

Negative Pressure Wound Therapy

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INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

PLAN PRODUCT AND BENEFIT APPLICATION

Commercial

Medicaid/OHP*

Medicare**

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered “**not medically necessary**” for Medicare members.

COVERAGE CRITERIA

Initial Coverage:

- I. A negative pressure wound therapy (NNPWT) pump (E2402) and supplies (A6550, A7000) may be considered **medically necessary** for ulcers and wounds in the home setting when **all** of the following criteria are met:
 - A. The member has a chronic Stage 3 or 4 pressure ulcer (defined in [Policy Guidelines](#)), neuropathic (for example, diabetic) ulcer, venous or arterial insufficiency ulcer, or a chronic (being present for at least 30 days) ulcer of mixed etiology; **and**
 - B. A complete wound therapy program that meets both general and wound-specific measures (defined in [Policy Guidelines](#)) has been tried or considered and ruled out prior to application of NPWT.

- II. A negative pressure wound therapy (NNPWT) pump (E2402) and supplies (A6550, A7000) may be considered **medically necessary** for ulcers and wounds encountered in an inpatient setting when **either** of the following criteria are met:
 - A. Criterion I.A-B are met; **or**
 - B. The member has 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, other conditions of the member that will not allow for healing times achievable with other topical wound treatments).

- III. The use of a NPWT pump and supplies is considered **not medically necessary** when criterion

I or II above is not met.

- IV. More than one NPWT pump (E2402) billed per member for the same time period is considered **not medically necessary**.

Exclusions from Coverage:

- V. An NPWT pump and supplies is considered **not medically necessary** if **any one** of the following (A.-D.) criteria are met:
- A. The presence in the wound of necrotic tissue with eschar, if debridement is not attempted; **and/or**
 - B. Untreated osteomyelitis within the vicinity of the wound that is not concurrently being treated with intent to cure; **and/or**
 - C. Cancer present in the wound; **and/or**
 - D. The presence of a fistula to an organ or body cavity within the vicinity of the wound.
- VI. Disposable and non-powered wound suction pumps (e.g., PICO Single Use Negative Pressure Wound Therapy System, SNaP Wound Care System, PREVENA™ Incision Management System) and related supplies (A9272) are considered **not medically necessary**.

Continued Coverage:

- VII. Continued treatment of wounds and ulcers with NPWT may be considered **medically necessary** when both of the following criteria are met (A.-B.):
- A. Ulcers and wounds meet criteria I.A or I.B; **and**
 - B. A licensed medical professional has performed all of the following (1.-3.):
 - 1. Directly assess the wound(s) being treated with the NPWT pump on a regular basis; **and**
 - 2. Supervise or directly perform the NPWT dressing changes on a regular basis; **and**
 - 3. On at least a monthly basis, document changes in the ulcer's dimensions and characteristics.
- VIII. Continued coverage of an NPWT pump and supplies is considered **not medically necessary** when criterion VII. above is not met.

When Coverage Ends:

- IX. For wounds and ulcers described under criteria I.A. or I.B. above, an NPWT pump and supplies is considered **not medically necessary** when any of the following (A.-E.) criteria are met, whichever occurs earliest:
- A. Criteria VII.A.-VI.B. cease to occur; **or**
 - B. In the judgment of the treating provider, adequate wound healing has occurred to the degree that NPWT may be discontinued; **or**

- C. Any measurable degree of wound healing has failed to occur over the prior month; **or**
- D. Four 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; **or**
- E. Once equipment or supplies are no longer being used for the patient, whether or not by the physician's order.

Link to [Evidence Summary](#)

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be [accessed here](#).

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

In order to determine the medical necessity of the request, the following documentation must be provided at the time of the request. Medical records to include documentation of all of the following:

- Information describing the history, previous treatment regimens (if applicable), and current wound management for which an NPWT pump is being billed must be present in the member's medical record and be available for review upon request. This documentation must include such elements as length of sessions of use, dressing types and frequency of change, and changes in wound conditions, including precise measurements, quantity of exudates, presence of granulation and necrotic tissue and concurrent measures being addressed relevant to wound therapy (debridement, nutritional concerns, support surfaces in use, positioning, incontinence control, etc.).
- Information describing the wound evaluation and treatment, recorded in the member's medical record, must indicate regular evaluation and treatment of the member's wounds, as detailed in the policy criteria below.
- Documentation of quantitative measurements of wound characteristics including wound length and width (surface area), and depth, and amount of wound exudate (drainage), indicating progress of healing must be entered at least monthly.
- The supplier of the NPWT equipment and supplies must obtain from the treating clinician, an assessment of wound healing progress, based upon the wound measurement as documented in the member's medical record, in order to determine whether the equipment and supplies continue to qualify for coverage.

- The medical record must include a statement from the treating provider describing the initial condition of the wound (including measurements) and the efforts to address all aspects of wound care. For each subsequent month, the medical record must include updated wound measurements and what changes are being applied to effect wound healing.
- If the initiation of NPWT occurs during an inpatient stay, in order to accurately account for the duration of treatment, the initial inpatient date of service must be documented. This date must be available upon request.

