

MEDICAL POLICY



SUBJECT: NEGATIVE PRESSURE WOUND THERAPY (VACUUM ASSISTED CLOSURE)

POLICY NUMBER: 1.01.38

CATEGORY: Technology Assessment

EFFECTIVE DATE: 09/19/02

REVISED DATE: 07/17/03, 06/17/04, 06/16/05, 05/18/06, 06/21/07, 04/17/08, 05/28/09, 05/27/10, 08/18/11, 10/18/12, 10/17/13

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- *If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.*
- *Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.*
- *Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.*

POLICY STATEMENT:

- I. Based upon our criteria and assessment of the peer-reviewed literature, negative pressure wound therapy (NPWT) using a powered NPWT device has been medically proven to be effective and therefore, is **medically appropriate** for the following indications:
 - A. Skin ulcers refractory to a complete wound therapy program:
 1. Chronic stage III or IV pressure ulcers (*refer to the description section for definitions of stages*);
 2. Neuropathic (e.g. diabetic) ulcers;
 3. Venous or arterial insufficiency ulcers; or
 4. Chronic ulcers (those present for at least 30 days) of mixed etiology.

When there are recurrent requests for treatment of the same ulcer site, patient adherence with measures for pressure relief and skin care will be taken into consideration.
 - B. Complications (e.g., infection, dehiscence) of *surgically created wounds*; which may include the use of skin grafts to assist in wound closure; or
 - C. Traumatic wounds, wounds refractory to standard wound regimens, or burns where there is documentation of the medical necessity for improved formation of granulation tissue which cannot be achieved by other available topical wound treatments.
- II. Contraindications - According to the U. S. Food and Drug Administration (FDA) NPWT is contraindicated in patients with the following wound types/conditions:
 - A. necrotic tissue with eschar present,
 - B. untreated osteomyelitis,
 - C. non-enteric and unexplored fistulas,
 - D. malignancy in the wound, or
 - E. exposed vasculature, nerves, anastomotic site, or organs.
- III. Based upon our criteria and the lack of peer-reviewed literature, negative pressure wound therapy (NPWT) following pilonidal cyst/sinus excision is considered **investigational**.
- IV. Based upon our criteria and assessment of the peer-reviewed literature, negative pressure wound therapy (NPWT) using a non-powered NPWT system (e.g., SNaP® system) has not been proven to be medically effective and is, therefore, considered to be **investigational** in the treatment of acute or chronic wounds.

POLICY GUIDELINES:

- I. Medical documentation of all of the following is required for consideration of NPWT:
 - A. A prescription or written order from the physician for the device.
 - B. Documentation of the history, wound type, previous treatment regimens (where applicable), and current wound management for which the device is being ordered should be reflected in the medical record. Documentation must include an assessment of wound healing progress, the length of sessions in use, dressing types and frequency of change, changes in the wound condition including the precise wound length, width, and depth

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measurements, presence of granulation and necrotic tissue, and concurrent measures being addressed relative to wound therapy (e.g., debridement, nutritional concerns, use of support surfaces, positioning, incontinence control) and co-morbid conditions (e.g., diabetes).

- C. The goal, or endpoint, of wound therapy is satisfactory healing. Satisfactory healing is defined as obliteration of the wound cavity sufficient to allow surface dressings, closure of the wound by suture, myocutaneous flap, or skin graft (delayed primary intention), or complete healing of the wound (delayed secondary closure).
- D. Weekly wound measurements should be performed to document progress in wound healing. A steady decrease in wound volume should be noted from week to week.
- E. The average length of treatment is 4 to 6 weeks. For patients who are not surgical candidates, NPWT may be continued as long as satisfactory progress is documented.

II. Durable Medical Equipment rider/coverage is required.

DESCRIPTION:

Negative pressure wound therapy (NPWT), or vacuum assisted wound therapy, is the controlled application of subatmospheric pressure to a wound. Powered NPWT systems include a vacuum pump, drainage tubing, and a dressing set. The pump may be stationary or portable, relies on AC or battery power, allows for regulation of the suction strength, has alarms to indicate loss of suction, and has a replaceable collection canister. The dressing sets contain either foam or gauze dressing to be placed in the wound and an adhesive film drape for sealing the wound. The drainage tubes come in a variety of configurations depending on the dressings used or wound being treated.

