

***Negative Pressure Wound Therapy***

<b>Origination:</b> 06/29/04	<b>Revised:</b> 03/03/10	<b>Annual Review:</b> 12/15/11
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**Purpose:**

The Medical Technology Assessment Committee will review published scientific literature and information from appropriate government regulatory bodies (when available) related to Negative Pressure Wound Therapy in order to determine inclusion in the benefit plan.

**Compliance Status:**

- Centers for Medicare & Medicaid Services (CMS)

**Recommendation:**

A recommendation was made by the MTAC following discussion by committee members based on current literature:

***Additional Information***

- Members receiving NPWT are required to be enrolled in the Care Management Wound Care Program

**Prior Authorization Requirement Statements:**

- Prior authorization is required for *initial and subsequent* NPWT requests and is handled through contracted durable medical equipment vendor.
- Services rendered prior to issuance of authorization will not be processed for payment.

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### **Recommendation, continued:**

#### *Appendix*

The staging of pressure ulcers used in the procedure is as follows:

- **Stage I** - Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area. The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue. Stage I may be difficult to detect in individuals with dark skin tones. May indicate “at risk” persons (a heralding sign of risk).
- **Stage II** - Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister. Presents as a shiny or dry shallow ulcer without slough or bruising. \*This stage should not be used to describe skin tears, tape burns, perineal dermatitis, maceration or excoriation. \*Bruising indicated suspected deep tissue injury.
- **Stage III** - Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling. The depth of a stage III pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and stage III ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep stage III pressure ulcers. Bone/tendon is not visible or directly palpable.
- **Stage IV** - Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunneling. The depth of a stage IV pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and these ulcers can be shallow. Stage IV ulcers can extend into muscle and/or supporting structures (e.g., fascia, tendon or joint capsule) making osteomyelitis possible. Exposed bone/tendon is visible or directly palpable.
- **Unstageable:** Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed. Until enough slough and/or eschar is removed to expose the base of the wound, the true depth, and therefore stage, cannot be determined. Stable (dry, adherent, intact without erythema or fluctuance) eschar on the heels serves as “the body’s natural (biological) cover” and should not be removed.

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### **Recommendation, continued:**

#### *Eligibility Criteria*

#### **INITIAL COVERAGE (Medicare and Commercial):**

An NPWT pump and supplies are covered when either criterion A or B is met:

#### *A) Members with Ulcers and Wounds in the Home Setting:*

The Member has a chronic Stage III or IV pressure ulcer (see Appendices Section), neuropathic (for example, diabetic) ulcer, venous or arterial insufficiency ulcer, or a chronic (being present for at least 30 days) ulcer of mixed etiology. A complete wound therapy program described by criterion 1 and criteria 2, 3, or 4, as applicable depending on the type of wound, should have been tried or considered and ruled out prior to application of NPWT.

- 1) For all ulcers or wounds, the following components of a wound therapy program must include a minimum of all of the following general measures, which should be addressed, applied, or considered and ruled out prior to application of NPWT:
  - a) Documentation in the Member's medical record of evaluation, care, and wound measurements by a licensed medical professional, **and**
  - b) Application of dressings to maintain a moist wound environment, **and**
  - c) Debridement of necrotic tissue if present, **and**
  - d) Evaluation of and provision for adequate nutritional status.
  
- 2) For Stage III or IV pressure ulcers:
  - a) The Member has been appropriately turned and positioned, **and**
  - b) The Member has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis (see DMERC medical policy on support surfaces), (a group 2 or 3 support surface is not required if the ulcer is not on the trunk or pelvis) **and**
  - c) The Member's moisture and incontinence have been appropriately managed.
  
- 3) For neuropathic (for example, diabetic) ulcers:
  - a) The Member has been on a comprehensive diabetic management program, **and**
  - b) Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities.
  
- 4) For venous insufficiency ulcers for a period of up to 6 weeks (time frame is an independent decision by AvMed):
  - a) Compression bandages and/or garments have been consistently applied, **and**
  - b) Leg elevation and ambulation have been encouraged.

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### **Recommendation, continued:**

#### ***Eligibility Criteria, continued***

### **INITIAL COVERAGE: (Medicare and Commercial), continued**

An NPWT pump and supplies are covered when either criterion A or B is met, continued:

#### ***B) Members with Ulcers and Wounds in an Inpatient Setting:***

1) An ulcer or wound (described under A above) is encountered in an inpatient setting and, after wound treatments described under A-1 through A-4 have been tried or considered and ruled out, NPWT is initiated because it is considered in the judgment of the treating independent practicing practitioner, the best available treatment option.

