
Subject:	Vacuum Assisted Wound Therapy in the Outpatient Setting	Publish Date:	07/07/2021
Guideline #:	CG-DME-48	Last Review Date:	05/13/2021
Status:	New		

Description

This document addresses the use of vacuum assisted wound therapy (also known as negative pressure wound therapy or NPWT) in the outpatient setting for a variety of wounds, including such as ulcers related to pressure sores, venous or arterial insufficiency or neuropathy. These devices have several attributes that are used to differentiate them from each other, including being stationary vs. portable, if they are operated electrically vs. mechanically, and if they are reusable or disposable. Each device has some combination of these attributes.

Note: For additional information regarding wound care, please refer to:

- **[CG-MED-71 Chronic Wound Care in the Home or Outpatient Setting](#)**
- **[SURG.00011 Allogeneic, Xenographic, Synthetic and Composite Products for Wound Healing and Soft Tissue Grafting](#)**

Clinical Indications

Note: In some circumstances, the use of this treatment modality when initiated in the inpatient setting may not meet criteria for use in the outpatient setting.

Medically Necessary:

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Clinical UM Guideline

Vacuum Assisted Wound Therapy in the Outpatient Setting

Vacuum assisted wound therapy is considered medically necessary when the individual meets all of the criteria (A, B, and C) below:

A. A complete wound care program, which meets ALL of the requirements below, has been tried:

1. Documentation in the individual's medical record of evaluation, care, and wound measurements by a licensed medical professional; and
2. Application of dressings to maintain a moist environment; and
3. Debridement of necrotic tissue if present; and
4. Evaluation of and provision for adequate nutritional status; and
5. Underlying medical conditions (e.g., diabetes, venous insufficiency) are being appropriately managed; and

B. An eligible condition is documented (individual must meet one or more of the following):

1. Stage III or IV pressure ulcers (see key terms below) at initiation of vacuum assisted wound therapy, in individuals who meet ALL of the following:
 - a. The individual has been appropriately turned and positioned; and
 - b. The individual 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
 - c. The individual's moisture and incontinence have been appropriately managed; or
2. Neuropathic ulcers in individuals who meet BOTH of the following:
 - a. The individual has been on a comprehensive diabetic management program; and
 - b. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities; or
3. Ulcers related to venous or arterial insufficiency, in individuals who meet ALL of the following:
 - a. Compression bandages and/or garments have been consistently applied; and
 - b. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities; and
 - c. For initiation of therapy in the home setting, presence of the ulcer for at least 30 days; or
4. Dehisced wounds or wound with exposed hardware or bone; or

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Clinical UM Guideline

Vacuum Assisted Wound Therapy in the Outpatient Setting

5. Post sternotomy wound infection or mediastinitis; or
6. Complications of a surgically created wound where accelerated granulation therapy is necessary and cannot be achieved by other available topical wound treatment; and

C. The wound to be treated is free from all of the following absolute contraindications to vacuum assisted wound therapy:

1. Exposed anastomotic site; or
2. Exposed nerves; or
3. Exposed organs; or
4. Exposed vasculature; or
5. Malignancy in the wound; or
6. Necrotic tissue with eschar present; or
7. Non-enteric and unexplored fistulas; or
8. Untreated osteomyelitis.

Continued use of vacuum assisted wound therapy is considered medically necessary when:

A. Weekly assessment of the wound's dimensions and characteristics by a licensed health care professional is documented; and

A.B. Progressive wound healing is demonstrated.

Progressive wound healing is demonstrated.

Not Medically Necessary:

Continued use of vacuum assisted wound therapy is considered not medically necessary when the continuation of treatment criteria above have not been met.

Investigational and Not Medically Necessary:

Electrically powered Vacuum assisted wound therapy is considered investigational and not medically necessary for all other applications not meeting the medical necessity criteria above, including when any absolute contraindications to vacuum assisted wound therapy are present.

