Evaluation of Healthcare Common Procedure Coding System Coding for Negative Pressure Wound Therapy Devices

This report describes a Healthcare Common Procedure Coding System (HCPCS) evaluation performed by the Centers for Medicare & Medicaid Services (CMS) on negative pressure wound therapy (NPWT) devices. Section 154(c)(3) the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires the Secretary to evaluate the HCPCS codes for NPWT using an existing process, and to consider all relevant studies and information in making the evaluation.

The CMS utilized its existing public process for evaluating HCPCS coding and determined that the current HCPCS codes for NPWT are appropriate and should not be changed. The available evidence does not support differentiating among what are substantially equivalent products.

Background

The NPWT is a treatment approach used for skin ulcers or wounds. The NPWT device is a stationary or portable pump that applies a localized vacuum to draw the edges of the wound together while providing a moist environment conducive for rapid wound healing. While there are currently 13 manufacturers of NPWT devices, all the devices are comprised of the same basic components: a dressing applied to the wound, a suction pump which is applied to the dressing, tubing and a collection canister. The dressing varies in some of the devices. The two most common wound dressings used are foam and gauze. The Food and Drug Administration (FDA) has approved these devices for use under the 510(k) review process, using the KCI VAC device as the predicate product.

The HCPCS codes are used by suppliers to describe items and services on claims for payment submitted to Medicare and other payers (e.g., Medicaid and commercial insurers). There are currently three codes that apply to all NPWT systems. These codes describe the mechanical pump, the dressing, and the canister. In order for CMS to establish a separate HCPCS code for a particular NPWT product, CMS would require clinical evidence demonstrating a significant functional distinction or a significant therapeutic distinction (i.e., improved medical benefit) when compared to similar products that share the same code category.

NPWT Coding Evaluation

<u>Current HCPCS Code Review Process Overview</u>

Generally, similar or equivalent items and services are classified under the same HCPCS code(s). There generally are not separate codes for items based on manufacturer. CMS may establish a unique HCPCS code for a product if, in addition to meeting certain other criteria (e.g., FDA approval, claims activity or volume), clinical evidence revealed that the product performs a significantly different function (significant functional distinction), or that a feature (or the use) of a particular product conferred a significantly improved clinical benefit for patients (significant therapeutic distinction), when compared to similar products which share the same code category. The established HCPCS code review process begins with an application from a manufacturer or

other party requesting a modification to the HCPCS code set. In support of the application, applicants claiming significant therapeutic distinction provide clinical evidence substantiating that there is a significant therapeutic distinction between their product and other similar products within that coding category. The applications and submitted evidence are reviewed by a workgroup comprised of representatives of CMS, Medicaid state agencies, Medicare contractors, and private insurers. As part of the standard coding review process, CMS' Pricing, Data Analysis and Coding (PDAC) contractor routinely consults with the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) on all coding evaluations, as was done in the NPWT review. The panel develops a recommendation for a preliminary decision, which is ultimately made by CMS. The preliminary decisions are then published on CMS Web site at: www.cms.hhs.gov/medhcpcsgeninfo and an opportunity for public comment is provided through a public meeting process. The workgroup then reconsiders each application based on the additional input presented by stakeholders and the public. CMS considers the recommendations of the workgroup and makes the final decision on all coding applications.

NPWT Code Review Nuances

In applying the existing process to the NPWT evaluation, CMS viewed the MIPPA provision as a proxy for a manufacturer's application. In addition, to ensure that CMS considered all relevant studies and information about NPWT products, in accordance with MIPPA, the existing HCPCS code review process was enhanced in the following ways:

- The CMS partnered with the Agency for Healthcare Research and Quality (AHRQ) to solicit information from stakeholders. The AHRQ requested submission of research studies that compare clinical outcomes using various NPWT devices. The information received as a result of this solicitation was considered by CMS in its decision making process.

