacturers offer disposable NPWT products for use in patient homes and other non-hospital settings. These disposable NPWT products offer the same benefits and functionality as the traditional NPWT offered to patients in a hospital setting and are used by patients to address conditions like the ones identified in the Covered Indications section of the draft LCD.

The draft LCD does not offer a basis for First Coast’s findings that the disposable NPWT technologies billed with 97607 and 97608 are not medically reasonable or necessary.

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NPWT technologies are offered in both traditional and disposable forms. None of the CPT codes for NPWT (97605, 97606, 97607, or 97608) make any reference to whether the NPWT is electrically powered. Additionally, the FDA indication for use is the same for both disposable and non-disposable NPWT technologies and both types of devices use similar mechanisms of action to apply a sustained level of negative pressure to the wound bed and surrounding tissue to remove exudate and to promote wound healing. Lastly, the descriptors for all NPWT CPT codes (97605, 97606, 97607, and 97608) specifically note that both disposable and non-disposable versions of NPWT technologies may offer vacuum assisted drainage collection.

**Conclusion**

The draft LCD appears to draw an incorrect distinction between the benefits of disposable versus non-disposable NPWT technologies. However, the therapeutic benefits associated with both types of NPWT are similar regardless of durability. As such, AdvaMed recommends that the draft LCD be revised to include coverage for disposable NPWT devices billed with CPT codes 97607 and 97608. This change will ensure continued access to these innovative devices by the Medicare beneficiaries who need them in both the hospital and other care settings.

AdvaMed appreciates the opportunity to bring this issue to your attention and looks forward to working with First Coast to resolve our concern. We would be pleased to answer any questions regarding this letter. Please contact DeChane L. Dorsey, Esq. at (202) 434-7218 or Chandra Branham, Esq. at (202) 434-7219, if we can be of further assistance.

Sincerely,

Donald May  
Executive Vice President,  
Payment and Health Care Delivery