

Protocol

Negative Pressure Wound Therapy in the Outpatient Setting

(10116)

Medical Benefit		Effective Date: 07/01/18	Next Review Date: 05/21
Preauthorization	No	Review Dates: 11/07, 09/08, 09/09, 09/10, 05/11, 05/12, 05/13, 05/14, 05/15, 05/16, 05/17, 05/18, 05/19, 05/20	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With diabetic lower-extremity ulcers or amputation wounds	Interventions of interest are: • Outpatient negative pressure wound therapy	Comparators of interest are: • Standard wound care	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With chronic pressure ulcers	Interventions of interest are: • Outpatient negative pressure wound therapy	Comparators of interest are: • Standard wound care	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With lower-extremity ulcers due to venous insufficiency	Interventions of interest are: • Outpatient negative pressure wound therapy	Comparators of interest are: • Compression therapy	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With burn wounds	Interventions of interest are: • Outpatient negative pressure wound therapy	Comparators of interest are: • Standard wound care	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With traumatic or surgical wounds	Interventions of interest are: • Outpatient negative pressure wound therapy	Comparators of interest are: • Standard wound care	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> • With any wound type (acute or nonhealing) 	Interventions of interest are: <ul style="list-style-type: none"> • Portable single-use outpatient negative pressure wound therapy 	Comparators of interest are: <ul style="list-style-type: none"> • Standard negative pressure wound therapy 	Relevant outcomes include: <ul style="list-style-type: none"> • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity

DESCRIPTION

Negative pressure wound therapy (NPWT) involves the use of negative pressure or suction device to aspirate and remove fluids, debris, and infectious materials from the wound bed to promote the formation of granulation tissue and wound healing.

SUMMARY OF EVIDENCE

For individuals who have diabetic lower-extremity ulcers or amputation wounds who receive outpatient NPWT, the evidence includes RCTs and systematic reviews of RCTs. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life (QOL), and treatment-related morbidity. There was a higher rate of wound healing and fewer amputations with NPWT, although the studies were at risk of bias due to lack of blinding. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have chronic pressure ulcers who receive outpatient NPWT, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. All trials are of low-quality and at high-risk of bias. Also, most study populations were treated in inpatient settings. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have lower-extremity ulcers due to venous insufficiency who receive outpatient NPWT, the evidence includes an RCT and a systematic review. The relevant outcomes are symptoms, change in disease status, morbid events, QOL quality of life, and treatment-related morbidity. A single RCT in patients with nonhealing leg ulcers who were treated with skin grafts found a faster rate of healing with NPWT when used in the inpatient setting. No studies were identified on the effectiveness of NPWT as a primary treatment for leg ulcers or for the use of NPWT in the outpatient setting. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have burn wounds who receive outpatient NPWT, the evidence includes RCTs, systematic reviews, and case series. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. An interim report of an RCT evaluating NPWT in partial-thickness burns, summarized in a Cochrane review, did not permit conclusions on the efficacy of NPWT for this indication. A separate RCT comparing NPWT with split-skin grafts in patients with full-thickness burns did not show differences in graft take and wound epithelialization. A retrospective case series reported functional outcomes for most patients who were treated with NPWT at a single-center. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have traumatic or surgical wounds who receive outpatient NPWT, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. There are limited data on NPWT as a primary treatment of partial-thickness burns. One RCT found no benefit of NPWT on graft take and wound epithelialization in patients with full-

thickness burns. NPWT showed no benefit in the treatment of patients with surgical wounds or skin grafts healing by primary intention, and a systematic review of NPWT for traumatic and surgical wounds found no differences between standard dressing and NPWT for any wound outcome measure. However, a small RCT has suggested that prophylactic NPWT may reduce the number of dressing changes and pain when used in an outpatient setting. A small retrospective study reported improved epithelialization with NPWT in patients free of comorbidities. Additional study in larger samples is needed to evaluate this outcome measure. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have any wound type (acute or nonhealing) who receive portable single-use outpatient NPWT, the evidence includes systematic reviews and RCTs. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. The evidence includes an RCT of the PICO Single Use Negative Pressure Wound Therapy System, an RCT of the non-powered Smart Negative Pressure Wound Care System, and a pseudorandomized study of the Prevena Incision Management System. The PICO device was studied in an adequately powered but unblinded RCT of combined in- and outpatient use following total joint arthroplasty; also, a 2017 RCT compared the PICO device with standard dressing following abdominal surgery. Results showed some benefits, though not statistically significant. One study with the Smart Negative Pressure non-powered Wound Care System showed noninferiority to a vacuum-assisted closure device. However, interpretation of this trial is limited by a high loss to follow-up and lack of a control group treated with dressings. These studies are insufficient to draw conclusions about its efficacy. Well-designed comparative studies with larger numbers of patients are needed to determine the effects of these technologies with greater certainty. The evidence is insufficient to determine the effects of the technology on health outcomes.

