MEDICAL POLICY STATEMENT		
Effective Date	**Next Annual Review Date**	**Last Review / Revision Date**
8/2009	**7/2013**	**7/2012**
Author		
James Foster, MD		

CareSource

CSMG Medical Policy Statements are derived from literature based and supported clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services are those health care services or supplies which are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative and are not provided mainly for the convenience of the member or provider.

A. SUBJECT

Vacuum Assisted Wound Therapy

B. BACKGROUND

Vacuum Assisted Wound Therapy is a type of medical therapy that involves the use of suction (negative pressure) underneath airtight wound dressings to promote the healing of open wounds that have resisted previous treatments

Definitions:

- **Dehisced Wounds:** A condition where a wound has a premature opening or splitting along natural or surgical suture lines due to improper healing

- **Eschar:** A dry scab that forms on skin that has been burned or exposed to corrosive agents

- **Group 2 or 3 Support Surfaces:** Two groups within the three classifications of specialized pressure reducing bed types available as a preventive measure for bedsores.

    - **The classification system is as follows**:
    - Group 1 - Pressure reducing mattress overlays. These overlays may be filled with air, water, foam or gel and are intended for placement over a standard mattress.
    - Group 2 - Special mattresses alone or fully integrated into a bed. These mattresses may be filled with air, water, foam or gel and are intended as a replacement for a standard mattress.
    - Group 3 - Air Fluidized Beds. These are devices that employ the circulation of filtered air through silicone coated ceramic beads that create the characteristics of fluid, creating a sensation of floating.

- **Mediastinitis:** A condition characterized by inflammation of the cavity that holds the heart and other organs

- **Neuropathic Ulcer:** An ulcer resulting from the loss of sensation (e.g., pain, touch, stretch), as well as protective reflexes, due to loss of nerve supply to a body part

- **Post-Sternotomy:** The period of time immediately following any surgery where the sternum or breastbone is opened to gain access to the chest cavity

- **Pressure Ulcer** (National Pressure Ulcer Advisory Panel, 2007) A pressure ulcer is localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear and/or friction. A number of contributing or confounding factors are also associated with pressure ulcers; the significance of these factors is yet to be elucidated.

- **Pressure Ulcer Stages:** Age of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.

  Further description: Deep tissue injury may be difficult to detect in individuals with dark skin tones. Evolution may include a thin blister over a dark wound bed. The wound may further evolve and become covered by thin eschar. Evolution may be rapid exposing additional layers of tissue even with optimal treatment.

  1. **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.

     Further description:
     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)

  2. **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.

     Further description: 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 indicates suspected deep tissue injury.

  3. **Stage III**:
     Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscles are not exposed. Slough may be present, but does not obscure the depth of tissue loss. May include undermining and tunneling.

Further description: 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.

4. **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.

   Further description: 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.

5. **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.

   Further description: 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.

C. POLICY

For Special Needs Plan members, reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD).

Vacuum assisted wound therapy is considered **medically necessary** when the patient meets the following criteria categorized according to: Participation in a complete wound care program ***and*** presence of eligible conditions.

1. **Participation in a complete wound care program:**
   A complete wound care program has been tried or considered and ruled out prior to the addition of vacuum assisted wound therapy to the overall management of wounds in ALL patients in ALL settings. Such a wound care program should include ALL of the following:
   a. Documentation in the patient's medical record of evaluation, care and wound measurements by a licensed medical professional, **AND**
   b. Application of dressings to maintain a moist environment, **AND**
   c. Debridement of necrotic tissue if present, without presence of fistula formation, macroscopic contamination or presence of malignant cells, **AND**
   d. Evaluation of and provision for adequate nutritional status, **AND**

e. All underlying medical conditions have been stabilized or are under current management (e.g., diabetes, venous insufficiency).

2. **Eligible condition (patient must meet <u>ONE</u> of the following):**
    a. Stage III or IV pressure ulcers (see key terms below) at initiation of vacuum assisted wound therapy, who meet ALL of the following:
        1. The patient has been appropriately turned and positioned, and
        2. The patient has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis (no special support surface is required for ulcers not located on the trunk or pelvis), and
        3. The patient's moisture and incontinence have been appropriately managed
    b. **Neuropathic ulcers who meet ALL of the following**:
        1. The patient has been on a comprehensive diabetic management program, and
        2. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities
    c. **Ulcers related to venous or arterial insufficiency, who meet ALL of the following criteria:**
        1. Compression bandages and/or garments have been consistently applied, and
        2. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities, and
        3. For initiation of therapy in the home setting, presence of the ulcer for at least 30 days, or
    d. Dehisced wounds or wound with exposed hardware or bone, or
    e. Post sternotomy wound infection or mediastinitis, or
    f. Complications of a surgically created wound where accelerated granulation therapy is necessary and cannot be achieved by other available topical wound treatment.

