

Medical Policy Manual

Approved Revised Policy: Do Not Implement Until 8/30/25

Negative Pressure Wound Therapy in the Outpatient Setting

DESCRIPTION

Negative pressure wound therapy (NPWT) consists of the use of a negative pressure or suction device to aspirate and remove fluid, debris, and infectious materials from the wound bed to promote the formation of granulation tissue. NPWT uses a specialized dressing and vacuum drainage to remove blood or serous fluid from a wound or surgical site while maintaining a moist wound environment. It is delivered through an integrated system of a suction pump, separate exudate collection chamber, and dressing sets to a qualified wound. When the exposed end of the drain tube is connected to sub-atmospheric pressure or a vacuum source, fluid is drawn from the wound through the foam into a reservoir, for subsequent disposal. Negative pressure wound therapy may be delivered using mechanically powered or electrically powered devices.

POLICY

- Powered negative pressure wound therapy may be considered **medically necessary** if the medical appropriateness criteria are met (**See Medical Appropriateness below**).
- Non-powered negative pressure wound therapy devices for the treatment of wounds are considered **investigational**.

MEDICAL APPROPRIATENESS

- Powered negative pressure wound therapy is considered **medically appropriate** if **ALL** of the following have been met:
 - Powered negative pressure wound therapy device is indicated for **ANY ONE** of the following:
 - Initial 30 day trial for **ANY ONE** of the following qualifying wounds:
 - Stage III or IV pressure ulcer when **ALL** of the following are met:
 - Wound has failed to heal after 90 days of optimal wound care (e.g., appropriately turned and positioned, moisture/incontinence managed)
 - The individual has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis (e.g., pressure reducing air mattress, air flotation bed, air-fluidized bed)
 - Documentation of **ANY ONE** of the following:
 - High-volume drainage interfering with healing
 - Standard dressings cannot be maintained due to anatomic factors
 - Venous insufficiency ulcers when **ALL** of the following are met:
 - High-volume drainage interfering with wound healing
 - Wound has failed to heal after 90 days of optimal wound care that includes **ALL** of the following:
 - Compression bandages and/or garments have been consistently applied
 - Leg elevation and ambulation have been encouraged, or is not applicable
 - Wounds in individuals with an underlying clinical condition (i.e., diabetes, marasmus [protein/calorie malnutrition], small vessel disease, morbid obesity) that have failed to heal after 30 days of optimal wound care (e.g., appropriately turned and positioned, moisture/incontinence managed)
 - Traumatic or surgical wounds with **ALL** of the following:
 - Delayed closure due to exposed bone, cartilage, tendon, muscle, subcutaneous tissue, or foreign material within the wound.

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- Continuation of powered negative pressure wound therapy is indicated when **ALL** of the following are met:
 - Completion of an initial 30 day therapeutic trial with documentation of **ANY ONE** of the following:
 - Development of granulation tissue
 - Decreasing wound size
 - Decreasing wound depth
 - Epithelial spread from the wound margins
 - Documented **ABSENCE of ALL** of the following:
 - Necrotic tissue with eschar
 - Untreated osteomyelitis
 - Nonenteric and unexplored fistula
 - Malignancy in the wound
 - Exposed nerve
 - Exposed anastomotic site (communication between blood vessels)
 - Exposed organ

IMPORTANT REMINDERS

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g. statement.
- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

ADDITIONAL INFORMATION

Evidence from comparative clinical trials demonstrated that use of NPWT may provide a significant clinical benefit in a subset of problematic wounds. Due to clinical variability, it is not possible to determine prospectively which wounds are most likely to respond favorably to NPWT. For this reason, a thirty-day therapeutic trial of NPWT is considered medically appropriate for chronic wounds that have failed to heal despite intense conventional wound therapy.

Current studies of a small number of individuals using the non-powered (mechanical) gauze based NPWT system are insufficient to draw conclusions about its impact on net health outcome.

