Molina Clinical Policy
Wound Care: Policy No. 407

Last Approval: 12/8/2021
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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.[1] References included were accurate at the time of policy approval and publication.

OVERVIEW

Wound care is defined as care of wounds that are refractory to healing or have complicated healing cycles either because of the nature of the wound itself or because of complicating metabolic and/or physiological factors. This does not include management of acute wounds; care of wounds that typically heal by primary intention (e.g., clean, incised traumatic wounds); or surgical wounds that are closed primarily and other postoperative wound care not separately covered during the surgical global period. Wound care involves the evaluation and treatment of a wound, including identifying potential causes of delayed wound healing and the modification of treatment when indicated. Wound evaluations may require a comprehensive medical evaluation, other specific evaluations (e.g., vascular, orthopedic, functional, metabolic/nutritional), and a plan of care. Reduction of pressure and/or control of infection have been shown to facilitate healing and may reduce the need for repeated debridement services. (CMS, 2017).

Wound care must be performed in accordance with accepted standards for medical and surgical treatment of wounds. The goal of most chronic wound care should be eventual wound closure (with or without grafts), skin replacements, or other surgery (e.g., amputation, wound excision, etc.). Adjunctive measures include but are not limited to appropriate control of complicating factors such as pressure (e.g., off-loading, padding, appropriate footwear), infection, vascular insufficiency, metabolic derangement and/or nutritional deficiency. While complete healing may be the primary objective, a secondary desired objective is that (with appropriate management) a wound may reach a state at which care may be performed primarily by the Member and/or the Member's caregiver with periodic physician assessment and supervision. Active wound care procedures involve selective and non-selective debridement techniques and are performed to remove devitalized tissue and promote healing. The Provider is required to have direct (one-on-one) Member contact when performing active wound care management. Appropriate interval and frequency of debridement depends on the individual clinical characteristics of the patient and the extent of the wound. (CMS, 2017).

Negative Pressure Wound Care (NPWT) utilizes either durable or disposable medical equipment and is a method of wound care to manage wound exudates and promote wound closure. The vacuum-assisted drainage collection (e.g., NPWT) may be applied in an effort to cleanse the wound by removing fluids and stimulate the wound bed in order to reduce localized edema and improve local oxygen supply. 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. (CMS, 2017).

Food and Drug Administration (FDA)

While Negative Pressure Wound Therapy (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 (below). Currently there is 1 NPWT device with a QFC product code (Hayes, 2021):

- NPWT device for reduction of wound complication (21 CFR 878.4783; product code, QFC); and
- Powered suction pump (21 CFR 878.4780; product code, OMP)

The following are FDA-cleared devices for NPWT (Hayes, 2021):

- 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

Prophylactic Negative Pressure Wound Therapy (pNPWT) in Elective Open Abdominal Surgeries

Prophylactic NPWT (pMPWT) is an alternative to standard primary closure of open abdominal wounds following elective surgery with the goal of preventing surgical site infections (SSIs). It is a therapeutic dressing system that allows negative pressure to be continuously or intermittently applied to the wound. A device includes an occlusive dressing that is sealed over the wound and connected to drainage tubing connected to a suction pump. The pump delivers negative pressure (−50 to −125 mm Hg). The goal of pMPWT is to aid wound healing, commonly in those with a higher risk of SSI – this is achieved by removing the exudate or debris, reducing bacterial contamination, increasing local blood flow, and producing granulation tissue. While NPWT is commonly used for the treatment for open wounds, post-debridement of acute or chronic wounds, and after reconstructive surgery, NPWT can be an important preventive measure to lower patient risk of SSI and other postoperative complications following elective abdominal surgery however continued research is needed. SSIs are a healthcare-associated infections (HAIs) related to surgery; there is a mortality rate of 3% and 75% of SSI-related deaths. Approximately 1 million additional inpatient days are related to SSIs and are the costliest type of HAI (estimated annual cost of $3.3 billion). To prevent extended length of stay (LOS) and complications (e.g., wound dehiscence, seroma, hematoma), NPWT after elective open abdominal surgery is recommended. (Hayes, 2021). Upon review of the level of recommendation by Hayes and due to low evidence, NPWT is not covered for elective open abdominal surgeries.

