Negative Pressure Wound Therapy
Corporate Medical Policy

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File code: UM.DME.10
Origination: 12/15/2010
Last Review: 03/2014 (ICD-10 remediation only)
Next Review: 2014
Effective Date: 07/01/2011

Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract language, the member’s contract language takes precedence.

Description

Vacuum assisted therapy for the promotion of wound closure utilizes a device known as a negative pressure wound therapy pump (NPWTP). This technique is designed to promote the formation of granulation tissue in the wound bed of acute or chronic wounds. It can be employed as an adjunct to surgery or in lieu of surgery in individuals who have failed a complete wound therapy program or in whom surgery has been ruled out due to extreme debilitation. The components of the system include specially designed foam dressings which are placed in the wound along with a drainage tube which leads to a canister that is attached to the negative pressure pump. The wound is sealed with an occlusive dressing, creating a vacuum within the wound. The pump can be set to either intermittent on continuous negative pressure, the intent of which is to remove excess interstitial fluid from the wound which is theorized to decrease edema and increase blood flow within the wound, thus promoting healing.

Policy

The initiation and continued use (up to 4 months) of a negative pressure wound therapy pump for the treatment of acute and chronic wounds is considered medically...
necessary if the medical appropriateness criteria are initially met and continue to be met over the course of the treatment.

When service or procedure is covered

Vacuum assisted wound therapy for the treatment of acute and chronic wounds is considered medically necessary when the individual meets ALL of the following criteria:

- Participation in a complete wound care program.

  A complete wound care program has been completed, tried, and failed or considered and ruled out prior to the addition of vacuum assisted wound therapy to the overall management of wounds in ALL individuals in ALL settings. Such a wound care program should include ALL of the following:

  o Documentation in the individual’s medical record of evaluation, care, and wound measurements by a licensed medical professional; and
  o Application of dressings to maintain a moist environment; and
  o Debridement of necrotic tissue if present; and
  o Appropriate positioning and turning of the individual who is incapable of doing this on their own;
  o Use of a support surface for pressure ulcers on the posterior trunk or pelvis;
  o Appropriate management of moisture and incontinence;
  o Evaluation of and provision for adequate nutritional status; and
  o All underlying medical conditions have been stabilized or are under current management (i.e., diabetes, venous insufficiency).

Supplies

- Up to a maximum of 15 dressing kits per month is considered medically necessary unless there is documentation that the wound size requires more than one dressing kit for each dressing change.
- Up to a maximum of 10 canister sets per month is considered medically necessary unless there is documentation showing a large volume of drainage (greater than 90 ml of exudate per day), a stationery pump with a large capacity canister must be used.

When service or procedure may not be covered

Vacuum assisted wound therapy is not covered in the presence of ANY of the following:

- The wound is a Stage I or Stage II pressure ulcer; or
- necrotic tissue with eschar present; or
- untreated osteomyelitis within the vicinity of the wound; or
• presence of a fistula to an organ or body cavity within the cavity of the wound; or
• malignancy in the wound; or
• exposed vasculature; or
• exposed nerves; or
• exposed anastomotic site; or
• exposed organs; or
• active bleeding; or
• use of anti-coagulation therapy, systemic corticosteroids, or immunosuppressant drugs; or
• non-compliant patient.

Vacuum assisted wound therapy is considered investigational and not medically necessary when ANY of the following criteria is present:

• Documentation of weekly assessment of the wound's dimensions and characteristics by a licensed health care professional indicates absence of adequate progress; or
• Failure of progressive wound healing without intervening complications; or
• In the judgment of the treating physician, adequate wound healing has occurred to the degree that vacuum assisted wound therapy may be discontinued; or
• Other applications of vacuum assisted wound therapy not meeting the medical necessity criteria above.
• The continued use of an NPTWP after four (4) months with a lack of improvement in the wound is considered investigational. The definition of lack of improvement in a wound is lack of progress in quantitative measurements of wound characteristics (i.e. wound length, width, surface area and/or depth).

Information required (if plan approval required)

A written order for the NPWT and supplies, signed and dated by the treating physician who is responsible for managing the wound care.

The written physician’s order must be accompanied by clinical notes which document ALL of the following:

• The nutritional status of the patient;
• History and previous treatment of the wound Stabilization and management of all underlying conditions, including but not limited to ANY ONE of the following conditions:
  o Diabetes;
  o Edema;
  o Venous insufficiency;
  o Arterial insufficiency;
  o Incontinence;
  o Dietary/ nutritional deficiency.
• Wound description at the time NPWTP is initiated, from a nurse or physician who is responsible for the wound dressing changes which includes ALL of the following:
  
  o Location of the wound;
  o Wound measurement including length, width and depth;
  o Description of the wound, including color, odor, etc.
  o Quantity and description of drainage;
  o Presence of granulation and necrotic tissue;
  o Debridement of necrotic tissue if present.

• Documentation of the existence of ANY ONE of the following ulcer types:
  
  o A stage III pressure ulcer (see description of stages);
  o A Stage IV pressure ulcer;
  o Neuropathic ulcers (i.e. diabetic);
  o Venous or arterial insufficiency ulcers unresponsive to standard therapy where:
    
    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;
  
  o For initiation of therapy in the home setting, with presence of the ulcer for at least 30 days.
  o A surgically created wound (i.e. dehiscence; dehisced wounds or wound with exposed hardware or bone; or post sternotomy wound infection or mediastinitis; complications of a surgically created wound where accelerated granulation therapy is necessary and cannot be achieved by other available topical wound treatment.)
  o A traumatic wound (i.e. pre-operative flap or graft).

