Wound Care Policy Update

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OVERVIEW

- Policy Updates Impacting Current Traditional Processes to Attain Wound Care Reimbursement
- How Health Care Reform Issues Will Shift Way Wound Care Products will be Reimbursed
  - Linking Payment to Quality
  - Integrated Models of Care- Innovations in Programs
- Health Care Reform and Regulatory Issues Impacting Manufacturers
FOUNDATIONS OF REIMBURSEMENT

Coding
Language that describes the service or procedure

Coverage
Defines criteria for and extent of benefits

Payment
Proper coding and coverage do not guarantee adequate payment, but payment will not exist without them
Key person is reimbursement staff or consultant

First Step- FDA Process

- NEW-Policy Issue-FDA transferring oversight responsibilities for certain wound care products containing live cells from CDRH to CBER
- FDA examining minimally manipulated CTPs- WSJ article

Determining Site of Service

- Variety of settings- may be included in prospective payment system, procedure code (CPT) or HCPCS product code

HCPCS Coding (product coding)

- New or already existing code?
- Obtaining new code difficult- process not transparent, timely, predictable or understandable
- Policy Issue- Alliance for HCPCS II Coding Reform to meet with CMS Senior Staff in October to discuss changes in coding process
REIMBURSEMENT STRATEGY PROCESS

Coverage

- National coverage decision versus local
- Durable medical equipment - local coverage policies (LCDs) by Durable Medical Equipment Medicare Administrative Carriers (DMEMACs)
- Cellular and/or Tissue-based products for wounds (CTPs) (skin substitutes)- LCDs by A/B MACs
- Policy Issue- CMS requests evidence both for coding and for coverage and the bar gets raised higher every year

Payment

- DMEPOs- have fee schedule
- Policy Issue- Competitive Bidding impacts NPWT
  - AAHomecare- HR 1717 - 154 co-sponsors Medicare DMEPOS Pricing Program Act of 2013- market pricing program
Basis of Current Payment Systems

Payment Volume of services

Patient Condition and Complexity

RUGs
CMGs
HHRGs
DRGs

Outcomes
<table>
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<tr>
<th>Health Care Reform’s Emerging Themes</th>
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<td><strong>Refining / Changing Payment Methodologies</strong></td>
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<td><strong>Linking Payment to Quality</strong></td>
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<td><strong>Integrated Models of Care – Innovation in Programs</strong></td>
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<td><strong>Expansion of Coverage</strong></td>
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<td><strong>Program Integrity</strong></td>
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Value-based health aims to improve quality, lower cost, and drive toward value in healthcare delivery. The demand for value requires greater accountability on the part of all stakeholders within healthcare.

- Identification of best practices
- Provider adherence to best practices
- Measurement of provider performance
- Benefit design
- Cost-effectiveness

Value
Patient Centered Outcomes Research Institute (PCORI)

- Independent, nonprofit health research organization created by the ACA whose mission is help people make informed health care decisions, and improves health care delivery and outcomes, by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers and the broader health care community.

- Sept 10- approved more than 114 M in funding for 71 new projects to conduct comparative effectiveness research. To date- approved 197 research awards totally $273.5M

- Types of projects:
  - Assessment of prevention, diagnosis and treatment options
  - Improving healthcare systems
  - Communication and dissemination research
  - Addressing disparities
  - Accelerating Patient-Centered Outcomes Research and Methodological Research

- [www.pcori.org](http://www.pcori.org)
How Does This Impact Wound Care?

- Better and more evidence is needed in order to gain coverage and ultimately payment for wound care products
- Comparative Effectiveness Research is here to stay
  - ECRI meeting on data-November- What Healthcare Decision Makers are Using Now
- Alliance Created “Consensus Principles for Wound Care Research Obtained Using a Delphi Process”
  - Principles to provide direction to all stakeholders involved in clinical or comparative effectiveness research in wound healing thru a modified Delphi.
  - Published in May/June 2012 Wound Repair and Regeneration.
- Alliance met with CMS senior coverage staff and AHRQ to educate them on these important issues and recognition of type of wound care research companies should engage in
  - Spoke with CMS staff to send this to DMEMAC and A/B MAC medical directors
## Examples of Linking Payments to Quality—Measures in Every Setting

