ALLIANCE OF
Wound
Care
Stakeholders

September 23, 2011

Paul J. Hughes, MD
Medical Director, DME MAC, Jurisdiction A
NHIC Corp.
75 Sgt. William B. Terry Drive
Hingham, MA 02043

Re: Draft Local Coverage Determination for Suction Pumps (DL11494) and Policy Article for Suction Pumps (A51299)

Dear Doctors Hughes, Brennan, Hoover and Whitten,

The Alliance of Wound Care Stakeholders ("Alliance") is pleased to provide comments on the Draft Local Coverage Determination for suction pumps (DL11494) and Policy Article for Suction Pumps (A51299). The Alliance is a 501 (c) (6) multidisciplinary trade association consisting of 19 physician, clinical, provider, and patient organizations, whose mission is to promote quality care and patient access to wound care products and services. These comments were written with the advice of Alliance organizations that not only possess expert knowledge in complex acute and chronic wounds, but also in wound care and research. We appreciate the opportunity to offer our comments.

Our comments are directed at the clinical aspects of this suction pump policy. Many, if not most, wound care physicians and clinicians use devices in their practices that are included in the HCPCS codes under both the negative pressure wound therapy (E2402) and suction pump (K0743) local coverage determinations (LCDs) These devices perform the same clinical functions and are used in most cases to treat patients with chronic wounds (e.g., venous stasis ulcers and diabetic foot ulcers.) Different devices are selected according to patient compliance, ability to maintain patient treatment in the home, ability of patient ability to change the dressing in the home, the ability to maintain a seal on wounds, the amount of exudate being removed, and the location of the wound.

Considering this information, the Alliance is concerned that the suction pump policy does not include the clinical indication for the circumstances under which these products are covered under the Medicare program. We believe that these devices are reasonable and necessary in the treatment for patients with chronic wounds. The only difference in technology between the devices in the wound suction pump LCD (pump and dressing with integrated canister) and the NPWT LCD (pump, dressing and canister) is the canister. It is our understanding that the device currently coded under the wound suction

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pump code (K0743) was cleared by the FDA in the same product class as the other three conventional NPWT systems using the OMP classification and have essentially identical indications for use. As stated above, physicians and clinicians use both NPWT devices and wound suction pump for the same patient population with the same clinical indications. **Therefore, we recommend that the DME MAC medical directors cover the wound suction pump codes under Medicare with the same clinical indications that are in the NPWT LCD.**

In addition, we are asking for clarification on two issues regarding the following sentences contained in the draft suction pump LCD. The sentences states, "Wound suction to remove exudate can be accomplished with the use of non-covered disposable suction devices such as a Jackson – Pratt drain or via straight drainage. When a non-covered alternative exists, it is not reasonable and necessary to use a covered DME item."

The issues are:

- What are the criteria for disposable suction devices such that both the Jackson Pratt drain and straight drainage would be included in this category?
- The second sentence is confusing since the items of covered DME are not clearly identified. If the covered DME item is K0743 then this example is inappropriate since it is our understanding that the Jackson Pratt and straight drainage are both used for acute surgical wounds and the K0743 is used for chronic wounds.

  A Jackson Pratt drain or straight drainage is not comparable to the KO743 in terms of technology or clinical indications for which they are both utilized for the following reasons:

  1.Jackson Pratt drains or straight catheters are utilized for draining a body cavity or surgical sites / traumatic injury sites to remove excessive blood, fluids and/ or contaminated drainage. They are placed into a cavity or under the skin or muscle and then connected to a bulb syringe or wall or portable suction. This technique, employing direct pressure, is used to facilitate removal of the unwanted or infected bodily fluids rapidly for usually short periods of time, hours – days. The amount of pressure is not monitored or regulated nor are these sites sealed. Jackson Pratt drains or straight catheters are almost always used in a facility setting to remove acute drainage from open, acute wounds or post-operative surgical sites.

  More specifically, a Jackson Pratt is a bulb syringe connected to tubing. The tubing is placed under the incision and the incision is sutured over it. It is held in place by a suture wrapped around the tubing. The bulb syringe is compressed at intervals and drainage which might accumulate under the incision will drain into it, thus preventing a hematoma. It is removed a few days after surgery. The suture is clipped and it slides out. It is strictly for a very short term use. Sometimes it is placed in an abscess or area where a cyst or infection is drained to pump out a high volume of fluid.

Straight drainage could be like a penrose drain. It is again placed into the incision post op to allow drainage to escape and not build up. It is also removed a few days after surgery. It is strictly allowing a channel for any drainage to escape. It can be covered by a pouch or dressing.

2. A Jackson Pratt catheter or straight drain/catheter would never be inserted into a diabetic foot ulcer or venous ulcers to drain wound exudate. These catheters could cause erosion of fragile tissue or create pressure points causing more damage to a chronic ulcer.

3.Portable pumps, which attach to these type of draining tubes have no standardized range of pressure, have no mechanism to monitor the 'draw' through the pump into the Jackson Pratt or straight catheter and no set criteria.

Therefore, these two products are not appropriate to be used in this example to compare that they would have the same clinical indications (acute wounds in this case versus chronic wounds in the case for the KO743 devices). In addition, these products are to be used to collect a large volume of fluid; whereas since the KO743 does not have a canister only a moderate volume of fluid would be collected.

Thus, the Alliance recommends that this example be deleted from the LCD.

We appreciate the opportunity to comment on this important policy that impacts our clinical organizations. Please call on us if we can answer any questions.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director