Molina Clinical Policy
Negative Pressure Wound Therapy: Policy No. 407

Last Approval: 2/8/2023
Next Review Due By: February 2024

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Negative Pressure Wound Therapy (NPWT), also referred to as vacuum-assisted wound closure, is a method of wound care used to manage wound exudates and promote wound closure. In NPWT, a wound dressing system comprised of durable or disposable medical equipment is connected to the wound via a foam or gauze dressing. The system provides continuous or intermittent sub-atmospheric pressure to the wound. The resulting negative pressure helps to cleanse the wound by removing exudate and reducing localized edema, stimulate the wound bed to improve vascularization and local oxygen supply, and encourage the growth of new granulation tissue to optimize wound healing. NPWT is also associated with indirect effects including diminished inflammatory response, altered bacterial burden, and changes in wound biochemistry.

In addition to accelerated wound healing, advantages of NPWT in comparison to traditional wound therapy include reduced frequency of dressing changes and increased ability to customize the size and positioning of dressings for wounds that may otherwise be challenging to dress. The main disadvantage, from a patient perspective, is the burden of carrying the portable pump. Contraindications to NPWT include exposed vital structures (e.g., exposed vital organs, arteries, or veins) and presence of malignant tissue. Relative contraindications include use in ischemic wounds, use in wounds that have not undergone adequate debridement, use in wounds with ongoing infection (e.g., osteomyelitis, cellulitis), active bleeding, or use with patients with adhesive allergy or fragile skin. While NPWT is generally safe and well tolerated, complications can include bleeding, infection, and organ damage; any of which could potentially lead to death. Complications are more likely to occur when NPWT is used in patients with contraindications.

Prophylactic Negative Pressure Wound Therapy (pNPWT)

Prophylactic NPWT has been proposed as an alternative to standard primary closure of surgical wounds following abdominal, vascular, and orthopedic surgeries with the primary goal of preventing surgical site infections (SSIs). Potential effects leading to this goal include removing the exudate or debris, reducing bacterial contamination, increasing local blood flow, and producing granulation tissue. However, evidence has not confirmed these benefits and the usefulness of pNPWT as a primary means of surgical wound closure remains uncertain (Gestring, 2022).

Food and Drug Administration (FDA)

While NPWT is a procedure and not subject to FDA regulation, medical devices used as part of this procedure are. Devices are regulated as a Class II device. Devices FDA approved for NPWT include, but are not limited to:

- NPWT device for reduction of wound complication (21 CFR 878.4783; product code, QFC)
- NPWT Powered Suction Pump (21 CFR 878.4780; product code, OMP)
- PREVENA 125 and PREVENA PLUS 125 Therapy Units
- PICO 7 Single Use Negative Pressure Wound Therapy System, PICO 7Y Single Use Negative Pressure Wound Therapy System, PICO 14 Single Use Negative Pressure Wound Therapy System, PICO Fluid Management Pack
- ACTIV.A.C. Negative Pressure Wound Therapy System

COVERAGE POLICY

Negative Pressure Wound Therapy (NPWT) (or vacuum-assisted wound closure) **may be considered medically necessary** when **ALL** of the following are present:**

1. Wound as indicated by **ONE** or more of the following:

    a. There is a chronic, non-healing ulcer with lack of improvement despite standard wound therapy, including the application of dressings, debridement of necrotic tissue (if present), maintenance of an adequate nutritional status, and weekly evaluations with documentation of wound measurements (e.g., length, width, and depth) in ONE of the following clinical situations:
    - Subacute and dehisced wounds; **OR**
    - Traumatic wounds; **OR**
    - Chronic Stage III or Stage IV pressure ulcer; **OR**
    - Chronic diabetic neuropathic ulcer; **OR**
    - Chronic venous ulcer; **OR**
    - Flaps and grafts; **OR**

    b. Diabetic ulcer or wound, as indicated by 1 or more of the following:
    - Complex diabetic ulcer or wound (e.g., Wagner or University of Texas classification grade 2 wound)^^; **OR**
    - Postamputation diabetic wound; **OR**
    - Superficial ulcer or wound (e.g., Wagner or University of Texas classification grade 1 diabetic wound)^^ that has not responded to 4 weeks of conventional treatment.

