DOCUMENTATION CHECKLIST

JURISDICTIONS B & C

NEGATIVE PRESSURE WOUND THERAPY PUMPS (NPWT)

REQUIRED DOCUMENTATION

- ☐ **Standard Written Order** that contains **ALL** of the following elements:
  - ○ Beneficiary's name or Medicare Beneficiary Identifier (MBI)
  - ○ General description of the item:
    - ☐ The description can be either a general description (e.g., wheelchair or hospital bed), a HCPCS code, a HCPCS code narrative, or a brand name/model number
    - ☐ For equipment - In addition to the description of the base item, the SWO may include all concurrently ordered options, accessories or additional features that are separately billed or require an upgraded code (List each separately)
    - ☐ For supplies – In addition to the description of the base item, the DMEPOS order/ prescription may include all concurrently ordered supplies that are separately billed (List each separately)
  - ○ Quantity to be dispensed, if applicable
  - ○ Order Date
  - ○ Treating Practitioner Name or NPI
  - ○ Treating Practitioner's signature
  - ○ Any changes or corrections have been initialed/signed and dated by the prescriber.
- ☐ Practitioner's signature on the written order meets **CMS Signature Requirements** https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6698.pdf
- ☐ **Refill Request**

For dates of service prior to January 1, 2024

Items Were Obtained In Person at a Retail Store	Written Refill Request Received from the Beneficiary	Telephone Conversation Between Supplier and Beneficiary
☐ Signed Delivery Slip ○ Beneficiary's name ○ Date ○ List of items purchased ○ Quantity received ○ Signature of person receiving the items **OR** ☐ Itemized Sales Receipt ○ Beneficiary's name ○ Date ○ Detailed list of items purchased ○ Quantity received	☐ Name of beneficiary or authorized rep (indicate relationship) ☐ Description of each item being requested ☐ Date of request ☐ Quantity of each item beneficiary still has remaining ☐ Request was not received any sooner than 14 calendar days prior to the delivery/shipping date ☐ Shipment/delivery occurred no sooner than 10 calendar days prior to the end of usage for the current product	☐ Beneficiary's name ☐ Name of person contacted (if someone other than the beneficiary include this person's relationship to the beneficiary) ☐ Description of each item being requested ☐ Date of contact ☐ Quantity of each item beneficiary still has remaining ☐ Contact was not made any sooner than 14 calendar days prior to the delivery/shipping date ☐ Shipment/delivery occurred no sooner than 10 calendar days prior to the end of usage for the current product

For dates of service on and after January 1, 2024	
Items Were Obtained In Person at a Retail Store	**Delivered Refill Communications**
☐ Signed delivery slip or copy of itemized sales receipt ☐ Delivery slip/receipt should indicate items were picked up at store front	☐ Beneficiary name and/or authorized representative (Suggested: if someone other than the beneficiary include this person's relationship to the beneficiary) ☐ Date of Request ☐ Description of each item requested ☐ Documentation of affirmative response indicating a need for the refill ☐ Contact must occur no sooner than 30 calendar days prior to the expected end of the current supply ☐ Shipment/delivery occur no sooner than 10 calendar days prior to expected end of current supply

☐ **Delivery Documentation**

Direct Delivery	Shipped/Mail Order Tracking Slip	Shipped/Mail Order Return Post-Paid Delivery Invoice
☐ Beneficiary's name ☐ Delivery address ☐ Quantity delivered ☐ A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number. ☐ Delivery date ☐ Signature of person accepting delivery ☐ Relationship to beneficiary	☐ Shipping invoice ○ Beneficiary's name ○ Delivery address ○ A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number. ○ Quantity shipped ☐ Tracking slip ○ References each individual package ○ Delivery address ○ Package I.D. #number ○ Date shipped ○ Date delivered ☐ A common reference number (package ID #, PO #, etc.) links the invoice and tracking slip (may be handwritten on one or both forms by the supplier)	☐ Shipping invoice ○ Beneficiary's name ○ Delivery address ○ A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number. ○ Quantity shipped ○ Date shipped ○ Signature of person accepting delivery ○ Relationship to beneficiary ○ Delivery date

NOTE: If a supplier utilizes a shipping service or mail order, suppliers have two options for the DOS to use on the claim:

1. Suppliers may use the shipping date as the DOS. The shipping date is defined as the date the delivery/shipping service label is created or the date the item is retrieved by the shipping service for delivery. However, such dates should not demonstrate significant variation.
2. Suppliers may use the date of delivery as the DOS on the claim.

MEDICAL NECESSITY DOCUMENTATION REQUIREMENTS FOR ALL ULCERS OR WOUNDS

☐ Clinician signature(s) on medical records meets **CMS Signature Requirements** https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6698.pdf

☐ Medical Records document one or more of the following:

- ○ The beneficiary has a chronic Stage 3 or 4 pressure ulcer, neuropathic (for example, diabetic) ulcer, venous or arterial insufficiency ulcer, or a chronic (being present for at least 30 days) ulcer of mixed etiology.
- ○ Beneficiary has complications of a surgically created wound (ex. dehiscence) or a traumatic wound (ex. pre-operative flap or graft).

