Reimbursement Landscape for Long-Acting IV Antibiotics

April 23, 2013

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AGENDA

• Key Takeaways

• Coverage, Coding & Payment
  - Q&A/Break

• Shift Towards Outpatient Care

• Market in a Post-Health Reform Environment
  - Q&A/End
Key Takeaways

1. Adequate coding, coverage and reimbursement pathways are available for long-acting IV antibiotics

2. Health reform is accelerating payment system reforms aimed at promoting care quality instead of quantity
   - Incentives and penalties emphasize improving health outcomes and patient satisfaction
   - Health plans and Medicare are moving away from unit-based to outcomes-based payment
   - Medication adherence is key to avoiding costly readmissions

3. The emphasis on cost savings has increased the focus on optimizing settings of care
   - Providers increasingly focus on avoiding the utilization of short-term inpatient admissions
   - Outpatient settings allow for appropriate drug payment
Coverage, Coding & Payment
Coding

Adequate coding options are currently in place

• Current ICD-9/10 and CPT® codes **adequately** describe ABSSSI conditions of interest
• Existing Evaluation & Management (E/M) and infusion CPT codes **adequately** describe services related to patient management and drug infusion services

Lack of unique code not an impediment to market uptake

• The absence of a unique HCPCS code for a new long-acting antibiotic upon launch does **not impede** market uptake
  • Providers will use unclassified HCPCS codes until a unique code becomes available
  • Although unclassified codes require manual processing initially, process accelerates over time
• The process of obtaining unique HCPCS code(s) is straightforward, the same for all new products, and unlikely to cause complications that would delay market uptake

Coding for long-acting IV antibiotics will follow the same process as all physician-administered drugs
Coverage

High likelihood of payer coverage of long-acting IV antibiotics

- As payers focus on overall health system value, appropriate coverage for these products is likely across most payers regardless of the setting of care
  - Payers may not have specific policies, deferring to hospital/physician decision making
  - Payers may encourage the use of drugs that are shown to shift care to lower cost settings
  - Coverage requirements likely to be consistent with minimal variation across payers

Limited use of Utilization Management (UM) possible among commercial payers

- Some commercial payers will require UM before the drug can be prescribed or administered
  - UM is not typically required by payers for emergent conditions when treated in the ED
  - Fee-for-service Medicare does not allow UM for services rendered in any setting of care

Payers are likely to cover long-acting IV antibiotics when medically necessary

ED: emergency department
### Payment Overview

Payment for physician-administered drugs, including long-acting IV antibiotics, varies by setting of care and payer.

<table>
<thead>
<tr>
<th>Setting of Care</th>
<th>Drug Payment</th>
<th>Payment Mechanism</th>
<th>Medicare</th>
<th>Medicaid</th>
<th>Private</th>
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</thead>
<tbody>
<tr>
<td>Hospital Inpatient</td>
<td>Included in payment</td>
<td>Diagnosis Related Groups (DRGs)</td>
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<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Percent of Charges</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Per Diems</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Hospital Outpatient</td>
<td>Separately payable</td>
<td>Ambulatory Payment Classifications (APCs)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fee Schedule</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td></td>
<td></td>
<td>Percent of Charges</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td></td>
<td></td>
<td>Per Diems</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Physician Office</td>
<td>Separately payable</td>
<td>Fee Schedule</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Percent of Charges</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td></td>
<td></td>
<td>Capitation</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td></td>
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<td>Contracted Medicare Advantage Plans</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Contracted Managed Care Organizations</td>
<td></td>
<td></td>
<td>✓</td>
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<tr>
<td>Skilled Nursing Facility</td>
<td>Included in payment</td>
<td>Resource Utilization Group (RUG)</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Per Diems</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Private payers typically follow Medicare reimbursement methodologies, although some will use alternate payment models.
Long-Acting IV Antibiotics Will Be Paid Under Medicare’s Medical Benefit (Part B)

