Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Negative Pressure Wound Therapy (NPWT) Devices
Thursday, July 9, 2009

Introduction and Overview

Approximately 85 people attended. The agenda included a single item.

Cindy Hake of CMS' Center for Medicare Management provided background concerning CMS' review of coding and payments for NPWT devices, and an overview of the HCPCS Public Meeting as it relates to the overall HCPCS coding process.

Karen Lohmann Siegel, P.T., M.A., Health Scientist Administrator, of the Agency for Healthcare Research and Quality (AHRQ) gave an Overview of the AHRQ Technology Assessment Program (TAP).

Karen Schoelles, M.D., Medical Director of the Health Technology Assessment Group provided a detailed reporting on the methods and findings of ECRI's Technology Assessment for NPWT devices.

Prior to the Public Meetings, CMS HCPCS workgroup meets to formulate preliminary coding recommendations. CMS also makes preliminary recommendations regarding the applicable Medicare payment category and methodology that will be used to set a payment amount for the items on the agenda. The preliminary coding and payment recommendations are posted on the HCPCS website at: www.cms.hhs.gov/MedHCPCSGenInfo/, as part of the HCPCS public meeting agendas.

Following the public meetings, CMS' HCPCS workgroup reconvenes, and considers all the input provided at the Public Meetings regarding its preliminary coding recommendations. CMS also reconsiders its Medicare payment recommendations. CMS maintains the permanent HCPCS level II codes, and reserves final decision making authority concerning requests for permanent HCPCS codes. Final decisions regarding Medicare payment are made by CMS and must comply with the Statute and Regulations. Payment determinations for non-Medicare insurers, (e.g., state Medicaid Agencies or Private Insurers) are made by the individual state or insurer.

The HCPCS Annual Update will be published at:
http://www.cms.hhs.gov/HCPCSReleaseCodeSets/ by mid November.

Detailed information regarding CMS' HCPCS coding procedures and a decision-tree outlining CMS' decision-making criteria are at: www.cms.hhs.gov/MedHCPCSGeninfo/.

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

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

For the agenda item, 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. Presentations will be followed by an opportunity for questions regarding that particular agenda item. These meetings offer an opportunity for the general public to provide additional input related to requests on modifying the HCPCS code set. Final decisions are not made at the public meetings. They will be reflected in the HCPCS Annual Update published in November.

The agenda includes a summary of all the HCPCS code applications. The information provided in the summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the Federal government.

Manufacturers 13; Other Stakeholders Designees 4

AGENDA ITEM #1
Kinetic Concepts, Inc. (KCI)

Primary Speaker: Dr. Todd Fruchterman, M.D., Ph.D., of Kinetic Concepts, Inc.

AGENDA ITEM #2
ConvaTec

Primary Speaker: Mr. Joseph Rolley, Vice President, Global Government Affairs and Health Policy of ConvaTec

AGENDA ITEM #3
Kalypto Medical

Primary Speaker: Mr. Philip Vierling of Kalypto Medical

AGENDA ITEM #4
Talley Medical

Primary Speaker: Mr. Jack Van Dyke of Talley Medical

AGENDA ITEM #5
Prospera®

Primary Speaker: Ms. Cindy Ahearn, M.S., R.N., E.T., C.W.C.N., F.N.P.-B.C., of Prospera®

AGENDA ITEM #6
Ohio Medical Corporation™

Primary Speaker: Mr. David Finney, President/Chief Executive Officer of Ohio Medical Corporation™

AGENDA ITEM #7
Smith & Nephew

Primary Speaker: Dr. Doran Edwards, M.D., C.O.O., on Behalf of Smith & Nephew

AGENDA ITEM #8
Medela, Inc.

Primary Speaker: Dr. Mark D. Cregan, Ph.D., Director of Medical Relations & Education, Medela Healthcare

AGENDA ITEM #9
Innovative Therapies, Inc.

No comments were provided.

AGENDA ITEM #10
Genadyne Biotechnologies

No comments were provided.

AGENDA ITEM #11
Premco Medical Systems, Inc.

No comments were provided.

AGENDA ITEM #12
Atmos Medizin Technik

No comments were provided.

AGENDA ITEM #13
The Wound Care Company

No comments were provided.

