
Please complete the blue highlighted area to send to the applicable payer

[Insert Provider Letterhead and Address]

[Date]

[Name and Title of Contact] *usually the Medical Director, OR the Medical Benefits Manager, OR the Claim Representative*

[Name of Health Insurance Company]

[Street Address]

[City, State, ZIP Code]

Re: [Patient's Name]

[Patient's Date of Birth]

[Policy Holder's Name]

[Policy ID Number]

[Policy Group Number]

Dear [Name of Contact]:

I am writing on behalf of my patient _____ to request **[prior authorization OR benefit appeal consideration]** for approval to apply PICO Single-Use Negative Pressure Wound Therapy (sNPWT) to effectively manage the patient's (wound description).

Include the following major points in your appeal letter:

- Reason for filing an appeal (denial of coverage, medical necessity, etc.)
- Date of denial/denial letter (if the payer requires this information in their appeal process)
- Denial reason and associated denial code, if applicable
- Patient's diagnosis and course of treatment including any adverse outcomes
- Current wound dimensions (length, width, & depth)
- In-depth description of the current state of the wound
- Presence and extent of obvious signs of infection, if applicable
- Presence and extent of necrotic, devitalized or non-viable tissue, if applicable
- Contributory medical conditions affecting the course of treatment
- Description of sNPWT in detail with applicable procedure codes (CPT 97607/08)
- Rationale and medical benefit of applying sNPWT based on clinical points & supported by published clinical research

Over the past 20 years, Negative Pressure Wound Therapy (NPWT) has played a significant role in achieving well-established means of effectively treating a variety of complex wounds to facilitate the path to closure. This is also rapidly becoming true for surgical incisions where NPWT has been shown to reduce the incidence of surgical site complications. Most cases of surgical site infection or wound dehiscence manifest after discharge from the hospital. These patients are five times more likely to require hospital readmission.¹ SSI is the most common reason for unplanned readmission following surgery.^{4,7}

Historically, NPWT has been mostly initiated in the hospital setting before patients get sent home. However, with the introduction of portable single-use negative pressure wound therapy (sNPWT), the use of NPWT in the homecare setting has increased, thereby

facilitating earlier discharge of patients from the hospital. Portable NPWT devices have the potential to impact positively on patients' quality of life allowing increased mobility and freedom to undertake normal activities of daily living.

PICO Single-Use Negative Pressure Wound Therapy System provides an ultra-portable solution that consists of a small sNPWT pump that functions for a period of 7 days and is connected to a 4-layer fluid management dressing that eliminates the need for bulky canisters and may reduce the number of dressing changes per week. The 4-layer dressing (fluid management system) is designed to enable NPWT to be delivered to the wound bed, wound margin and adjacent periwound tissue surrounding wounds and closed incisions.

PICO System is an electrically-powered single-use NPWT device. Similar to other medical devices powered by a battery (pacemakers, spine stimulators, etc.), the PICO System is electrically powered by a battery. The PICO System has been commercially available since receiving FDA clearance on May 16, 2012. PICO 7 and PICO 7Y Therapy Systems both provide up to 7 days of therapy. PICO 7Y sNPWT includes a y-connector which allows two incisions or wound surfaces to be treated simultaneously with one pump while the PICO 14 Therapy System provides up to 14 days of therapy with one pump.

Several key published studies support PICO sNPWT's efficacy in the treatment of both surgical incisions and open wounds. The PICO System's role in reducing the risk of surgical site complications has been highlighted in a meta-analysis published in *Surgical Infections*. The meta-analysis included over 1800 patients with approximately 2200 various types of surgical incisions and demonstrated a 58% reduction in surgical site infections (SSI), 26% reduction in dehiscence and half-day reduction in length of stay as compared to standard care.^{2,8}

A recent meta-analysis compared PICO sNPWT to conventional post-operative dressings. The data included nearly 6000 patients in 29 published clinical papers including 11 RCTs and 16 observational studies. The following outcomes were reported in favor of PICO sNPWT over conventional dressings:³

- The odds of **surgical site infections** were reduced by 63%
- The odds of **wound dehiscence** were reduced by 30%
- The odds of **seroma** were reduced by 77%
- The odds of **necrosis** were reduced by 89%
- Length of hospital stay was reduced by 1.75 days

In a Multi-center, phase 4, randomized, comparative efficacy study published in *Wound Repair and Regeneration* in 2019, the PICO System met non-inferiority and achieved statistical superiority vs. traditional NPWT in terms of wound progression toward healing over the treatment period.⁶