    OR

    c. Open fracture; **OR**

    d. Sternal infection; **OR**

    e. Due to 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); **OR**

    f. Traumatic wound (e.g., preoperative flap or graft, exposed bones or tendons) and a need for accelerated formation of granulation tissue not achievable by other topical wound treatments (e.g., the individual has comorbidities that will not allow for healing times usually achievable with other available topical wound treatments);

AND

2. **ALL** of the following are met:
    a. Conventional wound management ongoing (e.g., debridement as indicated); **AND**
    b. No active bleeding or exposed vasculature in wound; **AND**
    c. No eschar or necrotic tissue; **AND**
    d. No exposed cortical bone, nerves, or organs; **AND**
    e. No malignancy in wound; **AND**
    f. No uncontrolled soft tissue infection or osteomyelitis; **AND**
    g. No unexplored fistulas or fistulas to body organs or cavities.

** NPWT has been shown to be safe and effective in children.
^^ The Wagner classification system is the most commonly used scale for grading the severity of diabetic foot ulcers. Grade 1 refers to superficial diabetic ulcers and grade 2 refers to ulcers that have extended to ligament, tendon, joint capsule, or deep fascia. The University of Texas diabetic wound classification system is a similar grading scale: grade 1 refers to superficial wounds and grade 2 refers to wounds that penetrate to tendon or capsule. The University of Texas system also allows for specifying the presence of infection or ischemia in the wound.

As part of documentation submitted, photographs of the wound are preferred.

Continuation of Therapy

Coverage for wound care on a continuing basis for a given wound is contingent upon evidence documented in the medical record that the wound is improving in response to the wound care being provided. Evidence of improvement may include measurable changes in the following:

- Drainage; **OR**
- Inflammation; **OR**
- Swelling; **OR**
- Pain and/or tenderness; **OR**
- Wound dimensions (surface measurements, depth); **OR**
- Granulation tissue; **OR**
- Necrotic tissue/slough; **OR**
- Tunneling or undermining.

Approval is for a total of 12 weeks in 30-day increments. Continuation requires documentation and evidence of evaluation by the treating Provider, including progress notes and treatment plan. Specific information describing wound should also be provided (e.g., measurements, location, drainage, etc.). Recommended maximum treatment duration is for 3 months, unless otherwise medically indicated.

Contraindications

The list of general product-specific contraindications for the use of NPWT includes, but is not limited to:

- Untreated infection, including osteomyelitis within the vicinity of the wound, that is not concurrently being treated with intent to cure; **OR**
- Malignant wounds (with the exception of palliative care); **OR**
- Non-enteric and unexplored fistulae; **OR**
- Exposed arteries, veins, organs, or anastomotic sites; **OR**
- Necrotic tissue with eschar dry/wounds; **OR**
- Severe peripheral arterial disease; **OR**
- Any cavity/sinus of which the organ is not clearly visible; **OR**
- Uncontrolled bleeding; **OR**
- Allergy to adhesive dressing or silver (for silver-based foam).

Limitations and Exclusions

The following limitations and exclusions apply:

1. Comprehensive wound management with the absence of measures noted below – coverage requires that all applicable adjunctive measures are also employed:
   - Appropriate control of complicating factors (e.g., unrelieved pressure, infection, vascular and/or uncontrolled metabolic derangement); **AND/OR**
   - Nutritional deficiency in addition to appropriate debridement.
2. A wound that shows no improvement after 30 days may require a new approach.
3. Procedures performed for cosmetic reasons or to prepare tissues for cosmetic procedures.
4. NPWT for any of the following wound types/conditions:
   - Placement over surgically closed incisions, unless wound meets the above criteria for coverage (e.g., dehiscence); **OR**
   - Necrotic tissue with or without eschar present; **OR**
   - Osteomyelitis; **OR**
   - Non-enteric and unexplored fistulas; **OR**
   - Malignancy in the wound; **OR**
   - Exposed vasculature, nerves, anastomotic site, **OR** organs.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