- The CMS and AHRQ commissioned the ECRI Evidence-Based Practice Center to conduct a Technological Assessment of NPWT devices and components. We tasked ECRI to independently assess whether any single NPWT system, or component within the NPWT system, confers a significant therapeutic distinction in terms of improved clinical outcomes (wound healing) or fewer adverse events (such as less pain, bleeding, infection, other complications, or mortality) when compared to another. To perform this assessment, ECRI reviewed available literature and the information received as a result of the stakeholder solicitation.

- As part of the technological assessment, ECRI applied commonly accepted standards of evidence inclusion criteria, excluding items from their analysis such as animal studies, studies with small sample sizes, and testimonials. ECRI found no studies that directly or indirectly compared one NPWT system to another NPWT system. ECRI also found no studies that directly compared one NPWT system component (such as KCI's foam dressing) to another NPWT system component.

The ECRI assessment concluded that the available evidence does not support a significant therapeutic distinction of a NPWT system or component of a system. ECRI developed a draft

report of their findings in March 2009, which AHRQ made publicly available for comment. The final report, which considered public comments, was made publicly available in June 2009 (http://www.ahrq.gov/clinic/ta/negpresswtd/). The final report informed the CMS as the CMS formulated its preliminary coding decision.

Formulation of an NPWT Preliminary Coding Decision

The CMS considered the information submitted by stakeholders, the ECRI final report, and other available information and concluded that evidence supporting a significant therapeutic distinction (e.g., significantly improved clinical benefit) currently does not exist for any particular NPWT device. Therefore, the CMS published a preliminary HCPCS coding decision that the existing HCPCS codes adequately describe all NPWT devices.

NPWT Public Meeting

The HCPCS coding process allows stakeholders and the general public an opportunity to provide input to the CMS about preliminary decisions through public meetings. On July 9, the CMS hosted a public meeting to gather public input regarding the NPWT preliminary coding decision.

- Eight of the 13 NPWT manufacturers gave formal presentations at the meeting. Seven concurred with the CMS' preliminary decision and supported ECRI's technological assessment methodology.

- One manufacturer criticized the ECRI report, stating that because ECRI excluded animal and cellular studies in the technological assessment, the CMS failed to meet the MIPPA mandate to consider all relevant evidence in the coding evaluation. This manufacturer also claimed that the CMS inappropriately applied evidence of the one product's efficacy to other NPWT products.

- Industry representatives including clinicians who use NPWT devices, a director of a large chain of home health agencies, and other industry consultants also provided comments during the public meeting. These stakeholders described the advantages of NPWT therapy and concurred with the CMS' preliminary decision.

- Some stated that the ECRI assessment should have included animal and cell studies while acknowledging that the final outcome of the assessment would not be different.

The CMS' Final Evaluation

In formulating a final HCPCS coding decision for NPWT, the CMS considered the ECRI final report together with all of the evidence which was submitted as a result of the stakeholder solicitation, testimony from the July 9, 2009 public meeting, and other related evidence.

While the ECRI technological assessment applied standard evidence inclusion criteria to the evidence submitted as a result of the stakeholder solicitation, the panel and the CMS considered all submitted evidence, including the 41 animal and cellular studies which the ECRI analysis

excluded. Specifically, the CMS reviewed nine animal studies which compared different dressing types. These studies did not reveal a difference in healing attributable to dressing type. The CMS also considered 25 studies which described the cellular level benefits of all NPWT devices, such as blood flow in the wound, and tissue granulation, but were not specific to any one NPWT device or aspect of the device. Other studies showed general wound healing resulting from negative wound pressure. However, these studies also did not reveal a significant therapeutic distinction associated with any one device.

The CMS' Coding Determination

After reviewing all relevant evidence, the CMS found no direct or indirect studies that compared clinical outcomes using different manufacturer's NPWT devices, or that compared clinical outcomes using foam dressings verses gauze dressings using the same or different NPWT devices. The CMS determined that there is insufficient data at this time to demonstrate significant functional distinction or significant therapeutic distinction between NPWT products, or any NPWT product component, to justify a separate HCPCS code(s). The CMS' conclusion is that the existing NPWT codes adequately identify the NPWT products on the market.