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Clinical UM Guideline

Vacuum Assisted Wound Therapy in the Outpatient Setting

Non-electrically powered vacuum assisted wound therapy (for example, the SNaPTM Wound Care Device) is considered investigational and not medically necessary for all conditions.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

97605

Negative pressure wound therapy (eg, 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

Negative pressure wound therapy (eg, 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 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 instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters [when specified as utilizing a battery-powered device]

97608

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

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Clinical UM Guideline

Vacuum Assisted Wound Therapy in the Outpatient Setting

instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters [when specified as utilizing a battery powered device]

HCPCS

A6550

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

A9272

Wound suction, disposable, includes dressing, all accessories and components, any type each [when specified as a battery powered disposable device]

E2402

Negative pressure wound therapy electrical pump, stationary or portable

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:

For the procedure codes listed above when criteria are not met for continuation of therapy.

When services are Investigational and Not Medically Necessary:

For the procedure codes listed above when criteria are not met or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

When services are also Investigational and Not Medically Necessary:

CPT

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 instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters [when specified as utilizing a manual device]

97608

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

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Vacuum Assisted Wound Therapy in the Outpatient Setting

instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters [when specified as utilizing a manual device]

HCPCS

A9272

Wound suction, disposable, includes dressing, all accessories and components, any type each [when specified as a manual device]

ICD-10 Diagnosis

All diagnoses

Discussion/General Information

The management and treatment of chronic wounds, including pressure ulcers, remains a challenge. Most chronic wounds will heal only if the underlying cause, such as venous stasis, pressure, or infection, is addressed. In addition, cleaning the wound to remove non-viable tissue, microorganisms and foreign bodies is essential to create the optimal conditions for either re-epithelialization or preparation for wound closure with skin grafts or flaps. Therefore, debridement, irrigation, whirlpool treatments and wet to dry dressings are common components of chronic wound care.

Vacuum assisted wound therapy is an adjunct to the basic principles of wound care described above. This technique involves applying initial continuous and subsequent intermittent topical negative pressure to an entire wound. The action removes excess fluid from the interstitial space of the wound, thereby enhancing vascular perfusion through vessels compressed by the excess fluid pressure. Additionally, it is believed that removal of excess fluid removes an accumulation of healing-inhibitory factors. Finally, mechanical stretching results in deformation of cellular bridges, which increases cellular proliferation, protein synthesis, and granulation tissue. The net result is accelerated wound closure by re-epithelialization or preparation for wound closure with suturing, skin grafts or flaps (delayed primary intention).

The currently available vacuum assisted wound therapy devices all have some combination of attributes which are used to differentiate them from each other. These attributes include being stationary vs. portable,

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Clinical UM Guideline

Vacuum Assisted Wound Therapy in the Outpatient Setting

being operated electrically vs. mechanically, and being reusable or disposable. Stationary devices are usually large and plug into an electrical socket for power. They are intended to be used either in the hospital or some other location where the individual being treated is not very mobile. Newly available portable devices are much lighterweigh less and are intended for the treatment of less severely illclinically stable individuals who are mobile. Some devices may operate electrically and others via a mechanical mechanism (for example, being spring loaded) to create the necessary vacuum for treatment. The vast majority of devices available currently are electrically operated. Finally, there are reusable vs. disposable devices. The aAavailable stationary devices are all reusable and used in conjunction with disposable items like bandages and tubing. The dDisposable devices are usually entirely disposable, and no portion of the devices is reused or saved.

NPWT is generally accepted for use in the outpatient setting for the select treatment of wounds, including pressure ulcers, neuropathic ulcers, ulcers related to venous or arterial insufficiency, dehisced wounds, post-sternotomy wounds, and surgically created wounds requiring accelerated granulation therapy, when a complete wound care program has been attempted, and no absolute contraindications to vacuum assisted wound therapy exist. Available evidence supportings the use of traditional electric NPWT systems includes , with multiple reasonably designed and conducted trials investigating the use of these devices have demonstratinged a benefit with regard to decreased infection, and complication rates, or some parameter of wound healing when compared to standard care. Several published randomized controlled trials (RCT) and comparative trials of NPWT using electrically powered devices have reported positive results according to some parameter of wound healing (Armstrong, 2005; Blume, 2008; Canaino, 2005; Costa, 2018; De Franzo, 2001; Doss, 2002; Eginton, 2003; Gupta, 2017; Seidel, 2020; Smid, 2017; Stannard, 2009; Stannard, 2012). Additionally, a number of many case series have reported positive resultssupportive data (Baillot, 2010; Ford, 2002; Garner, 2001; Hersh, 2001; Moisidis, 2004; Moues, 2004; O'Connor, 2005). When clinically appropriate, vacuum assisted wound therapy may also be applied using battery powered portable devices. Multiple reasonable designed andA number of conducted trials ofstudies evaluating battery powered NPWT have demonstrated a benefit with regard to decreased infection and complication rates when compared to standard of care for skin grafts, surgical wounds, traumatic wounds, and diabetic leg ulcers (Gabriel, 2013; Hudson, 2013; Kirsner, 2019; Pellino, 2013; Pellino, 2014; Selvaggi, 2014). The use of NPWT in pediatric populations has also been addressed in multiple studies (Baharestani, 2007; Caniano, 2005; Chen, 2017; Gabriel, 2009; Li, 2013; Mouës, 2007; Petkar, 2011; Visser, 2017; Yang 2017). At this time, available

