



Negative Pressure Wound Therapy (NPWT)

Clinical Guidelines for Medical Necessity Review

Version: 1.0
Effective Date: October 23, 2023

Important Notices

Notices & Disclaimers:

GUIDELINES SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION MAKING OF END USERS.

Cohere Health, Inc. ("**Cohere**") has published these clinical guidelines to determine medical necessity of services (the "**Guidelines**") for informational purposes only, and solely for use by Cohere's authorized "**End Users**". These Guidelines (and any attachments or linked third party content) are not intended to be a substitute for medical advice, diagnosis, or treatment directed by an appropriately licensed healthcare professional. These Guidelines are not in any way intended to support clinical decision making of any kind; their sole purpose and intended use is to summarize certain criteria Cohere may use when reviewing the medical necessity of any service requests submitted to Cohere by End Users. Always seek the advice of a qualified healthcare professional regarding any medical questions, treatment decisions, or other clinical guidance. The Guidelines, including any attachments or linked content, are subject to change at any time without notice.

©2023 Cohere Health, Inc. All Rights Reserved.

Other Notices:

HCPCS® and CPT® copyright 2022 American Medical Association. All rights reserved.

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

HCPCS and CPT are registered trademarks of the American Medical Association.

Guideline Information:

Specialty Area: Diseases & Disorders of the Musculoskeletal System (M00-M99)

Guideline Name: Negative Pressure Wound Therapy

Literature review current through: 10/20/2023

Document last updated: 10/23/2023

Type: Adult (18+ yo) | Pediatric (0-17yo)

Table of Contents

| | |
|--------------------------------------------------------|-----------|
| Important Notices | 2 |
| Table of Contents | 3 |
| Medical Necessity Criteria | 4 |
| Service: | 4 |
| General Guidelines | 4 |
| Medical Necessity Criteria | 4 |
| Indications | 4 |
| Non-Indications | 6 |
| Level of Care Criteria | 7 |
| Procedure Codes (HCPCS/CPT) | 7 |
| Medical Evidence | 8 |
| References | 10 |
| Clinical Guideline Revision History/Information | 12 |

Medical Necessity Criteria

Service: Negative Pressure Wound Therapy

General Guidelines

- **Units, Frequency, & Duration:** Frequency and duration depend on wound improvement.
- **Criteria for Subsequent Requests:** Approval when medical necessity criteria are met.
- **Recommended Clinical Approach:** Negative pressure wound therapy (NPWT) is a method of wound care to manage wound exudates and promote wound closure utilizing durable or disposable medical equipment. NPWT involves the application of controlled or intermittent negative pressure to a properly dressed wound cavity. Suction (negative pressure) is applied under airtight wound dressings to promote the healing of open wounds resistant to prior treatments. A vacuum-assisted drainage collection may cleanse the wound by removing fluids and stimulating the wound bed to reduce localized edema. Local oxygen supply also improves.¹⁻²
- **Exclusions:** None.

Medical Necessity Criteria

Indications

- **Negative Pressure Wound Therapy (NPWT)** is considered appropriate if **ANY** of the following is **TRUE**:
- ◆ The patient has **ANY** of the following:
 - Complications of a **surgically created wound** (e.g., dehiscence, post sternotomy disunion with exposed sternal bone, post sternotomy mediastinitis, or postoperative disunion of the abdominal wall)¹⁻²; **OR**
 - A **traumatic wound** (e.g., preoperative flap or graft, exposed bones, tendons, or vessels) requiring accelerated formation of granulation tissue, which is not achievable by other topical wound treatments (e.g., comorbidities that will not allow for healing times usually achievable with other available topical wound treatments)¹⁻²; **OR**

- A **chronic, non-healing ulcer** and **ALL** of the following are **TRUE**:
 - No improvement with standard wound therapy (e.g., application of dressings, debridement of necrotic tissue [if present], maintenance of an adequate nutritional status)¹⁻²; **AND**
 - Weekly evaluations with documentation of wound measurements (e.g., length, width, and depth) in **ANY** of the following clinical situations:¹⁻²
 - ◆ Acute wounds; **OR**
 - ◆ Subacute and dehisced wounds; **OR**
 - ◆ Traumatic wounds; **OR**
 - ◆ Ulcers (e.g., diabetic or pressure); **OR**³⁻⁴
 - ◆ Chronic Stage III or Stage IV pressure ulcer; **OR**
 - ◆ Chronic diabetic neuropathic ulcer; **OR**
 - ◆ Chronic venous ulcer; **OR**
 - ◆ Flaps and grafts; **AND**
- ◆ The patient will receive treatment in **ANY** of the following settings:⁵
 - For the Home Setting when **ALL** of the following are **TRUE**:
 - Patient is in a wound therapy program that includes **ALL** of the following, which should either be addressed, applied, or considered and ruled out prior to application of NPWT:
 - ◆ Documentation of evaluation, care, and wound measurements; **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**
 - The patient has **ANY** of the following:
 - ◆ Stage 3 or 4 pressure ulcer with **ALL** of the following:
 - Patient has been appropriately turned and positioned; **AND**
 - Patient has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis; **AND**

