


PROVIDENCE HEALTH PLANS AND PROVIDENCE HEALTH ASSURANCE MEDICAL POLICY	Wound Therapy: Negative Pressure Wound Therapy (NPWT) V.A.C Vacuum Assisted Closure	
Effective Date: 7/1/2018	Section: DME	Policy No: 377
 7/1/18	Technology Assessment Committee Approved Date: 10/10; 10/13; 9/14: 9/15; 4/16	
	Medical Policy Committee Approved Date: 3/03; 4/04; 5/05; 9/07; 11/09; 5/11;12/11; 6/13; 5/17; 6/18	
Medical Officer	Date	

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) for coverage determinations.

For other lines of business, refer to the Policy Criteria section below:

POLICY CRITERIA

Negative pressure wound therapy (NPWT) may be covered subject to benefit and Plan criteria listed below when ordered by a wound care specialist. **PHP Prior Authorization** is required on a month-to-month basis, with a 4-month maximum.

The use of Single-use NPWT devices (e.g., PICO Single Use Negative Pressure Wound Therapy System; Prevena Incision Management System) experimental and investigational for all indications due to lack of insufficient evidence of their safety and effectiveness.

The staging of pressure ulcers used in this policy is as follows:

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.

A negative pressure wound therapy pump and supplies are covered when either criterion A or B is met:

A) Ulcers and Wounds in the Home Setting with a non-portable device:

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 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, should 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 a 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 group 2 or 3 support surface if the pressure ulcer is on the posterior trunk or pelvis.
 - c. The patient's moisture and incontinence have been appropriately managed.
3. For neuropathic (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.

B) Ulcers and Wounds Encountered in an Inpatient Setting:

1. An ulcer or wound (described under A above) is encountered in the inpatient setting and, after wound treatments described under A-1 through A-4 have been tried or considered in the judgment of the treating physician, the best available treatment option.
2. The patient has complications of a surgically created wound (example, dehiscence) or a

traumatic wound (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 (example, other conditions of the patient that will not allow for healing times achievable with other topical wound treatments).

Note: In either situation B-1 or B-2, NPWT will be covered when treatment continuation is ordered beyond discharge to the home setting. If criterion A or B above is not met, the NPWT pump and supplies will be denied as not medically necessary.

NPWT pumps (E2402) must be capable of accommodating more than one wound dressing set for multiple wounds on a patient. Therefore, more than one E2402 billed per patient for the same time period will be denied as not medically necessary.

Portable devices

SNaP and Kaylpto are devices for smaller non-healing ulcers. They may be covered for Stage II or III leg ulcers, usually venous stasis disease with failure/non healing by standard therapies.

A trial of 3 weeks showing significant response is required for these shallow ulcers. Treatment longer than 2 months is not covered. Conversion from a standard pump for final healing is not covered since the wound should close at this stage.

OTHER EXCLUSIONS FROM COVERAGE:

An NPWT pump and supplies are not covered at any time if one or more of the following are present:

- The presence in the wound of necrotic tissue with eschar, if debridement is not attempted;
- Untreated osteomyelitis within the vicinity of the wound;
- Cancer present in the wound;
- The presence of a fistula to an organ or body cavity within the vicinity of the wound.

CONTINUED COVERAGE:

C). For wounds and ulcers described under A or B above, once placed on an NPWT pump and supplies, in order for coverage to continue 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 above criteria C-1 and C-2 are not fulfilled, continued coverage of the NPWT pump and supplies are not covered.

WHEN COVERAGE ENDS:

D). For wounds and ulcers described under A or B above, an NPWT pump and supplies will be denied as not medically necessary with and of the following, whichever occurs earliest:

1. Criteria C1-C2 cease to occur

2. In the judgment of the treating physician, adequate wound healing has occurred to the degree that NPWT may be discontinued.
3. 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.
4. 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.
5. Once equipment or supplies are no longer being used for the patient, whether or not by the physician's order.

SUPPLIES:

Coverage is provided up to a maximum of 15 dressing kits (A6550) per wound per month unless there is documentation that the wound size requires more than one dressing kit for each dressing change.