Overall, the evidence from comparative clinical trials has demonstrated there is a subset of problematic wounds for which the use of NPWT may provide a significant clinical benefit. However, due to clinical variability and limited data, it is not possible to determine prospectively which wounds are most likely to respond favorably to NPWT. In addition, clinical input supports a therapeutic trial of NPWT for chronic pressure ulcers that have failed to heal, for traumatic or surgical wounds that have failed to close when there is exposed bone, cartilage, tendon, or foreign material within the wound, and for nonhealing wounds in patients with underlying clinical conditions known to negatively impact wound healing. Therefore, a therapeutic trial of NPWT of not less than 14 days may be considered medically necessary for chronic wounds that have failed to heal, despite intense conventional wound therapy for at least 90 days, or for wounds of at least 30 days that have a high probability of failure to heal due to compounding factors involving the wound and the patient. For continued use of NPWT beyond 14 days to meet criteria for medical necessity, there must be objective evidence of wound healing, such as the development of healthy granulation tissue and progressive wound contracture.

POLICY

INITIATION OF POWERED NEGATIVE PRESSURE WOUND THERAPY:

An initial therapeutic trial of not less than two weeks using a powered negative pressure wound therapy (NPWT) system, as part of a comprehensive wound care program that includes controlling factors (e.g., diabetes, nutrition, relief of pressure) may be considered **medically necessary** in the following indications:

- Chronic (greater than 90 days) stage III or IV pressure ulcers that have failed to heal despite optimal wound care when there is high-volume drainage that interferes with healing and/or when standard dressings cannot be maintained due to anatomic factors; OR
- Wounds in patients with underlying clinical conditions that are known to negatively impact wound healing, which are non-healing (at least 30 days), despite optimal wound care. (Examples of underlying conditions include, but are not limited to diabetes, malnutrition, small vessel disease, and morbid obesity. Malnutrition, while a risk factor, must be addressed simultaneously with the NPWT); OR

- Traumatic or surgical wounds where there has been a failure of immediate or delayed primary closure AND there is exposed bone, cartilage, tendon, or foreign material within the wound.

Continuation of Powered NPWT

Continuation of the powered NPWT system, as part of a comprehensive wound care program, may be considered **medically necessary** following an initial therapeutic trial of not less than two weeks if the treatment trial has resulted in documented objective improvements in the wound and if there is ongoing objective improvement during subsequent treatment. Objective improvements in the wound should include the development and presence of healthy granulation tissue, progressive wound contracture and decreasing depth, and/or the commencement of epithelial spread from the wound margins.

Continuation of the powered NPWT system is considered **not medically necessary** when any of the following occurs:

- The therapeutic trial or subsequent treatment period has not resulted in documented objective improvement in the wound, OR
- The wound has developed evidence of wound complications contraindicating continued NPWT, OR
- The wound has healed to an extent that either grafting can be performed or the wound can be anticipated to heal completely with other wound care treatments.

Therapeutic trials of powered NPWT systems for the treatment of other acute or chronic wounds except as noted above are considered **not medically necessary**.

Use of non-powered NPWT systems for the treatment of acute or chronic wounds is **investigational**.

POLICY GUIDELINES

Contraindications to the use of NPWT systems include the following conditions as noted by a November 2009 U.S. Food and Drug Administration (FDA) alert: necrotic tissue with eschar, untreated osteomyelitis, nonenteric and unexplored fistulas, malignancy in the wound, exposed nerve, exposed anastomotic site, and exposed organ.

In a 2011 update, the FDA noted additional deaths and injury reports with NPWT since 2009. Although rare, these complications can occur wherever NPWT systems are used, including hospitals, long-term care facilities, and at home. Bleeding was the cause of the most serious adverse events, including deaths. Most reports of wound infection were related to the retention of dressing pieces in the wounds. FDA recommendations for healthcare providers include the following: select patients for NPWT carefully knowing that NPWT systems are contraindicated for certain wound types, and patient risk factors must be thoroughly considered before use; assure that the patient is monitored frequently in an appropriate care setting by a trained practitioner; be aware of complications associated with dressing changes such as infection and bleeding; be vigilant for potentially life-threatening complications, such as bleeding, and be prepared to take prompt action if they occur. The FDA reported that the safety and effectiveness of NPWT systems in newborns, infants and children has not been established at this time and currently, there are no NPWT systems cleared for use in these populations.

