MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Negative Pressure Wound Therapy (Vacuum-Assisted Closure)**
Policy Number	**1.01.38**
Category	**Technology Assessment**
Original Effective Date	**09/19/02**
Committee Approval 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, 10/16/14, 10/15/15, 10/20/16, 10/19/17, 11/15/18, 11/21/19, 09/17/20, 09/16/21, 09/15/22, 09/21/23, 09/19/24**
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Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

The focus of this policy is for the use of negative pressure wound therapy (NPWT) in the outpatient setting.

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 considered **medically appropriate** in the absence of the following contraindications in accordance with the U.S. Food and Drug Administration (FDA):

A. Necrotic tissue with eschar present;
B. Untreated osteomyelitis;
C. Non-enteric and unexplored fistulas;
D. Malignancy in the wound;
E. Exposed vasculature, nerves, anastomotic site, or organs; for **ALL** the following indications:

1. Skin ulcers refractory to a complete wound therapy program:
   a. Chronic stage III or IV pressure ulcers (*refer to the Description section for definitions of stages*);
   b. Neuropathic (e.g., diabetic) ulcers;
   c. Venous or arterial insufficiency ulcers; **or**
   d. 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.)
2. Complications (e.g., infection, dehiscence) of surgically created wounds, which may include the use of skin grafts to assist in wound closure; or
3. Traumatic wounds (e.g., preoperative flap or graft, exposed bones and tendons), wounds refractory to standard wound regimens, or burns, where there is documentation of the medical necessity for improved formation of granulation tissue that cannot be achieved by other available topical wound treatments (e.g.,

the individual has comorbidities that will not allow for healing times usually achievable with other available topical wound treatments).

II. Based upon our criteria and the lack of peer-reviewed literature, NPWT following pilonidal cyst/sinus excision has not been medically proven to be effective and, therefore, is considered **investigational**.

III. Based upon our criteria and the lack of peer-reviewed literature, NPWT using a non-powered NPWT system (e.g., the SNaP system) or a battery-operated, disposable system (e.g., the PICO system) has not been medically proven to be effective and, therefore, is considered **investigational** in the treatment of acute or chronic wounds.

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

POLICY GUIDELINES

I. Medical documentation of **ALL** the following is required for consideration of NPWT:
   A. A physician must issue a prescription or written order 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 must be submitted. The documentation, which should be reflected in the medical record, 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 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 any co-morbid conditions (e.g., diabetes);
   C. Weekly wound measurements are performed to document progress in wound healing. A steady decrease in wound volume must be noted from week to week.

II. The average length of treatment is four (4) to six (6) weeks. For patients who are not surgical candidates, NPWT may be continued as long as satisfactory progress is documented;

III. 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).

DESCRIPTION

NPWT, or vacuum-assisted wound therapy, is the controlled application of sub-atmospheric 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 that is 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 FDA Section 510(k) clearance for marketing in the U.S. include, but may not be limited to, the following:

I. ActiV.A.C. Therapy Unit;
II. Engenex Advanced NPWT System;
III. Exusdex wound drainage pump;
IV. EZCARE Negative Pressure Wound Therapy;
V. Genadyne A4 Wound Vacuum System;
VI. InfoV.A.C. Therapy Unit;
VII. Invia Liberty Wound Therapy;
VIII. Invia Vario 18 c/i Wound Therapy;
IX. Mini V.A.C.;
X. MobIVac;
XI. NPD 1000 Negative Pressure Wound Therapy System;

XII. Prodigy NPWT System (PMS-800 and PMS-800V);
XIII. PRO-I, PRO-II, PRO-III;
XIV. RENASYS EZ Negative Pressure Wound Therapy;
XV. SVEDMAN and SVED Wound Treatment Systems;
XVI. V.A.C. (Vacuum Assisted Closure), V.A.C. ATS, V.A.C. Freedom, V.A.C. Instill, V.A.C. Therapy Unit, V.A.C. Ultra, V.A.C. Via NPWT System;
XVII. Venturi Negative Pressure Wound Therapy; and
XVIII. 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.

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 a 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, and 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.

A non-powered, portable, disposable NPWT system, the Smart Negative Pressure (SNaP) Wound Care System, received Section 510(k) clearance from the FDA in 2009. The SNaP system is designed to remove small amounts of exudate from chronic, traumatic, dehisced, acute, or subacute wounds, as well as diabetic and pressure ulcers. The device consists of a cartridge that acts as the negative pressure source, a dressing, and a strap; it can be worn under clothing. The cartridge, which utilizes specialized springs that generate continuous negative pressure and is preset at negative 75, 100, or 125 mmHg, weighs less than three 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.)

A single-use, disposable NPWT device, the PICO system, received Section 510(k) clearance from the FDA in 2012 and is designed to remove low-to-moderate amounts of exudate. The system uses batteries instead of electrical power, and, instead of using a canister, the exudate is absorbed into the dressing. The pump is programmed to stop working after 168 hours (seven days) of use and will not restart after that time, even with new batteries.