For coverage to be considered medically necessary beyond the initial approval period of one (1) month, medical records indicating weekly assessment of wound dimensions and other characteristics should be submitted, in addition to documentation of progressive wound healing without intervening complications submitted at least monthly.

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 (i.e., 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.

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

Vacuum assisted wound therapy: 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

Pressure ulcer staging

Suspected deep tissue injury
Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage 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. Note: 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. The following staging criteria are based on the National Pressure Ulcer Advisory Panel (NPAUP) staging system.
Stage I
Non-blanchable redness of intact skin light toned skin, or darker or violet hue in darkly pigmented skin. Note: 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 involving epidermis and/or dermis. Note: 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

Stage III
Full thickness skin loss involving damage or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia. Note: 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 extensive destruction, tissue necrosis or damage to bone, muscle, or supporting structures. Note: 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.

Administrative and Contractual Guidance

Benefit Determination Guidance
Prior approval is required and benefits are subject to all terms, limitations and conditions of the subscriber contract.

An approved referral authorization for members of the New England Health Plan (NEHP) is required. A prior approval for Access Blue New England (ABNE) members is required. NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member’s health plan.

Benefits for FEP members may vary. Please consult the FEP Service Plan Brochure.
Coverage varies according to the member’s group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through a self-funded (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member’s plan documents or contact the customer service department.

**Billing and Coding/Physician Documentation Information**

Click the links below for attachments, coding tables & instructions.

- Attachment I - CPT & HCPCS Code List & Instructions
- Attachment II - Eligible Diagnosis Codes

**Audit Information**

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

**Eligible Providers**

Allopathic Physician (M.D.)
Osteopathic Physician (D.O.)

**Policy Implementation/Update Information**

<table>
<thead>
<tr>
<th>Date</th>
<th>Information</th>
</tr>
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<tbody>
<tr>
<td>3/2014</td>
<td>ICD-10 remediation. RLJ.</td>
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**Scientific Background and Reference Resources**

This policy is based in part upon Medicare DMERC medical necessity criteria for negative pressure wound therapy pumps (NPWTP).

On November 13, 2009, the U.S. Food and Drug Administration released a Medical Device Alert regarding the use of negative pressure wound therapy systems. This alert was intended to notify medical practitioners of possible death or serious complications due to the use of vacuum assisted wound therapy systems. The FDA states that it has received reports of six deaths and 77 injuries associated with NPWT systems over the past two years. Major complications reported include bleeding and infection. The warning provides recommendations to reduce the risk of NPWT including:

- More careful selection of patients for vacuum assisted wound therapy
• Assure that the patient is monitored frequently in an appropriate care setting by a trained practitioner. In determining the frequency of monitoring, consider the patient’s condition, including the wound status, wound location and co-morbidities.

• Obtain appropriate training prior to prescribing and using NPWT.

• Instructions for proper home use of vacuum assisted wound therapy systems

In addition, the FDA stated that vacuum assisted wound therapy is contraindicated for wounds with:

• necrotic tissue with eschar present
• untreated osteomyelitis
• non-enteric and unexplored fistulas
• malignancy (within the wound)
• exposed blood vessels, nerves, anastomoses, or organs

For the full text of the warning, please see: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm190658.htm

Peer Reviewed Publications:


Government Agency, Medical Society, and Other Authoritative Publications:

4. U.S. FDA; Serious Complications Associated with Negative Pressure Wound Therapy Systems. November 13, 2009. Available at:
Attachment I
CPT & HCPCS Code List & Instructions

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Number</th>
<th>Description</th>
<th>Policy Instructions</th>
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<tbody>
<tr>
<td>CPT</td>
<td>97605</td>
<td>Negative pressure wound therapy (e.g., vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters</td>
<td>No Prior Approval Required</td>
</tr>
<tr>
<td>CPT</td>
<td>HCPCS</td>
<td>Description</td>
<td>Place of Service</td>
</tr>
<tr>
<td>--------</td>
<td>---------</td>
<td>------------------------------------------------------------------------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>97606</td>
<td>A6550</td>
<td>Negative pressure wound therapy (e.g., vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters</td>
<td>No Prior Approval Required</td>
</tr>
<tr>
<td></td>
<td>K0743</td>
<td>Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories</td>
<td>All DME or DME supplies with a purchase price greater than $500.00 (including rentals)</td>
</tr>
<tr>
<td></td>
<td>K0744</td>
<td>Suction pump, home model, portable, for use on wounds</td>
<td>All DME or DME supplies with a purchase price greater than $500.00 (including rentals)</td>
</tr>
<tr>
<td></td>
<td>K0745</td>
<td>Absorptive wound dressing for use with suction pump, home model, portable, pad size 16 square inches or less</td>
<td>All DME or DME supplies with a purchase price greater than $500.00 (including rentals)</td>
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<tr>
<td></td>
<td>K0746</td>
<td>Absorptive wound dressing for use with suction pump, home model, portable, pad size greater than 48 square inches</td>
<td>All DME or DME supplies with a purchase price greater than $500.00 (including rentals)</td>
</tr>
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**Type of Service**: Medicine, Durable Medical Equipment

**Place of Service**: Inpatient, Outpatient, Home

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**Attachment II**

[Click HERE for Applicable ICD (diagnosis) Codes]