LifeWise
Health Plan of Washington

# MEDICAL POLICY – 1.01.508

# Negative Pressure Wound Therapy (NPWT) Devices

BCBSA Ref. Policy: 1.01.16

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|---|---|---|
| Effective Date: | Sep. 4, 2026 | RELATED MEDICAL POLICIES: |
| Last Revised: | May 12, 2026 | 2.01.57 Electrostimulation and Electromagnetic Therapy for Treating Wounds |
| Replaces: | N/A | 7.01.113 Bioengineered Skin and Soft Tissue Substitutes |

**Select a hyperlink below to be directed to that section.**

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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## Introduction

Negative pressure wound therapy (NPWT) devices, also known as wound vacuums, are medical tools intended to help wounds heal faster. These devices use gentle suction to remove fluids and infection from a wound, which helps keep the area clean and promotes the growth of healthy tissue. A special dressing is placed over the wound and connected to a small pump that creates the suction. NPWT is often used for large or hard-to-heal wounds, such as those from surgery, injuries, or chronic conditions like diabetic ulcers or pressure sores. This policy describes when NPWT devices may be considered medically necessary.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## Policy Coverage Criteria

| Service | Medical Necessity |
|---|---|
| **Initiation of powered negative pressure wound therapy (97605, 97606)** | **An initial therapeutic trial of not less than 2 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 adults for ANY of the following indications:**<br>• Chronic (greater than 90 days) stage III or IV pressure ulcers (see Related Information) that have failed to heal despite optimal wound care<br>**AND**<br>• When there is high-volume drainage* that interferes with healing and/or when standard dressings cannot be maintained due to anatomic factors<br>• **OR**<br>• Wounds in individuals with underlying clinical conditions that are known to negatively impact wound healing, which are nonhealing (at least 30 days), despite optimal wound care<br>  ○ Examples of underlying conditions include, but are not limited to diabetes, malnutrition, small vessel disease**, and morbid obesity***<br>  ○ Malnutrition, while a risk factor, must be addressed simultaneously with the NPWT<br>• **OR**<br>• Traumatic or surgical wounds where there has been a failure of immediate or delayed primary closure<br>**AND**<br>• There is exposed bone, cartilage, tendon, or foreign material within the wound<br><br>*High-volume drainage is defined as exudate exceeding 150–200 mL/day that overwhelms NPWT dressings, breaks seal integrity, and hinders healing.<br>**Small vessel disease is defined as microvascular damage that restricts perfusion and impairs NPWT effectiveness.<br>*** Morbid obesity that negatively affects NPWT is defined as BMI ≥40 kg/$m^2$ with poor perfusion and elevated wound complication risk. |

| Service | Medical Necessity |
|---|---|
| **Continuation of powered negative pressure wound therapy (97605, 97606)** | **Continuation of the powered NPWT system, as part of a comprehensive wound care program, may be considered medically necessary in adults following an initial 2-week therapeutic trial with ALL of the following criteria are met:**<br>• If the treatment trial has resulted in documented objective improvements in the wound<br>**AND**<br>• If there is an ongoing objective improvement during subsequent treatment<br>  ○ Objective improvements in the wound should include the development and presence of at least ALL of the following:<br>  ▪ Healthy granulation tissue<br>  ▪ Progressive wound contracture with decreasing depth<br>  ▪ Commencement of epithelial spread from the wound margins<br><br>**Continuation of the powered NPWT system is considered not medically necessary when ANY of the following occurs:**<br>• The therapeutic trial or subsequent treatment period has not resulted in documented objective improvement in the wound<br>**OR**<br>• The wound has developed evidence of wound complications contraindicating continued NPWT<br>**OR**<br>• The wound has healed to the 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** | **Therapeutic trials of powered NPWT systems for the treatment of other acute or chronic wounds that do not meet the above criteria are considered not medically necessary.** |

| Service | Investigational |
|---|---|
| **Single use NPWT systems (powered or non-powered) (97607, 97608)** | **Use of single-use NPWT systems (powered or nonpowered) is considered investigational for the treatment of acute or chronic wounds, including but not limited to any of the following wound types:**<br>• Diabetic<br>• Venous<br>• Surgical<br>• Traumatic wounds |
| **Use of NPWT systems in young children** | **Use of NPWT systems is considered investigational for individuals aged 11 years and under.** |