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Clinical UM Guideline

Vacuum Assisted Wound Therapy in the Outpatient Setting

evidence also shows that the use of NPWT in pediatric populations results in an improvement in wound healing, and that age appears to have no impact on treatment outcomes.

Mechanically powered vacuum assisted wound therapy devices, also referred to as ultraportable vacuum therapy systems, (SNAP Wound Care Device, KCI USA, Inc., San Antonio, TX) utilizes specialized springs to create the vacuum needed for negative pressure wound therapy. The available data addressing this type of mechanically powered vacuum assisted wound therapy include is limited. Early literature included small studies that had high rates of lost to follow-up as well as bias due to lack of blinding or industry sponsored trials. The data from two trials evaluating several studies showing improved healing of neuropathic or venous stasis ulcers showed improved healing using NPWT though both trials were small with significant loss to follow up (Fong, 2010; Lerman, 2010). The results of other trials showed promising results with have demonstrated non-inferiority to standard NPWT devices for the treatment of lower extremity diabetic or venous stasis ulcers; though the studies also had loss to follow up and had small sample sizes (Armstrong, 2011; Armstrong, 2012; Bradbury, 2015; Marston, 2015). Cuomo and others (2017) evaluated the use of NANOVA™ Therapy System (KCI USA, Inc. San Antonio, TX) for the treatment of 10 individuals with chronic venous leg ulcers undergoing skin grafting. The device was well tolerated and contributed to successful engraftment after 14 days for 8 individuals, with 2 individuals requiring additional time for healing. Cuomo and colleagues (2021) performed a three part comparative analysis for ultraportable negative pressure wound therapy devices. The first phase evaluated the specifications of each device included in the study; the second phase enrolled 125 individuals with venous leg ulcers, traumatic wounds, diabetic ulcers, surgical wound diastases, and arteriopathic ulcers. The third phase was a systematic review on classic and portable negative pressure wound devices. This study evaluated the advantages and disadvantages of each device and did not compare wound-healing statistics since the wounds were not homogenous. The conclusion of this study is that each wound is unique and a the variety of devices allows the wound care treatment team to have options for the optimal match for successful healing.

Additional outpatient uses for NPWT have been evaluated for a variety of wounds such as traumatic wounds from dog bites and routine prophylactic use in postoperative settings (that is: for surgically created wounds without complications, where accelerated granulation therapy is not necessary or can be achieved by other available topical wound treatment). Rui-Feng and others (2016) published the results of an RCT

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Clinical UM Guideline

Vacuum Assisted Wound Therapy in the Outpatient Setting

investigating NPWT for serious dog bite wounds; this study found that infection rates were decreased for individuals treated with NPWT compared to sterile dressings (4.0% versus 9.1%, respectively). Due to a lack of additional credible published evidence, NPWT for the use in serious dog bite wounds is not yet a generally accepted standard of practice. Routine Prophylactic NPWT for postoperative care has been evaluated by a number of methodically flawed studies; however, many studies exhibit methodological flaws, including lack of standardized definitions for reporting adverse events or inclusion criteria, publication biases, and heterogeneity due to wide ranges of surgical procedures evaluated, and short follow-up (Cagney 2020; Curran, 2019; Fleming, 2018; Galiano, 2018; Gombert, 2020; Hyldig, 2019; Kenney, 2019; Saunders, 2021; Shiroky, 2020; Strugala; 2017; Zwanenburg 2020). Overall evidence for the effectiveness of NPWT on post-operative wound healing compared to standard care remains uncertain. Furthermore, evidence that prophylactic NPWT equivalence to standard care is lacking (Costa, 2020; De Vries, 2016; De Vries, 2017; Flynn, 2019; Karlakki, 2016; Meyer, 2020; O'Neill, 2020; Sexton, 2020; Tuuli, 2020). Norman and colleagues (2020) published the results of a Cochrane systematic review and concluded with moderate-certainty evidence that prophylactic NPWT reduced surgical site infections, however there was low-certainty evidence for the reduction of deaths or wound dehiscence. In addition, the evidence was low or very low for other secondary outcomes evaluated. There lacks a general acceptance and agreement from medical literature despite a number of published studies and meta-analysis evaluating for use of prophylactic NPWT for postoperative indications, data does not support routine use.