COVERAGE POLICY

Wound Care **may be considered medically necessary** when **ANY** of the following criteria are met (CMS, 2017):

1. **Wound Type.** Member has **ANY** of the following types of wounds:
   a. Surgical wounds that must be left open to heal by secondary intention; **OR**
   b. Infected open wounds induced by trauma or surgery; **OR**
   c. Wounds with biofilm; **OR**
   d. Wounds associated with complicating autoimmune, metabolic, and vascular or pressure factors; **OR**
   e. Open or closed wounds complicated by necrotic tissue and/or eschar.

OR

2. **Active Wound Care Management.** Debridement **may be medically necessary** whenever necrotic tissue as well as cellular or proteinaceous debris is present on an open wound in order to keep the wound in an active state of healing.

   Debridement **may also be considered medically necessary** in cases of abnormal wound healing or repair. The routine application of a topical or local anesthetic does not elevate active wound care management to surgical debridement:

   a. Wound Care Selective Debridement including removal of specific, targeted areas of devitalized or necrotic tissue from a wound along the margin of viable tissue by sharp dissection utilizing scissors, scalpel, curettes, and/or tweezers/forceps. This procedure typically requires no anesthesia and generally has no or minimal associated bleeding.

   OR

   b. Wound Care Non-Selective Debridement may include:

      - *Mechanical Debridement* includes the removal of necrotic tissue by cleansing or application of a wet-to-dry or dry-to-dry dressing technique. Wet-to-dry dressings should be used judiciously as maceration of surrounding tissue may hinder healing. Dressing changes are not considered a skilled service; **OR**

- *Enzymatic Debridement* includes the use of topical enzymes when the necrotic substances to be removed from a wound are protein, fiber, and collagen. The Provider is responsible for reviewing and complying with the manufacturer's product insert, indications, contraindications, precautions, dosage and administration guidelines; **OR**

- *Autolytic Debridement* is indicated where manageable amounts of necrotic tissue are present and no infection is present. Autolytic debridement occurs when the enzymes that are naturally found in wound fluids are sequestered under synthetic dressings; **OR**

- *Maggot/Larvae Therapy* is a type of debridement with medical-grade maggots in wounds.

OR

3. **Wound Care Surgical Debridement** includes conditions that may require surgical debridement of large amounts of skin and may include, but is not limited to: rapidly spreading necrotizing process (sometimes seen with aggressive streptococcal infections), severe eczema, extensive skin trauma (including large abraded areas with ground-in dirt), or autoimmune skin diseases.

   Surgical debridement occurs only if material has been excised and is typically reported for the treatment of a wound to clear and maintain the site free of devitalized tissue including, but not limited to: necrosis, eschar, slough, infected tissue, biofilm, abnormal granulation tissue, etc., and should be accomplished to the margins of viable tissue. These procedures can be very effective but represent extensive debridement. They may be complex in nature and may on occasion require the use of anesthesia.

OR

4. **Use of Evaluation and Management (E/M) Codes in Conjunction with Surgical Debridement.**

   Patients who have chronic wounds may frequently have underlying medical problems that require concomitant management in order to bring about wound closure. Patients may require education, other services, and coordination of care both in the preoperative and postoperative phases of the debridement procedure. An E/M service provided and documented on the same day as a debridement service may be covered only when the documentation clearly establishes the service as a "separately identifiable service" that was reasonable and necessary, as well as distinct, from the debridement service(s) provided.

OR

5. **Low-Frequency, Non-Contact, Non-Thermal Ultrasound (MIST Therapy)** describes a system that uses continuous low-frequency ultrasonic energy to produce and propel a mist of liquid and deliver continuous low-frequency ultrasound to the wound bed. MIST Therapy **is considered reasonable and necessary** wound therapy and when provided for **ANY** of the following:

   a. Wounds and ulcers which are too painful for sharp or excisional debridement and have failed conventional debridement with documentation supporting the same; **OR**

   b. Wounds and ulcers meeting coverage for debridement but with documented contraindications to sharp or excisional debridement; **OR**

   c. Wounds and ulcers meeting coverage for debridement but with documented evidence of no signs of improvement after 30 days of standard wound care.

