Are You Looking at Offering Negative Pressure Wound Therapy?

Beginning of Medical Policy (LCD)

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Coverage Criteria

Covered when in the home setting or inpatient.

1. Ulcers and Wounds in the Home Setting

   A. Chronic Stage III or IV pressure ulcer, or

   B. Neuropathic ulcer ---diabetic, or

   C. Venous or Arterial Insufficiency ulcer, or

   D. Chronic ulcer mixed etiology –present for at least 30 days

And – A Complete wound therapy program –next slide

Ulcers and Wounds in the Home Setting: Coverage Criteria A

Complete wound therapy program that meets 1 **and** 2 or 3 or 4 that must have been tried or considered and ruled out prior to NPWT

1. All ulcers or wounds, the following elements include a minimum of all listed measures that should either be addressed, applied, or considered and ruled out prior to application:
   - ✓ Documentation in medical record of evaluation, care and wound measurements by a LMP, and
   - ✓ Application of dressings to maintain a moist wound environment, and
   - ✓ Debridement of necrotic tissue if present, and
   - ✓ Evaluation of and provision for adequate nutritional status

Need ICD-10 code that describes the wound being treated

Ulcers and Wounds in the Home Setting: Coverage Criteria A

Complete wound therapy program that meets 2 or 3 or 4 that must have been tried or considered and ruled out prior to NPWT

2. For Stage III or IV pressure ulcers:
   - ✓ Patient been turned and positioned appropriately, and
   - ✓ Use group 2 or 3 support surface for pressure ulcers on posterior trunk or pelvis, and
   - ✓ Moisture and incontinence have been managed appropriately

3. Neuropathic ulcers—diabetic:
   - ✓ Been on a comprehensive diabetic management program, and
   - ✓ Reduction in pressure on a foot ulcer accomplished with appropriate modalities

4. Venous Insufficiency Ulcers:
   - ✓ Compression Bandages and/or garments consistently applied, and
   - ✓ Leg elevation and ambulation been encouraged

Ulcers and Wounds from Inpatient Setting: Coverage Criteria B

1. An ulcer or wound encountered during inpatient setting and after wound treatments have been tried or considered and ruled out, then NWPT is considered best treatment by physician, or

2. Complications of a surgically created wound or traumatic wound (i.e. pre-op flap or granuloma) documentation of medical necessity for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments

In either situation above, treatment will be covered beyond discharge

Make sure to have the initial date of service for the inpatient stay– helps with determining duration of treatment

General Information to consider:

- A LHCP= physician, PA, RN, LPN, or PT = should be licensed to assess wounds and/or administer care within same state patient receiving treatment
- NPWT pumps must be coded by PDAC or coverage will deny
  check PDAC at www.dmepdac.com
- NPWT pumps (E2402) must be capable of accommodating more than one wound dressing set for multiple wounds. Only one covered per patient.
- The following are exclusions and are not considered for coverage:
  - The presence in the wound of necrotic tissue with eschar, if debridement is not attempted
  - Osteomyelitis within the vicinity of the wound that isn't concurrently being treated with intent to cure
  - Cancer present in the wound
  - The presence of an open fistula to an organ or body cavity within the vicinity of the wound

Documentation

Medical record includes:

- History and previous treatment, and current wound management
- Current wound management for use of the NPWT pump
  - ✓ Length of sessions of use
  - ✓ Dressing types
  - ✓ Frequency of use
  - ✓ Changes in wound condition
    - Precise measurements
    - Quantity of exudates
    - Presence of granulation and necrotic tissue
    - Concurrent measures being addressed related to wound therapy such as nutrition, debridement, support surfaces using, positioning, & incontinence control
- Initial assessment must include statement from treating physician with:
  - ✓ Condition of wound – including measurements
  - ✓ Efforts to address all aspects of wound care

NPWT Policy Article

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS discussed below.

Information describing the history, previous treatment regimens (if applicable), and current wound management for which an NPWT pump is being billed must be present in the beneficiary's medical record and be available for review upon request. This documentation must include such elements as length of sessions of use, dressing types and frequency of change, and changes in wound conditions, including precise measurements, quantity of exudates, presence of granulation and necrotic tissue and concurrent measures being addressed relevant to wound therapy (debridement, nutritional concerns, support surfaces in use, positioning, incontinence control, etc.).