NPWT

Hurd et al. (2021) published the *International Consensus Panel Recommendations for the Optimization of Traditional and Single-Use NPWT in the Treatment of Acute and Chronic Wounds.* Consensus statements were based on the factors below when considering initiation or discontinuation of NPWT:

1. **Therapeutic Goals.** Includes initiation of NPWT when there is a need to (1) promote granulation tissue; (2) prepare a wound for closure by various methods; (3) control edema; (4) manage exudate; (5) achieve wound stabilization; and (6) assist in stabilization of patients with complex and traumatic wounds.

2. **Wound-Related Factors.** Four consensus statements focus on considerations of single-use NPWT (sNPWT) and traditional NPWT (tNPWT) with respect to wound size, depth, and exudate amount as well as management capacity. sNPWT may be considered as a bolster dressing for wounds in which closure is being obtained via a split-thickness skin graft (STSG) or application of a skin substitute. Also, there is a consensus statement that notes wound reassessment at intervals of ideally two weeks to determine continuation of and appropriateness of transition from tNPWT to sNPWT.

3. **Patient Satisfaction and Quality of Life.** One consensus statement focuses on the appropriateness of NPWT for acute and chronic wounds; sNPWT should be the first-line modality to increase patient quality of life. A second consensus statement notes that sNPWT may be optimal for ambulatory patients who must return to work or who have barriers to follow-up appointments (e.g., transportation).

4. **Care Setting-Related Factors.** tNPWT is noted for patients with acute or chronic wounds that may be large or complex. Patients report stabilization of the wound and increased mobility. In addition, there is a quicker transition from critical care units to step-down units and reduced hospital length of stay.

5. **Economic-Related Factors.** sNPWT as the initial NPWT modality (or as conversion from tNPWT) can reduce overall health care costs and assist in the transition of patients from inpatient to outpatient care.

6. **NPWT System-Related Factors.** Providers should base the use of a NPWT system on the following: (1) published evidence demonstrating the effect on wound management and healing; (2) system ease of use; (3) ease of system device and supply procurement; (4) logistical and technical support provided; (4) cost effectiveness of individual systems; and (5) user/patient acceptability.

Gao et al. (2021) conducted a meta-analysis to compare the efficacy of NPWT with conventional treatment methods in the treatment of surgical site infection. All trials studied reported the use of NPWT for surgical site infection treatment, regardless of surgery type. The primary outcome measure was wound healing; secondary outcomes included length of hospital stay, medical costs, adverse events, and reoperation rates. Of the identified 13 eligible trial comparisons, two were randomized controlled trials and 11 were cohort studies. Patients with SSIs receiving NPWT had accelerated wound healing time, increased daily wound healing area, reduced hospital length of stay and reduced adverse events. In conclusion, NPWT was found to be more effective for the treatment of SSIs relative to conventional debridement, dressings and other treatments. Additional quality randomized controlled trials are needed to further determine the most optimal application of NPWT.

pNPWT to Reduce SSIs

Javed et al. (2019) studied the efficacy of NPWT for SSI after open pancreaticoduodenectomy. The single center randomized controlled trial evaluated the effect of pNPWT on rates of SSI in patients after surgical incision closure following pancreaticoduodenectomy. A total of 123 patients were randomized to either the NPWT group or the standard

closure group at the time of closure of the surgical incision. Nearly 10% of patients had an SSI in the NPWT group and in 31% of patients in the standard closure group. A relative risk reduction of 69% was reported and SSIs were found to increase hospitalization costs by 24%. The authors concluded that NPWT significantly lowered the risk of SSIs and that incorporating the intervention may decrease a complication that increases patient harm and healthcare costs.