   Low-frequency, non-contact, non-thermal ultrasound (MIST Therapy) may be provided two to three times per week to be considered reasonable and necessary. The length of individual treatments will vary per wound size.

   Observable, documented improvements in the wound(s) should be evident after six treatments. Improvements include documented reduction in pain, necrotic tissue, or wound size, or improved granulation tissue.

OR

6. **Application of Paste Boot (Unna Boot) or Application of Multi-Layer Compression System** which may be useful adjuncts to wound care management.

OR

7. **Negative Pressure Wound Therapy (NPWT)**

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

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

   - 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:
     - Acute wounds; **OR**
     - Subacute and dehisced wounds; **OR**
     - Traumatic wounds; **OR**
     - Ulcers (such as diabetic or pressure); **OR**
     - Chronic Stage III or Stage IV pressure ulcer; **OR**
     - Chronic diabetic neuropathic ulcer; **OR**
     - Chronic venous ulcer; **OR**
     - Flaps and grafts.
   - 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

   - Open fracture; **OR**
   - Sternal infection; **OR**
   - 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**
   - Traumatic wound (e.g., preoperative flap or graft, exposed bones, tendons, or vessels) 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); **OR**

   AND all of the following:

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

** Negative pressure wound therapy 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 in a given Member is contingent upon evidence documented in the medical record that the wound is improving in response to the wound care being provided (CMS, 2017). 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 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.).

Alternatives

The following are alternatives for the indications listed:

- For arterial ulcers: revascularization procedures
- For diabetic ulcers: topical wound treatment (e.g., alginate dressings, foam dressings), hyperbaric oxygen therapy, pressure relieving and offloading devices, or tissue-engineered skin substitutes.
- For open abdominal wounds: temporary abdominal closure, dressings, Bogota bag system.
- For pressure injuries: protein or amino acid supplementation, hydrocolloid or foam wound dressings, or pressure redistribution devices.
- For venous stasis ulcers: graduated compression therapy, tissue-engineered skin substitutes, saphenous vein radiofrequency ablation, or saphenous vein stripping.
- For wounds on weight-bearing surface: pressure relieving and offloading devices.
- For wounds with active infection: treatment directed at decreasing signs and symptoms of infection.
- For wounds with eschar or other necrotic tissue: surgical, autolytic, biological, or enzymatic debridement.
- For wounds with significant edema: compression stockings.
- Self-care and education.
- Standard wound care with dressings that maintain a moist wound bed.

Contraindications

The list of general product-specific contraindications for the use of NPWT includes, but is not limited to (Hayes, 2021):

- Untreated infection, including osteomyelitis; **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

CMS (2017) has noted the following limitations and exclusions:

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. Debridement for a wound that is clean and free of necrotic tissue/slough.
3. Debridements are considered selective or non-selective unless the medical record supports that a surgical excisional debridement was performed. Debridements are best provided under an individualized plan of care.
4. Wound care may be of a palliative nature.

   Wounds of some Medicare beneficiaries residing in Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs) may not close, heal, or be amenable to self-care despite therapy. For those where wound closure, healing, or self-care is not likely, the goals of wound care may include prevention of hospitalization and improvement in quality of life.
5. Complicating circumstances that support additional wound care services as reasonable and necessary must be supported by adequate medical record documentation.
6. Autolytic debridement for infected wounds.
7. Debridement of extensive eczematous or infected skin is not appropriate for debridement of a localized amount of tissue normally associated with a circumscribed lesion (e.g., ulcers, furuncles, and localized skin infections).
8. Surgical debridement when documentation indicates the wound is without devitalized, fibrotic, nonviable tissue, infection, necrosis, foreign matter, or if the wound has pink to red granulated tissue.
9. Wound debridement utilizing a method considered unproven by medical literature.
10. If a treatment is investigational, under waiver of liability provisions of Medicare law, an Advance Beneficiary Notice (ABN) must be obtained for the beneficiary.
11. When performed in conjunction with another wound care service, the dressing change is considered an integral component of that service and is not a separately covered service.
12. A wound that shows no improvement after 30 days may require a new approach.
13. Procedures performed for cosmetic reasons or to prepare tissues for cosmetic procedures.
14. Local infiltration, metacarpal/metatarsal/digital block or topical anesthesia are included in the reimbursement for wound care services and are not separately covered.
15. The following are considered part of an E/M service and not separately covered with another E/M service:
    - Removal of necrotic tissue by cleansing and dressing, including wet or dry-to-dry dressing changes;
    - Cleansing and dressing small or superficial lesions; and
    - Removal of coagulated serum from normal skin surrounding an ulcer.
16. NPWT for any of the following wound types/conditions:
    - Elective open abdominal surgery; **OR**
    - Necrotic tissue with eschar present; **OR**
    - Untreated osteomyelitis; **OR**
    - Non-enteric and unexplored fistulas; **OR**
    - Malignancy in the wound; **OR**