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 90ml of exudate per day).

For high volume exudative wounds, a stationary pump with the largest capacity canister must be used.

CPT/HCPCS CODES

All Lines of Business	
Prior Authorization Required	
67608	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
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

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	care, per session; total wound(s) surface area less than or equal to 50 square centimeters
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 square inches or less
K0745	Absorptive wound dressing for use with suction pump, home model, portable, pad size more than 16 square inches but less than or equal to 48 square inches
K0746	Absorptive wound dressing for use with suction pump, home model, portable, pad size greater than 48 square inches
No Prior Authorization Required	
A6550	Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories
A7000	Canister, disposable, used with suction pump, each

DESCRIPTION

Negative pressure wound therapy (NPWT) is the controlled application of subatmospheric pressure to a wound using an electrical pump to intermittently or continuously convey subatmospheric pressure through connecting tubing to a specialized wound dressing which includes a resilient, open-cell foam surface dressing, sealed with an occlusive dressing that is meant to contain the subatmospheric pressure at the wound site.

Negative pressure wound therapy is prescribed for traumatic and chronic wound patients in the hospital, long-term care facility, or in the home.

- Promotes granulation tissue formation through promotion of wound healing.
- Uniformly draws wounds closed by applying controlled, localized negative pressure.
- Removes interstitial fluid allowing tissue decompression.
- Removes infectious material.
- Provides a closed, moist wound-healing environment.

Two portable devices available are the Kalypto and the SNaP/disposable. A palm sized wound vacuum, runs on AA batteries. The all-in-one dressing applies much like a band aid with no canisters. Utilizing negative pressure, drainage stays in the super-absorbent bandage and lasts up to three days. This device is used for smaller wounds; usually for Stage II venous stasis ulcers. There is scarce, poor quality evidence on the portable devices. However, clinical experts feel it is valuable for limited use.

INSTRUCTIONS FOR USE

Providence Health Plan (PHP) and Providence Health Assurance (PHA) Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a

guarantee of coverage. PHP and PHA 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. PHP and PHA reserve the right to determine the application of Medical Policies and make revisions to its Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

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 PHP and PHA Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

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.

REFERENCES

ECRI:

Custom Product Briefs - Guidance

PICO Single-use Negative Pressure Wound Therapy System (Smith & Nephew, Inc.)

Published 10/14/2015

Hayes:

Clinical Research Response

Product comparison

Negative Pressure Wound Therapy for Closed Incisions

January 14, 2016

PubMed:

1. J Wound Care. 2015 Feb;24 Suppl 2:S4-9. doi: 10.12968/jowc.2015.24.Sup2.S4.

Single-use negative pressure wound therapy for the treatment of chronic lower leg wounds.

Schwartz JA1, Goss SG, Facchin F, Gendics C, Lantis JC.

2. Int Wound J. 2015 Apr;12(2):195-201. doi: 10.1111/iwj.12080. Epub 2013 May 7.

Simplified negative pressure wound therapy: clinical evaluation of an ultraportable, no-canister system.

Hudson DA1, Adams KG, Van Huyssteen A, Martin R, Huddleston EM.

3. Br J Community Nurs. 2015 Jun;Suppl Community Wound Care:S14, S16-20. doi:

10.12968/bjcn.2015.20.Sup6.S14.

Providing cost-effective treatment of hard-to-heal wounds in the community through use of NPWT.

Hampton J1.

4. Eplasty. 2014 Apr 28;14:e20. eCollection 2014.

Application of the Single Use Negative Pressure Wound Therapy Device (PICO) on a Heterogeneous Group of Surgical and Traumatic Wounds.
Payne C1, Edwards D1.

5. Ostomy Wound Manage. 2014 Mar;60(3):30-6.

Use of a portable, single-use negative pressure wound therapy device in home care patients with low to moderately exuding wounds: a case series.

Hurd T1, Trueman P2, Rossington A3.

6. Eplasty. 2014 Apr 2;14:e15. eCollection 2014.

Biological effects of a disposable, canisterless negative pressure wound therapy system.

Malmsjö M1, Huddleston E2, Martin R2.