I. Policy: Negative Pressure Wound Therapy

II. Purpose/Objective:
To provide a policy of coverage regarding Negative Pressure Wound Therapy

III. Responsibility:
A. Medical Directors
B. Medical Management

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit will assist the Member to achieve or maintain maximum functional
capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

**ALL Durable Medical Equipment** provided for home use requires advanced determination of coverage. Devices furnished at inpatient or outpatient centers are **NOT SEPARATELY REIMBURSABLE**. Negative Pressure Wound Therapy devices must be obtained through a participating Durable Medical Equipment Vendor(s).

**DESCRIPTION:**
Vacuum assisted wound closure is a technique used to promote healing of chronic wounds. It can be used as an adjunct to surgery or as an alternative to surgery for patients who are debilitated or are non-surgical candidates. A special foam dressing with an attached evacuation tube is inserted into the wound. The wound is sealed with an adhesive occlusive dressing. The evacuation tube leads from the wound to a canister that is attached to a negative pressure pump. The negative pressure removes the excess interstitial fluid from the wound. This results in decreased edema that allows for increased blood flow in the wound bed. It is hypothesized that the increased blood flow provides oxygen and nutrients to the wound, thus promoting the formation of granulation tissue. It also draws the edges of the wound closer together.

**INDICATIONS:**
- Chronic open wounds
- Diabetic ulcers refractory to conventional treatment
- Trauma or surgically created wound complication (such as but not limited to dehisced surgical incisions or mesh graft and tissue flap) where there is documentation of medical necessity for accelerated function of granulation tissue which cannot be achieved by other available topical wound treatment
- Stasis ulcers
- Pressure ulcers

**CRITERIA FOR COVERAGE:**
The staging of pressure ulcers used in this policy is as follows:

**Stage I:**
Observable pressure related alteration of intact skin whose indicators as compared to the adjacent or opposite area on the body may include changes in one or more of the following: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel) and/or sensation (pain, itching). The ulcer appears as a defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue, or purple hues.

**Stage II:**
Partial thickness skin loss involving epidermis and/or dermis. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.

**Stage III:**
Full thickness skin loss involving damage or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.

**Stage IV**
Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone or supporting structures. Undermining and sinus tracts also may be associated with Stage IV pressure ulcers.

Vacuum-assisted closure of wounds may be considered medically necessary for patients with a chronic Stage III or IV pressure ulcer, neuropathic ulcer, venous or arterial insufficiency ulcer, or a chronic ulcer of mixed etiology. A complete wound therapy program described in 1 through 4 below, depending on the type of wound, should have been tried, or considered and ruled out prior to application of vacuum-assisted closure.

1. For all ulcers or chronic open wounds, the following components of a wound therapy program must include a minimum of all of the following general measures, which should be addressed prior to application of vacuum-assisted closure:
   a. Documentation of evaluation, care, and wound measurements by a licensed professional; and
   b. Moist wound dressings; 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. Appropriate turning and positioning has been documented; **and**
   b. A group 2 or 3 support surface has been utilized if pressure ulcer(s) is on the posterior trunk or pelvis, **and**
   c. Body moisture and/or incontinence issues have been appropriately managed

3. For neuropathic ulcers (example, diabetic ulcers):
   a. The member has been participating in a comprehensive diabetic management program to improve their diabetic control; **and**
   b. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities

4. For venous insufficiency ulcers:
   a. Compression bandages and/or garments have been appropriately and consistently applied, **and**
   b. Leg elevation and ambulation have been included in the treatment plan.

**CONTINUED COVERAGE:**
If the member meets the criteria for coverage, authorization will be approved in four-week time increments, up to the limitation of the benefit document or applicable rider.

1. Every 30 days from the date of the initial approval a licensed healthcare professional (i.e. treating physician, PA, nurse, or physical therapist) must provide documentation:
   - Wound characteristics including size (length, width, and depth) and drainage (color, odor).
   - Most recent health care professional clinical notes indicating supervision or performing dressing changes.
   - The recorded wound measurements must demonstrate progressive wound healing for continued coverage.
   - Failure to provide this documentation will result in medical necessity denial (per Medicare guidelines).