SOURCES

American Academy of Orthopaedic Surgeons. (2022, March). *Prevention of surgical site infections after major extremity trauma*. Retrieved February 28, 2023 from <http://www.aaos.org/ssitraumacpg>.

Bertges, D., Smith, L., Scully, R., Wyers, M., Eldrup-Jorgensen, J., & Suckow, B., et al. (2021). A multicenter, prospective randomized trial of negative pressure wound therapy for infrainguinal revascularization with a groin incision. *Journal of Vascular Surgery*, 74 (1), 257–267.e1. Abstract retrieved March 1, 2023 from PubMed database.

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BlueCross BlueShield Association. Evidence Positioning System. (2:2025). *Negative pressure wound therapy in the outpatient setting*. (1.01.16) Retrieved April 10, 2025 from www.bcbsaoca.com/eps/. (52 articles and/or guidelines reviewed)

CGS Administrators, LLC. (2021, January). Local Coverage Article: *Pressure reducing support surfaces – group 2 – policy article* (A52490). Retrieved January 21, 2021 from www.cms.gov.

CGS Administrators, LLC. (2021, January). Local Coverage Article: *Pressure reducing support surfaces – group 3 – policy article* (A52468). Retrieved January 21, 2021 from www.cms.gov.

CGS Administrators, LLC. (2021, August). Local Coverage Article: *Negative pressure wound therapy pumps – policy article* (A52511). Retrieved December 16, 2021 from www.cms.gov.

Chen, L., Zhang, S., Da, J., Wu, W., Ma, F., & Tang, C. (2021). A systematic review and meta-analysis of efficacy and safety of negative pressure wound therapy in the treatment of diabetic foot ulcer. *Annals of Palliative Medicine*, 10 (10), 10830–10839. (Level 2 evidence)

CMS.gov: Centers for Medicare & Medicaid Services. CGS Administrators, LLC. (2024, January). *Negative pressure wound therapy pumps*. (LCD ID: L33821). Retrieved April 23, 2024 from www.cms.gov.

De Vries, F., Wallert, E., Solomkin, J., Allegranzi, B., Egger, M., Dellinger, E., & Boermeester, M. (2016). A systematic review and meta-analysis including GRADE qualification of the risk of surgical site infections after prophylactic negative pressure wound therapy compared with conventional dressings in clean and contaminated surgery. *Medicine*, 95 (36), e4673. (Level 2 evidence)

Hussamy, D., Wortman, A., McIntire, D., Leveno, K., Casey, B., & Roberts, S. (2019). Closed incision negative pressure therapy in morbidly obese women undergoing cesarean delivery: A randomized controlled trial. *Obstetrics and Gynecology*, 134 (4), 781-789. (Level 2 evidence)

Janssen, A.H.J., Wegdam, J.A., Reilingh, T., Eskes, A.M., Vermeulen, H. (2020). Negative pressure wound therapy for patients with hard-to-heal wounds: a systematic review. *Journal of Wound Care*, 29 (4), 206-212. Abstract retrieved May 5, 2020 from PubMed database.

Karlakki, S.L., Hamad, A.K., Whittall, C., Graham, N.M., Banerjee, R.D., & Kuiper, J.H. (2016). Incisional negative pressure wound therapy dressings (iNPWTd) in routine primary hip and knee arthroplasties: A randomised controlled trial. *Bone & Joint Research*, 5 (8), 328-337. (Level 2 evidence)

Kim, J.H., Kim, H.J., & Lee, D.H. (2019). Comparison of the efficacy between closed incisional negative-pressure wound therapy and conventional wound management after total hip and knee arthroplasties: a systematic review and meta-analysis. *Journal of Arthroplasty*, doi: 10.1016/j.arth.2019.06.020. Abstract retrieved July 15, 2019 from PubMed database. [Epub ahead of print]

Kirsner, R., Dove, C., Reyzelman, A., Vayser, D., & Jaimes, H. (2019). A prospective, randomized, controlled clinical trial on the efficacy of a single-use negative pressure wound therapy system, compared to traditional negative pressure wound therapy in the treatment of chronic ulcers of the lower extremities. *Wound Repair and Regeneration*, 27 (5), 519-529. (Level 2 evidence)