Medical Benefit (Part B)

- **Patient**
  - Cost Sharing (typically coinsurance or payment for drugs)
  - Physician administers drug to patient

- **Physician’s Office or other Facility**

Pharmacy Benefit (Part D)

- **Patient**
  - Cost Sharing (typically a co-pay or payment for drug)
  - Pharmacy dispenses supply of drugs to patient

- **Pharmacy**

- **Patient self-administers drug on own as prescribed for course of treatment**

- Medicare typically charges a 20% coinsurance for outpatient drugs under the medical benefit
- Private payers typically charge a different coinsurance/copayment amount for the physician service and the drug
  - Some payers are moving towards the Medicare model

Majority of Medicare beneficiaries have supplemental insurance (~90 percent) that mitigates cost sharing obligation

Kaiser Family Foundation Medicare Policy Issue Brief. Medigap Reform; Setting the Context. Sept 2011
Medicare Drug Payment Example in HOPD / ED without Admission

- Most Medicare drugs in outpatient settings are **paid separately**; in 2013, ASP + 6% is the payment amount**
- Commercial payers sometimes **pay separately** for drugs in outpatient settings but tend to use cost-to-charge-based payment (payment is not on a drug-specific basis)

Medicare pays separately for each drug costing >$80 in outpatient settings; private payers also make a separate payment for drugs

ASP: Average Sales Price; ED = Emergency Department; *2013 threshold and rate. Subject to change annually
**Not accounting for sequestration, which reduced to ~ASP + 4.3%
Payment for Administration

Evaluation & Management (E/M) codes are not typically billed or paid for scheduled infusion services

- E/M codes are **not routinely billed** on the same day as a scheduled infusion
  - E/Ms are only paid if the reason of the visit is a separately identifiable service from the drug administration and a 25 modifier is appended to the code
  - An Avalere analysis of provider billing patterns for infusions of three commonly-prescribed IV antibiotics found that in HOPDs and physician offices, E/M codes are billed in addition to infusion codes on average only about 2% and 22% of the time, respectively

**Lower administration frequency may be offset by emerging payment models**

- The margin on the infused drug reimbursement is typically the main revenue driver
- Infusion administrations are generally fairly low margin services
  - **If lower overall treatment costs can be shown**, long-acting IV antibiotics may fit into cost reduction focus of emerging payment models

**Health systems are increasingly evaluating system-wide or episode-of-care-based costs rather than individual visit basis**

Shift Towards Outpatient Care
The Percentage of Hospital Revenue from Outpatient Sources Continues to Grow

**Distribution of Outpatient vs. Inpatient Hospital Revenues, 1989–2009**

Source: Avalere Health analysis of American Hospital Association Annual Survey data, 2009, for community hospitals
Shift Towards Observation Stays and Outpatient Care

- Medicare pays hospitals under a fixed-payment model (DRGs)
- Hospitals consistently focus on reducing patient length of stay (LOS) to maximize profit margins
- However, given increased scrutiny of 1-day and 2-day inpatient stays by Medicare and private payers, hospitals are increasingly shifting appropriate patients from inpatient care to outpatient or observation care

Figure: Vanguard Health Systems Observation Stay Growth FY2010–FY2013

Long-acting IV antibiotics may enable hospitals to lower costs by moving appropriate patients to outpatient care settings

Source: Vanguard Health Systems Investor Presentation January 2013
Market in a Post-Health Reform Environment
Shift from Care Quantity to Care Quality