2) The Member has complications of a surgically created wound (for example, dehiscence) or a traumatic wound (for example, pre-operative flap or graft) where there is documentation of the medical necessity for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments (for example, other conditions of the Member that will not allow for healing times achievable with other topical wound treatments).

In either situation B-1 or B-2, NPWT will be covered when treatment continuation is ordered beyond discharge to the home setting.

### **CONTINUED COVERAGE (Medicare and Commercial):**

**For Commercial Members, in addition to the above criteria, the following limitations will also apply:**

For Single Infected Stage III pressure ulcers:

Coverage limit is seven (7) days without further review

For Stage IV Non-infected or multiple Stage III pressure ulcers:

Coverage limit is 14 days without further review

For Stage IV infected or multiple Stage IV pressure ulcers:

Coverage limit is 21 days without further review

For wounds due to Surgical Dehiscence, Burns, graft, flap, or amputation:

Coverage limited to seven (7) days without further review

For wounds due to moist cell desquamation or necrotizing Fasciitis:

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Coverage limited to 21 days without further review

### **Recommendation, continued:**

### ***Eligibility Criteria, continued***

### **CONTINUED COVERAGE (Medicare and Commercial), continued:**

**For Commercial Members, in addition to the above criteria, the following limitations will also apply, continued:**

*C) For wounds and ulcers described under A or B above, once placed on an NPWT pump and supplies, in order for coverage to continue a licensed medical professional must do the following:*

- 1) On a regular basis,
  - a) directly assess the wound(s) being treated with the NPWT pump, **and**
  - b) supervise or directly perform the NPWT dressing changes, **and**
- 2) On at least a monthly basis, document changes in the ulcer's dimensions and characteristics.

If criteria C-1 and C-2 are not fulfilled, continued coverage of the NPWT pump and supplies will be denied as not medically necessary.

### **WHEN COVERAGE ENDS (Medicare and Commercial):**

*D) For wounds and ulcers described under A or B above, an NPWT pump and supplies will be denied as not medically necessary with any of the following, whichever occurs earliest:*

- 1) Criteria C1-C2 cease to occur, when:
  - a) In the judgment of the treating independent practicing practitioner, adequate wound healing has occurred to the degree that NPWT may be discontinued,
  - b) Any measurable degree of wound healing has failed to occur over the prior month. Wound healing is defined as improvement occurring in either surface area (length times width) or depth of the wound.
  - c) Four (4) months (including the time NPWT was applied in an inpatient setting prior to discharge to the home) have elapsed using an NPWT pump in the treatment of the most recent wound.

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- d) Once equipment or supplies are no longer being used for the Member, whether or not by the independent practicing practitioner's order.

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### **Recommendation, continued:**

#### *Exclusions from Coverage*

If criterion A or B above is not met, the NPWT pump and supplies will be denied as not medically necessary.

An NPWT pump and supplies will be denied at any time as not medically necessary if one (1) or more of the following are present:

- The presence in the wound of necrotic tissue with eschar, if debridement is not attempted; untreated osteomyelitis within the vicinity of the wound;
- Cancer present in the wound;
- The presence of a fistula to an organ or body cavity within the vicinity of the wound.

NPWT pumps and their supplies, which have not been specifically designated as being qualified for use of HCPCS code E2402 for billing to the DMERC via written instructions from the SADMERC, will be denied as not medically necessary.

NPWT pumps (E2402) must be capable of accommodating more than one (1) wound dressing set for multiple wounds on a Member. Therefore, more than one (1) E2402 billed per Member for the same time period will be denied as not medically necessary.

### **References:**

1. V.A.C.<sup>®</sup> (Vacuum Assisted Closure<sup>™</sup>) Therapy<sup>™</sup>. [Online.]
2. Centers for Medicare & Medicaid Services (CMS).
3. Wound Technology Network (information related to Commercial sections).
4. *National Pressure Ulcer Advisory Panel (NPUAP)*. Updated 02/2007.

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### **Disclaimer Information:**

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed to determine coverage for AvMed Health Plan benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plan makes coverage decisions using these guidelines, along with the Member's benefit document. The use of this guideline is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the AvMed Health Plan service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations.

Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change.