| Length of Approval | |
|---|---|
| **Approval** | **Criteria** |
| **Initial authorization** | **Initial therapeutic trial of using a powered negative pressure wound therapy (NPWT) system, as part of a comprehensive wound care program when criteria are met may be approved for 30-days.** |
| **Re-authorization criteria** | **Continuation of the powered NPWT system, as part of a comprehensive wound care program, may be approved for another 30-day time period with documented objective improvements in the wound.** |

## Documentation Requirements

**The patient's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:**

- Office visit notes that contain the relevant history and physical
- **AND**
- For the INTIAL two-week trial of powered NPWT documentation must include the following:
  - Provider documentation for the reason powered NPWT is required due to ANY of the following
    - Documentation of Stage III or Stage IV pressure ulcers
      - present greater than 90 days
      - failed to heal despite optimal wound care **OR**

## Documentation Requirements

- Presence of high-volume drainage that documented to
  - interferes with healing **AND/OR**
- When standard dressings cannot be maintained due to anatomic factors.

- **OR**
  - Provider documentation for the reason powered NPWT is required due to ANY of the following:
    - Non-healing wound for at least 30 days despite optimal wound care in any individual who has ANY of the following clinical conditions known to negatively impact wound healing:
      - Diabetes
      - Malnutrition
      - Small vessel disease
      - Morbid obesity
      - Malnutrition (must document treatment simultaneous with the NPWT)
  - **OR**
    - Traumatic or surgical wounds where there has been a failure of immediate or delayed primary closure
  - **OR**
    - There is exposed bone cartilage, tendon, or foreign material within the wound

- For the CONTINUATION of the powered NPWT as the follow up after the initial two-week trial of powered NPWT, documentation must include the following:
  - If the initial treatment trial has resulted in documented objective improvements in the wound as evidenced by AT LEAST ONE of the following:
    - Healthy granulation tissue
    - Progressive wound contracture and decreasing depth
    - Commencement of epithelial spread from the wound margins

# Coding

| Code | Description |
|---|---|
| **CPT** | |
| 97605 | Negative pressure wound therapy (e.g., vacuum-assisted drainage collection), utilizing durable medical equipment (DME), including topical application(s), wound assessment, |

| Code | Description |
|---|---|
| | 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 (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 greater than 50 square centimeters |
| 97607 | 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 | 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 greater than 50 square centimeters |
| **HCPCS** | |
| A6550 | Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories |
| A9272 | Wound suction, disposable, includes dressing and 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 |

**Note**: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information

## Definition of Terms

**Stage I pressure ulcers** affect the upper layer of the skin with no skin breaks

**Stage II pressure ulcers** have a break in the top two layers of the skin

**Stage III pressure ulcers** affect the top two layers of skin, as well as fatty tissue

**Stage IV pressure ulcers** are deep wounds that may impact muscle, tendons, ligaments, and bone

## Contraindications and Considerations

Contraindications to the use of negative pressure wound therapy (NPWT) systems include the following conditions as noted in a 2009 US Food and Drug Administration (FDA) alert: necrotic tissue with eschar, untreated osteomyelitis, nonenteric and unexplored fistulae, 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. Recommendations for health care providers include the following: select individuals for NPWT carefully knowing that NPWT systems are contraindicated for certain wound types, and individual risk factors must be thoroughly considered before use; assure that the individual 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 had not been established 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 of 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 5 mm of the surface, and the wound edges were reduced to 2 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 the use of NPWT in the outpatient setting.

## Consideration of Age

NPWT systems are only FDA approved for use in adolescents and adults aged 12 years and older. NPWT systems are not FDA approved in newborns, infants and children ages newborn to less than 12 years.

# Evidence Review

## Description

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

## Background

### *Chronic Wounds*

#### Management

The management and treatment of chronic wounds, including decubitus ulcers, is challenging. Furthermore, certain racial and ethnic groups, including African Americans, Hispanics, and Native Americans, experience higher diabetes prevalence, contributing to disparities in the risk for diabetic ulcers; these disparities are exacerbated when inequalities in access to health care result in delayed diagnosis and management.