This Randomized Controlled Trial (RCT) compared the percentage change in target ulcer dimensions (area, depth, volume*) in lower extremity wounds such as VLUs and DFUs (www.clinicaltrials.gov) when comparing PICO sNPWT to tNPWT. The PICO System demonstrated superior wound closure rates of lower extremity ulcers combined over 12 weeks compared to tNPWT.³

Using sNPWT for VLUs and DFUs is likely to be more cost-effective than tNPWT from the US payer perspective and may provide an opportunity for policymakers to reduce the economic burden of lower extremity ulcers.⁵

On June 15, 2018, the National Institute for Health and Care Excellence (NICE) published a Medtech Innovation Briefing (MIB) and stated that the prophylactic use of PICO sNPWT is a potentially more effective alternative than standard surgical dressings in the prevention of surgical site complications (SSCs).⁹ This is the first and only MIB published by NICE on a NPWT device for preventing SSCs (see <https://www.nice.org.uk/advice/mib149>). NICE guidance supports the use of PICO sNPWT for closed surgical incisions based on the strength as referenced in numerous clinical evidence publications. While the pricing and payment methods differ in the UK, the disruptive value of PICO sNPWT is clear.

The potential cost savings is significant in comparison to traditional NPWT. In a recent publication Medicare claims were analyzed comparing the longitudinal costs of tNPWT to sNPWT. The authors report that sNPWT costs 1/3 that of tNPWT. This suggests that health plans can potentially reduce NPWT costs by as much as 2/3 when using PICO sNPWT.⁵

While there are similarities between sNPWT (CPT codes 97607/08) and tNPWT (CPT codes 97605/06) in the clinical assessment, dressing application/fluid management component, and patient/caregiver instructions on proper wound management, there are also significant differences.

Traditional NPWT triggers three additional and distinct Medicare payments to the DME supplier for the reusable pump, exudate canisters and supply kits. In addition, professional service payments are associated with multiple canisters and dressing changes. This amounts to four payable codes for traditional NPWT as compared to one code for single-use NPWT.

Please forward your coverage approval for this service to me at: [\[fax number or mailing address\]](#). Please do not hesitate to contact me for further information. I can be reached at [\[phone number\]](#) if you have any questions.

Thank you in advance for your consideration. I look forward to hearing from you soon regarding this very important request.

Sincerely,

[\[Physician's Name\]](#)
[\[Physician's Practice Name\]](#)

* These statistics come from two patient populations, which include outliers in the dataset.

Sources:

¹Zmistowski, B., et al. Unplanned Readmission After Total Joint Arthroplasty: Rates, Reasons, and Risk Factors. 2013

²Saunders, D. I., Murray, D., Pichel, a C., Varley, S., Peden, C. J., & UK Emergency Laparotomy Network. (2012). Variations in mortality after emergency laparotomy: the first report of the UK Emergency Laparotomy Network. *British Journal of Anaesthesia*, 109(3), 368–375. <https://doi.org/10.1093/bja/aes165>

³Kirsner, R. ,Dove, C. ,Reyzelman, A. ,Vayser, D. and Jaimes, H. (2019). A prospective, randomized, controlled clinical trial on the efficacy of a single-use negative pressure wound

therapy system, compared to traditional negative pressure wound therapy in the treatment of chronic ulcers of the lower extremities. *Wound Rep Reg*. doi:10.1111/wrr.12727

⁴ JAMA, February 3, 2015, Volume 313, Number 5 Authors: Merkow, R, et al.

⁵ Kirsner RS, Delhougne G, Searle RJ. A cost-effectiveness analysis comparing single-use and traditional negative pressure wound therapy to treat chronic venous and diabetic foot ulcers. *Wound Manag Prev*. 2020;66(3):30–38.

⁶ Gary Delhougne, JD, MHA; Christopher Hogan, PhD; Kim Tarka, BA; Sunitha Nair, MD, FACPWA. "Disposable Negative Pressure Wound Therapy (NPWT): A Solution for Significantly Reducing of NPWT", Symposium on Advanced Wound Care, April 2017

⁷ Serena MD, Dr. Thomas. "When Acute Healing Goes Wrong: Surgical Wounds and Surgical Site Infections." *WoundSource Practice Accelerator Webinar*, 30 October 2018

⁸ Strugala, V., Martin, R. Meta-analysis of comparative trials evaluating a prophylactic single-use negative pressure wound therapy system for the prevention of surgical site complications. *Surgical Infections*, Vol. 18, No. 00, 2017.

⁹ NICE Medical technology guidance - PICO negative pressure wound dressings for closed surgical incisions. May 2019.