NEGATIVE PRESSURE WOUND THERAPY
INTERPRETIVE GUIDELINES
MARCH 2012

These guidelines are intended to provide interpretive guidance to CMS approved accrediting organizations to use in their accreditation of suppliers that provide Negative Pressure Wound Therapy (NPWT) equipment to Medicare beneficiaries. These guidelines also apply to suppliers that are furnishing NPWT equipment to Medicare beneficiaries. This document is intended to assist the supplier in understanding their responsibilities related to this equipment in order to be in compliance with the DMEPOS quality standards.

NPWT is defined as the application of sub-atmospheric pressure to a wound to remove exudate and debris from wounds. NPWT is delivered through an integrated system of a suction pump, separate exudates collection chamber and dressing sets to a qualified wound. In these systems, exudate is completely removed from the wound site to the collection chamber.

These guidelines, while assisting the supplier of NPWT to fulfill all Medicare quality standards, do not contain a detailed discussion of all coverage and documentation requirements pertinent to this subject. Please consult the appropriate LCD (L) and Article (A) for this complete information:

Jurisdiction A: L11500; A35347

Jurisdiction B: L27023; A47111

Jurisdiction C: L5008; A35363

Jurisdiction D: L11489; A20459

These interpretive guidelines do not address clinical aspects of NPWT, nor do they intend to assign clinical responsibilities to DMEPOS suppliers that provide the NPWT equipment to Medicare beneficiaries.

Section I: Supplier Business Services Requirements

D. Consumer Services
CMS DMEPOS Quality Standard:
The supplier shall provide information and telephone number(s) for customer service, regular business hours, after-hours access, equipment and/or item(s) repair, and emergency coverage.
Interpretive Guidelines:
The supplier shall demonstrate that they have provided the beneficiary/caregiver with the following information:

- How to contact the supplier for equipment problems both during business hours and after hours through a 24/7 support function provided by the manufacturer or supplier.
- How to access supplier staff for 24/7 technical product consultation.
- That they should call their physician or 911 if a medical emergency arises.

F. Product Safety

CMS DMEPOS Quality Standards:

The supplier shall implement a program that promotes the safe use of equipment and item(s) and minimizes safety risks, infections, and hazards both for its staff and for beneficiaries;

The supplier shall implement and maintain a plan for identifying, monitoring and reporting equipment and item(s) failure, repair and preventive maintenance provided to beneficiaries.

Interpretive Guideline:

- The supplier has demonstrated that they have ensured the equipment is cleaned between use by different beneficiaries per the manufacturers' recommendations.

Section II: Supplier Product-Specific Service Requirements

A. Intake & Assessment

CMS DMEPOS Quality Standard:

The supplier shall consult with the prescribing physician as needed to confirm the order and to recommend any necessary changes, refinements, or additional evaluations to the prescribed equipment, item(s), and/or service(s).

Interpretive Guidelines:

The supplier shall:

- Ensure the physician order contains all of the documentation requirements in the LCD, including the pump type and necessary supplies.
- Identify and document in the patient's record the home health care provider by contacting the physician, if there is a home health agency involved in the patient's care.

CMS DMEPOS Quality Standard:

The supplier shall review the beneficiary's record as appropriate and incorporate any pertinent information, related to the beneficiary's condition(s) which affect the provision of the DMEPOS and collaboration with the prescribing physician.

Interpretative Guideline:

The supplier shall:

- Confirm that the wound type or risk factors in the patient record are not among those listed in the most recent public health notification of the U.S Food and Drug Administration. Refer to the FDA's link for all of the specific clinical information at http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm190704.htm
- Confirm that if the wound type or any of the risk factors included in the patient's record are also in the most recent guidance issued by the FDA, there is a written approval from the patient's physician that the NPWT equipment is appropriate for this patient.
- Not supply the NPWT equipment to a beneficiary without the physician's written approval.

B. Delivery & Set-up

CMS DMEPOS Quality Standard:

The supplier shall deliver and set-up, or coordinate set-up with another supplier, all equipment and item(s) in a timely manner as agreed upon by the beneficiary and/or caregiver, supplier, and prescribing physician.

Interpretive Guidelines:

The supplier shall:

- Coordinate the delivery of the equipment with the home health care providers' home visit, if there is a home health agency involved in the patient's care.
- Deliver the NPWT pump, dressings and supplies prior to a beneficiary's discharge from the hospital, if the patient is being discharged from an acute care facility.

CMS DMEPOS Quality Standard:
The supplier shall provide all equipment and item(s) that are necessary to operate the equipment or item(s) and perform any further adjustments as applicable.