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 conditions 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 nonpowered (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.

## Summary of Evidence

For individuals who have diabetic lower-extremity ulcers or amputation wounds who receive outpatient negative pressure wound therapy (NPWT), the evidence includes systematic reviews of randomized controlled trials (RCTs). 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 an improvement in the net health outcome.

For individuals who have diabetic lower-extremity ulcers or amputation wounds who receive portable, single-use outpatient NPWT, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. A 2019 RCT compared the PICO device with standard NPWT. In this study, the PICO device demonstrated noninferiority for wound area reduction. A statistically significant benefit in

complete wound closure was noted for patients with diabetic foot ulcers, but was not duplicated in the per protocol population due to a high number of exclusions. One study of the simplified negative pressure wound therapy (SNaP) System showed noninferiority to a vacuum-assisted closure (V.A.C.) device for wound size reduction. No significant difference in complete wound closure was reported. Interpretation of this study is limited by a high loss to follow-up. Well-designed comparative studies with larger numbers of patients powered to detect differences in complete wound closure are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic pressure ulcers who receive outpatient NPWT, the evidence includes RCTs and systematic reviews. 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 that the technology results in an improvement in the net health outcome.

For individuals who have lower-extremity ulcers due to venous insufficiency who receive outpatient NPWT, the evidence includes an RCT and a systematic review. Relevant outcomes are symptoms, change in disease status, morbid events, QOL, 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 that the technology results in an improvement in the net health outcome.

For individuals who have lower-extremity ulcers due to venous insufficiency who receive portable, single-use outpatient NPWT, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. A 2019 RCT compared the PICO device with standard NPWT. In this study, the PICO device demonstrated noninferiority for wound area reduction. No significant benefit in complete wound closure was found in patients with venous ulcers. One study of the SNaP System showed noninferiority to a V.A.C. device for wound size reduction. A subgroup analysis of this study found a significant difference in complete wound closure for patients with venous ulcers. However, interpretation of this study is limited by a high loss to follow-up and lack of a control group treated with standard dressings. Well-designed comparative studies with larger numbers of patients powered to detect differences in complete wound closure are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have burn wounds who receive outpatient NPWT, the evidence includes RCTs, systematic reviews, and case series. 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 good functional outcomes for most patients who were treated with NPWT at a single center. A meta-analysis of international trials found that NPWT was associated with faster healing times; however, the analysis was limited by substantial heterogeneity, inconsistent intervention protocols, and a moderate risk of bias across several studies. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have traumatic or surgical wounds who receive NPWT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. Systematic reviews of RCTs in patients with surgical wounds have generally found lower risk of surgical site infection (SSI); however, many studies are limited to short-term use of NPWT limiting applicability to the outpatient setting. For patients with traumatic wounds, a Cochrane review failed to find significant improvement in patients treated with NPWT. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have traumatic or surgical wounds who receive portable, single-use outpatient NPWT, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. The PICO device was studied in an adequately powered but unblinded RCT of combined in- and outpatient use after total joint arthroplasty, and 2 single-center RCTs of combined in- and outpatient use after cesarean delivery in women with obesity or other risk factors for poor wound healing. The evidence base for the Prevena System in the outpatient setting is not sufficiently robust for conclusions on efficacy to be drawn. Well-designed comparative studies with larger numbers of patients treated in an outpatient setting are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**Additional Information**

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.

## Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in **Table 1**.

