

Medicare Medical Policy

Negative Pressure Wound Therapy (NPWT)

MEDICARE MEDICAL POLICY NUMBER: 192

Effective Date: 10/1/2022

Last Review Date: 8/2022

Next Annual Review: 8/2023

MEDICARE COVERAGE CRITERIA.....	2
POLICY CROSS REFERENCES.....	3
POLICY GUIDELINES.....	3
REGULATORY STATUS.....	3
BILLING GUIDELINES AND CODING	4
REFERENCES.....	6
POLICY REVISION HISTORY.....	6

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
<p>Negative Pressure Wound Therapy (NPWT) Pumps</p>	<ul style="list-style-type: none"> • When provided as durable medical equipment (DME) for the member to use at home: Local Coverage Determination (LCD): Negative Pressure Wound Therapy Pumps (L33821) • When provided in a physician’s office: LCD: Wound and Ulcer Care (L38904) and LCA A58567 • When provided as part of home health plan: Medicare Claims Processing Manual, Chapter 10 - Home Health Agency Billing, §90.3 – Billing Instructions for Disposable Negative Pressure Wound Therapy Services <p>NOTES:</p> <ul style="list-style-type: none"> • Disposable negative pressure wound therapy (NPWT or dNPWT) suction systems such as the SNaP (Spiracure), PICO (Smith and Nephew), VAC Via (KCI) systems are not eligible for coverage as DME when used by the member in the home setting (LCAs A52511 and A52519). In these situations, dNPWT devices must be reported with HCPCS code A9272 and they are not medically necessary (LCA A52511) • However, dNPWT may be eligible for coverage when not provided as DME for use in the home, such as when rendered as part of a home health plan of care or provided in a physician’s office. When provided in this manner, CPT codes 97607 or 97608 would be used.¹

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member’s benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. (*Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021*)

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be [accessed here](#).

POLICY GUIDELINES

BACKGROUND

Medicare defines negative pressure wound therapy (NPWT) as the application of sub-atmospheric pressure to a wound to remove exudate and debris from wounds through an integrated system of a suction pump to a collection chamber. (*LCD L33821*) In these systems, exudate removed from a wound is **collected into a canister**. These systems are described by codes E2402 (pump) and A6550/A7000 (supplies).

Other devices provide controlled sub-atmospheric pressure designed for use with dressings instead of a canister (e.g., the Kalypto[®] system). In these systems, exudate removed from a wound is **retained in the dressing materials**, rather than a canister. The use of a canister is considered by Medicare to be a significant defining component of NPWT. These alternate wound devices are reported with HCPCS codes K0743-K0746 and are **not** addressed in this medical policy. (e.g., the Kalypto[®] system).

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

Negative pressure therapy or suction devices cleared by the U.S. Food and Drug Administration (FDA) for treating chronic wounds include, but are not limited to: Vacuum-Assisted Closure[®] Therapy (V.A.C., also known as negative pressure wound therapy; KCI); Versatile 1[™] (V1) Wound Vacuum System (Blue Sky Medical), RENASYS[™] EZ PLUS (Smith & Nephew), Foryou NPWT NP32 Device (Foryou Medical Electronics), SVED[®] (Cardinal Health), and PICO Single Use Negative Pressure Wound Therapy System (Smith & Nephew).

Portable systems include the RENASYS[™] GO (Smith & Nephew), XLR8 PLUS (Genadyne Biotechnologies), extriCARE[®] 2400 NPWT System (Devon Medical), the V.A.C. Via[™] (KCI), NPWT PRO to GO (Cardinal Health), and the PICO Single Use Negative Pressure Wound Therapy System (Smith & Nephew). The Prevena[™] Incision Management System (KCI) is designed specifically for closed surgical incisions.

A nonpowered NPWT device, the SNaP[®] Wound Care System (Spiracur, acquired by Acelyty in 2015), is a class II device requiring notification to market but not having the FDA premarket approval. This device is portable and lightweight (3 oz) and can be worn underneath clothing. In 2009, it was cleared for

marketing by the FDA through the 510(k) pathway (K081406) and is designed to remove small amounts of exudate from chronic, traumatic, dehisced, acute, or subacute wounds and diabetic and pressure ulcers. The system is reported to generate negative pressure levels similar to other NPWT systems, but is fully disposable.