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Li, H.Z., Xu, X.H., Wang, D.W., Lin, Y.M., Lin, N., & Lu, H.D. (2019). Negative pressure wound therapy for surgical site infections: a systematic review and meta-analysis of randomized controlled trials. *Clinical Microbiology and Infection*, doi: 10.1016/j.cmi.2019.06.005. Abstract retrieved July 15, 2019 from PubMed database. [Epub ahead of print]

Liu, S., He, C., Cai, Y., Xing, Q., Guo, Y., Chen, Z, et al. (2017). Evaluation of negative-pressure wound therapy for patients with diabetic foot ulcers: systematic review and analysis. *Therapeutics and Clinical Risk Management*, 13, 533-534. (Level 2 evidence)

Murphy, P.B., Knowles, S., Chadi, S.A., Vogt, K., Brackstone, M., Koughnett, J.A.V., & Ott, M.C. Negative pressure wound therapy use to decrease surgical nosocomial events in colorectal resections (NEPTUNE): A randomized controlled trial. *Annals of Surgery*, 270 (1), 38-42. Abstract retrieved January 22, 2021 from PubMed database.

National Institute for Health and Care Excellence. (2013, November). *Negative pressure wound therapy for the open abdomen*. Retrieved October 7, 2015 from <http://www.nice.org.uk/ipg467>.

National Institute for Health and Care Excellence. (2014, April). *Pressure ulcers: prevention and management*. Retrieved June 25, 2018 from <http://www.nice.org.uk/guidance/cg179>.

National Institute for Health and Care Excellence. (2015, August, last update search October 2019). *Diabetic foot problems: prevention and management*. Retrieved May 4, 2020 from <http://www.nice.org.uk/guidance/ng19>.

National Institute for Health and Care Excellence. (2019, May). *PICO negative pressure wound dressings for closed surgical incisions*. Retrieved January 22, 2021 from <http://www.nice.org.uk/guidance/mtg43>.

Norman, G., Goh, E.L., Dumville, J.C., Shi, C., Liu, Z., Chiverton, L., et al. (2020). Negative pressure wound therapy for surgical wounds healing by primary closure (Review). *Cochrane Database of Systematic Reviews*, 5 (5), CD009261. (Level 2 evidence)

Peterson, A., Bakaysa, S., Driscoll, J., Kalyanaraman, R., & House, M. (2021). Randomized controlled trial of single-use negative-pressure wound therapy dressings in morbidly obese patients undergoing cesarean delivery. *American Journal of Obstetrics & Gynecology MFM*, 3 (5), 100410. Abstract retrieved March 1, 2023 from PubMed database.

Seidel, D., Diedrich, S., Herrle, F., Thielemann, H., Marusch, F., Schirren, R., et al. (2020). Negative pressure wound therapy vs conventional wound treatment in subcutaneous abdominal wound healing impairment: The SAWHI randomized clinical trial. *JAMA Surgery*, 155 (6), 469-478. (Level 2 evidence)

U. S. Food and Drug Administration. (2013, November). Center for Devices and Radiologic Health. 510(k) *Premarket Notification Database*. K132741. Retrieved October 7, 2015 from <http://www.fda.gov>.

Winifred S. Hayes, Inc. Medical Technology Directory. (2020, February; last update search March 2023). *Negative pressure wound therapy after surgery for pilonidal disease*. Retrieved April 24, 2024 from www.Hayes.com/subscribers. (22 articles and/or guidelines reviewed).

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Winifred S. Hayes, Inc. Medical Technology Directory. (2021, February; last update search March 2024).

Prophylactic negative pressure wound therapy in elective open abdominal surgeries. Retrieved April 24, 2024 from www.Hayes.com/subscribers. (58 articles and/or guidelines reviewed).

EFFECTIVE DATE

8/30/2025

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