## Table 1. Summary of Key Trials

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| **Ongoing** | | | |
| **NCT05389410** | Comparison of Surgical Wound Healing and Complications Following Revision Hip and Knee Replacements, Utilising a 7-day Versus 14-day Negative Pressure Wound Therapy (NPWT) Dressing. A Randomised Controlled Trial | 164 | Feb 2027 |
| **NCT05615844** | A Randomized Controlled Trial Comparing Antibiotic Cement Bead Pouch Versus Negative Pressure Wound Therapy for the Management of Severe Open Tibia Fracture Wounds | 312 | Oct 2027 |
| **NCT01913132** | PICO Versus Standard Dressing Above Groin Incisions After Vascular Surgery - A Prospective Randomized Trial | 644 | Dec 2026 |
| **Unknown Status** | | | |

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| NCT05877378 | Efficacy of PICO Single-use System in Chronic Ulcers | 42 | Apr 2024 |
| NCT05064696 | Prospective Comparison of Wound Complications After Anterior Total Ankle Arthroplasty With and Without PICO Negative Pressure Incisional Dressing | 150 | Sep 2025 |
| NCT05071443 | VACuum-Assisted Closure for Necrotizing Soft Tissue infecTIONs | 130 | Jun 2025 |
| NCT03773575[a] | Evaluation of Closed Incision Negative Pressure Dressing (PREVENA) to Prevent Lower Extremity Amputation Wound Complications (PREVENA-AMP) | 440 | Aug 2024 |
| NCT02813161 | A Real World, Observational Registry of Diabetic Foot Ulcers and Quality of Care in Clinical Practice (DFUR) | 10,000 | Feb 2025 |
| **Unpublished** | | | |
| NCT03414762 | PICO Negative Pressure Wound Therapy in Obese Women Undergoing Elective Cesarean Delivery | 153 | Sep 2022 |
| NCT04584957 | Prophylactic Negative Pressure Wound Therapy in Gynecologic Oncology: a Prospective Controlled Randomized Trial (GO-VAC) | 196 | Sep 2021 |
| NCT03948412 | Negative Pressure Wound Therapy (PREVENA) Versus Standard Dressings for Incision Management After Renal Transplant (IMPART) | 500 | Sep 2021 |
| NCT01191567 | Negative Pressure Wound Therapy. Therapy Effects and the Impact on the Patient's Quality of Life | 200 | Terminated |
| NCT02195310[a] | The Use of Prevena Incision Management System on Clean Closed Sternal Midline Incisions in Subjects at High Risk for Surgical Site Occurrences | 342 | Terminated |

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

## Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

### *2010 Input*

In response to requests, input was received from 2 physician specialty societies and 3 academic medical centers while this policy was under review in 2010. The input was near uniform in support of a therapeutic trial of negative pressure wound therapy (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. Most input affirmed that therapeutic trials of NPWT for other acute or chronic wounds would not be medically necessary.

## Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

## *American Academy of Orthopaedic Surgeons*

The American Academy of Orthopaedic Surgeons (AAOS) 2022 guidelines for prevention of surgical site infections after major extremity trauma included recommendations for NPWT.[45] 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.

## *American College of Physicians*

In 2015, the American College of Physicians published guidelines (now inactive) on the treatment of pressure ulcers.[46] The guidelines stated there was low-quality evidence that the overall treatment effect of NPWT did not differ from the standard of care. Of note, the American College of Physicians considers these guidelines inactive since they are more than 5 years old.

## *Association for the Advancement of Wound Care*

In 2010, the Association for the Advancement of Wound Care (AAWC) published guidelines on the care of pressure ulcers. Negative pressure wound therapy was included as a potential second-line intervention if first-line treatments did not result in wound healing (level B evidence). The guidelines indicated that patients must be selected carefully for this procedure. The guidelines were updated in 2014 with additional validation.[47]

In 2010, the AAWC published guidelines on the care of venous ulcers.[47] The guidelines listed NPWT as a potential adjunctive therapy if conservative therapy does not work in 30 days. The guidelines noted there is limited evidence for NPWT (level B) compared with other adjunctive therapies.

## *International Multidisciplinary Consensus Recommendations*

Willy et al (2017) presented evidence-based consensus guidelines on the use of closed incision negative pressure therapy (ciNPT) following surgery.[48] Among the studies found were 100 randomized controlled studies on ciNPT, most of which found an association between the use of

ciNPT and improved outcomes. Based on the evidence, the consensus panel recommended that surgeons evaluate risk in patients before surgery to determine whether patient comorbidities (i.e., obesity or diabetes) or the nature of the surgery presents an increased danger of infection. In such cases, the panel recommended the use of ciNPT.

