

## OHCA Guideline

<b>Medical Procedure Class:</b>	Negative Pressure Wound Therapy
Initial Implementation Date:	January 2008
Last Review Date:	7/30/2019
Effective Date:	10/1/2019
Next Review/Revision Date:	July 2022
* This document is not a contract, and these guidelines do not reflect or represent every conceivable situation. Although all items contained in these guidelines may be met, this does not reflect, or imply, any responsibility of this agency or department to change the plan provision to include the stated service as an eligible benefit.	
<input type="checkbox"/> New Criteria <span style="float: right;"><input checked="" type="checkbox"/> Revision of Existing Criteria</span>	
<b>Summary</b>	
<b>Purpose:</b>	To provide guidelines to assure medical necessity and consistency in the prior authorization process.
<b>Definitions</b>	
<p><b>Acute wounds</b> – Wounds that transition through the normal healing process of hemostasis, inflammation, cellular migration and proliferation, and remodeling, until the skin’s structure and function are restored.</p> <p><b>Adiposity</b> – The quality or state of being fat.</p> <p><b>Anastomosis</b> – The union of blood vessels to interconnect.</p> <p><b>Blanch</b> – To become white or pale.</p> <p><b>Chronic wounds</b> – Wounds that have failed to pass through the normal healing process in an orderly and timely manner and often remain in the inflammation phase. A wound may be considered chronic if it has not entered the cellular migration and proliferation phase after four weeks.</p> <p><b>Dehiscence</b> – The parting of the sutured lips of a surgical wound.</p> <p><b>Dermis</b> – The vascular, thick layer of skin lying below the epidermis.</p> <p><b>Dermatitis</b> – Inflammation of the skin.</p> <p><b>Erythema</b> – Abnormal redness of the skin due to capillary congestion.</p> <p><b>Eschar</b> – A scab formed especially after a burn.</p> <p><b>Exudate</b> – The material composed of serum, fibrin, and white blood cells that escapes from blood vessels into a superficial lesion or area of inflammation.</p> <p><b>Fascia</b> – A sheet of connective tissue covering or binding together body structures.</p> <p><b>Granulation tissue</b> – Tissue made up of granulations that temporarily replace lost tissue in a wound.</p> <p><b>Osteomyelitis</b> – An infectious usually painful inflammatory disease of bone.</p> <p><b>Pressure ulcers (injuries)</b> – Injuries to skin and underlying tissue resulting from prolonged pressure on the skin.</p> <p><b>Slough</b> – Dead tissue separating from living tissue.</p> <p><b>Tunneling</b> – The act of creating a bodily passageway.</p>	
<b>Description</b>	
<p>Negative Pressure Wound Therapy (NPWT)</p> <ul style="list-style-type: none"> <li>Applies sub-atmospheric pressure to a wound to remove exudate and debris. 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.</li> </ul>	

Pressure Injury Stages (National Pressure Ulcer Advisory Panel, 2016)

- **Stage 1 Pressure Injury: Non-blanchable erythema of intact skin** – Intact skin with a localized area of non-blanchable erythema, which may appear differently in darkly pigmented skin. Presence of blanchable erythema or changes in sensation, temperature, or firmness may precede visual changes. Color changes do not include purple or maroon discoloration; these may indicate deep tissue pressure injury.
- **Stage 2 Pressure Injury: Partial-thickness skin loss with exposed dermis** – Partial-thickness loss of skin with exposed dermis. The wound bed is viable, pink or red, moist, and may also present as an intact or ruptured serum-filled blister. Adipose (fat) is not visible and deeper tissues are not visible. Granulation tissue, slough and eschar are not present. These injuries commonly result from adverse microclimate and shear in the skin over the pelvis and shear in the heel. This stage should not be used to describe moisture associated skin damage (MASD) including incontinence associated dermatitis (IAD), intertriginous dermatitis (ITD), medical adhesive related skin injury (MARS), or traumatic wounds (skin tears, burns, abrasions).
- **Stage 3 Pressure Injury: Full-thickness skin loss** – Full-thickness loss of skin, in which adipose (fat) is visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough and/or eschar may be visible. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage and/or bone are not exposed. If slough or eschar obscures the extent of tissue loss, this is an Unstageable Pressure Injury.
- **Stage 4 Pressure Injury: Full-thickness skin and tissue loss** – Full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer. Slough and/or eschar may be visible. Epibole (rolled edges), undermining and/or tunneling often occur. Depth varies by anatomical location. If slough or eschar obscured the extent of tissue loss, this is an Unstageable Pressure Injury.
- **Unstageable Pressure Injury: Obscured full-thickness skin and tissue loss** – Full-thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because it is obscured by slough or eschar. If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed. Stable eschar (i.e. dry, adherent, intact without erythema or fluctuance) on the heel or ischemic limb should not be softened or removed.
- **Deep Tissue Pressure Injury: Persistent non-blanchable deep red, maroon or purple discoloration** – Intact or non-intact skin with localized area of persistent non-blanchable deep red, maroon, purple discoloration or epidermal separation revealing a dark wound bed or blood filled blister. Pain and temperature change often precede skin color changes. Discoloration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly to reveal the actual extent of tissue injury, or may resolve without tissue loss. If necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle or other underlying structures are visible, this indicates a full thickness pressure injury (Unstageable, Stage 3 or Stage 4). Do not use Deep Tissue Pressure Injury to describe vascular, traumatic, neuropathic, or dermatologic conditions.