- Exposed vasculature, nerves, anastomotic site, **OR** organs.

17. Continuing MIST treatments for wounds demonstrating no improvement after six (6) treatments.
18. Certain wound debridement services.
19. Wet-to-dry dressings, jet hydrotherapy, or wound irrigations should be used cautiously as maceration of surrounding tissue may hinder healing.
20. Jet therapy and wound irrigation for wound debridement must be performed by skilled personnel in order to be considered reasonable and necessary.
21. CMS expects that with appropriate care wound volume or surface dimension should decrease or wounds optimally will demonstrate granulation tissue.
22. Debridements of the wound(s) if indicated must be performed judiciously and at appropriate intervals.

For a list of all Limitations and Exclusions, refer to CMS LCD L37166 (CMS, 2017). Note that CMS LCD L37166 does not address specific wound care procedures described by NCDs including:

- *Hyperbaric Oxygen (HBO) Therapy* (LCD L36504)
- *Therapy and Rehabilitation Services* (LCD L33413)
- *Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities* (LCD L36377)
- *Electrical Stimulation and Electromagnetic Therapy of Specified Wounds* (NCD 270.1)
- Strapping
- Treatment of Burns

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

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 sNPWT and 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 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 negative pressure wound therapy.

Jayed et al. (2019) studied the efficacy of NPWT for SSI after open pancreaticoduodenectomy. While improvements are found in infection control, SSIs continue to be a cause of morbidity following abdominal surgery as well as being associated with an increased risk of reoperation, prolonged hospitalization, readmission, and higher costs. A single center randomized, controlled trial evaluated surgical incision closure during pancreaticoduodenectomy using NPWT in high-risk patients for SSI. A total of 123 patients were randomized at the time of closure of the surgical incision. Nearly 10% of patients had a 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.

Lozano-Balderas et al. (2017) studied infection rates of those techniques in contaminated and dirty/infected wounds. A total of 81 laparotomized patients (Class III or IV surgical wounds) were included in a three-arm randomized prospective study. Twenty-seven patients received primary closure, 29 delayed primary closure, and 25 vacuum-assisted closure, with no exclusions for analysis. Nearly 40% of SSIs were present in patients treated with primary closure and 17% with primary delayed closure; there were no patients who received vacuum-assisted closure. Overall, the authors found that wound site infections can increase costs, hospital stay, morbidity, and mortality.

pNWT to Reduce SSIs

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.

PICO Dressings

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.

Hayes Health Technology Assessment

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). Vacuum wound closure is recommended as it may reduce the rate of SSIs, specifically for open colorectal surgeries (abdominal incisions) and vascular cases with a groin incision over stapled skin (Ban et al., 2016).

The **World Health Organization (WHO)** (2016) published the *Global Guidelines for the Prevention of Surgical Site Infection* (2016). While based on low-quality evidence, the WHO suggests that pNPWT may be used on primarily closed surgical incisions in high risk wounds with a goal of preventing SSIs. (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)** (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 (2016) published a Medtech Innovation Briefing (MIB) on the *Prevena Incision Management System for Closed Surgical Incisions*. Seven studies were reviewed which were considered good quality and demonstrate that Prevena can lead to significant decreases in incision site complications.

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 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

12/8/2021 New policy.