Other Registered Public Speakers

AGENDA ITEM #14
Mr. Kevin Woo On Behalf of the Wound Union of Wound Healing Societies (WUWHS)

AGENDA ITEM #15
Dr. Mark E. Chariker, M.D., F.A.C.S., of the University of Louisville/Division of Plastic Surgery

AGENDA ITEM #16
Dr. Raymond M. Dunn, M.D., of UMass Memorial Plastic Surgery

AGENDA ITEM #17
Ms. Laurie L. McNichol, M.S.N., R.N., G.N.P., C.W.O.C.N., of Advanced Home Care

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 the available clinical evidence, ECRI Institute did not identify a significant therapeutic distinction of one NPWT system or component over another through the use of head-to-head comparison or through the use of indirect comparison methods. The final report is published on AHRQ's homepage for the Technology Assessment program at http://www.ahrq.gov/clinic/techix.htm. The report was considered by CMS' HCPCS workgroup in its evaluation of NPWT devices. The HCPCS workgroup preliminary decided that the available evidence cannot be used to determine a significant therapeutic distinction of a NPWT system.

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 A6550, Pricing = 34
For A7000, Pricing = 32

Comments from NPWT device Manufacturers:

#1 Kinetic Concepts, Inc. (KCI)

Primary Speaker: Dr. Todd Fruchterman, M.D., Ph.D., of Kinetic Concepts, Inc.

Summary Statement Provided by KCI:
"KCI is opposed to the preliminary coding decision that assigns all Negative Pressure Wound Therapy (NPWT) products to the current NPWT HCPCS codes. From a procedural standpoint, HHS was directed to conduct the NPWT code review by Congress through the Medicare Improvements for Patients and Providers Act of 2008. However, MIPPA did not limit the code review to the comparative clinical data evaluated in the recent AHRQ NPWT Technology Assessment. In fact, it specially states that "all relevant studies and information" should be considered in order to ensure that NPWT products are coded correctly. Since CMS has stated that the preliminary coding decision was influenced by the findings of the AHRQ report, KCI believes that CMS did not consider all relevant evidence and information in reaching the preliminary coding decision. Therefore, in keeping with Congressional intent, KCI presents newer scientific evidence and regulatory information that justifies the creation of separate codes for foam-based NPWT systems and gauze-based wound drainage systems based on comparisons of both FDA clearances and clinical evidence for these products."

#2 ConvaTec

Primary Speaker: Mr. Joseph Rolley of ConvaTec

Summary Statement Provided by ConvaTec:
"ConvaTec agrees with the Preliminary Decision of the HCPCS Panel that the existing HCPCS codes E2402, A6550 and A7000 adequately describe NPWT pumps, wound care sets and canisters based on the comparative evidence currently available for NPWT technologies. The creation of tissue strain at the wound interface and easy removal of the NPWT dressing are two features impacting the effectiveness of NPWT devices. While ConvaTec agrees with the Preliminary Decision of the HCPCS Panel at this time, we would encourage CMS and the HCPCS Panel to revisit this issue as available evidence for NPWT technologies continues to grow."

#3 Kalypto Medical

Primary Speaker: Mr. Philip Vierling of Kalypto Medical

Summary Statement Provided by Kalypto Medical:

"We concur with CMS's proposed decision to maintain one code for negative pressure wound therapy devices (E2402) at this time. There is sufficient differentiation among accessories for NPWT devices that the existing supply code A6550 for the wound care set is inadequate to accurately describe the products on the market, reflect the different combinations of accessories used with different devices, and ensure appropriate payment policy. Additional CMS action in this area is warranted."

"We support CMS's proposed decision to maintain one code for negative pressure wound therapy devices (E2402) at this time. We accept CMS's conclusion that the ECRI Institute literature review did not provide justification for the creation of new codes for NPWT devices."

#4 Talley Medical

Primary Speaker: Mr. Jack Van Dyke of Talley Medical

Summary Statement Provided by Talley Medical:

Code E2404 "Negative Pressure Wound Therapy Electrical Pump, Stationary or Portable", adequately describes the NPWT pump, provided however, that the FDA has issued a 510(k) clearance letter AND classified the device under product code OMP NPWT system. Many systems were submitted to FDA under JCX or BTA which describe suction units and were not scrutinized as therapeutic devices. Some companies have submitted to FDA as simple suction pumps, but then market to health care providers as a wound therapy device."

