

**Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda
for Negative Pressure Wound Therapy (NPWT) Devices
Thursday, July 9, 2009, 9:00 am – 5:00 pm
CMS Auditorium
7500 Security Boulevard
Baltimore (Woodlawn), Maryland 21244-1850**

The Guidelines for participation in HCPCS Public Meetings as published in the document entitled “2009 Guidelines for Participation” located on CMS’ HCPCS website @ http://www.cms.hhs.gov/MedHCPCSGenInfo/Downloads/Participation_Guidelines.pdf applies to the July 9, 2009 HCPCS Public Meeting for NPWT, with the following exception: Each manufacturer of NPWT devices may designate one “primary speaker” to make a presentation of a maximum of 15 minutes. Manufacturers may speak or designate one speaker to represent the company’s views regarding CMS’ preliminary HCPCS coding recommendation. While we believe we have identified and contacted all manufacturers of NPWT devices, if you are a manufacturer of NPWT devices and we have not already contacted you, please immediately contact either Jennifer Carver at Jennifer.carver@cms.hhs.gov or (410) 786-6610; or Felicia Eggleston at Felicia.eggleston@cms.hhs.gov or (410) 786-9287.

We have reserved a 2 hour block of time for additional stakeholders who wish to provide a presentation. This two hour timeframe will be equally divided among the number of additional registered speakers, not to exceed 10 minutes per speaker. These speakers must register in advance of the meeting. CMS will contact these speakers shortly after the registration deadline to advise them regarding the actual number of minutes they will have for their presentations.

All presenters, including manufacturers and other stakeholders, must register to speak by contacting Jennifer Carver or Felicia Eggleston (as above); submit presentation materials; and submit a summary of speaking points by June 25, 2009.

We will reserve the last hour of the day for comments from 5-minute speakers. Meeting attendees will be permitted to sign up at the meeting, on a first-come, first-served basis, to make 5-minute presentations. Pre-registration and use of audio-visuals is not available for 5-minute speakers.

Please remember that all attendees must register on-line. This list is used by the Security guards to permit access into the building.

A written overview of the topic and CMS’s preliminary coding decision is provided. An overview of Medicare pricing/payment methodology is also attached to this agenda. Preliminary decisions are not final or binding upon any payer, and are subject to change. Meeting participants will hear presentations about the agenda item from the registered primary speakers and other speakers (if any). Presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meetings provide an opportunity for the general public to provide additional input related to requests to modify the HCPCS code set.

Final decisions are not made at the public meetings. Applicants will be notified of final decisions in November.

8:15 a.m. Arrival and sign-in

9:00 a.m. Welcome
Opening Remarks from Centers for Medicare & Medicaid Services (CMS)

Comments from Agency for Healthcare Research and Quality (AHRQ) regarding
Tech Assessment Process

ECRI Review of Methods and Findings of NPWT Assessment and Q&A's
regarding Methodology

10:00 a.m. Primary Speakers, (Manufacturers or designees)

2:00 p.m. (approximately) Other registered public speakers

4:00 p.m. 5-minute speakers

**HCPCS Public Meeting
July 9, 2009**

Topic/Issue:

HCPCS coding and Medicare payment for Negative Pressure Wound Therapy (NPWT) devices.

Background/Discussion:

The Medicare Improvements for Patients and Providers Act of 2008 required the Secretary to evaluate existing HCPCS codes for NPWT devices to ensure accurate reporting and billing for the items and services under such codes; use an existing process for the consideration of coding changes; and consider all relevant studies and information furnished through the process.

CMS partnered with Agency of Healthcare Research and Quality (AHRQ) to commission a review of NPWT devices to ensure all relevant studies and information on NPWT were captured. ECRI Institute solicited information from stakeholders and searched literature in conducting this review. A draft report of their findings was published for comment in April 2009. After analysis of comments received, ECRI concluded that the available evidence does not support significant therapeutic distinction of a NPWT system or component of a system. The report informed CMS' HCPCS workgroup's decision. The final report will be publicly available no later than June 10, 2009 on AHRQ's homepage for the Technology Assessment program at <http://www.ahrq.gov/clinic/techix.htm>.

CMS HCPCS Preliminary Coding Decision:

Existing code E2402 NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, STATIONARY OR PORTABLE adequately identifies the NPWT pump. Existing code A7000 CANISTER, DISPOSABLE, USED WITH SUCTION PUMP, EACH adequately identifies the canister set. Existing code A6550 WOUND CARE SET, FOR NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, INCLUDES ALL SUPPLIES AND ACCESSORIES adequately identifies the dressing, wound care set, including foam products.

Medicare Payment:

The payment rules and amounts associated with the existing codes apply to these products.

For E2402, Pricing = 36

For A7000, Pricing = 32

For A6550, Pricing = 34

PAYMENT FOR DMEPOS

DMEPOS

The term DMEPOS, which stands for durable medical equipment (DME), prosthetics, orthotics and supplies, is used in the Medicare program to describe a set of Medicare Part B device and supply benefits for which claims are processed by four DME Medicare Administrative Contractors (DME MACs). The Part B device benefits covered by this term include:

- DME – equipment used in the home which can withstand repeated use, is primarily and customarily used to serve a medical purpose, and is generally not useful in the absence of an illness or injury;
- Prosthetic Devices – devices that replace all or part of an internal body organ, including ostomy, tracheostomy and urological supplies, parenteral and enteral nutrients, equipment and supplies (PEN), intraocular lenses (IOLs), and one pair of conventional eyeglasses or contact lenses after each cataract surgery;
- Prosthetics – artificial legs, arms, and eyes;
- Orthotics – rigid or semi-rigid leg, arm, back, and neck braces;
- Home Dialysis Supplies and Equipment
- Surgical Dressings
- Therapeutic Shoes and Inserts

Depending on the item or the setting in which the item is furnished, Medicare claims for some of these items may also be processed by local carriers and fiscal intermediaries (e.g., claims for DME implanted in an ambulatory surgical center are processed by local carriers). Claims for DME and ostomy, tracheostomy and urological supplies furnished by a home health agency are processed by Regional Home Health Intermediaries (RHHIs).