Information describing the wound evaluation and treatment, recorded in the beneficiary's medical record, must indicate regular evaluation and treatment of the beneficiary's wounds, as detailed in the Coverage Indications, Limitations and/or Medical Necessity section of the related LCD.

Documentation of quantitative measurements of wound characteristics including wound length and width (surface area), and depth, and amount of wound exudate (drainage), indicating progress of healing must be entered at least monthly. The supplier of the NPWT equipment and supplies must obtain from the treating clinician, an assessment of wound healing progress, based upon the wound measurement as documented in the beneficiary's medical record, in order to determine whether the equipment and supplies continue to qualify for Medicare coverage. (The supplier need not view the medical records in order to bill for continued use of NPWT. Whether the supplier ascertains that wound healing is occurring from month to month via verbal or written communication is left to the discretion of the supplier. However, the beneficiary's medical records may be requested in order to corroborate that wound healing is/was occurring as represented on the supplier's claims for reimbursement.)

When billing for NPWT, a diagnosis code (specific to the 5th digit or narrative diagnosis), describing the wound being treated by NPWT, must be included on each claim for the equipment and related supplies.

The medical record must include 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 (listed in A1 through A4 in the related LCD). For each subsequent month, the medical record must include updated wound measurements and what changes are being applied to effect wound healing.

Month-to-month comparisons of wound size must compare like measurements i.e. depth compared to depth or surface area compared to surface area.

If the initiation of NPWT occurs during an inpatient stay, in order to accurately account for the duration of treatment, the initial inpatient date of service must be documented. This date must be available upon request.

Detailed Written Order

- ❑ Patient's name
- ❑ Date of order
- ❑ Detailed description of each item being ordered
- ❑ Printed name of physician
- ❑ Physician's signature and signature date

- Supplier can complete entire order then have physician sign and date
- Signature and date stamps not acceptable
- Documentation needs to be in medical record and not on order

Supply allowance: only dispense 1 month at a time

Dressing kits (A6550)- up to 15 per month per wound

Canister (A7000) up to 10 per month per wound
Large volume allowed when drainage exceeds 90 ml per day
Then stationary pump with large canister allowed

Modifiers:
KX: means documentation meets requirements
If denial is expected, make sure to use ABN, apply either:
GZ – item expected to be denied as no R & N
GA – ABN on file
Pump is a capped rental

Continued Coverage Criteria

- Regular basis, the LMP needs to assess the wound
- LMP needs to oversee or directly perform dressing change
- Changes in the ulcers dimensions and characteristics need documented at least monthly
  Length, width, and depth of wound, amount of exudate, and indicate healing progression
- Supplier must have this documentation on file to ensure the NWPT equipment is still reasonable and necessary
  This is required so the supplier knows that the evaluations are occurring—that's there is communication between all necessary parties
  Documents comparisons of the wound size from month to month
- Coverage usually doesn't occur beyond 4 months – if it does make sure have complete and clear reason why medically necessary- have to use the appeals process

Coverage exceeds 4 months, follow appeals process

- Individual consideration for additional month at a time may be sought using the appeals process.
- Information from the treating physician's medical record, concurrent with each requested one-month treatment time period extension, must be submitted with each appeal explaining the special circumstances necessitating the extended month of therapy
- No published medical literature demonstrating evidence of a clinical benefit for the use of NPWT to complete wound healing
- General, vague or nonspecific statements in the medical record such as "doing well, want to continue until healed" provide insufficient information to justify the need for extension of treatment
- Medical record must provide specific and detailed information to explain the continuing problems with the wound, what additional measures are being undertaken to address those problems and promote healing and why a switch to alternative treatments alone is not possible

Billing Situations

How to bill for wound A for the four covered months when the coverage criteria has been met.

Month 1 – E2402RRKHKX
Month 2 – E2402RRKIKX
Month 3 – E2402RRKIKX
Month 4 – E2402RRKJKX – Therapy is discontinued for wound A during 4th month

Billing for wound A for a fifth month of therapy due to individual circumstances it is believed that an extra month of therapy is necessary (coverage is limited to four months of therapy per wound unless upon individual consideration at the redetermination level it is approved).

- Month 1 – E2402RRKHKX
- Month 2 – E2402RRKIKX
- Month 3 – E2402RRKIKX
- Month 4 – E2402RRKJKX
- Month 5 – E2402RRKJGA or E2402RRKJGZ – The KX modifier may not be used.