Code "A7000 Canister, Disposable, Used with Suction Pump, Each Code A7000 adequately describes most of the products available on the market which are nearly all simple inexpensive off-the-shelf clear canisters with snap-on lids. To these simple canisters must be added exudata solidifiers, carbon odor filters, overflow alarms, etc., at added expenses. The Talley Venturi canister (and of several other competitors) is proprietary, sealed to prevent inadvertent contact with infectious exudates within, and containing the solidifiers, carbon filter and overflow alarms. This patient and caregiver safety item is more expensive to produce and the cost to the DME dealers well exceeds the CMS reimbursement level which is based upon the less costly products. Talley respectfully submits that a modifier code be added that allows a higher reimbursement for these infection control canisters."

"Code A6550 Wound Care Set, for Negative Pressure Wound Therapy Electrical Pump, includes all supplies and accessories… adequately describes the dressing, wound care set, including foam or gauze based wound filler materials."

"For E2402, Pricing = 36. It is Talley's position the Capped Rental is not applicable to NPWT as it is generally contraindicated for the therapy to continue for that length of time. Clinical evidence points to termination of the therapy after several months if no progress is made. Exceptions may apply, but should be infrequent. Inasmuch as the patient is seen by a nurse or wound care consultant approximately 3 times per week for dressing changes, perhaps Pricing = 31 Frequently Serviced Items may better apply.

For A7000, Pricing = 32 adequately addresses payment for this item.

For A6550, Pricing = 34 adequately addresses payment for this item.

#5 Prospera®

Primary Speaker: Ms. Cindy Ahearn, M.S., R.N., E.T., C.W.C.N., F.N.P.-B.C., Director of Clinical Services at Prospera®

Summary Statement Provided by Prospera®:
"Prospera® wishes to express its gratitude to the ECRI, AHRQ, CMS and HCPCS Workgroup for including them in this important review process as required by the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA"). Prospera concurs with the findings of the AHRQ and the preliminary decision of the CMS. Prospera respectfully requests that the CMS finalize it preliminary decision."

#6 Ohio Medical Corporation™

Primary Speaker: Mr. David Finney, President and Chief Executive Officer of Ohio Medical Corporation™

Summary Statement Provided by Ohio Medical Corporation (OMC):
"Ohio Medical Corporation (OMC) agrees with the CMS HCPCS Workgroup's coding and Medicare payment decision." OMC thanked CMS for the invitation to attend. OMC also thanked AHRQ for their expert analysis.

#7 Smith & Nephew

Primary Speaker: Dr. Doran Edwards, M.D., C.O.O., on Behalf of Smith & Nephew

Summary Statement Provided by Smith & Nephew:
"Smith & Nephew strongly concurs with CMS' preliminary decision to maintain the existing HCPCS codes for NPWT systems (E2402, A7000, A6550). The Company requests that the Workgroup finalize its preliminary recommendation. The presentation emphasizes that

CMS' preliminary decision is appropriate based upon the findings of the NPWT technology assessment from the Agency for Healthcare Research and Quality. It also highlights Smith & Nephew's belief that revisions or additions to the existing HCPCS codes for NPWT systems are not warranted under the HCPCS Workgroup's coding criteria. Finally, the presentation asserts that the preliminary decision fulfills the goal of the coding review required under the Medicare Improvements for Patients and Providers Act of 2008."

#8 Medela, Inc.

Primary Speaker: Dr. Mark D. Cregan, Ph.D., Director of Medical Relations & Education, Medela Healthcare

Summary Statement Provided by Medela, Inc.

On behalf of NPWT manufacturer Medela, Inc., Dr. Mark Cregan provided the following comments: "Medela agrees with the definitions and recommendations set forth by the CMS. As such Medela believes that its products are adequately described under all three of the coding categories."

Summary of Studies Previously Submitted:

- Medela submitted evidence that showed comparable results between gauze-based NPWT and other types of dressings.