Continuation of healing during use of the NPWT system should be monitored on a frequency not less than every 14 days.

Complete healing of a wound would normally be anticipated if all bone, cartilage, tendons, and foreign material were completely covered, healthy granulation were present to within five mm of the surface, and the wound edges were reduced to two cm in width or diameter.

Powered NPWT systems should be used as part of a comprehensive wound care program that includes attention to other factors that impact wound healing such as diabetes control, nutritional status and relief of pressure.

The focus of these policy statements and guidelines is for use of NPWT in the outpatient setting.

MEDICARE ADVANTAGE

For Medicare Advantage a NPWT pump and supplies are **medically necessary** when the following criterion is met:

The patient has a chronic Stage III or IV pressure ulcer*, neuropathic (for example, diabetic) ulcer, venous or arterial insufficiency ulcer, or a chronic (being present for at least 30 days) ulcer of mixed etiology. A complete wound therapy program described by criterion 1 and criteria 2, 3, or 4, as applicable depending on the type of wound, must have been tried or considered and ruled out prior to application of NPWT.

1. For all ulcers or wounds, the following components of a wound therapy program must include a minimum of all of the following general measures, which should either be addressed, applied, or considered and ruled out prior to application of NPWT:
 - a. Documentation in the patient's medical record of evaluation, care, and wound measurements by a licensed medical professional, and
 - b. Application of dressings to maintain a moist wound environment, 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. The patient has been appropriately turned and positioned, and
 - b. The patient has used a support surface for pressure ulcers on the posterior trunk or pelvis, and
 - c. The patient's moisture and incontinence have been appropriately managed.
3. For neuropathic (for example, diabetic) ulcers:
 - a. The patient has been on a comprehensive diabetic management program, 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 consistently applied, and
 - b. Leg elevation and ambulation have been encouraged.
5. Surgically created wounds and traumatic wounds that met the following criteria in the inpatient setting and need treatment beyond discharge to the home setting: Complications of a surgically created wound (for example dehiscence) or a traumatic wound (for example, pre-operative flap or graft) where there is documentation of the medical necessity for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments (for example, where other medical conditions of the patient will not allow for healing times achievable with other topical wound treatments).

If criterion above is not met, the NPWT pump and supplies are **not medically necessary**.

NPWT pumps need to be capable of accommodating more than one wound dressing set in the case when the patient has multiple wounds. In other words, it would be **not medically necessary** for more than one NPWT pump at a time.

An NPWT pump and supplies are **not medically necessary** for the following:

- Stage I or II pressure ulcers;
- The presence in the wound of necrotic tissue with eschar, if debridement is not attempted;
- Osteomyelitis within the vicinity of the wound that is not concurrently being treated with intent to cure;
- Cancer present in the wound;
- Active bleeding;
- The presence of an open fistula to an organ or body cavity within the vicinity of the wound.

Continued medical appropriateness:

For wounds and ulcers described above, once placed on an NPWT pump and supplies, in order to continue to be considered **medically necessary** a licensed medical professional must do the following:

1. On a regular basis:
 - a. directly assess the wound(s) being treated with the NPWT pump, and
 - b. supervise or directly perform the NPWT dressing changes, and
2. On at least a monthly basis, document changes in the ulcer's dimensions and characteristics.

If these criteria are not fulfilled, continued coverage of the NPWT pump is **not medically necessary**.

An NPWT pump and supplies are **not medically necessary** with any of the following, whichever occurs earliest:

- A) Continued medical appropriateness criteria are no longer met,
- B) In the judgment of the treating physician, adequate wound healing has occurred to the degree that NPWT may be discontinued,
- C) Any measurable degree of wound healing has failed to occur over the prior month. Wound healing is defined as improvement occurring in either surface area (length times width) or depth of the wound,
- D) Four (4) months (including the time NPWT was applied in an inpatient setting prior to discharge to the home) have elapsed using an NPWT pump in the treatment of the most recent wound,
- E) Once equipment or supplies are no longer being used for the patient, whether or not by the physician's order.

* The staging of pressure ulcers used in this protocol is based on the National Pressure Ulcer Advisory Panel (NPUAP) Pressure Injury Stages.