This policy may be primarily based on the following Center for Medicare and Medicaid Services (CMS) guidances:

- Local Coverage Determination (LCD): Negative Pressure Wound Therapy Pumps (L33821)¹
- Local Coverage Article (LCA): Negative Pressure Wound Therapy Pumps (A52511)²

Definitions:

Pressure Ulcer Staging

Suspected Deep Tissue Injury: Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.

Stage I: Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area.

Stage II: Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister.

Stage III: Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscles are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.

Stage IV: Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunneling

Unstageable: Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed.

Complete Wound Therapy Program:

For all ulcers or wounds, the following components of a general wound therapy program must include a minimum of all the following general measures, which should either be addressed, applied, or considered and ruled out prior to application of NPWT:

- Documentation in the member's medical record of evaluation, care, and wound measurements by a licensed medical professional; and
- Application of dressings to maintain a moist wound environment; and
- Debridement of necrotic tissue if present; and
- Evaluation of and provision for adequate nutritional status

For Stage 3 or 4 pressure ulcers:

- The program must include all components of a general wound therapy program; and
- The member has been appropriately turned and positioned; and
- The member has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis; and
- The member's moisture and incontinence have been appropriately managed

For neuropathic (for example, diabetic) ulcers:

- The program must include all components of a general wound therapy program; and
- The member has been on a comprehensive diabetic management program; and
- Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities

For venous insufficiency ulcers:

- The program must include all components of a general wound therapy program; and
- Compression bandages and/or garments have been consistently applied; and
- Leg elevation and ambulation have been encouraged

Licensed Health Care Professional: A licensed health care professional, for the purposes of this policy, may be a physician, physician's assistant (PA), registered nurse (RN), licensed practical nurse (LPN), or physical therapist (PT). The practitioner should be licensed to assess wounds and/or administer wound care within the state where the beneficiary is receiving NPWT.

Equipment

- Code E2402 describes a stationary or portable Negative Pressure Wound Therapy (NPWT) electrical pump which provides controlled sub-atmospheric pressure that is designed for use with NPWT dressings (A6550) and canisters (A7000) to promote wound healing. The NPWT pump must be capable of being selectively switched between continuous and intermittent modes of operation and is controllable to adjust the degree of sub-atmospheric pressure conveyed to the wound in a range of 40-80 mm Hg sub-atmospheric pressure. The system must contain sensors and alarms to monitor pressure variations and exudate volume in the collection canister.
- Code A6550 describes an allowance for a dressing set which is used in conjunction with a stationary or portable NPWT pump (E2402). A single code A6550 is used for each single, complete dressing change, and contains all necessary components, including but not limited to any separate, non-adherent porous dressing(s), drainage tubing, and an occlusive dressing(s)

which creates a seal around the wound site for maintaining sub-atmospheric pressure at the wound.

- HCPCS code A7000 describes a canister set which is used in conjunction with a stationary or portable NPWT pump and contains all necessary components, including but not limited to a container, to collect wound exudate. Canisters may be various sizes to accommodate stationary or portable NPWT pumps.

Requirements for continued coverage

- Month-to-month comparisons of wound size must compare like measurements i.e., depth compared to depth or surface area compared to surface area.
- When NPWT therapy exceeds 4 months on the most recent wound and reimbursement ends, individual consideration for one additional month at a time may be sought using the appeals process. Information from the treating provider's medical record, contemporaneous with each requested one-month treatment time period extension, must be submitted with each appeal explaining the special circumstances necessitating the extended month of therapy. General, vague or nonspecific statements in the medical record such as "doing well, want to continue until healed" provide insufficient information to justify the need for extension of treatment. The medical record must provide specific and detailed information to explain the continuing problems with the wound, what additional measures are being undertaken to address those problems and promote healing and why a switch to alternative treatments alone is not possible.
- When billing for quantities of canisters greater than those described in the below criteria as the usual maximum amounts, there must be clear and explicit information in the medical record that justifies the additional quantities.

BACKGROUND

Negative Pressure Wound Therapy

Negative Pressure Wound Therapy (NPWT) is defined as the application of sub-atmospheric pressure to a wound to remove exudate and debris from wounds. NPWT is delivered through an integrated system of a suction pump, separate exudate collection chamber and dressing sets to a qualified wound. In these systems, exudate is completely removed from the wound site to the collection chamber.

SNaP Wound Care System

The SNaP (smart negative pressure) Wound Care System (Spiracur Inc.) is a disposable, portable, negative pressure wound therapy device designed to provide the same level of negative pressure therapy as traditional devices, but without electric or battery power. The device comprises three components: the SNaP Wound Care Cartridge; the SNaP Wound Care Dressing; and the SNaP Wound Care Strap. The dressing is an absorptive, thin hydrocolloid that creates a complete seal around the

wound and periwound skin. The disposable cartridge provides constant negative pressure levels ranging from 75 to 125 millimeters of mercury (mm Hg), and collects exudate. The SNaP Wound Care Strap connects the cartridge to the patient's leg and due to its small size and light weight (approximately 2.2 ounces), the SNaP Wound Care System is designed to be worn continuously and is fully functional during mobility. The SNaP Wound Care System is indicated for wound management in patients who would benefit from a suction device to promote wound healing through the removal of excess exudates, infectious material, and tissue debris.