There are several powered NPWT systems currently available in the U.S. Devices that have U.S. Food and Drug Administration (FDA) 510(k) clearance for marketing in the U.S. include, but may not be limited to, the:

- I. ActiV.A.C.® Therapy Unit,
- II. Engenex® Advanced NPWT System,
- III. Exusdex® wound drainage pump,
- IV. EZCARE Negative Pressure Wound Therapy,
- V. InfoV.A.C.® Therapy Unit,
- VI. Invia Liberty Wound Therapy,
- VII. Invia Vario 18 c/i Wound Therapy,
- VIII. Mini V.A.C.®,
- IX. NPD 1000™ Negative Pressure Wound Therapy System,
- X. Prodigy™ NPWT System (PMS-800 and PMS-800V),
- XI. PRO-I™, PRO-II™, PRO-III™,
- XII. RENASYS™ EZ Negative Pressure Wound Therapy,
- XIII. SVEDMAN™ and SVED™ Wound Treatment Systems,
- XIV. V.A.C.® (Vacuum Assisted Closure™), V.A.C.® ATSTM, V.A.C.® Freedom™, V.A.C.® Instill Device, V.A.C.® Therapy Unit, V.A.C.® Via™ NPWT System,
- XV. Venturi™ Negative Pressure Wound Therapy, and
- XVI. V1STA Negative Pressure Wound Therapy.

The electric pump applies intermittent or continuous negative pressure to an open cell foam or gauze wound dressing. The dressing evenly distributes pressure to the wound surface. In early stages of healing, fluid is withdrawn by the device, reportedly removing inhibitory factors and reducing bacterial counts. In later stages, tensile forces applied to surrounding tissues by the dressing are thought to stimulate cellular proliferation and protein synthesis.

A non-powered, portable, disposable NPWT system, the Smart Negative Pressure (SNaP®) Wound Care System, received 510(k) clearance from the U.S. Food and Drug Administration in 2009 and is designed to remove small amounts of exudate from chronic, traumatic, dehisced, acute, or subacute wounds and diabetic and pressure ulcers. The device consists of a cartridge that acts as the negative pressure source, a dressing, and a strap and can be worn under clothing.

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The cartridge utilizes specialized springs that generate continuous negative pressure and is preset at negative 75, 100, or 125 mmHg, weighs less than 3 ounces, and has a 60 cc capacity. The dressing is a hydrocolloid dressing with an antimicrobial gauze wound interface layer. (Powered NPWT systems usually have a foam-based interface layer.)

NPWT has been used for chronic non-healing diabetic skin ulcers, venous/vasculitis ulcers, decubitus ulcers, burns, degloving injuries, acute wounds, post-sternotomy mediastinitis, and dehisced or open surgical wounds.

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. Pressure ulcers are defined by stages:

- I. 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.
- II. 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.
- III. 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.
- IV. 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 includes undermining and tunneling.

RATIONALE:

The available studies published in peer-reviewed literature have demonstrated that use of NPWT has resulted in improvement in wound size sufficient to allow for secondary closure with skin grafting in patients with chronic ulcers, surgically created wounds, and traumatic wounds.

A literature search specifically addressing NPWT and pilonidal disease identified 11 articles; all published between 2003 and 2011. A review of this literature identified 5 case studies totaling 14 patients and one literature review addressing the use of NPWT following surgical excision of complex pilonidal disease. No literature was identified that addresses the use of NPWT following standard disease excision. Literature generally concludes that randomized controlled studies are needed before conclusions can be drawn regarding the efficacy of NPWT in pilonidal disease.

Published studies are insufficient to draw conclusions regarding the impact on net health outcomes of the non-powered wound care system (SNaP® device) itself and in comparison with current care standards. Well-designed comparative studies are needed to answer questions that remain regarding its efficacy and tolerability.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT: 97605 Negative pressure wound therapy (eg, 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

97606 total wound(s) surface area greater than 50 square centimeters

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HCPCS: A6550 Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories

A9272 (E/I) Mechanical wound suction, disposable, includes dressing and all accessories and components, each

E2402 Negative pressure wound therapy electrical pump, stationary or portable

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G0456 (E/I) Negative pressure wound therapy, (e.g., vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wounds(s) surface area less than or equal to 50 square centimeters

G0457 (E/I) Negative pressure wound therapy, (e.g., vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wounds(s) surface area greater than 50 square centimeters

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 square inches or less

K0745 Absorptive wound dressing for use with suction pump, home model, portable, pad size more than 16 square inches but less than or equal to 48 square inches

K0746 Absorptive wound dressing for use with suction pump, home model, portable, pad size greater than 48 square inches

ICD9: Various

ICD10: Various

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KEY WORDS:

Negative pressure wound therapy, Topical negative pressure therapy, Vacuum Assisted Closure therapy.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) for Negative Pressure Wound Therapy Pumps. Please refer to the following website for Medicare Members:

http://www.medicarenhic.com/dme/medical_review/mr_lcds/mr_lcd_current/L11500_2011-10-01_rev_2013-04_PA_2011-10.pdf.