KAISER PERMANENTE® Mid-Atlantic States	**Negative Pressure Wound Therapy Medical Coverage Policy**

Utilization *ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document.
- For Medicare members, please refer to CMS guidelines through Medicare Coverage Database requirements.
- Note: After searching the Medicare Coverage Database, if no NCD/LCD/LCA is found, then use the policy referenced above for coverage guidelines

I. Service or Procedure: Negative Pressure Wound Therapy (NPWT)

II. Specialty: General, and Plastic Surgery, Wound Management

III. Description

Negative Pressure Wound Therapy is a class 2 type device intended to promote wound healing and wound closure of certain types of open wounds through creation of a controlled or intermittent negative pressure environment within a well-sealed wound site. The removal of wound exudates, fluids, and infectious materials from the wound bed is thought to aid in fluid removal, increase blood flow and cell proliferation in the wound, drawing wound edges together.

NPWT suction device consists of a pump to generate a vacuum, an airtight dressing material to pack and seal the wound, and a tubing and a canister to collect & remove fluids, exudates, and other infectious/waste materials from the wound.

IV. Indication for Referral, Pediatric

NPWT system is not routinely indicated for pediatric use as its' safety and effectiveness has not been established stablished among newborns, infants, and children.

IV. Indications for Referral, Adult

NPWT is considered medically necessary for adult use when the patient meets **ALL of** the following criteria**:**

A. The wound therapy program has been tried or considered and ruled out prior to application of NPWT, which should include **ALL** the following measures:
   1. Documentation in the patient's medical record of evaluation, care, and wound measurements by a licensed medical professional; and
   2. Application of dressings to maintain a moist wound environment, and
   3. Debridement of necrotic tissue if present, and

4. Underlying medical condition or cause related to the wound or ulcer (such as diabetes, venous stasis, pressure, or infection) are properly addressed or managed; and
5. Evaluation, provision, and maintenance of adequate nutritional status

B. **Evaluation and documentation of the ulcer or wound** based on Wagner or University of Texas" wound classification by a licensed medical professional; and

C. The patient has **one or more documented eligible conditions** as a potential candidate for NPWT use, (see section V); and

D. Identification of the type, condition, and characteristic of the wound for which application of NPWT is not **contraindicated** (refer to section VI); and

E. The patient and/or caregiver can receive, understand, comprehend, and demonstrate competence to follow instruction and directions on appropriate home use of NPWT in addition to becoming familiar with the features of the device and how to use it in a safe and effective manner including information on potential risks, complications, and adverse reactions of use.

	University of Texas [7]	Meggitt-Wagner [8]
Grades:		
Grade 0	Pre- or post-ulcerative or healed wound	Healed or pre-ulcerative wound
Grade 1	Superficial wound not involving tendon, capsule or bone	Superficial ulcer without penetrating to deeper layers
Grade 2	Wound penetrating to tendon or capsule	Deeper ulcer and reaches tendon, bone or joint capsule
Grade 3	Wound penetrating to bone or joint	Deeper tissues are involved and there is abscess formation, osteomyelitis, or tendinitis
Grade 4	—	Limited gangrene (part of the foot)
Grade 5	—	Extensive gangrene (whole foot)
Stages*:		
Stage A	*No infection or ischemia*	
Stage B	*Infection present*	
Stage C	*Ischemia present*	
Stage D	*Infection and ischemia present*	

**Assessment of the wound stages was not part of this study*

Figure 1 Wound classification according to the University of Texas (UT) and the Meggitt-Wagner (MW) systems.

V. Clinical indication

Ulcers and Wound in the Home Setting

Negative Pressure Wound Therapy may be indicated if all the requirements described in section IV are met and one or more of the following eligible conditions are documented.

A. Chronic non-healing ulcer with lack of improvement despite conventional wound management, described in section IV-A and weekly evaluation with documentation of wound measurements (such as length, width, and depth) and ONE of the following conditions:

1. **Stage III or IV pressure ulcers** at initiation of NPWT therapy in patients who meet ALL the following:
   a. Has been appropriately turned and positioned; and
   b. Has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis (Note: Group 2 or 3 special support surface is not required for ulcers that are not located on the trunk or pelvis); and
   c. The patient's moisture and incontinence have been appropriately managed; or

2. **Neuropathic ulcer** such as chronic diabetic ulcer that meets BOTH of the following:
   a. The patient has been on a comprehensive diabetic management program; and
   b. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities; or