- ☐ Medical records document the history of the wound(s) including previous treatment regimens and current wound management.
- ☐ Medical records document that a complete wound therapy program, as applicable depending on the type of wound, has been tried or considered and ruled out prior to the application of NPWT. At a minimum, the wound therapy program must include all of the following general measures:
  - ○ Evaluation, care and wound measurements (width, length and depth, plus amount of exudate) by a licensed medical professional, **and**
  - ○ Application of dressings to maintain a moist wound environment (including types of dressings and frequency of change), **and**
  - ○ Debridement of necrotic tissue if present, **and**
  - ○ Evaluation of provision for adequate nutritional status.
- ☐ The medical record includes a statement from the treating practitioner describing the initial condition of the wound (including measurements) and the efforts to address all aspects of wound care.
- ☐ If initiation of NPWT occurred during an inpatient stay. The initial inpatient date of service is documented.

Additional Medical Necessity Documentation for Stage 3 or 4 Pressure Ulcers	Additional Medical Necessity Documentation for Neuropathic Ulcers	Additional Medical Necessity Documentation for Venous Insufficiency Ulcers	Additional Medical Necessity Documentation for Surgically Created Or Traumatic Wounds
☐ The beneficiary has been appropriately turned and positioned, **and** ☐ The beneficiary has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis ☐ The beneficiary's moisture and incontinence have been appropriately managed	☐ The beneficiary has been on a comprehensive diabetic management program, **and** ☐ Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities.	☐ Comprehensive bandages and/or garments have been consistently applied, **and** ☐ Leg elevation and ambulation have been encouraged.	☐ It is medically necessary for there to be accelerated formation of granulation tissue, **and** ☐ Medical records support that this cannot be achieved by other available topical wound treatments.

MEDICAL NECESSITY DOCUMENTATION REQUIREMENTS FOR CONTINUED COVERAGE: ALL ULCERS OR WOUNDS

- ☐ Medical records document that a licensed medical professional, on a regular basis, has:
  - ○ Directly assessed the wound(s) being treated with the NPWT pump, and
  - ○ Supervised or directly performed the NPWT dressing changes, and
  - ○ Documented changes in the ulcer's dimensions and characteristics (must be done at least monthly).
- ☐ Documentation of wound evaluation and treatment includes:
  - ○ Wound length and width (surface area),
  - ○ Wound depth,
  - ○ Amount of wound exudate (drainage),
  - ○ Presence of granulation and necrotic tissue,
  - ○ Length of sessions of NPWT use,
  - ○ Dressing types and frequency of change,
  - ○ Concurrent measures being addressed relevant to wound therapy, and
  - ○ Changes in therapy being applied to effect wound healing.

ATTENTION!

- A licensed health care professional, for the purposes of this policy, may be a physician, physician's assistant (PA), registered nurse (RN), licensed practical nurse (LPN), or physical therapist (PT). The practitioner should be licensed to assess wounds and/or administer wound care within the state where the beneficiary is receiving NPWT.
- Exclusions from coverage include:
  - Presence of necrotic tissue with eschar in the wound, if debridement is not attempted;
  - Osteomylelitis within the vicinity of the wound that is not concurrently being treated with intent to cure;

  - Cancer present in the wound; or
  - The presence of an open fistula to an organ or body cavity within the vicinity of the wound.

- Coverage of an NPWT pump and supplies will be denied as not medically necessary with any of the following, whichever occurs earliest:
  - The criteria for continued coverage (see above) are not being met,
  - The treating practitioner documents that adequate wound healing has occurred to the degree that the NPWT may be discontinued,
  - Measureable (surface area or depth) wound healing failed to occur over the prior month,
  - 4 months (including the time NPWT was applied in an inbeneficiary setting prior to discharge to the home) have elapsed using an NPWT pump in the treatment of the most recent wound, or
  - The beneficiary (with or without a practitioner's order) is no longer using the equipment or supplies.
- Refer to the NPWT LCD for maximum monthly supply allowances.
- On a monthly basis, the supplier must obtain an assessment of wound healing progress from the treating practitioner. Communication with the practitioner may be verbal or written but the beneficiary's medical record may be requested in order to corroborate that wound healing is/was occurring as represented on the supplier's NPWT claims.

REMINDERS

- Suppliers **must** add a KX modifier to a code only if all of the coverage criteria have been met.
- The KX modifier **must** not be used with an NPWT pump and supplies for wounds if:
  - The pump has been used to treat a single wound and the claim is for the 5th or subsequent month's rental, **or**
  - The pump has been used to treat more than one wound and the claim is for the 5th or subsequent month's rental after therapy has begun on the most recently treated wound. In this situation, the KX modifier may be billed for more than 4 total months of rental.
- If all of the coverage criteria have not been met, the GA or GZ modifier **must** be added to a claim line for the NPWT pump and supplies. When there is an expectation of a medical necessity denial, suppliers **must** enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.
- Claim lines billed without a KX, GA, or GZ modifier will be **rejected** as missing information.
- Items with no physician or other licensed health care provider order must be submitted with an "EY" modifier added to each affected HCPCS code.

ONLINE RESOURCES

- **DME MAC Supplier Manual**
  - **JB:** https://www.cgsmedicare.com/jb/pubs/supman/index.html
  - **JC:** https://www.cgsmedicare.com/jc/pubs/supman/index.html
- **Local Coverage Determinations (LCDs) and Policy Articles**
  - **JB:** https://www.cgsmedicare.com/jb/coverage/lcdinfo.html
  - **JC:** https://www.cgsmedicare.com/jc/coverage/LCDinfo.html

DISCLAIMER

This document was prepared as an educational tool and is not intended to grant rights or impose obligations. This checklist may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either written law or regulations. Suppliers are encouraged to consult the *DME MAC Supplier Manual* and the Local Coverage Determination/Policy Article for full and accurate details concerning policies and regulations.