Negative Pressure Wound Therapy
DME-011

Iowa Medicaid Program	Prior Authorization	**Effective Date**	9/11/2009
Revision Number	11	**Last Rev Date**	10/18/2024
Reviewed By	Medicaid Medical Director	**Next Rev Date**	10/17/2025
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	6/4/2018

Criteria

Negative pressure wound therapy (NPWT), also called vacuum-assisted wound closure, refers to wound dressing systems that continuously or intermittently apply sub-atmospheric pressure to the system, which provides a positive pressure to the surface of a wound. NPWT has become a popular treatment modality for the management of many acute and chronic wounds. This therapy should be considered an adjunct to the basic principles of wound care.

NPWT exerts its effect through direct and indirect effects of sub-atmospheric pressure. These effects include stabilization of the wound environment, increased blood flow, and deformation of the wound. Deformation is a powerful stimulus for cellular processes that stimulate granulation tissue and accelerate wound healing. The dressing and tubing are typically changed every 48 to 120 hours (2 to 5 days) depending upon the clinical situation.

Both systemic and local wound factors can contribute to delayed wound healing. Systemic factors (e.g., poor nutrition, wound ischemia) should be identified and corrected to the extent that is possible. Local wound factors that interfere with normal healing include desiccation, tissue edema, excessive exudate, poor tissue apposition (e.g., grafts and flaps), and wound infection. Stagnant fluid is associated with cytogenetic factors that impede wound healing.

NPWT has been applied to a wide range of clinical situations, including the open abdomen, following surgical debridement of acute or chronic wounds (e.g., orthopedic, necrotizing infection, pressure ulcer), diabetic foot ulcers, and reconstructive surgery (e.g., burns, skin graft, muscle flap). It has also been used to prevent surgical wound infection (prophylaxis) and as a means of instillation therapy.

Contraindications

NPWT should not be used when any of the following situations are present:

- Exposed vital structures – NPWT, in the presence of exposed organs, blood vessels, or vascular grafts, increases the risk for tissue erosion, which can lead to enteric fistula formulation or hemorrhage. NPWT is generally avoided until an intervening granulation layer or tissue flap, or graft provides coverage. Although some clinicians report success using barrier dressings, caution is advised when implementing this practice.
- Presence of malignant tissue – As with normal tissues, growth of malignant tissue is promoted in the presence of sub-atmospheric pressure. Malignant tissue is also more friable and prone to bleeding.

Relative Contraindications

- Ischemic wounds – Although not absolutely contraindicated, no benefit has been demonstrated with the use of NPWT in patients with ischemic wounds. The application of negative pressure to these wounds would be expected to worsen tissue ischemia, in keeping with the biomechanism of this device.

- Ongoing infection or devitalized tissue – Adequate debridement of devitalized tissue and treatment of infection should generally be undertaken prior to using NPWT. However, instillation therapy has allowed the use of NPWT in the presence of infection, or to augment the surgical management of infection.

- Fragile skin – Caution should be used when using NPWT in patients with fragile skin due to age, chronic corticosteroid use, or collagen vascular disorder. Shearing forces at the wound margin can lead to skin avulsion and necrosis. NPWT may nevertheless offer considerable benefits in at-risk patients if the perimeter of the wound is adequately protected.

- Adhesive allergy – NPWT requires an adequate seal to maintain the applied suction. The adhesive cover typically overlaps the skin 4 to 5 cm with a significant amount of adhesive in contact with the patient's skin. Sensitive patients can develop shearing of the skin and bullae formation.

Complications

- Bleeding
- Infection
- Enterocutaneous fistula

The use of non-powered (mechanical) NPWT devices (e.g., the Smart Negative Pressure [SNaP] Wound Care System) is considered experimental and investigational because their effectiveness has not been established.

