

Suction Pumps August 2011 Draft LCD - Summary of Comments With Responses

Comment: Many 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 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

Response: Disagree. NPWT and suction pump are not considered as interchangeable devices. Although both types can remove exudate from the base of a wound, NPWT also (1) removes exudate from the wound sites entirely sequestering it in a collection canister, and (2) "jump starts" healing in appropriately treated wounds where healing has been delayed. There is no published clinical evidence that suction pumps achieve these same clinical outcome. We do agree that it is important and appropriate to match the therapy to the clinical scenario for devices that are within the same category. The numerous products classified as NPWT afford that selection.

Comment: The suction pump policy does not include the clinical indications 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.

Response: We agree that a clear statement about coverage is important. That is the reason for this revision of the existing Suction Pumps LCD.

Comment: The device currently coded under the wound suction 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 has essentially identical indications for use. Before one agency can come to a different conclusion from another agency there should be a clear rationale.

Response: The FDA determines whether an item may be marketed. The rigor and complexity of their assessment varies across categories of products. This product was evaluated using the FDA 510(k) process, which evaluates by analogy to existing or past products. FDA product classification categories are not identical to those used by Medicare. While FDA clearance is a prerequisite for Medicare coverage, the 510(k) premarket clearance process by itself is insufficient to establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, e.g., benefit category and other statutory requirements, coding and pricing guidelines, national and local coverage determinations and clinical evidence.

Comment: Coverage of the Kalypto system as NPWT will enable clear and consistent processing by HME suppliers. They are used to coverage of Kalypto as NPWT.

Response: Clear policy is important for consistent payment. The Suction LCD has been in place longer than the NPWT LCD. The assignment of these various products to an LCD is evident from the definitions within the policy, ensuring that the appropriate coverage criteria will be followed in a compliant manner.

Comment: Coverage of Kalypto as NPWT strengthens choice. Removal creates a barrier to quality and cost-effective care.

Response: Numerous alternative 3-component systems remain classified as NPWT, affording ample choice. The NPWT codes are reimbursed based upon the fee schedule, thus there is no cost advantage among similar systems. As there is no published literature directly comparing treatment effectiveness between 2- and 3-component systems, no valid quality or cost assessment comparisons can be made.

Comment: 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.

Response: Mechanical suction for wounds is appropriate in those clinical scenarios where the quantity of exudate exceeds the capacity of conservative measures such as dressings and wound fillers to contain it. Disposable items used to manage wound exudate are not eligible for coverage under the Durable Medical Equipment Benefit. When a noncovered item or service can be used to perform the same function as that performed with a covered item, it is not reasonable or necessary for Medicare to provide reimbursement for the covered item. We will clarify this section of the policy draft.

Comment: A Jackson-Pratt drain or straight drainage is not comparable to the K0743 in terms of the technology or clinical indications for which they are both utilized. Portable pumps, which attach to these types 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.

Response: We agree that the technologies are different, that is, an electric suction pump vs. a manual elastomeric pump. However, the function is the same in that they both develop sufficient suction to remove drainage from the wound site when used properly. The Suction Pump LCD, unlike the NPWT LCD, does not have specified pressure ranges, required alarms, etc. required as part of the coding guidelines.

Comment: It is important to add coverage criteria for the use of a gastric suction pump and related supplies to other local coverage determinations such as surgical dressings and ostomy supplies to ensure consistent coverage criteria across the wound care space.

Response: A gastric suction pump is used to remove fluids under continuous or intermittent suction via a tube. Inclusion of these pumps into the Surgical Dressings or Ostomy LCD would not be appropriate.

Comment: Kalypto has been covered and reimbursed under the Medicare program for almost three years.

Response: The Kalypto Medical pump and dressings were incorrectly included in the NPWT pump and dressing kit codes. Reimbursement was incorrectly provided under the NPWT codes. The Kalypto system items were recoded using Not Otherwise Classified codes when Medicare became aware of the inclusion of Kalypto Medical's pump and dressings in the NPWT codes. The Kalypto products were subsequently reclassified as a wound suction pump and related dressings with new coding (K0743-K0746).

Comment: While we recognize that the DMEMACs have great discretion and latitude when developing coverage policies, there would not have been as many concerns or areas of confusion had appropriate stakeholders been included prior to the development of the draft policy. As new and innovative technologies are being developed, we believe it is imperative for CMS and its contractors to meet with medical device manufacturers and the physicians and clinicians who use this technology in order to work together to ensure appropriate coverage policies for products which are clinically and cost effective.

Response: We agree that collaboration with stakeholders is important. The DME MACS and CMS had many meetings, conference calls and much correspondence with relevant parties throughout the coding assessment and draft policy development process. In addition, the comment period and public meeting afford opportunities for others to provide information and feedback.

Comment: Data has been presented that shows that the Kalypto system 1) treats chronic lower extremity wounds of similar scale as other NPWT systems, 2) can be used to promote wound epithelialization, and 3) heals wounds like other NPWT systems.

Response: We are aware of no published clinical studies supporting these assertions. We are aware of a single, unpublished, retrospective case analysis that examines clinical outcomes after the use of the Kalypto Medical product. The CMS Program Integrity Manual (Internet Only Manual 100-8, Ch. 13) requirements for assessing clinical evidence classify studies of this type with very low weight for evidence to support an LCD.

Comment: There were seven testimonial letters from users of the device stating their request for the Kalypto system to continue to be classified as NPWT. Clinician letters provided anecdotal evidence of efficacy, also.

Response: The CMS Program Integrity Manual (Internet Only Manual 100-8, Ch. 13) requirements for assessing clinical evidence classify letters of this type with very low weight for evidence to support an LCD.