## CPT Codes Covered Requiring Prior Authorization (PA)

- Wound therapy pump – **E2402** (Rental of 1 pump, PA required monthly)
- Wound therapy pump supplies – **A6550** (PA required to exceed 15 dressing kits per wound per month)
- Wound therapy pump canister – **A7000** (PA required to exceed 4 canister sets per month)

\*\*Please see HCPCS book for full definition of codes

## Approval Criteria

### I. GENERAL

A. Medical necessity must be met. All documentation submitted to request services or substantiate previously provided services must demonstrate through adequate objective medical records, evidence sufficient to justify the member's needs for the service, in the most cost-effective manner, in accordance with the OAC 317:30-3-1.

B. Documentation requirements include:

1. Documentation that a 30-day complete wound therapy program, described below, has been tried, including the results, prior to application of NPWT.
2. Documentation of chronic, non-healing ulcer(s) with a lack of improvement for at least the previous 30 days despite a complete wound therapy program.
3. Documentation of a surgical or traumatic wound dehiscence with a lack of improvement for at least the previous 30 days despite a complete wound therapy program.

### II. INDICATIONS

A NPWT pump and supplies are covered when:

A. Ulcers and Wounds in the Home Setting:

The member must have a chronic, non-healing ulcer: Stage 3 or Stage 4 pressure ulcer, neuropathic ulcer, venous or arterial insufficiency ulcer, or a chronic (present for at least 30 days) ulcer of mixed etiology. A 30-day complete wound therapy program, described below, consisting of criterion 1 and criteria 2, 3, or 4, must have been tried prior to application of NPWT. If a 30-day complete wound therapy program was not tried, defer to a medical director for review.

1. For all ulcers or wounds, the following general measures must be applied and ruled out prior to application of NPWT:
  - Documentation in the member's medical records 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, **AND**
  - Non-smoking status, **OR**
  - If member is a smoker, counseling on the effects of smoking and wound healing should be documented, as well as the smoking cessation treatments offered
2. For Stage 3 or 4 pressure ulcers:
  - The member has been appropriately turned and positioned, **AND**

- The member has used a group 2 or 3 support surface (e.g. low air loss bed, air fluidized bed) for pressure ulcers on the posterior trunk or pelvis, **AND**
  - The member's moisture and incontinence have been appropriately managed
3. For neuropathic ulcers:
    - Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities, **AND**
    - If diabetic, the member has been on a comprehensive diabetic management program
  4. For venous insufficiency ulcers:
    - Compression bandages and/or garments have been consistently applied, **AND**
    - Lower extremity elevation and ambulation have been encouraged

**B. Surgical or Traumatic Wound Dehiscence**

1. A 30-day complete wound therapy program, described above in section **II.A.1**, must have been tried prior to application of NPWT for a surgical or traumatic wound dehiscence.

**C. Traumatic Injury or Burn – Resulting in Skin Graft**

1. Documentation of the medical necessity for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments.
2. NPWT must be placed immediately following the grafting.
3. These skin grafts are exempt from the 30-day complete wound therapy program requirement.

**D. Ulcers and Wounds in the Inpatient Setting:**

1. A chronic, non-healing ulcer: A 30-day complete wound therapy program, described above in section **II.A.1**, must have been tried prior to application of NPWT for a Stage 3 or Stage 4 pressure ulcer, neuropathic ulcer, venous or arterial insufficiency ulcer, or a chronic (present for at least 30 days) ulcer of mixed etiology encountered in the inpatient setting.
2. A surgical or traumatic wound dehiscence: A 30-day complete wound therapy program, described above in section **II.A.1**, must have been tried prior to application of NPWT for a surgical or traumatic wound dehiscence.
4. A traumatic injury or burn resulting in skin graft: Documentation of the medical necessity for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments; NPWT must be placed immediately following the grafting; these skin grafts are exempt from the 30-day complete wound therapy program requirement.

**III. FREQUENCY**

- A. Negative pressure wound therapy pump (**E2402**) – Rental (PA required monthly)
- B. Wound therapy pump supplies (**A6550**) – Up to a maximum of 15 dressing kits per wound per month unless there is documentation that the wound size requires more than one dressing kit for each dressing change.

- C. Wound therapy pump canister (**A7000**) – Up to a maximum of 4 canister sets per month unless there is documentation evidencing a large volume of drainage (greater than 90ml of exudate per day).
- D. Prior authorization is required on a monthly basis and may be approved for up to a total of four months (including the time NPWT was applied in an inpatient setting prior to discharge to the home); All PA requests for NPWT beyond four months of treatment will require review by a medical director.