The GA modifier is to only be appended if a properly executed ABN has been obtained. If an ABN was not properly executed, append the GZ modifier.

Billing Situations

Wound A has received its four months of covered therapy during the fourth month wound B (new wound) started receiving therapy. How do you bill for the fifth month?

- Month 1 – E2402RRKHKX
- Month 2 – E2402RRKIKX
- Month 3 – E2402RRKIKX
- Month 4 – E2402RRKJKX – Wound A 4th month and wound B 1st month
- Month 5 – E2402RRKJKX – Wound B 2nd covered month

A new capped rental period does not start in month 4 or 5 because there has been no break in medical necessity of 60+ days for the pump. The presence of a new wound does not, by itself, start a new capped rental period.

Billing Situations

Wound A received two months of NPWT while in home setting and then went into an inpatient setting for one month not receiving therapy and came back home on NPWT.

- Month 1 – E2402RRKHKX
- Month 2 – E2402RRKIKX

(1 month in an inpatient setting in between with no therapy)

- Month 3 – E2402RRKIKX – No new capped rental period would begin because there was not a 60+ day break in medical necessity
- Month 4 – E2402RRKJKX

Billing Situations

Wound A received two months of NPWT while in home setting and then went into inpatient setting for one month with continued NPWT and came back home on NPWT.

- Month 1 – E2402RRKHKX – 1st month of therapy covered by DME MAC
- Month 2 – E2402RRKIKX – 2nd month of therapy covered by DME MAC
- Month 3 – While in an inpatient setting not billed to DME MAC
- Month 4 – E2402RRKIKX – 4th month of therapy but 3rd month covered by DME MAC
- Month 5 – E2402RRKJGA or E2402RRKIGZ – 5th month of therapy but not covered by DME MAC unless allowed upon individual consideration at the appeals level. KX modifier may not be used. GA modifier is used only if a properly executed ABN has been obtained. If an ABN was not properly executed, append the GZ modifier.

Billing Situations

Wound A was treated with NPWT in an inpatient setting for the first two months. The beneficiary went home with continued NPWT for the last two months of covered therapy. The time the patient was treated with the NPWT in the inpatient setting goes toward the cumulative four months of covered therapy even though Medicare Part B did not pay for the therapy.

- Month 1 – While in an inpatient setting not billed to the DME MAC
- Month 2 – While in an inpatient setting not billed to DME MAC
- Month 3 – E2402RRKHKX – 3rd month of therapy but 1st month covered by DME MAC
- Month 4 – E2402RRKIKX – 4th month of therapy but 2nd month covered by DME MAC
- Month 5 – E2402RRKIGA or E2402RRKIGZ – 5th month of therapy not covered by DME MAC unless allowed upon individual consideration at the appeals level. KX modifier may not be used. GA modifier is used only if a properly executed ABN has been obtained. If an ABN was not properly executed, append the GZ modifier.

Billing Situations

Wound A received four months of covered therapy, NPWT was discontinued, and 60+ days have passed since the last month of therapy. Now wound B (a new wound) has presented and requires NPWT. This scenario describes a clear break in medical necessity and therefore a new capped rental period begins for wound B. For claims submitted electronically, complete the NTE line level segment (2400 loop) with the following information: The abbreviation "BIS" for break-in-medical need, "pick up" date of the previous equipment (MMDDYY), "delivery" date of the new equipment (MMDDYY), previous diagnosis code (ICD-10), and new diagnosis code (ICD-10).

Format: BIS MMDDYY MMDDYY ICD-10 ICD-10 (Example: BIS 100106 123006 379.31 V43.1)

•Month 1 – 010110 – E2402RRKHKX

•Month 2 – 020110 – E2402RRKIKX

•Month 3 – 030110 – E2402RRKIKX

•Month 4 – 040110 – E2402RRKJKX – Last month of therapy for wound A

(60+ days have passed)

•Month 1 – 070110 – E2402RRKHKX – First month for wound B

Refill Requests

Medical record must include:

