## Required Documentation in Supplier's File

- **Detailed Written Order That Contains All of the Following Elements:**
  - Beneficiary's name
  - Description of the item and usage instructions
  - List of all separately billed supplies to dispense with refill/replacement instructions
  - Length of need
  - The treating physician's signature
  - The date the treating physician signed the order

- **Physician's Signature on Written Order Meets CMS Signature Requirements**

- **Beneficiary Authorization**

### Refill Request

<table>
<thead>
<tr>
<th>Items Were Obtained in Person at a Retail Store</th>
<th>Written Refill Request Received from the Beneficiary</th>
<th>Telephone Conversation Between Supplier and Beneficiary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signed delivery slip or copy of itemized sales receipt</td>
<td>Name of beneficiary or authorized rep (indicate relationship)</td>
<td>Beneficiary's name</td>
</tr>
<tr>
<td></td>
<td>Statement that the beneficiary is requesting a refill</td>
<td>Name of person contacted (if someone other than the beneficiary include this person's relationship to the beneficiary)</td>
</tr>
<tr>
<td></td>
<td>Description of each item being requested</td>
<td>Description of each item being requested</td>
</tr>
<tr>
<td></td>
<td>Signature of requestor</td>
<td>Date of contact</td>
</tr>
<tr>
<td></td>
<td>Date of request</td>
<td>Quantity of each item beneficiary still has remaining</td>
</tr>
<tr>
<td></td>
<td>Quantity of each item beneficiary still has remaining</td>
<td>Quantity of each item beneficiary still has remaining</td>
</tr>
<tr>
<td></td>
<td>Request was not received any sooner than 14 calendar days prior to the delivery/shipping date</td>
<td>Contact was not made any sooner than 14 calendar days prior to the delivery/shipping date</td>
</tr>
<tr>
<td></td>
<td>Shipment/delivery occurred no sooner than 10 calendar days prior to the end of usage for the current product</td>
<td>Shipment/delivery occurred no sooner than 10 calendar days prior to the end of usage for the current product</td>
</tr>
</tbody>
</table>

### Delivery Documentation

- **Direct Delivery**
  - Beneficiary's name
  - Quantity delivered
  - Detailed description of item(s)
  - Brand
  - Serial number
  - Signature of person accepting delivery
  - Relationship to beneficiary

- **Shipped/Mail Order Tracking Slip**
  - Shipping invoice
    - Beneficiary's name
    - Delivery address
    - Detailed description of item(s) shipped
    - Quantity shipped
    - Brand
    - Serial number

- **Shipped/Mail Order Return Post-Paid Delivery Invoice**
  - Shipping invoice
    - Beneficiary's name
    - Delivery address
    - Detailed description of item(s) shipped
    - Quantity shipped
    - Brand
    - Serial number

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**NOTE:** In order for Medicare to cover the NPWT, the supplier must obtain the detailed written order prior to delivery. An NPWT cannot be delivered based on a dispensing (verbal, etc.) order. If the supplier delivers the item prior to receipt of a detailed written order, it will be denied as noncovered. If the detailed written order is not obtained prior to delivery, payment will not be made for that item even if a detailed written order is subsequently obtained.

Items delivered before a signed written order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.
MEDICAL NECESSITY DOCUMENTATION REQUIREMENTS FOR ALL ULCERS OR WOUNDS

☐ CLINICIAN SIGNATURE(S) ON MEDICAL RECORDS MEETS CMS SIGNATURE REQUIREMENTS

☐ MEDICAL RECORDS DOCUMENT ONE OR MORE OF THE FOLLOWING:

☐ Chronic (present for at least 30 days) stage III or IV pressure ulcer, OR
☐ Chronic (present for at least 30 days) neuropathic (i.e. diabetic) ulcer, OR
☐ Chronic (present for at least 30 days) venous or arterial insufficiency ulcer, OR
☐ Chronic (present for at least 30 days) ulcer of mixed etiology, OR
☐ Patient 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 PHYSICIAN 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.

<table>
<thead>
<tr>
<th>Additional Medical Necessity Documentation for Stage III or IV Pressure Ulcers</th>
<th>Additional Medical Necessity Documentation for Neuropathic Ulcers</th>
<th>Additional Medical Necessity Documentation for Venous Insufficiency Ulcers</th>
<th>Additional Medical Necessity Documentation for Surgically Created Or Traumatic Wounds</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ The patient has been appropriately turned and positioned, and</td>
<td>☐ The patient has been on a comprehensive diabetic management program, and</td>
<td>☐ Comprehensive bandages and/or garments have been consistently applied, and</td>
<td>☐ It is medically necessary for there to be accelerated formation of granulation tissue, and</td>
</tr>
</tbody>
</table>
The patient has used a group 2 or group 3 support surface if the pressure ulcer is on the posterior trunk or pelvis, and The patient’s moisture and incontinence have been appropriately managed.

Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities.

Leg elevation and ambulation have been encouraged.

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;
- Untreated osteomyelitis 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 physician 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 inpatient setting prior to discharge to the home) have elapsed using an NPWT pump in the treatment of the most recent wound, or
- The patient (with or without a physician’s order) is no longer using the equipment and 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 physician. Communication with the physician may be verbal or written but the patient’s medical record may be requested in order to corroborate that wound healing is/was occurring as represented on the supplier’s NPWT claims.
MODIFIER 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.

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 Jurisdiction C Supplier Manual and the Local Coverage Determination/Policy Article for full and accurate details concerning policies and regulations.