Boland et al. (2021) further note the benefits of pNPWT to reduce SSIs, especially in patients who have had emergency laparotomy and/or bowel surgery. Evidence has lacked overall agreement regarding the use of this method for the closure of laparotomy wounds. A systematic review of randomized controlled trials was conducted on standard dressings for closed laparotomy incisions. Primary outcomes included occurrence of SSIs at 30 days post-op. Secondary outcomes comprised of superficial and deep SSI, skin dehiscence, fascial dehiscence and length of stay. Of the 2182 publications reviewed, 467 patients were randomized to NPWT and 464 to standard dressings. Rates of SSIs over were nearly 19% compared to 24% in the NPWT and standard dressing groups, respectively. Deep SSI incidence was 2.6% in both groups; skin dehiscence and fascial dehiscence were higher in the standard dressing group (4% vs. 3%) and (0.9% versus 0.6%), respectively. The study observed that NPWT reduces the overall SSI for closed laparotomy wounds. In addition, data support the use of pNPWT dressings, particularly in high-risk patients (emergency and elective settings).

Meyer et al. (2020) reviewed studies to determine if pNPWT allows preventing SSI following laparotomy. Studies included open abdominal surgeries with and without pNPWT. The 21 studies included 2930 patients, 5 randomized controlled trials (RCTs), and 16 observational studies. It was found that pNPWT was protective against the incidence of SSI with a RR of 0.53. Existing studies suggest that pNPWT on closed wounds is protective against the occurrence of SSI in abdominal surgery, however additional high-quality evidence is needed, particularly among patients with an incidence of SSI ≥20% in the control arm.

Flynn et al. (2020) reviewed studies involving negative pressure dressings (such as PICO™) that have demonstrated decreased rates of SSIs. The authors focused on determining if PICO dressings improve outcomes of SSIs or other complications at the surgical site (especially in primarily closed laparotomy incisions in moderate-risk patients). Of 217 patients that were included in the trial, a total of 188 patients stayed in the trial (29 were excluded). Ninety-six received PICO and 92 received a standard dressing. Twenty-seven (14%) patients developed a surgical site infection; 13 received a PICO dressing and 14 received standard dressing which indicates that there is no difference in SSIs between the two types of dressing. Thirty-one patients developed other related surgical site complications; eleven patients received a PICO dressing and 20 received the standard dressing. In conclusion, the study does not support routine use of PICO dressings on uncomplicated laparotomy incisions in moderate-risk patients.

Leitao et al. (2021) conducted a RTC to estimate the efficacy of pNPWT in preventing wound complications in patients undergoing laparotomy for gynecologic surgery. A total of 505 patients were selected for randomization, 254 to pNPWT and 251 to standard gauze. The trial was stopped due to futility after the evaluation of results from 444 patients. In the 444 patients evaluated, the rate of wound complications was 17.3% in the pNPWT group and 16.3% in the gauze group. Skin blistering was found in 13% of patients in the pNPWT group and in 1.2% of patients in the gauze group, leading to the study conclusion that pNPWT after laparotomy for gynecologic surgery did not lower wound complication rates and lead to increased skin blistering.

Hayes (2021) conducted a literature search which identified 13 studies with a total of 50 to 394 patients. The goal was to evaluate the efficacy and safety of pNPWT in those who had elective open abdominal surgeries. This included 7 randomized controlled trials (RCTs) in 8 publications and 6 retrospective comparative cohort studies. All studies looked at NPWT with standard sterile dressing (SSD) except for one which compared NPWT to primary closure with SSD or delayed primary closure with SSD. All studies had a follow-up of 30 days with rare reporting of outcomes past 30 days post-operation. Despite the increase of medical literature supporting pNPWT, there is a lack of consensus regarding its use in laparotomy to prevent SSIs. Evidence also differs regarding preoperative risk for SSIs as the population of studies varies as well as a variance in the types of surgical procedures. Results from meta-analyses may give additional insight. Two meta-analyses included in a Hayes Health Technology Assessment support that NPWT can reduce the SSI rates in open abdominal surgeries based on available RCT evidence and observational studies.