There are several non-powered or battery-operated, disposable NPWT systems currently available in the U.S. Devices that have received FDA Section 510(k) clearance for marketing in the U.S. include, but may not be limited to, the following:

I. extriCARE 2400 NPWT System (Devon Medical);
II. MyNeWT Negative Pressure Wound Therapy System (Stortford Medical LLC);
III. PICO Single Use Negative Pressure Wound Therapy System (Smith & Nephew);
IV. Prevena Incision Management System (KCI);
V. RENASYS GO (Smith & Nephew);
VI. SNaP Wound Care System (Spiracur, acquired by Acelity in 2015);
VII. Uno Negative Pressure Wound Therapy System (Genadyne Biotechnologies, Inc.);
VIII. V.A.C. Via (KCI); and
IX. XLR8 PLUS (Genadyne Biotechnologies, Inc.).

RATIONALE

The available studies published in peer-reviewed literature have demonstrated that the 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 few studies have explored the use of NPWT after excision in pilonidal disease. 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.

Published studies addressing NPWT systems, including disposable systems (e.g., the PICO system, the Prevena Incision Management system), for the treatment of closed wounds have generally involved small patient populations or risk of bias. Further well-designed, comparative studies are needed before conclusions can be reached regarding the efficacy of disposable systems, the effects of the technology on health outcomes, and the patient population that would benefit from use of these devices.

A Cochrane review (Norman et al., 2020) assessed the impact of using NPWT for preventing surgical site infection (SSI), and the cost-effectiveness of NPWT in treating wounds healing through primary closure. A total of 44 randomized, controlled trials (with a total of 7,447 participants) and five economic studies were included. The authors determined that people who undergo primary wound closure of their surgical wound and are treated prophylactically with NPWT following surgery probably experience fewer SSIs than people treated with standard dressings (moderate-certainty evidence). They also raise the possibility that superficial SSI is reduced with little difference in deep SSI. No clear difference in number of deaths or wound dehiscence were found between people treated with NPWT and standard dressings (low-certainty evidence). There were also no clear differences in secondary outcomes where all evidence was low or very low certainty.

A 2022 Cochrane review update (Norman et al.) evaluated NPWT compared with standard dressings for surgical wound healing by primary closure. Negative pressure wound therapy was associated with a reduced risk of surgical site infection (SSI) (44 studies [N=11,403]; RR, 0.73; 95% CI, 0.63 to 0.85; I^2=29%). Mortality was lower with NPWT, but this was nonsignificant (11 studies [N=6384]; RR, 0.78; 95% CI, 0.47 to 1.30). No significant difference was found for wound dehiscence, reoperations, or wound-related readmission. The analysis is limited by inclusion of studies with mixed or unclear intervention types, no subgroup analysis for traditional or portable, single-use systems, and no discussion of use specific to outpatients. Uncertainty remains regarding if NPWT compared with a standard dressing reduced or increased the incidence of important outcomes such as mortality, dehiscence, seroma, or if it increased costs. These researchers stated that given the cost and widespread use of NPWT for SSI prophylaxis, there is an urgent need for larger, well-designed, and well-conducted trials to examine the effects of newer NPWT products designed for use on clean, closed surgical incisions.

The Wound Healing in Surgical Trauma (WHIST) trial (Costa et al., 2020), compared incisional negative pressure wound therapy to standard wound dressing, to determine efficacy in reducing the rate of deep SSI in wounds associated with surgery for a fracture in the context of major trauma to the lower limb. This randomized, controlled trial was conducted at 24 trauma hospitals in the U.K. and included 1,548 patients aged 16 years or older. Results showed no statistically significant difference in the rate of deep SSI at 30 days between incisional negative pressure wound therapy (5.8%) and standard wound dressing (6.7%). No significant differences were found for any of the secondary outcomes, including quality of life, disability, and local wound-healing complications.

The American Academy of Orthopaedic Surgeons (AAOS) 2022 guidelines for prevention of surgical site infections after major extremity trauma included recommendations for NPWT. The recommendations from AAOS do not support the continued use of NPWT in patients undergoing fracture fixation due to similar outcomes to standard wound care but with an increased healthcare burden. In patients with high-risk surgical incisions, the AAOS recommends that limited evidence

suggests NPWT may be an option; however, its use will be influenced by cost. Importantly, these guidelines do not specifically address use in the outpatient setting.

CODES

- *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.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
97605	Negative pressure wound therapy (e.g., vacuum assisted drainage collection), utilizing durable medical equipment (DME), 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
97607 **(E/I)**	Negative pressure wound therapy, (e.g., 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 **(E/I)**	total wound(s) surface area greater than 50 square centimeters

HCPCS Codes

Code	Description
A6550	Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories
A9272 **(E/I)**	Wound suction, disposable, includes dressing, all accessories and components, any type, each
E2402	Negative pressure wound therapy electrical pump, stationary or portable
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

ICD10 Codes

Code	Description
Various	

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*Key Article

KEY WORDS

Negative pressure wound therapy, PICO system, SNaP system, Topical negative pressure therapy, Vacuum Assisted Closure therapy

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) addressing Negative Pressure Wound Therapy Pumps (L33821). Please refer to the following website for Medicare Members:

[https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33821&DocID=L33821] accessed 08/05/24.

There is currently a Local Coverage Article (LCA) addressing Negative Pressure Wound Therapy Pumps (A52511). Please refer to the following website for Medicare Members:

[https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52511] accessed 08/05/24.