Interpretive Guidelines:

The supplier shall demonstrate that they have (prior to home delivery):

- Performed quality checks on pumps, tubing, dressings, drapes, containers and canisters per the manufacturer maintenance schedule, before delivery;
- Confirmed that each NPWT component is operational and that equipment and supplies are available and complete prior to setup or at the time of setup;
- Confirmed that all of the supplies are within expiration date;
- Confirmed that the number and sizes of dressings are correct and the packaging is sterile;
- Confirmed that the correct pump, containers/canisters, dressing, tubing is used for the specific brand of equipment according to manufacturer requirements;
- Confirmed that clamps are available if required;
- Confirmed that the exudate collection containers or canister are specific to the NPWT system being used;
- Confirmed that the beneficiary has sufficient number of exudate collection containers to meet his/her wound needs based on the patient's history of drainage amount;
- Confirmed that the alarms are setup and working properly, capable of sounding an audible alarm and/or visual alarm, dependent upon the pump type when desired pressures are not being achieved (that is, where there is a leak in the dressing seal) or the wound drainage container/canister is full or the battery is low;
- Confirmed that the pump and the wound system (stationary or portable) are operational during use.

CMS DMEPOS Quality Standard:
The supplier shall provide, or arrange for, loaner equipment equivalent to the original equipment during any repair period except for orthotics and prosthetics.

Interpretive Guidelines:

The supplier shall demonstrate that they have:

- Performed or arranged maintenance and repairs or replacement of the pump and supplies;
- Given information to the beneficiary and/or caregiver(s) on how to obtain service for purchased equipment.

C. Training/Instruction to Beneficiary and/or Caregiver(s)

CMS DMEPOS Quality Standards:
The supplier shall provide or coordinate the provision of, appropriate information related to the set-up, features, routine use, troubleshooting, cleaning, infection control practices and maintenance of all equipment and item(s) provided.

The supplier shall provide relevant information and/or instructions about infection control issues related to the use of all equipment and item(s) provided.

Interpretive Guidelines:

The supplier shall demonstrate that they have provided training to the beneficiary/caregiver:

- That is specific to the system being used;
- At a minimum it includes:
  - Verification that new packages are not torn, damaged or opened prior to use;
  - Operation of the pump and its settings;

- Written instructions that are left with the beneficiary/caregiver on the safety section of the manufacturer's manual after they have been reviewed by the supplier at a comprehension level applicable for the beneficiary/caregiver needs;
- Instructions on not servicing any of the equipment without calling the supplier first;
- What to do in case of equipment-related complications, including power failure, dislodged tube, accidental disconnection from pump and low battery;
- Equipment troubleshooting in case of equipment-related complications, including situations where tube replacement may be required; or alarm will not turn off or other failure of the pump or its supplies;
- How to contact the supplier if the physician changes settings, or the pump stops working or any review is necessary of the initial instruction;
- Contacting the supplier if the system shuts off;
- How to disconnect the system to take a shower or bath;
- How to disconnect the system when toileting, if the system is not portable;
- How to respond when the pump is turned off and the alarm sounds after a period of time;
- Review of the physician's order for the length of time per day that the pump has to be used;
- What to do if there is a sudden or rapid increase of blood under the drape, in the tubes or container;
- When to immediately turn off the pump;
- When to call the physician or other treating practitioner;
- Contacting the supplier if the NPWT is being discontinued or if the beneficiary is being transferred to another setting;
- How to arrange with the supplier for pickup or shipment of the system;
- The function of the clamps on the tubing both open and closed;
- How to attach, remove, and change the exudates collection container;
- Importance of infection control procedures such as good hand washing techniques when working with the pump and its supplies;
- How to keep the pump clean, the importance of not spilling liquids or food on the pump and wipe off spills immediately;
- Instruction on the frequency of canister changes. No canisters are to be re-used;
- Disposal procedure of the tubing, dressings and canister according to local waste policy requirements.
- The beneficiary/caregiver is given written warranty information for purchased equipment.

D. Follow-up

CMS DMEPOS Quality Standard:
The supplier shall provide follow-up services to the beneficiary and/or caregiver(s), consistent with the type(s) of equipment, item(s) and service(s) provided, and recommendations from the prescribing physician or healthcare team member(s).

Interpretive Guidelines:
The supplier shall have an on-going individualized service plan with a defined frequency that addresses, defines or confirms;

- The ongoing operation and maintenance of the equipment, operation and maintenance of the equipment;
- The frequency for scheduled/planned delivery or supply of additional supplies
- That the beneficiary is using the equipment per the physicians order
- The supplier picks up the equipment when it is no longer needed per the physicians orders.