Medicare

Accountable Care Organizations

Status: 252 ACOs already established; 3rd round will be selected shortly

Affected Population: 4M Medicare beneficiaries

Readmissions Reduction Policies

Status: Current law

Affected Population: All Medicare beneficiaries

Efficiency Measures

Status: Current law

Affected Population: All Medicare beneficiaries

Bundled Payments

Status: Awardees selected; risk-free trial until July 2013

Affected Population: 467 facilities participating in 8603 episodes

Physicians/ Hospitals

Status: Current law

Affected Population: All Medicare beneficiaries

Hospitals

Status: Current law

Affected Population: All Medicare beneficiaries

Hospitals

Status: Current law

Affected Population: All Medicare beneficiaries

PAC Providers/ Hospitals

Status: Awardees selected; risk-free trial until July 2013

Affected Population: 467 facilities participating in 8603 episodes

Private payers are also implementing these reforms

PAC: Post-Acute Care
## From “Fee-for-Service” to “Fee-for-Value”

<table>
<thead>
<tr>
<th>Model</th>
<th>Status</th>
<th>Impact</th>
</tr>
</thead>
</table>
| **Accountable Care Organization (ACO)** | - 252 organizations are participating in Medicare shared-savings initiatives, covering ~4M Medicare beneficiaries  
- 428 ACOs in 49 states operating in private sector, and number is growing  
- Growth is concentrated in larger population centers and has expanded to 49 different states  
- Most ACOs exist in only one state  
- Hospitals systems continue to be the primary backers of ACOs, but physician groups increasingly catching on | - Will create new relationships amongst customers and may shift locus of decision making  
- Increases focus on care coordination, particularly across settings  
- Creates incentives to use more cost effective products  
- Overall cost savings to the ACO may lead to value in using long-acting IV antibiotics regardless of cost of the drug (e.g., less services required for patient management)  
- Major commercial payers have started to introduce changes to their methods of reimbursement |

ACOs and other care coordination/cost containment initiatives are impacting how health systems view value for products and services

Medicare Is Reducing Payments for Hospital Readmissions

- ACA mandates that hospitals with excess readmissions within a 30 day readmission window receive a reduction in their base DRG payment amount, beginning in FY 2013.
- Private payers are also instituting readmission programs and policies (e.g., Highmark, Inc.)

**Example:** Over 20% of cellulitis patients are readmitted with cellulitis as their primary condition.

### Index-Stay Readmission Counts and Rates by Condition

<table>
<thead>
<tr>
<th>Condition</th>
<th>Same-Condition Readmissions</th>
<th>Same-Condition Readmission Rate</th>
<th>All-Other Readmissions</th>
<th>All-Other Readmission Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulitis</td>
<td>5,136</td>
<td>3.3%</td>
<td>20,138</td>
<td>13.0%</td>
</tr>
<tr>
<td>MRSA</td>
<td>2,358</td>
<td>3.4%</td>
<td>12,293</td>
<td>17.6%</td>
</tr>
<tr>
<td>Post-operative infection (other)</td>
<td>1,606</td>
<td>4.1%</td>
<td>6,318</td>
<td>16.0%</td>
</tr>
<tr>
<td>Pressure ulcer</td>
<td>605</td>
<td>3.8%</td>
<td>3,052</td>
<td>19.3%</td>
</tr>
<tr>
<td>MRSA septicemia</td>
<td>233</td>
<td>2.2%</td>
<td>2,842</td>
<td>26.6%</td>
</tr>
<tr>
<td>Bacterial PN due to Staph.</td>
<td>192</td>
<td>3.3%</td>
<td>1,663</td>
<td>28.3%</td>
</tr>
<tr>
<td>Osteomyelitis (unspecified)</td>
<td>179</td>
<td>2.1%</td>
<td>1,581</td>
<td>18.6%</td>
</tr>
<tr>
<td>Bacterial PN (unspecified)</td>
<td>94</td>
<td>0.5%</td>
<td>1,251</td>
<td>17.5%</td>
</tr>
<tr>
<td>Osteomyelitis (unspecified)</td>
<td>82</td>
<td>3.3%</td>
<td>571</td>
<td>23.0%</td>
</tr>
</tbody>
</table>

Ways to reduce readmissions continue to be studied and sought-after by hospitals and payers. If an initial admission can be avoided, readmissions become moot.