Medela Statement on the Nature of NPWT:

- There is no evidence to date demonstrating a singular component of this complete system is more important in Wound Care than any of the others.
- No NPWT system has been proven to be superior by means of RCTs.
- Current evidence DOES NOT support that one type of dressing is superior to any other.
- In clinical practice, vacuum pumps, drains and dressings are often interchanged.
- Not all wounds are equal, different wounds respond to different treatments (including dressings) and consequently Good Medical Practice requires multiple treatment options.

Two recent studies were discussed in support of Medela's argument:

- University Hospital Mannheim
    - Due for completion in March 2010.
    - Comparing gauze-based NPWT Invia Wound Therapy and V.A.C.® Abdominal Dressing System.
- Independent study by University of Chicago, Prospective Randomized Control Trial Comparing Two Methods of Negative Pressure Wound Therapy: Gauze Suction Versus Vacuum Assisted Closure

- Compared the efficacy of gauze-based NPWT and V.A.C.® Abdominal Dressing System.
- Concluded that gauze-based NPWT is as effective in facilitating wound healing, while decreasing pain and the need for pain medication and provided significant cost savings.

- No NPWT system is technically superior to any alternative.
- No dressing type has been proven to be superior to any other.
- Clinicians require multiple treatment options, including different types of wound dressings, to promote effective wound healing.

#9 Innovative Therapies, Inc.

No comments were provided.

#10 Genadyne Biotechnologies

No comments were provided.

#11 Premco Medical Systems, Inc.

No comments were provided.

#12 Atmos Medizin Technik

No comments were provided.

#13 The Wound Care Company

No comments were provided.

Other Registered Public Speakers:

#14 Kevin Woo RN, MS., spoke on behalf of the World Union for Wound Healing Societies (WUWHS)

Summary of Comments at the Public Meeting:
In considering coding for NPWT devices, scientific evidence should be combined with expert knowledge and patient preference. Multiple types of evidence should be considered. Proof of concepts for components of NPWT should also be considered. While Mr. Woo complimented ECRI's literature Review, he also stated that ECRI should have included case

studies and animal studies, as they may have shown differences in wound healing outcomes between devices. The speaker indicated that he believed only RCTs were considered.

#15 Dr. Mark E. Chariker, M.D., F.A.C.S., of the University of Louisville/Division of Plastic Surgery

Summary of Comments at the Public Meeting:
"NPWT started in 1980's. Various methods and wound interfaces have demonstrated efficacy. The core of the treatment is the creation of a stress on the wound surface. I strongly support CMS in the preliminary coding decision on NPWT. This is based on over 20 years of clinical experience with this method and a fundamental understanding of the process."

#16 Dr. Raymond Dunn, M.D., of University of Massachusetts Memorial, Plastic Surgery

Summary of Comments at the Public Meeting:
"Excellent clinical outcomes with use of NPWT on a variety of wound etiologies. Our clinical experience with different devices yielded no clinically discernable differences in results with some preference and ease of use considerations for staff and patients with different systems. The findings of the AHRQ Technology Assessment, Negative Pressure Wound Therapy Devices (May 26, 2009), are consistent with our clinical experience that there is currently no scientific evidence to support a significant therapeutic distinction between existing NPWT systems. We support CMS' preliminary coding decision."

#17 Ms. Laurie L. McNichol, M.S.N., R.N., G.N.P., C.W.O.C.N., of Advanced Home Care

Summary of Comments at the Public Meeting:
"I support the CMS HCPCS Preliminary Coding Decision that there is no evidence to support significant therapeutic distinction between the NPWT systems or the components of a system. The preliminary decision for the continuation of existing codes is appropriate based on clinical evidence." As the current Vice President of the National Pressure Ulcer Advisory Panel, Ms. McNichol authored a meta analysis of literature available on NPWT systems and "independently arrived at the same findings as AHRQ." "NPWT systems clearly satisfy HCPCS workgroup criteria for continued inclusion in existing HCPCS codes." "I am familiar with the literature relative to NPWT, having recently completed an extensive review as co-author of the treatment section of the National Pressure Ulcer Advisory Panel's (NPUAP) International Guideline for the Prevention and Treatment of Pressure Ulcers (February 2009). In my opinion, there is insufficient evidence to support a conclusion that a significant therapeutic distinction exists between NPWT systems."

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.