While NPWT is generally safe and well tolerated, complications can include bleeding, infection, pain, and organ damage. Complications are more likely to occur when NPWT is applied to individuals with contraindications to vacuum assisted wound therapy, such as exposed vital structures (for example, organs, blood vessels, vascular grafts), malignancy in the wound, necrotic tissue with eschar, non-enteric and unexplored fistulas, or untreated osteomyelitis.

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Clinical UM Guideline

Vacuum Assisted Wound Therapy in the Outpatient Setting

~~data from two trials evaluating neuropathic or venous stasis ulcers showed improved healing using NPWT though both trials were small with significant loss to follow up (Fong, 2010; Lerman, 2010). The results of other trials showed promising results with non-inferiority to standard NPWT devices for the treatment of lower extremity diabetic or venous stasis ulcers, though the studies also had loss to follow up and had small sample sizes (Armstrong, 2011; Armstrong, 2012; Bradbury, 2015; Marston, 2015). Cuomo and others (2017) evaluated the use of NANOVA™ Therapy System (KCI USA, Inc. San Antonio, TX) for the treatment of 10 individuals with chronic venous leg ulcers undergoing skin grafting. The device was well tolerated and contributed to successful engraftment after 14 days for 8 individuals, with 2 individuals requiring additional time for healing. Cuomo and colleagues (2021) performed a three part comparative analysis for ultraportable negative pressure wound therapy devices. The first phase evaluated the specifications of each device included in the study; the second phase enrolled 125 individuals with venous leg ulcers, traumatic wounds, diabetic ulcers, surgical wound diastases, and arteriopatric ulcers. The third phase was a systematic review on classic and portable negative pressure wound devices. This study evaluated the advantages and disadvantages of each device and did not compare wound healing statistics since the wounds were not homogenous. The conclusion of this study is that each wound is unique and the variety of devices allows the wound care treatment team to have options for the optimal match for successful healing.~~

Authoritative Organization Recommendations

In 2016 the Society for Vascular Surgery, the American Podiatric Medical Association, and the Society for Vascular Medicine released joint recommendations related to the management of diabetic foot wounds (Hingorani, 2016). In this document, they provide the following recommendation: “We suggest the use of negative pressure wound therapy for chronic diabetic foot wounds that do not demonstrate expected healing progression with standard or advanced wound dressings after 4 to 8 weeks of therapy (Grade 2B).”

Definitions

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

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Clinical UM Guideline

Vacuum Assisted Wound Therapy in the Outpatient Setting

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 Injury Advisory Panel, 2019): A pressure injury is localized damage to the skin and/or underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue.

Pressure ulcer stages:

Pressure Injury:

A pressure injury is localized damage to the skin and/or underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open

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Clinical UM Guideline

Vacuum Assisted Wound Therapy in the Outpatient Setting

ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue.

Stage 1 Pressure Injury: Non-blanchable erythema of intact skin

Intact skin with a localized area of non-blanchable erythema, which may appear differently in darkly pigmented skin. Presence of blanchable erythema or changes in sensation, temperature, or firmness may precede visual changes. Color changes do not include purple or maroon discoloration; these may indicate deep tissue pressure injury.

Stage 2 Pressure Injury: Partial-thickness skin loss with exposed dermis

Partial-thickness loss of skin with exposed dermis. The wound bed is viable, pink or red, moist, and may also present as an intact or ruptured serum-filled blister. Adipose (fat) is not visible and deeper tissues are not visible. Granulation tissue, slough and eschar are not present. These injuries commonly result from adverse microclimate and shear in the skin over the pelvis and shear in the heel. This stage should not be used to describe moisture associated skin damage (MASD) including incontinence associated dermatitis (IAD), intertriginous dermatitis (ITD), medical adhesive related skin injury (MRSI), or traumatic wounds (skin tears, burns, abrasions).