Source: AIS’s Health Business Daily. Communication Is Key to Fewer Readmissions, Highmark Says
http://aishealth.com/archive/nblu0213-07
*The percentage of readmission cases is based off of the index cases not the number of cases overall.*

**“NEHI Research Shows Patient Medication Non-adherence Costs Health Care System $290 Billion Annually”**
http://www.nehi.net/news/press_releases/110/nehi_research_shows_patient_medication_nonadherence_cost_health_care_system_290_billion_annually
Medication Adherence May Affect Readmissions

- Medication non-adherence costs the US healthcare system $100B - $300B every year
  - Leads to increased use of expensive components of healthcare, such as hospitalizations
- 75% of patient non-adherence is an active, conscious choice by the patient to not take prescribed medications as directed or at all
- Factors relevant to IV antibiotics that influence patients medication adherence include:
  - Perceived severity of the disease for which they are prescribed medication
  - The number of times a patient must take their medication each day
  - Poor patient-provider communication, and patient reluctance to ask provider questions about prescribed medications
  - Health-system related factors:
    - Prescription costs
    - Health illiteracy
    - Other barriers to access care

Less frequent dosing could be a benefit for any product that is used across multiple settings of care

## ACA: Renewed Interest in Quality Programs

<table>
<thead>
<tr>
<th>Program</th>
<th>Participation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Inpatient Quality Reporting Program (IQR)</td>
<td>Mandatory</td>
<td>• Incentivizes quality improvement through reporting on a variety of quality measures</td>
</tr>
<tr>
<td>Hospital Value-Based Purchasing (VBP) Program</td>
<td>Mandatory since 2013</td>
<td>• Awards payment bonuses to hospitals based on performance on select quality measures&lt;br&gt;• MRSA w/ bacteremia is not currently a measure for the VBP program, but its inclusion in the IQR measures makes it a candidate for inclusion as a VBP measure in the future</td>
</tr>
<tr>
<td>Hospital Readmissions Reduction Program</td>
<td>Mandatory since Oct. 2012</td>
<td>• Will implement payment penalties for hospitals with excessive rates of readmissions for select conditions</td>
</tr>
<tr>
<td>Hospital-Acquired Condition (HAC) Payment</td>
<td>Mandatory</td>
<td>• Implements non-payment for cases of specific hospital-acquired conditions deemed to be absent at the time of admission; MRSA was considered as an original HAC in 2008, but was not included; Could be in future</td>
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Overall, health reform offers opportunities for longer-acting products to fit within the current areas of focus/motivations of payers
Medicare Quality Reporting Is Already Impacting Hospital Payment

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<tbody>
<tr>
<td>Readmission Penalties</td>
<td>1%</td>
<td>2%</td>
<td>3%</td>
<td>3%</td>
<td>3%</td>
<td>3%</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Inpatient Value-Based Purchasing</td>
<td>1%</td>
<td>1.25%</td>
<td>1.5%</td>
<td>1.75%</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>HAC Penalties</td>
<td></td>
<td></td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>0%</td>
<td>2%</td>
<td>3.25%</td>
<td>4.5%</td>
<td>5.75%</td>
<td>6%</td>
<td>6%</td>
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</tr>
</thead>
<tbody>
<tr>
<td>Hospital Inpatient Quality Reporting Program (P4R)</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
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</tbody>
</table>

P4R: Pay for Reporting
* Payment reductions are calculated from base DRG
** Payment reductions are calculated from market basket update
### CMMI Bundled Payment Models Overview