Fee Schedule Payments

Prior to January 1, 1989, payment for most DMEPOS items and services was made on the basis of the reasonable charge methodology. Reasonable charges are calculated using suppliers' charges and are limited by an inflation adjustment factor. Payment is still made on a reasonable charge basis for home dialysis supplies and equipment and for IOLs inserted in a physician's office. There is a monthly limit per beneficiary on payments for home dialysis supplies and equipment. Payment for most of the other DMEPOS items and services is based on the lower of the actual charge for the item or a fee schedule amount. The Part B deductible and 20 percent coinsurance both apply to the DMEPOS items and services described above.

The Social Security Act requires that the DMEPOS fee schedule amounts be established based on average reasonable charges made during a base period (e.g., July 1, 1986 thru June 30, 1987 for prosthetic devices, prosthetics and orthotics). The fee schedule amounts are increased by annual update factors. Because the reasonable charge data required by the law in establishing fee schedule amounts does not exist for new DMEPOS items, the fee schedule amounts for new DMEPOS items are “gap-filled” using fees for comparable items, supplier price lists, manufacturer suggested retail prices, or wholesale prices plus a markup. The gap-filling methodology is used to estimate the average reasonable charge for the item from the base period.

DMEPOS Payment Categories/HCPCS Pricing Indicators

The Social Security Act separates DMEPOS into different Medicare payment categories, each with its own unique payment rules. The pricing indicators in the HCPCS identify which major payment category a code falls under. The pricing indicators applicable to DMEPOS are as follows:

- **Pricing = 00 Service Not Separately Priced**
Items or services described by the HCPCS codes that are either not covered under Medicare Part B or for which payment is bundled into the payment some other Medicare service or procedure.
- **Pricing = 31 Frequently Serviced Items**
Payment is generally made on a monthly rental fee schedule basis for items such as ventilators that require frequent and substantial servicing in order to avoid risk to the patient’s health.
- **Pricing = 32 Inexpensive and Other Routinely Purchased Items**
Payment is made on a purchase or rental fee schedule basis. This category includes items that have a purchase price of \$150 or less, are generally purchased 75 percent of the time or more, or which are accessories used in conjunction with a nebulizer, aspirator, continuous airway pressure device, or intermittent assist device with continuous airway pressure device. The beneficiary has the option to acquire the item on a purchase or monthly rental basis. Total payments for the item cannot exceed the purchase fee schedule amount for the item.
- **Pricing = 33 Oxygen and Oxygen Equipment**
Monthly fee schedule payments are made for furnishing oxygen and oxygen equipment. This monthly payment includes payment for all stationary oxygen equipment, supplies, and accessories and delivery of oxygen contents (stationary and portable). A monthly add-on to this payment is made for portable oxygen equipment only for those beneficiaries who require portable oxygen. The monthly payments for oxygen equipment cap after the 36th monthly payment is made, after

which monthly payments for the ongoing delivery of contents continue for gaseous or liquid systems.

- **Pricing = 34 Supplies Necessary for the Effective Use of DME**

Payment is made on a purchase fee schedule basis for supplies necessary for the effective use of DME (e.g., lancets that draw blood for use in blood glucose monitor).

- **Pricing = 35 Surgical Dressings**

Payment is made on a purchase fee schedule basis for surgical dressings.

- **Pricing = 36 Capped Rental Items**

Payment is made on a monthly rental fee schedule basis. For items furnished on or after January 1, 2006, the beneficiary takes over ownership of the item after the 13th rental payment is made. The rental fee for capped rental items for each of the first 3 months of rental is equal to 10 percent of the purchase fee for the item. The rental fee for months 4 through 13 is equal to 7.5 percent of the purchase fee for the item. Power wheelchairs can be purchased in the first month.

- **Pricing = 37 Ostomy, Tracheostomy and Urological Supplies**

Payment is made on a purchase fee schedule basis for ostomy, tracheostomy and urological supplies.

- **Pricing = 38 Orthotics, Prosthetics, Prosthetic Devices, and Vision Services (Prosthetic Lenses)**

Payment is made on a purchase fee schedule basis for orthotics, prosthetics, and prosthetic devices & lenses.

- **Pricing = 39 Parenteral and Enteral Nutrition (PEN)**

Payment is made on a purchase fee schedule basis for parenteral and enteral nutrients and supplies. Payment is made on a purchase or rental fee schedule basis for parenteral and enteral equipment. The beneficiary has the option to acquire the item on a purchase or monthly rental basis.

- **Pricing = 45 Customized DME**

Payment is made for lump-sum purchase of DME that meets the Medicare regulatory definition of customized DME at 42 CFR 414.224. The payment amount is based on the carrier's individual consideration of the item.

- **Pricing = 46 Carrier Priced Item**

For items falling under codes for miscellaneous or not otherwise classified items, the fee schedule or reasonable charge payment amount, whichever is applicable, is based on the carrier's individual consideration of the item.

- **Pricing = 52 Reasonable Charges**

Payment continues to be made on a reasonable charge basis in accordance with Medicare regulations at 42 CFR 405.500 for splints, casts, and other devices used to reduce a fracture or dislocation, dialysis supplies and equipment, and intraocular lenses (IOLs) inserted in physician's offices.