- Patient's moisture and incontinence have been appropriately managed; **OR**
- ◆ Neuropathic (e.g., diabetic) ulcers with **ALL** of the following:
 - Enrolled in a comprehensive diabetic management program; **AND**
 - Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities; **OR**
- ◆ Venous insufficiency ulcers with **ALL** of the following:
 - Compression bandages or garments have been consistently applied; **AND**
 - Leg elevation and ambulation have been encouraged; **OR**
- For the Inpatient Setting when **ALL** of the following are **TRUE**:
 - Criteria listed above for the Home Setting has been tried, considered, or ruled out; **AND**
 - NPWT is desired due to the potential to improve the patient's condition as it is the best available treatment option; **AND**
 - Patient has complications due to **ANY** of the following and acceleration of formation of granulation tissue is necessary:
 - ◆ Surgically created wound (e.g., dehiscence); **OR**
 - ◆ Traumatic wound (e.g., preoperative flap or graft).

Non-Indications

- **Negative Pressure Wound Therapy (NPWT)** is not considered appropriate if **ANY** of the following is **TRUE**.⁶⁻⁷
- ◆ Active bleeding or exposed vasculature in the wound; **OR**
 - ◆ Eschar or necrotic tissue; **OR**
 - ◆ Exposed cortical bone, nerves, or organs; **OR**
 - ◆ Fistulas to body organs or cavities that require investigation; **OR**
 - ◆ Malignancy; **OR**
 - ◆ Soft tissue infection or osteomyelitis that is unresponsive to treatment.

Level of Care Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

| HCPCS/CPT Code | Code Description |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 |
| 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 |
|--|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Medical Evidence

Seidel et al. (2022) report on the results of the randomized clinical trial (RCT) for post-surgical Subcutaneous Abdominal Wound Healing Impairments (SAWHI). Outpatient negative pressure wound therapy (NPWT) is recommended and reduces hospitalization and is an alternative to conventional wound treatment (CWT). Results show that NPWT treatment time is 7.8 days less than CWT. The wound closure rate is 20% higher with NPWT, yet hospitalization is two days longer than with CWT. Most patients in the study were in the hospital for less than 42 days.⁸⁻⁹

Seidel et al. (2022) also report on the DiaFu RCT that compared NPWT and standard moist wound care (SMWC) for diabetic foot ulcers following amputation, surgical debridement, or wound cleansing. A total of 368 patients were included and assigned to either the NPWT or SMWC group. Results support the use of NPWT with evidence of less frequent daily dressing changes, decreased treatment time (16 days less than with SMWC), and a decrease in time for surgical debridement (23.3 minutes less).¹⁰

National and Professional Organizations

The **American Academy of Orthopaedic Surgeons (AAOS)** published guidelines on the *Prevention of Surgical Site Infections After Major Extremity Trauma*. The AAOS does not recommend NPWT for patients requiring a fracture fixation. Limited evidence supports the use of NPWT for patients with high-risk surgical incisions. The guidelines also focus on the inpatient setting, and little information exists regarding the outpatient setting.¹¹

The **National Institute for Health and Clinical Excellence (NICE)** published the following guidelines highlighting NPWT:

- *The VAC Veraflo Therapy System for Acute Infected or Chronic Wounds That Are Failing to Heal* states that additional research and randomized control trials are needed. There is no formal recommendation.¹²
- *PICO Negative Pressure Wound Dressings for Closed Surgical Incisions* includes a NICE recommendation for the use of NPWT for closed

surgical incisions as evidence shows fewer infections and seromas when compared to standard wound dressings.¹³

- *Diabetic Foot Problems: Prevention and Management* includes recommendations for NPWT following surgical debridement.¹⁴
- *Pressure Ulcers: Prevention and Management* guides routine use of NPWT for adults unless required to limit the frequency of dressing changes. There is no guidance for NPWT for infants and children.¹⁵
- *Negative Pressure Wound Therapy for the Open Abdomen* includes recommendations for treating surgical wounds.¹⁶