National and Specialty Organizations

The **American College of Surgeons (ACS) / Surgical Infection Society (SIS)** published *Surgical Site Infection (SSI) Guidelines* (2016). The Guidelines note that although the use of pNPWT over closed incisions to decrease SSI is generally supported in the literature, studies to date have been too small or at risk of bias to support recommending routine use (Ban et al., 2016).

The **World Health Organization (WHO)** (2018) published the *Global Guidelines for the Prevention of Surgical Site Infection* (2016). The panel suggests that pNPWT may be used on primarily closed surgical incisions in high-risk wounds with a goal of preventing SSIs, however the recommendation noted the quality of evidence on this use is low. High risk wounds are defined as “poor tissue perfusion due to surrounding soft tissue/skin damage, decreased blood flow, bleeding/hematoma, dead space, intraoperative contamination."

In 2019, the **National Institute for Health and Care Excellence (NICE)** ([1]NICE, 2019) published a Medical Technologies Guidance (MTG) titled *PICO Negative Pressure Wound Dressings for Closed Surgical Incisions*. These types of dressings should be an option for patients at high risk for developing SSIs with closed surgical incisions. The guidance emphasizes that careful patient selection is important when using PICO dressing (e.g., surgery type, patient risk assessment for postoperative complications). Evidence was limited and specific recommendations based on surgery could not be issues.

In addition, NICE ([2]NICE, 2019) published a Medtech Innovation Briefing (MIB) on the *Prevena Incision Management System for Closed Surgical Incisions* based on evidence from seven studies which were considered good quality. The briefing on this pNPWT notes that studies show that Prevena may be more effective at reducing complications than standard care, however the sample populations were heterogenous making it difficult to draw general conclusions about the technology.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
97605	Negative pressure wound therapy (e.g., 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 (e.g., 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, (e.g., 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, (e.g., 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

HCPCS Codes

HCPCS	Description
A6550	Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories
E2402	Negative pressure wound therapy electrical pump, stationary or portable

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

02/08/2023	Summary of Evidence updated. Policy updated to address NPWT only, extraneous criteria removed. IRO Peer Review. Policy reviewed January 2023 by a physician board certified in wound care.
12/08/2021	New policy.

REFERENCES

Government Agency

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2. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Local coverage determination (LCD): Negative pressure wound therapy pumps (L33821). Available from CMS. Effective October 1, 2015. Revised May 1, 2021.
3. United States Food and Drug Administration (FDA). Establishment Registration & Device Listing. Available from FDA.

Evidence Based Reviews and Publications

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2. Hayes. Evidence analysis research brief: Negative pressure wound therapy for closed surgical incisions following total joint arthroplasty. Available from Hayes. Published October 18, 2022. Registration and login required.
3. Hayes. Evidence analysis research brief: Outpatient negative pressure wound therapy for treatment of chronic wounds. Available from Hayes. Published March 31, 2022. Registration and login required.
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5. Hayes. Health Technology Assessment: Prophylactic negative pressure wound therapy in elective open abdominal surgeries. Available from Hayes. Published February 4, 2021. Annual review January 18, 2022. Registration and login required.
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Peer Reviewed Publications

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2. Flynn J, Choy A, Leavy K, et al. Negative pressure dressings (PICO™) on laparotomy wounds do not reduce risk of surgical site infection. Surg Infect (Larchmt). 2020 Apr;21(3):231-238. Doi: 10.1089/sur.2019.078.
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7. Leitao MM Jr, Zhou QC, Schiavone MB, et al. Prophylactic Negative Pressure Wound Therapy After Laparotomy for Gynecologic Surgery: A Randomized Controlled Trial. Obstet Gynecol. 2021 Feb 1;137(2):334-341. Doi: 10.1097/AOG.0000000000004243.
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12. O'Leary DP, Peirce C, Anglim B, et al. Prophylactic Negative Pressure Dressing Use in Closed Laparotomy Wounds Following Abdominal Operations: A Randomized, Controlled, Open-label Trial: The P.I.C.O. Trial. Ann Surg. 2017 Jun;265(6):1082-1086. doi: 10.1097/SLA.0000000000002098.

National and Specialty Organizations

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