Negative Pressure Wound Therapy (for Kentucky Only)

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Instructions for Use

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Related Policies

- Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (for Kentucky Only)
- Skin and Soft Tissue Substitutes (for Kentucky Only)

Application

This Medical Policy only applies to the state of Kentucky.

Coverage Rationale

Notes:
- The proven and medically necessary coverage statements in this policy apply to the use of negative pressure wound therapy (NPWT) in the outpatient setting.
- The unproven and not medically necessary coverage statements in this policy apply to all settings.

NPWT in an outpatient setting or upon discharge from an inpatient setting is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Negative Pressure Wound Therapy (NPWT) Devices.

Click here to view the InterQual® criteria.

The following indications and devices are unproven and not medically necessary due to insufficient evidence of efficacy:
- NPWT for treating **all** other indications, including, but not limited to, pilonidal disease
- Disposable/single-use NPWT systems
- NPWT systems with instillation of wound solutions

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Coding Clarification: Suction pumps and dressing codes (K0743–K0746) apply to devices other than negative pressure wound therapy.

CPT Code	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 Code	Description
A6550	Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories
A9272	Wound suction, disposable, includes dressing, all accessories and components, any type, each
E2402	Negative pressure wound therapy electrical pump, stationary or portable

Description of Services

Negative pressure wound therapy (NPWT), also referred to as vacuum-assisted wound closure, is a therapeutic dressing system in which negative pressure is continuously or intermittently applied to the surface of a wound. The system includes dressings, a suction pump, tubing and a collection chamber. The wound and porous dressing are sealed with an occlusive dressing and connected to the drainage tubing connected to a suction pump that delivers subatmospheric pressure. NPWT is intended to assist wound healing by the removal of exudate or debris, reduction of bacterial contamination, increase in local blood flow, reduction of local edema, approximation of the wound edges and the production of granulation tissue . NPWT is intended as an adjunct treatment for wounds that do not respond to conventional treatment such as debridement, pressure relief and infection control.

Clinical Evidence

Pilonidal Disease

There is insufficient clinical evidence demonstrating the safety and/or efficacy of NPWT systems, including disposable systems, for treating pilonidal disease. Further results from prospective, high quality studies are needed to determine which patient population would benefit from the use of these devices.

A Hayes report on the use of NPWT after surgery for pilonidal disease concluded that the current body of overall very-low quality evidence does not allow for conclusions to be drawn regarding the benefits and potential associated risks of NPWT as a treatment adjunct over standard wound care methods alone. There is a need for additional, larger well-designed studies to evaluate this therapy and to determine which patients may benefit from NPWT after surgery for pilonidal disease (Hayes, 2020; updated 2022).

Danne et al. (2017) conducted a retrospective chart analysis of pilonidal sinus healing using NPWT versus alginate or gauze dressings. Thirty-two patients received NPWT and 30 received daily dressings. The median time to healing in the group

receiving daily dressings was 10 weeks compared to 8 weeks in the group receiving NPWT. Among patients who healed, the difference in average time to healing was 5.2 weeks. However, the differences were not statistically significant. Study limitations include retrospective design and small patient numbers. Larger prospective, RCTs are needed to evaluate the efficacy of NPWT for treating pilonidal disease.

Biter et al. (2014) evaluated the role of NPWT in treating pilonidal sinus disease. Forty-nine patients were randomly assigned to NPWT (n = 24) for 2 weeks or standard open wound care (n = 25) after surgical excision. NPWT resulted in a higher wound healing rate in the first 2 weeks after excision. However, no significant benefit of NPWT was seen with respect to time to complete wound healing and time to resume daily life activities. The authors noted that more research is needed before NPWT can be implemented as a standard treatment in patients with pilonidal sinus disease. This study is limited by the small patient numbers, short follow-up and lack of blinding.

NPWT with Instillation of Wound Solutions

Diehm et al. (2021) conducted a systematic review evaluating the use of NPWT with instillation and dwell time (NPWTi-d) for the treatment of acute and traumatic wounds. Ten articles (n = 109 acute and traumatic wounds) met inclusion criteria. No high-quality RCTs were identified. The majority of studies were retrospective cohort studies, followed by lesser-quality RCTs, comparative studies or prospective cohorts, and 2 retrospective comparative studies. While NPWTi-d showed promise to be effective in facilitating wound closure and reducing the time for wound closure, the authors found a relatively low level of evidence to support this effect. Large prospective, RCTs are necessary to determine the role of NPWTi-d in the clinical routine for this wound category.

Gabriel et al. (2021) performed a systematic review and meta-analysis of comparative studies evaluating the effects of NPWTi-d versus standard wound care in the treatment of multiple wound types. Thirteen studies (n = 720) were included in the analysis. NPWTi-d, when used in conjunction with good clinical practice (e.g., debridement, appropriate antibiotics), was found to be more beneficial than the comparator with respect to number of surgical debridements during therapy, time to readiness for final wound closure, number of patients with reduced bacterial bioburden, duration of therapy, and number of wounds closed, but similar with respect to hospital length of stay. However, author-noted study limitations, including low-level evidence and high patient and wound population heterogeneity across studies, suggested cautious interpretation of the results. Large prospective, RCTs are needed to confirm these results.

Kanapathy et al. (2020) conducted a systematic review and meta-analysis of studies evaluating the efficacy of NPWTi-d. Thirteen studies were included with a total of 624 wounds in 542 patients involving wounds of various etiology. These included surgical wounds (n = 186), trauma (n = 112), pressure ulcers (n = 73), neuropathic (n = 56), infection (n = 28), diabetic ulcers (n = 20), necrotizing fasciitis (n = 19), burns (n = 15), venous (n = 10) and vasculitis (n = 2). Normal saline was the most commonly used instillation solution. The pooled proportion of wounds that achieved complete healing was 93.65%. The authors concluded that although NPWTi-d has versatility to improve wound healing in a broad range of wounds, these conclusions are limited by the lack of high-quality level 1 evidence. The included studies were mostly small retrospective case series where NPWTi-d was performed on wounds of various etiologies and sizes along with different wound closure techniques. RCTs evaluating the efficacy of NPWTi-d against NPWT or standard dressings are needed.

Clinical Practice Guidelines

American Society of Colon and Rectal Surgeons (ASCRS)

ASCRS practice parameters for the management of pilonidal disease do not specifically address NPWT as a treatment option (Johnson et al., 2019).

National Institute for Health and Care Excellence (NICE)

A NICE guideline concluded that the VAC Veraflo Therapy system (wound instillation with negative pressure therapy) shows promise for treating acute infected or chronic wounds that are not healing. However, there is not enough good-quality evidence to support the case for routine adoption. Further research is recommended to show clinically meaningful benefits for the device compared with NPWT alone (NICE, 2021).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

For information on NPWT systems, refer to the following website (use product code OMP): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed December 5, 2022)

References

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Diehm YF, Fischer S, Wirth GA, et al. Management of acute and traumatic wounds with negative-pressure wound therapy with instillation and dwell time. Plast Reconstr Surg. 2021 Jan 1;147(1S-1):43S-53S.

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Policy History/Revision Information

Date	Summary of Changes
07/01/2023	**Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS157KY.07

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Kentucky Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage

Determination Guidelines, and Utilization Review Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.