PICO Single-use Negative Pressure Wound Therapy System

The PICO single-use system (Smith & Nephew, Inc., Andover, MA, USA) is intended to deliver NPWT to treat wounds with low-to-moderate exudate levels. Negative pressure technique for wound healing is based on two theories: 1) removal of excess interstitial fluid decreases edema and concentrations of inhibitory factors and increases local blood flow, and 2) tissue stretching and deformation by negative pressure are believed to disturb the extracellular matrix and introduce biochemical responses that promote wound healing.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

- In 2012, Armstrong and colleagues published results of a multicenter randomized controlled trial on SNAP wound care system versus traditional electrically powered devices for treating chronic lower extremity ulcers.^{3,4} The trial included 132 patients and evaluated treatment up to 16 weeks, or until closure was achieved. Eighty-three patients completed the study (N=41 for SNAP and N=42 for conventional NPWT). No significant differences (non-inferiority met) in proportion of participants with healed wounds was found and the authors concluded that the treatments were comparable. Small sample size and low patient adherence reduce the quality of the evidence and are a major limitation to interpreting the results.
- In 2023, ECRI published a clinical evidence assessment on PICO Single-Use Negative Pressure Wound Therapy System (Smith & Nephew, Inc.) for Surgical Wound Healing.⁵ The review included one systematic review with 16 studies (n=1863), 5 single-center RCTs, and 2 multi-center RCTs and one systematic review. All studies compared PICO to conventional dressings. The systematic review reported 5.2% of patients had surgical site infections (SSIs) with PICO

compared to conventional dressings (12.5%). Two RCTs found no difference in SSIs between PICO and conventional dressings post-surgery. The main limitation of all studies reviewed was the poor choice in comparator group. No study compared PICO to other NPWT systems and therefore the superiority of PICO cannot be determined over standard NPWT treatment. ECRI concluded that the evidence is “somewhat favorable” for PICO single-use NPWT systems for reducing SSIs and dehiscence in surgical incisions after hip, knee, or ankle arthroplasty, cesarean section, spinal fusion, breast surgery, or colorectal surgery.

BILLING GUIDELINES AND CODING

Supplies:

- Coverage is provided up to a maximum of 15 dressing kits (A6550) per wound per month.
- Coverage is provided up to a maximum of 10 canister sets (A7000) per month unless there is documentation evidencing a large volume of drainage (greater than 90 ml of exudate per day).
- For high volume exudative wounds, a stationary pump with the largest capacity canister must be used.
- When billing for quantities of canisters greater than those described in the policy as the usual maximum amounts, there must be clear and explicit information in the medical record that justifies the additional quantities.

NPWT is provided with an integrated system of components. This system contains a pump (E2402), dressing sets (A6550) and a separate collection canister (A7000). Wound suction systems that do not contain all of the required components are not classified as NPWT. See below for component specifications.

Disposable wound suction system pumps and related supplies must be coded A9272 (WOUND SUCTION, DISPOSABLE, INCLUDES DRESSING, ALL ACCESSORIES AND COMPONENTS, ANY TYPE, EACH).

Supplies used with disposable wound suction systems that are separately billed must be coded as A9900 (MISCELLANEOUS DME SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS CODE).

CODES*		
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 instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
	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 instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters
HCPCS	A9272	Wound suction, disposable, includes dressing, all accessories and components, any type, each
	A6550	Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories
	A7000	Canister, disposable, used with suction pump, each
	E2402	Negative pressure wound therapy electrical pump, stationary or portable

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- See the non-covered and prior authorization lists on the Company [Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website](#) for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Centers for Medicare & Medicaid Services. Local Coverage Determination: Negative Pressure Wound Therapy Pumps (L33821). Effective 5/1/2021. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33821>. Accessed 6/7/2023.
2. Centers for Medicaid & Medicare Services. Local Coverage Article: Negative Pressure Wound Therapy Pumps (A52511). Effective 8/15/2021. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52511>. Accessed 6/23/2022.
3. Armstrong DG, Marston WA, Reyzelman AM, Kirsner RS. Comparative effectiveness of mechanically and electrically powered negative pressure wound therapy devices: A multicenter randomized controlled trial. *Wound Repair and Regeneration*. 2012;20(3):332-341. <https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1524-475X.2012.00780.x>.
4. Armstrong DG, Marston WA, Reyzelman AM, Kirsner RS. Comparison of negative pressure wound therapy with an ultraportable mechanically powered device vs. traditional electrically powered device for the treatment of chronic lower extremity ulcers: A multicenter randomized-controlled trial. *Wound Repair and Regeneration*. 2011;19(2):173-180. <https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1524-475X.2010.00658.x>.

5. ECRI. PICO Single-use Negative Pressure Wound Therapy System (Smith & Nephew, Inc.) for Surgical Wound Healing.
<https://www.ecri.org/components/ProductBriefs/Pages/24018.aspx?tab=1>. Published 2023.
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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
8/2023	Annual update. Formatting changes to criteria.