2. Coverage will cease if any of the following occur
   - No clinically significant objectively measured degree of wound healing (either surface area (length times width) or depth of wound) as determined by the Plan Medical Director or designee has not occurred in the previous month. The recorded wound measurements must be consistently and regularly updated every two weeks and must have demonstrated progressive wound healing.
   - 4 months (Including the time the VAC was applied in an inpatient setting prior to discharge to home) have elapsed using a VAC pump in the treatment of any wound. Requests for coverage in excess of 4 months will be reviewed by the Plan Medical Management in conjunction with a Health Plan Medical Director.
   - If member is not using the device, whether or not by the physician’s order.

**CONTRAINDICATIONS:**
- Fistulas to organs or body cavities
- Exposed Organs
- Necrotic tissue in eschar
- Untreated osteomyelitis
- Malignancy in the wound
- Exposed vasculature
- Exposed nerves
- Exposed anastomotic site

**LIMITATIONS:**
As documented under specific line of business.

Member treated in a facility, either acute or sub-acute, will not be separately reimbursed for the device or related equipment. Reimbursement will be inclusive of the contracted per diem rates.

**EXCLUSIONS:**
Requests for coverage not meeting criteria, or application of this therapy for conditions listed under contraindications are **NOT COVERED**.

Non-powered mechanical negative pressure wound care systems or single use non-electrically powered negative pressure wound therapy systems, including but not limited to the following, are considered experimental, investigational or unproven and therefore **NOT COVERED** for any indication:
- SNaP® Wound Care System
• PICO™ Single Use Negative Pressure Wound Therapy
• V.A.C.Via™ Therapy System
• ciSNaP® Closed Incision System

CODING ASSOCIATED WITH: Negative Pressure Wound Therapy
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

E2402 Negative pressure wound therapy electrical pump, stationary or portable
A9272 Wound suction, disposable, includes dressing, all accessories and components, any type, each
A6550 Dressing set for negative pressure wound therapy electrical pump, stationary or portable, each
A7000 Canister, disposable, used with suction pump, each
A7001 canister, non-disposable, used with suction pump, each
K0743 suction pump, home model, portable, for use on wounds
K0744 absorptive wound dressing for use with suction pump, home model, portable, pad size 16 sq in or less
K0745 absorptive wound dressing for use with suction pump, home model, portable, pad size more than 16 sq in but less than or equal to 48 sq in
K0746 absorptive wound dressing for use with suction pump, home model, portable, pad size greater than 48 sq in
97605 Negative pressure wound therapy, wound assessment and instructions for ongoing care, per session; total wound surface area less than or equal to 50 square centimeters
97606 total wound surface area greater than 50 square centimeters
97607 Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
97608 total wound surface area greater than 50 square centimeters


LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD’s and NCD’s will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:


Geisinger Technology Assessment Committee, TAC Review: Wound Vac, July 12, 2000


Food and Drug Administration, FDA Safety Communication: UPDATE on Serious Complications Associated with Negative Pressure Wound Therapy Systems, Date Issued: February 24, 2011

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm244211.htm

ECRI Product Brief, SNaP Wound Care System (Spiracur, Inc) for Delivering Negative Pressure Wound Therapy, September 2014

Fong KD, Marston W. Advances in Wound Care. February 2012, 1(1): 41-43. SNaP® Wound Care System: Ultraportable Mechanically Powered Negative Pressure Wound Therapy

Hutton DW, Sheehan P. Comparative effectiveness of the SNaP® Wound Care System. Int Wound J. 2011 Apr;8(2):196-205


This policy will be revised as necessary and reviewed no less than annually.

Devised: 02/02

Revised: 6/03; 7/04 criteria; 8/05; 8/06; 8/09; 10/11 (wording, refs), 10/11 (added contraindications); 5/16 (added exclusion); 10/16 (Edited Criteria, Remove P/A)

Reviewed: 10/12, 10/13, 10/14, 10/15; 9/17, 9/18