#### **IV. CONTINUED MEDICAL NECESSITY**

- A. For wounds being treated with NPWT, a licensed medical professional must do the following:
  - 1. On a weekly basis, directly access the wound(s) being treated with the NPWT pump, **AND**
  - 2. Supervise or directly perform the NPWT dressing changes, **AND**
  - 3. On at least a monthly basis, document changes in the wound's dimensions and characteristics.

A licensed medical professional, for the purposes of this policy, may be a physician, physician's assistant (PA), advanced practice registered nurse (APRN), 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 member is receiving NPWT.

#### **Discontinuation Criteria**

A NPWT pump and supplies will be denied as not medically necessary with any of the following, whichever occurs earliest:

- In the judgement of the treating physician, adequate wound healing has occurred to the degree that NPWT may be discontinued;
- Any measureable degree of wound healing has failed to occur over the prior month. Wound healing is defined as improvement occurring in either surface area (length x width) or depth of the wound;
- Four months have elapsed using a NPWT pump (including the time NPWT was applied in an inpatient setting prior to discharge to the home) in the treatment of the most recent wound; All PA requests for NPWT beyond four months of treatment will require review by a medical director;
- Once equipment or supplies are no longer being used for the member, whether or not by the physician's order;
- When criteria under the Continued Medical Necessity section above cease to occur.

#### **Additional Information**

- Requests for negative pressure wound therapy outside of this guideline will be referred for medical director review.

## References

- Aetna. (2019). Medical clinical policy bulletins: Negative pressure wound therapy. Retrieved from [http://www.aetna.com/cpb/medical/data/300\\_399/0334.html](http://www.aetna.com/cpb/medical/data/300_399/0334.html)
- Agency for Healthcare Research and Quality. (2019, January 28). Technology Assessment program: Skin substitutes for treating chronic wounds. Retrieved from [https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/ta/drafts-for-review/skin-substitutes\\_draft.pdf](https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/ta/drafts-for-review/skin-substitutes_draft.pdf)
- BlueCross BlueShield of Oklahoma. (2018). Medical policies: Negative pressure wound therapy (NPWT) for the treatment of wounds. Retrieved from <http://www.medicalpolicy.hcsc.net/medical-policy/activePolicyPage?lid=j9wptvy3&corpEntCd=OK1>
- Centers for Medicare & Medicaid Services. (2017). Local coverage determination (LCD): Negative pressure wound therapy pumps (L33821). Retrieved from <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33821&ver=12&DocID=L33821&bc=gAAAABAAAA&>
- Centers for Medicare & Medicaid Services. (2019). Local coverage article: Billing and coding: Wound care (A53001). Retrieved from <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=53001&ver=21&Date=&DocID=A53001&bc=hAAAABAAAA&>
- Hingorani, A., LaMuraglia, G.M., Henke, P., Meissner, M.H., Loretz, L., Zinszer, K.M.,... & Murad, M.H. (2016). The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. *Journal of Vascular Surgery*, 63(2), 3S-21S. Doi: 10.1016/j.jvs.2015.10.003
- Humana. (2019). Medical coverage policies: Negative pressure wound therapy (NPWT). Retrieved from [http://apps.humana.com/tad/tad\\_new/Search.aspx?searchtype=beginswith&docbegin=N&policyType=medical](http://apps.humana.com/tad/tad_new/Search.aspx?searchtype=beginswith&docbegin=N&policyType=medical)
- Iheozor-Ejiofor, Z., Newton, K., Dumville, J.C., Costa, M.L., Norman, G., & Bruce, J. (2018). Negative pressure wound therapy for open traumatic wounds. *Cochrane Library: Cochrane Database of Systematic Reviews*. Retrieved from <https://doi.org/10.1002/14651858.CD012522.pub2>
- Kantak, N.A., Mistry, R., & Halvorson, E.G. (2016). A review of negative-pressure wound therapy in the management of burn wounds. *Burns*, 42(8), 1623-1633. Doi: 10.1016/j.burns.2016.06.011
- Liu, S., He, C., Cai, Y., Xing, Q., Guo, Y., Chen, Z.,... & Yang, L. (2017). Evaluation of negative-pressure wound therapy for patients with diabetic foot ulcers: Systematic review and meta-analysis. *Therapeutics and Clinical Risk Management*, 13, 533-544. Doi: 10.2147/TCRM.S131193
- Mayo Clinic. (2019). Bedsores (pressure ulcers). Retrieved from <https://www.mayoclinic.org/diseases-conditions/bed-sores/symptoms-causes/syc-20355893>
- Merriam-Webster, Incorporated. (2019). Merriam-Webster Dictionary. Retrieved from <https://www.merriam-webster.com/dictionary>
- National Pressure Ulcer Advisory Panel. (2016). NPUAP pressure injury stages. Retrieved from <https://www.npuap.org/resources/educational-and-clinical-resources/npuap-pressure-injury-stages/>

UnitedHealthcare. (2019). UnitedHealthcare commercial medical policy: Negative pressure wound therapy. Retrieved from <https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/negative-pressure-wound-therapy.pdf>