Negative pressure wound therapy devices with instillation include the V.A.C. VERAFLOR™ Therapy device (KCI/Acelity). It was cleared for marketing in 2011 by the FDA through the 510(k) pathway (K103156) and is designed to allow for controlled delivery and drainage of topical antiseptic and antimicrobial wound treatment solutions and suspensions. It is to be used with the V.A.C. Ultra unit, which is commercially marketed for use in the hospital setting. Instillation is also available with Simultaneous Irrigation™ Technology tubing sets (Cardinal Health) for use with Cardinal Health SVED® and PRO NPWT devices, however, its use is not indicated for use in a home care setting (K161418).

BILLING GUIDELINES AND CODING

GENERAL

The following HCPCS codes describe NPWT:

- 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
- A7000: Canister, disposable, used with suction pump, each

The following HCPCS code is used to report for a **disposable** NPWT system (e.g., the SNaP® [Smart Negative Pressure] or PICO™ systems) when requested for use in the home setting as DME:

- A9272: Wound suction, disposable, includes dressing, all accessories and components, any type, each

Devices reported with HCPCS code A9272 will be denied as not medically necessary. While HCPCS code A9272 describes some types of disposable wound suction device, disposable wound suction items other than those coded as A9272 must be coded A9270 (e.g., elastomeric suction device). (LCA A52519)

There are four CPT codes for active wound care management, which include the **application** of NPWT using **either durable medical equipment (DME) or disposable, nondurable equipment**:

- 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

CPT codes 97605-97608 include the application of and the removal of any protective or bulk dressings. If a dressing change is performed with **no** active wound procedure as described by these debridement codes, these debridement codes should not be reported. (LCA A58567) In addition, these codes include both the administration **and** the disposable NPWT device itself. Separate reporting for a device is not appropriate coding when these codes are used.²

See associated local coverage articles (LCAs) for related billing and coding guidance:

- LCA: Negative Pressure Wound Therapy Pumps ([A52511](#))
- LCA: Suction Pumps - Policy Article ([A52519](#))
- LCA: Billing and Coding: Wound and Ulcer Care ([A58567](#))

PRICING, DATA ANALYSIS AND CODING (PDAC) REVIEW

The only products which may be billed using HCPCS codes E2402 are those for which a written coding verification review (CVR) has been made by the PDAC contractor and published on the [Product Classification List \(PCL\) website](#). (Noridian LCAs A52511) Wound suction pumps and NPWT systems and their associated supplies, which have not been specifically designated as being qualified to use HCPCS code E2402 via written instructions from the PDAC Contractor may be denied as not reasonable and necessary. (L33821) Note that some items may be marketed as "negative pressure wound care systems," but do not meet Medicare PDAC requirements to qualify for reporting using HCPCS code E2402 (e.g., the MPD 1000 Negative Pressure Wound Care System by Kalypto Medical Inc.).

CODES*		
CPT	97605	Negative pressure wound therapy (eg, 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 (eg, 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, (eg, 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, (eg, 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	A6550	Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories
	A7000	Canister, disposable, used with suction pump, each
	A9270	Non-covered item or service
	A9272	Wound suction, disposable, includes dressing, all accessories and components, any type, each
	E2402	Negative pressure wound therapy electrical pump, stationary or portable

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, “presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare.” The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. (*Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician’s Fee Schedule, A. Physician’s Services*)
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company [Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website](#) for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Medicare MLN Matters Number: SE17027 for *Clarification of Billing and Payment Policies for Negative Pressure Wound Therapy (NPWT) Using a Disposable Device*; Available at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE17027.pdf>
2. Medicare Claims Processing Manual, Chapter 10 - Home Health Agency Billing, §90.3 - Billing Instructions for Disposable Negative Pressure Wound Therapy Services; Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c10.pdf>.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
10/2022	Annual review (converted to new format 2/2023)