References

1. Centers for Medicare and Medicaid Services (CMS). Local coverage determination: Wound care (L35125). Revision Effective Date July 23, 2020. Accessed October 9, 2023. <https://www.cms.gov/medicare-coverage-database/search.aspx>.
2. Centers for Medicare and Medicaid Services (CMS). Local coverage determination: Wound care (L37166). Revision Effective Date July 23, 2020. Accessed October 9, 2023. <https://www.cms.gov/medicare-coverage-database/search.aspx>.
3. Lavery LA, Davis KE, Berriman SJ, et al. WHS guidelines update: Diabetic foot ulcer treatment guidelines. *Wound Repair Regen*. 2016 Jan-Feb;24(1):112-26. doi: 10.1111/wrr.12391. PMID: 26663430.
4. Snyder RJ, Hanft JR. Diabetic foot ulcers – effects on QOL, costs, and mortality and the role of standard wound care and advanced-care therapies. *Ostomy Wound Manage*. 2009 Nov 1;55(11):28-38. PMID: 19934461.
5. Centers for Medicare and Medicaid Services (CMS). Local coverage determination: Negative pressure wound therapy pumps (L33821). Revision Effective Date May 1, 2021. Accessed October 9, 2023. <https://www.cms.gov/medicare-coverage-database/search.aspx>.
6. Huang C, Leavitt T, Bayer LR, et al. Effect of negative pressure wound therapy on wound healing. *Curr Probl Surg*. 2014 Jul;51(7):301-31. doi: 10.1067/j.cpsurg.2014.04.001. PMID: 24935079.
7. Vig S, Dowsett C, Berg L, et al. Evidence-based recommendations for the use of negative pressure wound therapy in chronic wounds: Steps towards an international consensus. *J Tissue Viability*. 2011 Dec;20 Suppl 1:S1-18. doi: 10.1016/j.jtv.2011.07.002. PMID: 22119531.
8. Seidel D, SAWHI Study Group. Ambulatory negative pressure wound therapy of subcutaneous abdominal wounds after surgery: Results of the SAWHI randomized clinical trial. *BMC Surg*. 2022 Dec 12;22(1):425. doi: 10.1186/s12893-022-01863-x. PMID: 36503505; PMCID: PMC9743503.
9. Seidel D, Rolf Lefering. NPWT resource use compared with conventional wound treatment in subcutaneous abdominal wounds with healing impairment after surgery: SAWHI randomized clinical trial results. *Ann Surg*. 2022 Feb 1;275(2):e290-e298. doi: 10.1097/SLA.0000000000004960. PMID: 34117147; PMCID: PMC8746894.
10. Seidel D, Lefering R; DiaFu Study Group. NPWT resource use compared with standard moist wound care in diabetic foot wounds: DiaFu randomized clinical trial results. *J Foot Ankle Res*. 2022 Sep 30;15(1):72. doi: 10.1186/s13047-022-00569-w. PMID: 36180953; PMCID: PMC9524075.
11. American Academy of Orthopaedic Surgeons (AAOS). Prevention of surgical site infections after major extremity trauma. Published March 21, 2022. Accessed October 10, 2023.

<https://www.aaos.org/globalassets/quality-and-practice-resources/dod/ssitrauma/ssitraumacpg.pdf>.

12. National Institute for Health and Care Excellence (NICE). The VAC Veraflo Therapy system for acute infected or chronic wounds that are failing to heal [MTG54]. Published January 27, 2021. Accessed October 10, 2023. <https://www.nice.org.uk/guidance/mtg54>.
13. National Institute for Health and Care Excellence (NICE). PICO negative pressure wound dressings for closed surgical incisions [MTG43]. Published May 9, 2019. Accessed October 10, 2023. <https://www.nice.org.uk/guidance/mtg43>.
14. National Institute for Health and Care Excellence (NICE). Diabetic foot problems: Prevention and management. Published August 26, 2015. Updated October 11, 2019. Accessed October 10, 2023. <https://www.nice.org.uk/guidance/ng19>.
15. National Institute for Health and Clinical Excellence (NICE). Pressure ulcers: Prevention and management [CG179]. Published April 23, 2014. Accessed October 10, 2023. <https://www.nice.org.uk/guidance/cg179>.
16. National Institute for Health and Clinical Excellence (NICE). Negative pressure wound therapy for the open abdomen [IPG467]. Published November 27, 2013. Accessed October 10, 2023. <https://www.nice.org.uk/guidance/ipg467>.

Clinical Guideline Revision History/Information

| | |
|---------------------------------|--|
| Original Date: October 23, 2023 | |
| Review History | |
| | |
| | |
| | |