REQUIRED DOCUMENTATION

☐ Written Documentation of a Dispensing Order (written, fax, or verbal order) that includes:
  ○ Description of the item
  ○ Date of the order
  ○ Name of the beneficiary
  ○ Prescribing physician/practitioner’s name
  ○ Prescribing physician/practitioner’s signature (if a written order) or supplier signature (if verbal order)

**NOTE:** A dispensing order for related supplies is only required if the items are dispensed prior to obtaining the detailed written order.

☐ Detailed Written Order that contains **ALL** of the following elements:
  ○ Date of the order
  ○ Beneficiary’s name
  ○ All items, options or additional features that are separately billed or require an upgraded code. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, a HCPCS code narrative, or a brand name/model number.
  ○ For supplies – list all supplies that are separately billable, and for each include the frequency of use (if applicable), and the quantity dispensed
  ○ Prescribing physician/practitioner’s signature (and date if applicable*)

* Someone other than the physician/practitioner may complete the DWO of the item unless statute, manual instructions, the contractor’s LCD or policy articles specify otherwise. However, the prescribing physician/practitioner must review the content and sign and date the document.

  ○ Any changes or corrections have been initialed/signed and dated by the prescriber.

☐ Physician’s signature on the written order meets CMS Signature Requirements

☐ 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</td>
<td>☐ Name of beneficiary or authorized rep (indicate relationship)</td>
<td>☐ Beneficiary’s name</td>
</tr>
<tr>
<td>○ Beneficiary’s name</td>
<td>☐ Description of each item being requested</td>
<td>☐ Name of person contacted (if someone other than the beneficiary include this person's relationship to the beneficiary)</td>
</tr>
<tr>
<td>○ Date</td>
<td>☐ Date of request</td>
<td>☐ Description of each item being requested</td>
</tr>
<tr>
<td>○ List of items purchased</td>
<td>☐ Quantity of each item</td>
<td>☐ Date of contact</td>
</tr>
<tr>
<td>○ Quantity received</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>○ Signature of person receiving the items</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>
<tr>
<td>OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Itemized Sales Receipt</td>
<td></td>
<td></td>
</tr>
<tr>
<td>○ Beneficiary’s name</td>
<td></td>
<td></td>
</tr>
<tr>
<td>○ Date</td>
<td></td>
<td></td>
</tr>
<tr>
<td>○ Detailed list of items purchased</td>
<td></td>
<td></td>
</tr>
<tr>
<td>○ Quantity received</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
NEGATIVE PRESSURE WOUND THERAPY PUMPS (NPWT)

DELIVERY DOCUMENTATION

- **Direct Delivery**
  - Beneficiary’s name
  - Shipping invoice
  - Delivery address
  - Beneficiary’s name
  - Quantity delivered
  - 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.
  - Tracking slip
  - Delivery date
  - Reference each individual package
  - Signature of person accepting delivery
  - Package I.D. number
  - Relationship to beneficiary
  - 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)

- **Shipped/Mail Order Tracking Slip**
  - Slipped/Mail order return post-paid delivery invoice
  - Shipped/Mail order tracking
  - Beneficiary’s name
  - Slipped/Mail order return post-paid delivery invoice
  - Shipped/Mail order tracking
  - Delivery address
  - Slip
  - Quantity shipped
  - 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.

- **Shipped/Mail Order Return Post-Paid Delivery Invoice**
  - Quantity shipped
  - 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

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

- Medical Records document one or more of the following:
  - The beneficiary has a chronic Stage III or IV 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.
  - 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.

### Additional Medical Necessity Documentation for Stage III or IV Pressure Ulcers
- The patient has been appropriately turned and positioned, and
- 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

### Additional Medical Necessity Documentation for Neuropathic Ulcers
- The patient has been on a comprehensive diabetic management program, and
- Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities.

### Additional Medical Necessity Documentation for Venous Insufficiency Ulcers
- Comprehensive bandages and/or garments have been consistently applied, and
- Leg elevation and ambulation have been encouraged.

### Additional Medical Necessity Documentation for Surgically Created Or Traumatic Wounds
- 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;
  - 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.

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

• 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.