Investigational and Not Medically Necessary:
Vacuum assisted wound therapy is considered investigational and not medically necessary when **ANY** of the following criteria are present:

a. Documentation of weekly assessment of the wound's dimensions and characteristics by a licensed health care professional indicate absence of adequate progress, or
b. Failure of progressive wound healing without intervening complications, or
c. In the judgment of the treating physician, adequate wound healing has occurred to the degree that vacuum assisted wound therapy may be discontinued, or
d. Other applications of vacuum assisted wound therapy not meeting the medical necessity criteria above.

For Medicare LCD Number L27025

http://www.adminastar.com/content.aspx?docid=20502

D. REVIEW / REVISION HISTORY

1. Armstrong DG, Lavery LA. Diabetic Foot Study Consortium. Negative pressure wound therapy after partial diabetic foot amputation: a multicentre, randomised controlled trial. Lancet. 2005; 366(9498):1704-1710.
2. Canaino DA, Ruth B, Teich S. Wound management with vacuum-assisted closure: Experience in 51 patients. J Pediatr Surg. 2005; 40:128-152.
3. De Franzo AJ, Argenta LC, Marks MW, et al. The use of vacuum-assisted closure therapy for the treatment of lower extremity wounds with exposed bone. Plast Reconstr Surg. 2001; 108:1184-1191.
4. Doss M, Martens S, Wood JP, et al. Vacuum assisted suction drainage versus conventional treatment in the management of poststernotomy osteomyelitis. Eur J Cardiothorac Surg. 2002; 22:934-938.
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6. Ford CN, Reinhard ER, Yeh D. Interim analysis of a prospective, randomized trial of vacuum-assisted closure versus the Healthpoint system in the management of pressure ulcers. Ann Plast Surg. 2002; 49:55-61.
7. Garner GB, Ware DN, Cocanour CS, et al. Vacuum-assisted wound closure provides early fascial reapproximation in trauma patients with open abdomens. Am J Surg. 2001; 82:630-638.
8. Hersh RE, Jack JM, Hahman MI, et al. the vacuum-assisted closure device as a bridge to sternal wound closure. Ann Plast Surg. 2001; 46:250-254.
9. Llanos S, Danilla S, Barraza C, et al. Effectiveness of negative pressure closure in the integration of split thickness skin grafts: a randomized, double-masked, controlled trial. Ann Surg. 2006; 244(5):700-705.
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11. Moues CM, Vos MC, van den Bemd GJJ, et al. Bacterial load in relation to vacuum-assisted closure wound therapy: a prospective randomized trial. Wound Repair Regen. 2004; 12:11-17.
12. O'Connor J, Kells A, Henry S, Scalea T. Vacuum-assisted closure for the treatment of complex chest wounds. Ann Thorac Surg. 2005; 79:1196-2000.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Centers for Medicare and Medicaid Services. National Coverage Determination for Treatment of Decubitus Ulcers. NCD #270.4. Effective date not posted. http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd. Accessed on June 13, 2008.
2. Hayes Medical Technology Directory. *Negative Pressure Wound Therapy for Wound Healing.* Winifred S. Hayes, Inc. November 9, 2007.
3. National Pressure Ulcer Advisory Panel. Pressure Ulcer Stages Revised by NPUAP. Available at: http://www.npuap.org/pr2.htm. Accessed on June 13, 2008.
4. Ubbink DT, Westerbos SJ, Evans D, Land L, Vermeulen H. Topical negative pressure for treating chronic wounds. Cochrane Database of Systematic Reviews 2001, Issue 1. Art.

No.: CD001898
5. Wasiak J, Cleland H. Topical negative pressure (TNP) for partial thickness burns. Cochrane Database of Systematic Reviews 2007, Issue 3. Art. No.: CD006215.

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E. REFERENCES

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.