BACKGROUND

CHRONIC WOUNDS

Management

The management and treatment of chronic wounds, including decubitus ulcers, is challenging. Most chronic wounds will heal only if the underlying cause (i.e., venous stasis, pressure, infection) is addressed. Also, cleaning the wound to remove nonviable tissue, microorganisms, and foreign bodies is essential to create optimal condi-

tions for either re-epithelialization (i.e., healing by secondary intention) or preparation for wound closure with skin grafts or flaps (i.e., healing by primary intention). Therefore, debridement, irrigation, whirlpool treatments, and wet-to-dry dressings are common components of chronic wound care.

Negative pressure wound therapy (NPWT) involves the use of a negative pressure therapy or suction device to aspirate and remove fluids, debris, and infectious materials from the wound bed to promote the formation of granulation tissue. The devices may also be used as an adjunct to surgical therapy or as an alternative to surgery in a debilitated patient. Although the exact mechanism has not been elucidated, it is hypothesized that negative pressure contributes to wound healing by removing excess interstitial fluid, increasing the vascularity of the wound, reducing edema, and/or creating beneficial mechanical forces that lead to cell growth and expansion.

A non-powered (mechanical) NPWT system has also been developed; the Smart Negative Pressure Wound Care System is portable and lightweight (3 oz) and can be worn underneath clothing. This system consists of a cartridge, dressing, and strap; the cartridge acts as the negative pressure source. The system is reported to generate negative pressure levels similar to other NPWT systems. This system is fully disposable.

The focus of this evidence review is the use of NPWT in the outpatient setting. It is recognized that patients may begin using the device in the inpatient setting as they transition to the outpatient setting.

REGULATORY STATUS

Negative pressure therapy or suction devices cleared by the FDA for treating chronic wounds include, but are not limited to: Vacuum-Assisted Closure® Therapy (V.A.C., also known as negative pressure wound therapy; KCI); Versatile 1™ (V1) Wound Vacuum System (Blue Sky Medical), RENASYS™ EZ PLUS (Smith & Nephew), Foryou NPWT NP32 Device (Foryou Medical Electronics), and PICO Single Use Negative Pressure Wound Therapy System (Smith & Nephew).

Portable systems include the RENASYS™ GO (Smith & Nephew), XLR8 PLUS (Genadyne Biotechnologies), extriCARE® 2400 NPWT System (Devon Medical), the V.A.C. Via™ (KCI), and the PICO Single Use Negative Pressure Wound Therapy System (Smith & Nephew). The Prevena™ Incision Management System (KCI) is designed specifically for closed surgical incisions.

A nonpowered NPWT device, the SNaP® Wound Care System (Spiracur, acquired by Acclity in 2015), is a class II device requiring notification to market but not having the FDA premarket approval. In 2009, it was cleared for marketing by the FDA through the 510(k) pathway (K081406) and is designed to remove small amounts of exudate from chronic, traumatic, dehisced, acute, or subacute wounds and diabetic and pressure ulcers.

NPWT devices with instillation include the V.A.C. VERAFLOR™ Therapy device (KCI/Aclity). It was cleared for marketing in 2011 by the FDA through the 510(k) pathway (K103156) and is designed to allow for controlled delivery and drainage of topical antiseptic and antimicrobial wound treatment solutions and suspensions.

No NPWT device has been cleared for use in infants and children.

In November 2009, the FDA issued an alert concerning complications and deaths associated with NPWT systems. An updated alert was issued in February 2011.¹

FDA product code: OMP.

RELATED PROTOCOLS

Autologous Platelet-Derived Growth Factors for Wound Healing and Other Non-Orthopedic Conditions

Bioengineered Skin and Soft Tissue Substitutes

Electrostimulation and Electromagnetic Therapy for Treating Wounds

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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60. National Government Services, Inc. (Primary Geographic Jurisdiction 06 & K - Illinois, Minnesota, Wisconsin, Connecticut, New York - Entire State, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont) Local Coverage Determination (LCD): Outpatient Physical and Occupational THERAPY Services (L33631), Revision Effective Date for services performed on or after 01/01/2020.
61. Noridian Healthcare Solutions, LLC, (Jurisdiction A - New York - Entire State, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, District of Columbia, Delaware, Maryland, New Jersey, Pennsylvania) Local Coverage Determination (LCD): Suction Pumps (L33612), Revision Effective Date For services performed on or after 01/01/2020.