<table>
<thead>
<tr>
<th>Healthcare Setting</th>
<th>Quality Program(s)</th>
<th>Mandatory Reporting</th>
<th>Payment Incentive/ Penalty</th>
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<tbody>
<tr>
<td>Inpatient (Acute Care Hospitals)</td>
<td>IQR, Readmissions &amp; VBP</td>
<td>Yes</td>
<td>Yes P4R &amp; P4P in 2013</td>
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<tr>
<td>Long Term Care Hospitals (LTCH)</td>
<td>Beginning in 2014</td>
<td>Yes Beginning Q4 2012</td>
<td>Yes P4R Penalty 2%</td>
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<tr>
<td>Inpatient Rehabilitation Facilities (IRF)</td>
<td>Beginning in 2014</td>
<td>Yes Beginning Q4 2012</td>
<td>Yes P4R Penalty 2%</td>
</tr>
<tr>
<td>Skilled Nursing Facilities (SNF)</td>
<td>MDS 3.0</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Hospice</td>
<td>Beginning in 2014</td>
<td>Yes Beginning Q4 2012</td>
<td>Yes P4R Penalty 2%</td>
</tr>
<tr>
<td>Home Health</td>
<td>OASIS, HH CAHPS</td>
<td>Yes</td>
<td>Yes P4R Penalty 2%</td>
</tr>
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</table>
| Outpatient                                              | PQRS                                            | Yes Beginning 2015                  | Yes P4P Incentive 0.5% until 2014
|                                                          |                                                 | (2013 data will inform 2015 penalty) | Penalty 1.5% in 2015 (based on 2013 data) |
| Accountable Care Organizations (ACO)                    | ACO program                                     | Yes Beginning in 2013               | P4P data performance tied to shared savings |
Traditional Fee for Service Shifts to Pay for Quality

Quality Measures is How MD will be paid
  - Legislative- Quality measures tied to SGR fix

Key will be look to how will wound care products be included under quality measures

Examples:
  - Hedis 2013 Measures- tool used by more than 90% of payers to measure performance on important dimensions of care and service (effectiveness of care- diabetes)
  - Accountable Care Organizations-Performance Standards-At risk population
2013- Alliance submitted the following wound care quality measures to Physicians Quality Reporting System (PQRS)

- Adequate compression for patients with existing venous stasis ulcers
- Adequate offloading of patients with diabetic foot ulcers stage III/IV pressure ulcers

2013- Working with Alliance members to develop other quality measures to submit
HOW QUALITY IS IMPLEMENTED---INTEGRATED MODELS OF CARE

- CMS Innovation Center
- Accountable Care Organizations
- Changing Payment Methodologies-Shift to Bundling
Supports the development and testing of innovative health care payment and service delivery models which include:

- Accountable care
- Bundled payments for care improvement
- Primary care transformation
- Initiatives focused on Medicaid and CHIP program
- Initiatives focused on Medicare-Medicaid enrollees
- Initiatives to speed the adoption of best practices
- Initiatives to accelerate the development and testing of new payment and service delivery models

http://innovation.cms.gov/
What is an Accountable Care Organization (ACO)?

- CMS’s Operational Definition:
  - A legal entity of certified Medicare providers or suppliers
  - Work together to manage & coordinate care for a defined population of Medicare beneficiaries
  - Shared governance over the ACO’s decision-making process
  - If meet specified quality performance standards, then payment for shared savings *if they can reduce spending growth below target amounts*
ACO Resources

ACO Dispersion

220 Medicare Shared Savings Programs ACOs
32 Pioneers
45 Advanced Payment
THREE CATEGORIES OF ACO PATIENTS

- Number of patients cared for by an entity participating in a government or commercial accountable care organization is now between 25 million and 31 million

2.4 million Medicare patients are cared for by an ACO

15 million non-Medicare patients are receiving care within a medical practice that is part of a Medicare ACO

8 million to 14 million commercially insured patients are in non-Medicare ACOs

Source: “The ACO Surprise” A. Wyman
How Can Manufacturers Work with ACOs?

- Move from “vendor” to “partner”
- New way of thinking- strategic partnership important
- Replace old lens of vendor to new one that addresses the value proposition
  - Can spend less compared to overall cost plus overall quality and medical management
  - Educate them on lower total cost to share in savings
  - Recognize they need to hit quality measures to get shared savings
Another Integrated Model of Care-Bundled Payments

- Single payment made for a defined group of services.
- May cover services furnished by a single entity or items and services furnished by several providers in multiple care delivery settings.
- Single negotiated episode payment of a predetermined amount for all services.
- Paid prospectively or retrospectively.

Source: CMMI Website FAQs
Bundled Payments for Care Improvement (BPCI) Initiative

Launched by the Innovation Center designed to encourage doctors, hospitals and other health care providers to work together to better coordinate care for patients both when they are in the hospital and after they are discharged.

Objectives:
- Support and encourage providers through three part aim (better health, better care, and lower costs through continuous improvement)
- Decrease the cost of an acute episode of care and the associated post-acute care while improving quality
- Develop and test new payment models for three-part aim outcomes for acute and post-acute medical care
- Shorten the cycle time for adoption of evidence-based care.
Bundling Initiative: Four Models

Model 1: Inpatient Stay Only (Physician services paid separately)

Model 2: Inpatient and PAC Stay (30 or 90 days)

Model 3: Discharge from Inpatient stay and PAC 30 days after

Model 4: Inpatient Stay (all services including physician)
How Does This Impact Wound Care?