Stage 3 Pressure Injury: Full-thickness skin loss

Full-thickness loss of skin, in which adipose (fat) is visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough and/or eschar may be visible. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage and/or bone are not exposed. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury.

Stage 4 Pressure Injury: Full-thickness skin and tissue loss

Full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer. Slough and/or eschar may be visible. Epibole (rolled edges), undermining

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Clinical UM Guideline

Vacuum Assisted Wound Therapy in the Outpatient Setting

and/or tunneling often occur. Depth varies by anatomical location. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury.

Unstageable Pressure Injury: Obscured full-thickness skin and tissue loss

Full-thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because it is obscured by slough or eschar. If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed. Stable eschar (i.e. dry, adherent, intact without erythema or fluctuance) on an ischemic limb or the heel(s) should not be removed.

Deep Tissue Pressure Injury:

Persistent non-blanchable deep red, maroon or purple discoloration. Intact or non-intact skin with localized area of persistent non-blanchable deep red, maroon, purple discoloration or epidermal separation revealing a dark wound bed or blood filled blister. Pain and temperature change often precede skin color changes. Discoloration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly to reveal the actual extent of tissue injury, or may resolve without tissue loss. If necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle or other underlying structures are visible, this indicates a full thickness pressure injury (Unstageable, Stage 3 or Stage 4). Do not use DTPI to describe vascular, traumatic, neuropathic, or dermatologic conditions.

Medical Device Related Pressure Injury:

This describes an etiology. Medical device related pressure injuries result from the use of devices designed and applied for diagnostic or therapeutic purposes. The resultant pressure injury generally conforms to the pattern or shape of the device. The injury should be staged using the staging system.

Mucosal Membrane Pressure Injury:

Mucosal membrane pressure injury is found on mucous membranes with a history of a medical device in use at the location of the injury. Due to the anatomy of the tissue these injuries cannot be staged.

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Clinical UM Guideline

Vacuum Assisted Wound Therapy in the Outpatient Setting

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.

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Vacuum Assisted Wound Therapy in the Outpatient Setting

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Clinical UM Guideline

Vacuum Assisted Wound Therapy in the Outpatient Setting

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Vacuum Assisted Wound Therapy in the Outpatient Setting

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Index

ABThera™ Open Abdomen Negative Pressure Therapy

ActiV.A.C.® Therapy System

Avelle Negative Pressure Wound Therapy System

Engenex® Advanced NPWT System

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Clinical UM Guideline

Vacuum Assisted Wound Therapy in the Outpatient Setting

Exusdex™ Wound Drainage Pump

InfoV.A.C.® Therapy System

Invia Liberty Wound Therapy

NANOVA Therapy System

Nexa Negative Pressure Wound Therapy System

PICO Single Use Negative Pressure Wound Therapy System

Prevena™ Incision Management System

Prodigy™ NPWT System (PMS-800 and PMS-800V)

PRO-I™

PRO-II™

PRO-III™

RENASYS EZ™

RENASYS GO™

SNAP Wound Care Device

SVED® Wound Treatment Systems

UNO Negative Pressure Wound Therapy System

V.A.C.

V.A.C. ATS®

V.A.C. Freedom®

VAC Simplicity™

V.A.C.Ultá™

V.A.C.Via Negative Pressure Wound Therapy System

VAWC Device

Vacuum Assisted Wound Closure System

Venturi™ Negative Pressure Wound Therapy

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

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Clinical UM Guideline

Vacuum Assisted Wound Therapy in the Outpatient Setting

<u>Status</u>	<u>Date</u>	<u>Action</u>
New	<u>05/13/2021</u>	<u>Medical Policy & Technology Assessment Committee (MPTAC) review.</u> <u>Initial document development. Moved content of DME.00009 Vacuum Assisted Wound Therapy in the Outpatient Setting to a new clinical utilization management guideline document with the same title. <u>Added</u> <u>Removed</u> non-electrically powered vacuum assisted wound therapy to <u>Medically Necessary Clinical Indications</u> from the Not Medically Necessary Clinical Indications.</u>

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