   Diabetic ulcer or wound, as indicated by 1 or more of the following:
   i. Complex diabetic ulcer or wound (Wagner or University of Texas classification grade 2 wound, Figure 1 below); or
   ii. Post amputation diabetic wound; or
   iii. Superficial ulcer or wound (Wagner or University of Texas classification grade 1 diabetic wound) which has not responded to 4 weeks of conventional treatment

3. **Chronic ulcer related to venous or arterial insufficiency** who meet ALL the following:
   a. Compression bandages and/or garments have been consistently applied; and
   b. Leg elevation and ambulation have been encouraged; and
   c. Ulcer of at least 30-day duration

B. Surgical wound

NPWT may be indicated for surgically created wounds to individuals with an existing NPWT from the inpatient setting and must continue it beyond discharge from a health care facility to home. In addition, NPWT may also be initiated in the home setting after recent surgery

NPWT application to surgically created wounds is medically necessary when accelerated granulation therapy and wound healing is necessary but not achievable by conventional wound management for the following conditions (the list is not exhaustive):

1. Dehiscence or wound with exposed hardware or bone; *or*
2. Post sternotomy wound infection or mediastinitis; or
3. Post disunion of the abdominal wall; or
4. Post skin graft or dermal substitute for acute or chronic wound.

C. Traumatic wound with the need for accelerated formation of granulation tissue, not achievable by other available wound treatments such as those with comorbidities that does not allow normal wound healing:

1. Pre-operative flap or graft

VI. Contraindication

The use of NPWT is not medically necessary if **any** of the following conditions are present.

A. NPWT is **absolutely contraindicated** in the presence of the following**:**
1. Necrotic tissue with eschar in the wound;
2. Uncontrolled soft tissue infection or untreated osteomyelitis within the vicinity of the wound;
3. Non-enteric and unexplored fistulas or an open fistula to an organ or body cavity within the vicinity of the wound;
4. Malignancy in the wound;
5. Exposed vasculature or active bleeding;
6. Exposed nerves;
7. Exposed anastomotic site;
8. Exposed bone or tendons; or
9. Exposed organs;

B. NPWT is **contraindicated** for the following condition due to possible bleeding complications (the list is not exhaustive):
1. Blood vessel graft on the leg;
2. Groin wounds;
3. Medications that affect coagulation and hemostasis such as anti-coagulants and platelet aggregation inhibitors; or
4. Other conditions that may predispose an individual to be high risk for bleeding and hemorrhage

VII. Risk Factors

The following condition should be carefully considered when using NPWT:

A. Friable vessels and infected blood vessels;
B. Vascular anastomosis;
C. Enteric fistulas;
D. Sharp edges (bone fragments);
E. Intermittent versus continuous pressure;
F. Use in MRI environment;
G. Use in hyperbaric chamber environment;
H. Use with defibrillation;
I. Spinal cord injury (stimulation of sympathetic nervous system);
J. Use near vagus nerve (bradycardia);
K. Protection of peri-wound skin;
L. Infected wound;
M. Transmission of infectious agents (standard precautions for infection control per institutional protocol);

N. Dressings retained in the wound;
O. Circumferential dressing application;
P. Patient size and weight; and
Q. Device component (such as pump and associated supplies) not specifically designated as qualified to use or compatible with the NPWT system

VIII. Length of use

A. Continued use

Ongoing use of NPWT is medically necessary when there is documentation by a licensed medical professional of **ALL** of the following criteria to support continued medical necessity.

1. Weekly assessment and documentation of the following:
   a. Wound dimensions and characteristics including size (depth, length, and width) and drainage (odor, color); and
   b. Documentation that reflects supervision or direct NPWT dressing changes by a licensed health care professional; and
2. Monthly assessment and documentation of wound dimensions and characteristics reflecting evidence of progressive wound healing.

B. To discontinue use

Continued use of NPWT is no longer medically necessary in the presence of **any** of the following:

1. The criteria to continue with the therapy described in section VIII, A are not met; or
2. The wound evaluation by the treating physician shows adequate healing has not occurred or
3. Absence of any evidence of wound healing for the past 30 days; or
4. The patient has been on NPWT for the duration of four months and require further evaluation from a licensed medical professional; or
5. The patient is not using NPWT with or without physician's order; or
6. For all other conditions not meeting the medical necessity requirement as described above; or the presence of conditions listed as contraindication including routine prophylactic use in the postoperative setting.

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Approval History

Effective June 01, 2016, state filing is no longer required per Maryland House Bill HB 798 – Health Insurance – Reporting

Date approved by RUMC	Date of Implementation
12/15/2021	12/15/2021
12/28/2022	12/28/2022
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*The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.