## *Infectious Diseases Society of America and International Working Group on the Diabetic Foot*

A 2023 guideline from the Society for the diagnosis and treatment of diabetic-related foot infections (DFIs) makes the following recommendation relevant to NPWT: "We suggest *not* using the following treatments to address DFIs: (a) adjunctive granulocyte colony-stimulating factor (G-CSF) treatment or (b) topical antiseptics, silver preparations, honey, bacteriophage therapy, or negative-pressure wound therapy (with or without instillation)."[49] This was graded as a conditional recommendation with low-quality evidence.

## *Wound Healing Society*

The 2023 Wound Healing Society (WHS) guideline for the treatment of pressure ulcers makes the following recommendations:[50]

"Incisional negative pressure wound therapy (iNPWT) may reduce post-operative complications after flap reconstruction for pressure ulcers."

"Negative pressure wound therapy (NPWT) is a safe and effective treatment for chronic stage III or IV pressure ulcers."

The guideline does not provide further information on the outpatient use of NPWT devices.

## *National Institute for Health and Care Excellence*

In 2013, NICE issued guidance on NPWT for surgical wounds, concluding that "current evidence on the safety and efficacy of negative pressure wound therapy (NPWT) for the open abdomen is adequate to support the use of this procedure."[51]

A 2015 NICE guidance on diabetic foot problems, updated in October 2019, has recommended consideration of NPWT after surgical debridement for diabetic foot ulcers on the advice of the

multidisciplinary foot care service.[52] It was noted that the evidence reviewed for NPWT was limited and of low quality, and that it would be useful to have more evidence for this commonly used treatment.

In 2014, NICE issued guidance on the prevention and management of pressure ulcers.[53] The guidance stated, "Do not routinely offer adults negative pressure wound therapy to treat a pressure ulcer, unless it is necessary to reduce the number of dressing changes (for example, in a wound with a large amount of exudate)." Also, the guidance did not recommend NPWT for neonates, infants, or children.

A 2019 NICE guidance recommends the use of the PICO7 negative pressure wound dressing for closed surgical incisions due to their association with fewer surgical site infections and seromas compared to standard wound dressings.[54] The device is considered an option for those who are at high risk for surgical site infections, which may be driven by several factors (e.g., age, underlying illness, obesity, smoking, wound classification, and site and complexity of procedure). The device is recommended for those with low to moderate levels of wound exudate who will require infrequent dressing changes.

A 2021 NICE guidance on cesarean birth recommends considering the use of NPWT for women with a body mass index ≥35 kg/$m^2$ to reduce the risk of wound infections.[55] Routine use of NPWT following cesarean delivery is not recommended. These recommendations were unchanged in a 2025 update to this guidance.

A 2021 NICE guidance states that while the V.A.C. Veraflo Therapy system shows promise in the treatment of acute infected or chronic non-healing wounds, there is not enough high-quality evidence to support the case for routine adoption.[56] The guidance recommends research in the form of an RCT comparing the V.A.C. Veraflo Therapy system (NPWT with wound instillation) to NPWT alone.

## Medicare National Coverage

There is no national coverage determination.

## Regulatory Status

Negative pressure therapy or suction devices cleared by the US Food and Drug Administration (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; 3M/KCI); Versatile 1 (V1) Wound Vacuum System (Blue Sky Medical), RENASYS EZ PLUS (Smith & Nephew), Foryou NPWT NP32 Device (Foryou Medical Electronics), SVED (Cardinal Health), 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), NPWT PRO to GO (Cardinal Health), 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 (now SNAP Therapy System) (3M/ previously Spiracur, acquired by Acelity in 2015), was cleared for marketing by the FDA in 2009 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.

Negative pressure wound therapy devices with instillation include the V.A.C. VERAFLO Therapy device (3M/KCI/Acelity). 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. It is to be used with the V.A.C. Ulta unit, which is commercially marketed for use in the hospital setting. Instillation is also available with Simultaneous Irrigation Technology tubing sets (Cardinal Health) for use with Cardinal Health SVED and PRO NPWT devices, however, its use is not indicated for use in a home care setting (K161418).