<table>
<thead>
<tr>
<th>Models</th>
<th>Episode</th>
<th>Services included in the bundle</th>
<th>Episode Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model 1</td>
<td>All acute patients, all DRGs</td>
<td>All Part-A DRG-based payments; at reduced, negotiated price</td>
<td>Inpatient hospital stay</td>
</tr>
<tr>
<td>Model 2</td>
<td>Selected DRGs + post-acute period</td>
<td>All Part A and B services</td>
<td>Inpatient hospital, plus 30/60/90 days post-hospital discharge</td>
</tr>
<tr>
<td>Model 3</td>
<td>Post-acute only for selected DRGs</td>
<td>All Part A and B services</td>
<td>30/60/90 days post hospital discharge</td>
</tr>
<tr>
<td>Model 4</td>
<td>Selected DRGs</td>
<td>All Part A and B services</td>
<td>Inpatient hospital, plus 30 days post-hospital discharge</td>
</tr>
</tbody>
</table>

Models 2 and 3 are the most popular in the initial pilot program. Private payers are also piloting and implementing bundled payment arrangements.
Strategic Opportunities to Effectively Manage Care within the Bundle Window

• At-risk providers will have to focus on reducing spending and increasing care efficiencies to be successful under a bundled payment system. Strategies include:
  – Reduce readmissions
  – Utilize lower cost settings and reduce length-of-stay in high-cost settings
  – Streamline care transitions and standardize care management
  – Implement cost containment strategies

Goals of bundled payment programs are in line with perceived goals of long-acting IV antibiotics. Cost savings and improved quality are essential to navigating evolving payment methodologies for episodes of care.
### Health Reform Environment: 5-10 Year Outlook

<table>
<thead>
<tr>
<th></th>
<th><strong>Downward price pressure, but expanded coverage</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>• 30+ million new insured&lt;br&gt;• Higher utilization but greater demand for value from payers facing cuts</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th><strong>Evolving ownership of “value”</strong></th>
</tr>
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<tbody>
<tr>
<td>2</td>
<td>• Stronger government role in post-registration evaluation of products&lt;br&gt;• Increased public/private payer role in defining quality through value-based purchasing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th><strong>Incentives for greater integration of care delivery</strong></th>
</tr>
</thead>
</table>
| 3 | • Large-scale pilot programs seeking to “coordinate” care<br>• Impact utilization of services and, ultimately, drug payment  
  - Bundled payments / episode of care-based payments |

**The focus on cost savings and access will be increasingly important over the next decade as 30+ million more people obtain health insurance.**
Key Takeaways

1. Adequate coding, coverage and reimbursement pathways are available for long-acting IV antibiotics

2. Health reform is accelerating payment system reforms aimed at promoting care quality instead of quantity
   - Incentives and penalties emphasize improving health outcomes and patient satisfaction
   - Health plans and Medicare are moving away from unit-based to outcomes-based payment
   - Medication adherence is key to avoiding costly readmissions

3. The emphasis on cost savings has increased the focus on optimizing settings of care
   - Providers increasingly focus on avoiding the utilization of short-term inpatient admissions
   - Outpatient settings allow for appropriate drug payment
Glossary

• **ICD-9/10** - International Statistical Classifications of Diseases versions 9 and 10
• **CPT** - Current Procedural Terminology
• **HCPCS** - Healthcare Common Procedure Coding System
• **DRG** - Diagnosis Related Group
• **Medicare Part A** – covers hospital inpatient, skilled nursing facility, and some home healthcare
• **Medicare Part B** – covers physician services including physician-administered drugs, hospital outpatient care, laboratory services, durable medical equipment, some home healthcare, outpatient mental health services, and physical, occupational, and speech therapy services
• **Medicare Part D** – allows beneficiaries to receive drug coverage through private Part D plans
• **ACO** - Accountable Care Organization
• **LTCH** - Long Term Acute Care Hospital
• **IRF** - Inpatient Rehabilitation Facility
• **SNF** - Skilled Nursing Facility
• **HHA** - Home Health Agency
• **DME** – Durable Medical Equipment
• **RAC** - Recovery Audit Contractor
• **ED** – Emergency Department
• **HOPD** – Hospital Outpatient Department
• **ACA** - Affordable Care Act
• **ABSSSI** - Acute Bacterial Skin and Skin Structure Infections