- Patient's name or authorized representative if different than the patient
- A description of each item that is being requested
- Date of refill request
- Consumable supplies – disposable such as a disposable canister – need to document remainder left until anniversary date of supplies
- Non-consumable supplies – document why it needs replaced- broken, worn out, etc.
- Must have contact with patient prior to dispensing refill requests
    - No sooner than 14 calendar days prior to shipping/delivery
    - Delivery no sooner than 10 calendar days prior to end of usage
- Supplying high quantities of canisters- more than allowed- there must be clear and explicit information in the medical record that justifies the additional quantities
- In-store pick-ups make sure delivery ticket reflects such--

Coverage Ends When:

- Wound has healed
- Wound healing has failed to occur over previous month in either surface area or depth
- Monthly assessments not met for continued coverage
- 4 months have elapsed in the treatment of most recent wound - this includes time applied during inpatient (can follow appeals process if needed beyond)
- Patient no longer using equipment

Q: *Why is NPWT considered a last resort?*
A: Medicare pays for least costly alternative. NPWT is aggressive therapy that may be avoided if alternative therapies are considered/tried and ruled out.

Q: *Who is responsible for performing wound measurements, the supplier or treating physician?*
A: The treating clinician. The supplier must obtain a copy to ensure continued coverage.

Q: *Is the depth of the wound one of the qualifying criteria?*
A: The depth of the wound is not a criterion by itself; however, must be documented prior to, during, and after therapy to support continued coverage.

Q: *If a wound is caused by cancer, but later the physician documents the "margins are clear", could NWPT be applied if all other coverage criteria is met?*
A: Yes if verified with a pathology report that all margins are clear.

Q: *If a beneficiary has a pressure ulcer on the trunk but is ambulatory, does the beneficiary still need incontinence management and group 2/3 support surface?*
A: Yes

Q: *How long should topical treatment be utilized prior to placing NPWT?*
A: This is left up to the judgment of the treating physician, but there must be documentation in the beneficiary's medical record to support accelerated formation of granulation tissue.

Q: *What documentation is required/acceptable to prove the beneficiary has been "turned and repositioned" in order to meet the goal of the Stage III or IV wound therapy program? This has been indicated on the Nursing Care Plan but not signed by the physician. Is this acceptable?*
A: Yes. There should be nursing notes supporting the care plan. The physician doesn't need to sign the care plan. If the beneficiary was a resident in a SNF, there are also tissue tolerances that are required on an annual basis and more frequently depending on the individual. There needs to be some type of documentation addressing skin integrity.

Q: *Is the NPWT pump, HCPCS code E2402, under the Home Health Consolidated Billing Master Code List?*
A: No, this code is not on the Home Health Consolidated Billing Master Code List and must be billed to the DME MAC.

What is needed "in your files"?

- Patient Profile: Order Intake Form
- Verification of current & permanent address
- Representative information if patient did not sign
- Attending physicians full name, address, NPI
- Assignment of Benefits (AOB)
- Dispensing order
- Detailed Written Order
- Medical records notes, and any other necessary supporting documentation

Proof of Delivery

Signed POD required to verify beneficiary received item

Requirements:

- Beneficiary's name
- Delivery address
- Detailed description to identify the item(s) being delivered
  - Brand name, serial #, narrative description
- Quantity delivered
- Date delivered
- Beneficiary signature
- Supplier signature

Can be signed by:

- Beneficiary
- Beneficiary's designee – relationship to beneficiary must be noted on delivery slip

Opportunities for Wound Care

New Areas for Growth with Different Referrals

– LTC, Rehab, Hospice, Retail, Home Health, Plastics, Podiatry, Internal Med, Vascular, etc.

- For each item, remember the point of service is going to determine how it's billed if it's a billable item
  - Educate your referral sources
    – Market to them at least 2 times a month
  - What is their pain point?

Marketing

- Market your services as a “solution” a “program”, “the complete package”
- You are the experts and interact with wound care patients everyday
- You help keep the payors costs down because you are good a what you do!
- Use a Multidisciplinary approach - Consult/refer to dietary, diabetic educators, orthotists, wound care centers, etc.

Negative Pressure Wound Therapy

Diabetic with a neuropathic ulcer – what’s going to help them heal?

- Nutritional Supplements
- Topical Cream – neuropathic pain
- Moisturizers and protectants
- Offloading boot and/or shoe
- Knee scooter

Thank you for your support!

For recorded webinars (handouts) and UPCOMING webinars visit www.vgm.com/reimbursement

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