Criteria

NWPT is considered medically necessary when **ALL** the following have been met:

1. A complete wound care program, which includes **ALL** the following has been implemented:
   a. Documentation of evaluation, care, and wound measurements by a licensed medical professional; **AND**
   b. Application of dressings to maintain a moist environment; **AND**
   c. Debridement of necrotic tissue when present; **AND**
   d. Underlying nutritional deficiencies have been addressed; **AND**
   e. Underlying comorbidities, such as diabetes or venous insufficiency, have been managed; **AND**
2. **ONE** or more of the following eligible conditions is present:
   a. Stage III or IV pressure ulcers; **OR**
   b. Neuropathic ulcers; **OR**
   c. Ulcers related to venous or arterial insufficiency; **OR**
   d. Wound dehiscence with exposed hardware or bone; **OR**
   e. Post sternotomy wound infection or mediastinitis; **OR**
   f. Complications of a surgically created wound where accelerated granulation therapy is necessary and cannot be achieved by other available topical wound treatment; **AND**
3. None of the following **contraindications** to NPWT are present:
   a. Exposed anastomotic site; **OR**
   b. Exposed nerve; **OR**
   c. Exposed organs; **OR**
   d. Exposed vasculature; **OR**
   e. Presence of cancer in the wound; **OR**
   f. Necrotic tissue with eschar; **OR**
   g. Non-enteric and unexplored fistulas; **OR**
   h. Untreated osteomyelitis.

NWPT for continued use is considered medically necessary when **ALL** the following are met:

1. Assessment of wound dimensions and characteristics are performed by a licensed healthcare professional on at least a monthly basis and documented in the medical record; **AND**
2. The measurements document progressive wound healing.

Definitions – Pressure Ulcer Stages

Pressure Injury:
A pressure injury is localized damage to the skin and/or underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. The injury occurs because of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities, and condition of the soft tissue.

Stage 1: 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: 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 including incontinence associated dermatitis, intertriginous dermatitis, medical adhesive related skin injury, or traumatic wounds (skin tears, burns, abrasions).

Stage 3: Full-thickness loss of skin, in which adipose (fat) is visible in the ulcer and granulation tissue with 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: 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 with rolled edges, undermining and/or tunneling often occur. Depth varies by anatomical location. If slough or eschar obscures the extent of tissue loss this is an unstageable pressure injury.

Coding

The following list of codes is provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS/CPT code is inappropriate.

HCPCS	Description
E2402	Negative pressure wound therapy electrical pump, stationary or portable.

References

Optum 360/EncoderPro.

Gestring M. negative pressure wound therapy. UpToDate. Topic last updated: Nov 17, 2023.

Negative Pressure Wound Therapy Pumps. Local Coverage Determination LCD ID L33821. CMS. Revision Effective Date: For services performed on or after 01/01/2024.

Negative Pressure Wound therapy. Milliman Clinical Guidelines Ambulatory Care 27th Ed. ACG: A-0346. MCG Health copyright 2023.

Zaver V. Negative Pressure Wound Therapy. National Center for Biotechnology Information. NIH. Last Update: September 4, 2023.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version

Signature

Change Date	Changed By	Description of Change	Version
10/18/2024	CAC	Annual Review. Added Relative Contraindications and Complications under Contraindications section. References updated.	11

Signature
William (Bill) Jagiello, DO

Change Date	Changed By	Description of Change	Version

Criteria Change History

11/14/2023	Medical Director	MMIS updated.	10
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
			9
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Change Date	**Changed By**	**Description of Change**	**Version**
10/21/2022	CAC	Criteria rewrite.	8
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Change Date	**Changed By**	**Description of Change**	**Version**
4/15/2022	CAC	Annual review.	7
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Change Date	**Changed By**	**Description of Change**	**Version**
4/16/2021	CAC	Annual review. Minor formatting changes.	6
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
4/20/2018	CAC	Added Criteria #5, #6, and #7.	5
Signature C. David Smith, MD			
Change Date	**Changed By**	**Description of Change**	**Version**
4/15/2016	CAC	Added criteria #4, #5, #6. Coverage position (outpatient and inpatient) removed “30 day timeframe”.	4
Signature			
Change Date	**Changed By**	**Description of Change**	**Version**
4/17/2015	CAC	Added paragraph in References.	3
Signature			
Change Date	**Changed By**	**Description of Change**	**Version**
4/18/2014	Medical Director	Changed name from Wound Vacuum to Negative Pressure Wound Therapy (NPWT). Added under Coverage Position (Outpatient) #1 “all wound measurements must be provided”. Formatting changes.	2
Signature			
Change Date	**Changed By**	**Description of Change**	**Version**
10/27/2012	CAC	Removed #1 and replaced as definition of chronic wounds. Re-number #2 and #3 to be #1 and #2. Removed “of the healing arts” from criterion #2.	1

Criteria Change History	
	Coverage positions added “Patient must meet ONE of the following:”. Removed wound/ulcer “with lack of healing” for outpatient setting #1.
Signature	