MEDICAL POLICY	Negative Pressure Wound Therapy (All Lines of Business Except Medicare)
Effective Date: 9/1/2021  9/1/2021 Medical Officer Date	Medical Policy Number: 168 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; 9/18; 3/19; 3/2020; 05/2020; 6/2021

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

SCOPE:

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

APPLIES TO:

All lines of business except Medicare

BENEFIT APPLICATION

Medicaid 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.

POLICY CRITERIA

Notes:

- Negative pressure wound therapy performed concurrently with hyperbaric oxygen therapy is not covered.
- The following policy criteria are based on the Centers for Medicare & Medicaid Services (CMS) Local Coverage Determination (LCD): Negative Pressure Wound Therapy Pumps (L33821), Local Coverage Article (LCA): Negative Pressure Wound Therapy Pumps (A52511), Local Coverage Determination (LCD): Suction Pumps (L33612), and Local Coverage Article: Suction Pumps - Policy Article (A52519).[1-4]

Initial Coverage:

I. A negative pressure wound therapy (NNPWT) pump (E2402) and supplies (A6550, A7000) may be considered **medically necessary and covered** 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 and covered** 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 members 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 and not covered** when criterion I. above is not met.

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

Exclusions from Coverage:

V. An NPWT pump and supplies is considered **not medically necessary and not covered** 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 wound suction pumps (e.g., PICO Single Use Negative Pressure Wound Therapy System and SNaP Wound Care System) and related supplies (A9272) are considered **not medically necessary and not covered**.

Continued Coverage:

VII. For continued treatment of wounds and ulcers with NPWT, the following criteria must be met:

A. Ulcers and wounds must meet criteria I.A or I.B; and
B. A licensed medical professional must do the following:

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 and not covered** 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 and not covered** 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.

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.

- 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.

- Month-to-month comparisons of wound size must compare like measurements i.e. depth compared to depth or surface area compared to surface area.

- 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.

- 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.

POLICY GUIDELINES

Definitions:

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.

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.

BILLING GUIDELINES

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).

CPT/HCPCS CODES

All Lines of Business	
Prior Authorization Required	
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
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
Not Covered	
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
A9272	Wound suction, disposable, includes dressing, all accessories and components, any type, each

DESCRIPTION

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.

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 Companies reserve the right to determine the application of Medical Policies and make revisions to 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 Company 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. 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.

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 5/3/2021.
2. Centers for Medicaid & Medicare Services. Local Coverage Article: Negative Pressure Wound Therapy Pumps (A52511). Effective 1/1/2020. https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52511. Accessed 5/3/2021.
3. Centers for Medicaid & Medicare Services. Local Coverage Determination (LCD): Suction Pumps (L33612). Effective 1/1/2020. https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33612. Accessed 5/3/2021.
4. Centers for Medicaid & Medicare Services. Local Coverage Article: Suction Pumps - Policy Article (A52519). Effective 4/3/2020. https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52519. Accessed 5/3/2021.