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Re: Future Local Coverage Determination for Negative Pressure Wound Therapy Pumps (NPWT)

Dear Drs. Hughes, Brennan, Hoover and Whitten:

On behalf of the American Association for Homecare (AAHomecare) and its members who furnish wound care products and related dressings and supplies, I would like to submit these comments in response to the future Local Coverage Determination (LCD) for Negative Pressure Wound Therapy Pumps that was released August 25, 2011. The Association is concerned that the LCD changes were not subject to public notice and comment under Program Integrity Manual §13.7.2. The LCD calls for significant changes regarding physician orders and physician documentation and so the timeframe for 30-day compliance for changes to policies and procedures as well as the education of physicians and clinicians about the new documentation requirements is extremely ambitious.

<u>New Definition of NPWT</u>
In the new LCD, NPWT is now defined as "the application of subatmospheric pressure to a wound to remove exudate and debris from wounds." It should be clarified that NPWT devices also increase granulation tissue, reduce swelling and they also include infection control that should be recognized in evaluating the need for continuing therapy. It is important to note that a

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variety of wound care products are used in the home care sector, such as suction pump systems as well as NPWT. The addition of 'other suction pump systems' in the LCD's initial coverage section is likely to create confusion and denials.

Treatment Program Tried Considered and Ruled Out

The new LCD now states that "A complete wound therapy program…***must*** have been tried or considered and ruled out prior to the application of NPWT." The current LCD states that "[a] complete wound therapy program ***should*** have been tried or considered and ruled out prior to application of NPWT" and requires that physicians have a comprehensive wound care plan. Regarding physician documentation, it is already challenging for physicians to document clearly what treatment the patient requires let alone be able to document all the treatments and therapies that the physician has NOT prescribed for the patient. It is appropriate that HME providers rely on clear physician notes and not be expected to apply different treatments or therapies to the patient. HME providers in the wound care market require clarity in coding, reimbursement and coverage and must be able to access standardized documentation records to ensure consistency of claims processing.

Under 'other exclusions from coverage,' the new LCD states that an NPWT pump and supplies will be denied if "osteomyelitis is present within the vicinity of the wound that is not concurrently being treated with intent to cure." "Intent to cure" does not exist in the current LCD. The question must be asked, "what clinical evidence proves an intent to cure? How does an HME provider comply with this coverage criteria? AAHomecare recommends that the DME MAC medical directors remove the "intent to cure" phrase.

Physician Medical Record Documentation

The current LCD states that coverage of NPWT ends arbitrarily with the fourth cycle of therapy. There is no clinical significance to the four month limit on duration of therapy so where continuous wound improvement has been documented, continued coverage of NPWT "may be sought using the appeals process." On appealing a decision, the current LCD does not limit the circumstances that would justify extending NPWT. The new LCD, however, requires that "information from the treating physician's medical record…must be submitted with each appeal explaining the special circumstances necessitating the extended month if therapy." This language attempts to restrict coverage for NPWT. Does this mean an additional face-to-face examination is required? What is the timeframe for physicians to submit the required documentation?

Validity of Physician Orders

The new LCD states that orders for NPWT are only valid for up to an initial four months of therapy. This language suggests that no orders may be written for extended therapy which is misleading, arbitrary and must be clarified. There may be hundreds of physician orders that were written for NPWT in June where coverage supposedly ends. The new LCD cannot be applied retroactively to physician orders written four months prior to the effective date of the new LCD. The effective date for this requirement of the LCD must be removed.

Delivery of Supplies and Limitation on Supply Quantities

Regarding the delivery of supplies, NPWT is a unique therapy and requires a clinician and/or home health nurse to provide wound care to the patient. Currently, it is up to the provider to work with the intermediary, such as the home health nurse, to find out what dressings are needed. As the wound is healing, the supply needs might change. The best person to contact with knowledge of the healing status of the wound is the home health nurse, not the patient, however it is very difficult to coordinate supplies deliveries with the home health nurse. For the provider to be able to track down the home health nurse requires multiple outbound calls.

AAHomecare proposes a modification to how supplies are delivered in order to improve the quality of care that providers are able to offer to patients and to improve clinical outcomes. As a proposed modification, AAHomecare has developed a set of recommended additional quality standards for Negative Pressure Wound Therapy regarding intake, delivery, equipment condition and training/instruction to the beneficiary, caregiver and clinician. The standards mandate that the supplier coordinate the delivery of pumps, dressings and supplies as well as training and follow-up with the home health agency or wound clinic. I have attached the proposed AAHomecare standards to this comment letter.

The current LCD states that coverage of supplies is provided up to a maximum of 15 dressing kits per wound per month unless there is documentation in the medical record that the wound size requires more than one dressing kit for each dressing change. The new LCD deletes language allowing for any additional supplies. It must be understood that medically necessary supplies should be made available to patients as needed.

In closing, AAHomecare recommends that the LCD be modified and that the DME MAC medical directors clarify the NPWT definition; explain the LCD versus FDA standards for indications and contraindications; maintain the validity of physician orders four months prior to the effective date of the new LCD; and, allow for the delivery of additional supplies when it is medically necessary.

AAHomecare appreciates the opportunity to submit these comments and our staff is available to discuss these issues in greater detail with you. Please feel free to contact Alexandra Bennewith, Senior Manager, Government Affairs at (703) 535-1891 or alexb@aahomecare.org.

Sincerely,

Walter Gorski
Vice President, Government Affairs
American Association for Homecare

Encl. AAHomecare Recommended NPWT Recommended Standards, April 28, 2011