No NPWT device has been FDA cleared for use in neonates, infants and children.[1, 57]

The FDA defines:

- Neonates (birth to 28 days)
- Infants (29 days to less than 2 years)
- Children (2 years to less than 12 years)

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.

## References

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## History

| Date | Comments |
|---|---|
| 06/25/98 | Add to Durable Medical Equipment Section - New Policy |
| 06/19/01 | Replace Policy - Policy revised with reference to TEC assessment; policy statement unchanged. |
| 10/08/02 | Replace Policy - Policy reviewed; policy statement unchanged. |
| 01/13/04 | Replace Policy - Policy reviewed; policy statement unchanged; new 2004 HCPCS codes added. |
| 06/08/04 | Replace Policy - Policy reviewed; policy statement updated; rationale/source section updated; references added. |
| 09/01/04 | Replace Policy - Policy renumbered from PR.1.01.108. No date changes. |
| 01/11/05 | Replace Policy - Policy reviewed; policy statement unchanged. |
| 01/10/06 | Replace Policy - Policy reviewed with literature search; policy statement unchanged. Title changed for clarification (old title: Vacuum-Assisted Closure of Wounds (Negative Wound Pressure Therapy). |
| 02/06/06 | Codes updated - No other changes. |
| 05/26/06 | Update Scope and Disclaimer - No other changes. |
| 01/09/06 | Replace Policy - Policy updated with literature review; references added. No change in policy statement. |
| 05/21/07 | Replace Policy - Policy Guidelines updated with descriptions of Stage I through IV pressure ulcers as adapted from NPUAP for clarification purposes. No other changes. |
| 01/08/08 | Replace Policy - Policy updated with literature review; no change in policy statement. Reference added. |

| Date | Comments |
|---|---|
| 07/14/09 | Replace Policy - Policy updated with literature review; no change in policy statement. Reference added. |
| 06/08/10 | New Policy - BC.1.01.16 - Policy replaces PR.1.01.508. Policy updated with literature search. On hold for 90 days, release to publish in November 2010. |
| 11/01/10 | Policy Published - Subsequent to release from 90-day hold. |
| 12/21/10 | Cross Update Only - No other changes. |
| 06/13/11 | Replace Policy – Policy updated with literature search, reference numbers 31-42 added, term "powered" added to existing policy statements which are unchanged, new policy statement added that nonpowered NPWT systems are investigational. |
| 01/25/12 | HCPCS code A9272 added to policy. |
| 03/13/12 | Replace Policy. Policy updated with literature search through November 2011; Rationale section revised; 10 references added and references reordered. Clinical input that had been received in 2010 and clinical guidelines added to policy; policy statement for continuation of powered NPWT clarified. |
| 09/01/25 | New policy, 1.01.508 Negative Pressure Wound Therapy (NPWT) Devices in Adults, approved August 12, 2025, effective for dates of service on or after December 4, 2025, following 90-day provider notification. Negative Wound Pressure Therapy Devices are considered medically necessary when criteria are met. |
| 09/16/25 | Minor formatting update. |
| 04/01/26 | Annual Review, approved March 9, 2026. Policy updated with literature review through November 14, 2025; references added. Policy statements unchanged. Deleted documentation section requesting documentation of wound evaluation location, specific DME, and measurements. Codes added to policy section for ease of interpretation and application. Removed HCPCS codes A7000 and A7001. |
| 04/09/26 | Minor edits to update for clarity to codes in criteria section. Minor grammatical edits. |
| 06/01/26 | Interim Review, approved May 12, 2026, effective for dates of service on or after September 4, 2026, following 90-day provider notification. Removed statement that this policy only applies to adults aged 19 and older. Title changed from 1.01.508 Negative Pressure Wound Therapy (NPWT) Devices in Adults to 1.01.508 Negative Pressure Wound Therapy (NPWT) Devices. Added policy statement that use of NPWT systems is considered investigational for individuals aged 11 years and younger. Consideration of age statement updated to: NPWT systems are only FDA approved for use in adolescents and adults aged 12 years and older. Added reference. |

**Disclaimer**: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit

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**Scope**: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.