- Wound care included in these initiatives but trend is to include products already bundled in procedure codes.

- 2013-CMS released Hospital Outpatient Prospective Payment System Proposed Rule which would bundle the Cellular and/or Tissue-Based Products for Wounds (CTPs) (skin substitutes) into the procedures at a low payment rate.
  - Problem: Low payment plus limited coverage = less access
  - Action Taken:
    - Reached out to other associations outside of wound care
    - Met with CMS Senior staff to address concerns - brought legal arguments, data and clinicians!
    - Mobilized Alliance organizations to submit comments

- Comments submitted Sept 2013; Final Rule Nov 2013
Wound Care Under Spotlight

- ASTM - Standard setting organization
  - Working with them on nomenclature and guidance document/Currently organizing Alliance members to participate in reviewing guidance document, participating in conference calls which will lead to a vote on new guidance document and name

- FDA - Oct 7 - Public Workshop on “Synergizing Efforts in Standards Development for Cellular Therapies and Regenerative Medicine Products”

- U.S. Pharmacopeial Convention (USP) - Workshops on cellular therapies - Issues monographs for CTPs
HEALTH CARE REFORM ISSUES IMPACTING MANUFACTURERS

- As Employers-Giving Health Care Insurance to Employees
  - Health Care Exchanges Incorporate “Essential Health Benefits” – Where do wound care products fit in?
- Sunshine Physician Payment Final Rule
- Medical Device Tax
- Unique Device Identifiers
Sunshine Physician Payment Final Rule

- Requires “applicable manufacturers” to report “payments or other transfers of value” to “covered recipients”
  - Payments or other transfers of value means a transfer of anything of value.
  - Certain identified payments/transfers are excluded
    - Covered Recipients are limited to physicians and teaching hospitals
    - Reportable information includes name and address of covered recipient, amount + date of payment, form of payment (e.g., cash, stock), nature of payment (e.g., consulting fees, gift, entertainment)
- Requires “any applicable manufacturer or applicable group purchasing organization” to report information regarding any physician ownership or investment interests
- Start date for collecting/tracking- Aug 1, 2013
- Must report to CMS March 31, 2014
What types/categories of payments must be reported by manufacturers?

- Charitable contributions
- Food and beverage
- Faculty/speaker payments
- Consulting fees
- Honoraria
- Gifts/entertainment
- Travel + lodging
- Education
- Royalty or license
- Current or prospective ownership interests
- Grants
- Research
Aug- CMS publishes “User Guide for Industry” regarding the OPEN PAYMENTS program (also known as Physician Payments Sunshine Act)


The Intent of Open Payments - National resource for beneficiaries, consumers, and providers to know more about the relationships among physicians, teaching hospitals, and industry.

How Open Payments Works

- Applicable manufacturers (“Reporting Entities”) will tell us every year about:
  - Payments and other transfers of value from applicable manufacturers of covered drugs, devices, biologics, or medical supplies to physicians and teaching hospitals (“Covered Recipients”).
  - Ownerships or investments held by physicians or their immediate family in applicable manufacturers.
SUNSHINE PHYSICIAN PAYMENT FINAL RULE

Resources

- Final Rule

- Top 50 Things to Know

- Quick reference guide
Section 4191 of the Internal Revenue Code imposes an excise tax on the sale of certain medical devices by the manufacturer or importer of the device. The tax applies to sales of taxable medical devices after Dec. 31, 2012. The tax is 2.3 percent of the sale price of the taxable medical device. See Chapter 5 of IRS Publication 510, Excise Taxes, and Notice 2012-77 for additional information on the determination of sale price.

Generally, the manufacturer or importer of a taxable medical device is responsible for filing Form 720, Quarterly Federal Excise Tax Return, and paying the tax to the IRS.

In general, a taxable medical device is a device that is listed as a device with the Food and Drug Administration under section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 CFR part 807, unless the device falls within an exemption from the tax, such as the retail exemption.

Statutory exemptions - eyeglasses, contact lenses, and hearing aids. There is also an exemption for other devices that are of a type that are generally purchased by the general public at retail for individual use (the retail exemption).
Unique Device Identifier (UDI)

- FDA released final rule on Sept 20 and will take effect Dec 23.
- Unique numeric or alphanumeric code that includes:
  - a device identifier, which is specific to a device model
  - A production identifier, which includes the current production information for that specific device – lot/batch number, serial number and/or expiration date
- Improve quality of information in medical device adverse reports
- Class III within one year/ Class II within 3 years/ Class I not exempted within 5 years
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