REFERENCES

Government Agency

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (search: “wound care L37166”). http://www.cms.gov/mcd/search.asp. Effective December 7, 2017. Revised July 23, 2020. Accessed September 15, 2021.

Other Evidence Based Reviews and Publications

1. Hayes. Evidence analysis research brief: Prophylactic negative pressure wound therapy in elective open abdominal surgeries. https://evidence.hayesinc.com. Published February 4, 2021. Accessed September 16, 2021. Registration and login required.
2. MCG. Negative pressure wound therapy (A-0346) (25th ed.). https://www.mcg.com/. Updated June 7, 2021. Accessed November 30, 2021. Registration and login required.

Peer Reviewed Publications

1. Boland PA, Kelly ME, Donlon NE, et al. Prophylactic negative pressure wound therapy for closed laparotomy wounds: A systematic review and meta-analysis of randomised controlled trials. Ir J Med Sci. 2021;190:261–267. https://doi.org/10.1007/s11845-020-02283-7. Accessed September 22, 2021.
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. Accessed September 22, 2021.
3. Gao J, Wang Y, Song J, Li Z, Ren J, Wang P. Negative pressure wound therapy for surgical site infections: A systematic review and meta-analysis. J Adv Nurs. 2021 Apr 27. doi: 10.1111/jan.14876. Accessed September 17, 2021.
4. Hurd T, Kirsner RS, Sancho-Insenser JJ, Fumarola S, Garten A, Patel M, et al. International Consensus Panel recommendations for the

optimization of traditional and single-use negative pressure wound therapy in the treatment of acute and chronic wounds. Wounds. 2021 Feb;33(suppl 2):S1-S11. https://pubmed.ncbi.nlm.nih.gov/33591931/. Accessed September 17, 2021.
5. Javed AA, Teinor J, Wright M, et al. Negative pressure wound therapy for surgical-site infections: A randomized trial. Ann Surg. 2019 Jun;269(6):1034-1040. doi: 10.1097/SLA.0000000000003056. Accessed September 22, 2021.
6. Lozano-Balderas G, Ruiz-Velasco-Santacruz A, Díaz-Elizondo JA, Gómez-Navarro JA, Flores-Villalba E. Surgical site infection rate drops to 0% using a vacuum-assisted closure in contaminated/dirty infected laparotomy wounds. Am Surg. 2017;83(5):512-514. https://pubmed.ncbi.nlm.nih.gov/28541864/. Accessed September 22, 2021.
7. Meyer J, Roos E, Abbassi Z, Buchs NC, Ris F, Toso C. Prophylactic negative-pressure wound therapy prevents surgical site infection in abdominal surgery: an updated systematic review and meta-analysis of randomized controlled trials and observational studies. Clinical Infectious Diseases, 2020; ciaa1203. https://doi.org/10.1093/cid/ciaa1203. Accessed September 22, 2021.

National and Specialty Organizations
1. Ban KA, Minei JP, Laronga C, et al. American College of Surgeons and Surgical Infection Society: surgical site infection guidelines, 2016 update.J AmColl Surg. 2017;224(1):59-74. doi: 10.1016/j.jamcollsurg.2016.10.029. Accessed September 17, 2021.
2. National Institute for Health and Care Excellence (NICE). PICO negative pressure wound dressings for closed surgical incisions. Medical technologies guidance [MTG43]. https://www.nice.org.uk/guidance/mtg43. Published May 9, 2019. Accessed September 17, 2021.
3. National Institute for Health and Care Excellence (NICE). Prevena incision management system for closed surgical incisions. Medtech innovation briefing [MIB173]. Published February 28, 2019. https://www.nice.org.uk/advice/MIB173. Accessed September 17, 2021.
4. World Health Organization (WHO). WHO global guidelines for the prevention of surgical site infection. https://apps.who.int/iris/bitstream/handle/10665/250680/9789241549882-eng.pdf. Published 2016. Accessed September 17, 2021.

APPENDIX

Reserved for State specific information *(to be provided by the individual States, not Corporate). Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

Washington-For Medicaid reviews for NPWT, reviewers reference a state-specific MERGE Policy guideline: Negative Pressure Wound Therapy.