AQUACEL® Ag Surgical Dressing and the Current American Joint Care Climate

Daniel C. Allison MD, FACS
Orthopedic Oncology and Advanced Reconstruction

Cedars-Sinai Medical Center
Children’s Hospital of Los Angeles
Previous Medicare Payment Model for Hip and Knee Replacement

- Inpatient prospective payment system (*IPPS*)
  - One of two Medicare Severity-Diagnosis Related Groups (MS-DRGs):
    - MS-DRG 469 (Major joint replacement or reattachment of lower extremity with Major Complications or Comorbidities (MCC)) or
    - MS-DRG 470 (Major joint replacement or reattachment of lower extremity without MCC).
  - Provider fees in addition

The average Medicare expenditure for surgery, hospitalization, and recovery ranges from $16,500 to $33,000 across geographic areas.

*CMS.gov*
Comprehensive Care for Joint Replacement (CJR or CCJR)

On April Fools Day 2016, The Centers for Medicare and Medicaid Services initiated the Comprehensive Care for Joint Replacement program

- Shift the payment model for Lower Extremity Joint Replacements from traditional fee-for-service to a retrospective bundled payment
- Incentivize hospitals, physicians, suppliers, and post-acute care providers to work together to lower costs, decrease complications, and improve quality
- The program will run for 5 years.

*CMS.gov*
What is the CJR Program?

- CMS will retrospectively bundle the *entire* payment for:
  - Procedure that is assigned to MS-DRG 469 or 470 upon beneficiary discharge and paid under the hospital inpatient prospective payment system (*IPPS*)
  - Episodes will begin with admission to an acute care hospital
  - Episodes will end 90 days after the date of discharge

- A target price will be set based on historical and regional data

- Hospitals with then share in the gains or in the losses

- Participation is mandatory for all *IPPS* hospitals (791) in 67 Metropolitan Statistical Areas (*MSAs*) with no ability to opt out (unless participating in BPCI)

*CMS.gov*
What Comprises the CJR Episode / Bundled Payment?

- LEJR procedure and all related costs within 90 days of discharge, including:
  - Medicare Part A & Part B Costs:
    » Inpatient Hospital care
    » Post-acute care (PAC) (including the skilled nursing facility (SNF) stay)
    » Related readmissions
    » Physician services
    » Long-term care hospital services
    » Inpatient rehabilitation facility services
    » Home health agency services; hospital outpatient services
    » Independent outpatient therapy services
    » Clinical laboratory services
    » Durable medical equipment
    » Part B drugs
    » Hospice

*CMS.gov
How is the CJR Target Price Set?

- Hospital-specific and regional pricing data determines the value
  - Historic price is based on last 3 years of spending
  - Historical benchmarks will be rebased every two years.
  - Risk stratification for hip fractures (only)

- The target price will include a 2% discount over expected episode spending, in an attempt to lower the price per episode over time.

- Throughout the year, Medicare would continue to pay providers and suppliers using existing Medicare payment models.

*CMS.gov*
Payments to Providers

- All providers (including SNFs) and suppliers will continue to be paid under the usual fee-for-service payment system rates, rules and procedures of the Medicare program for episode services throughout the year.

- After the completion of a performance year, the Medicare claims payments for services furnished to the beneficiary during the episode, based on claims data, will be combined to calculate an actual episode payment.

*CMS.gov, AHCA.com
Hospital Payments / Losses
(“The Back End”)

- At the end of the year, the actual episode payment will then be reconciled against the established CJR target price.

- The difference, if positive, will be paid to the participant hospital (“reconciliation payment”), as long as quality outcome measures are met.

- The difference, if negative, CMS will require the hospital to pay back some or all of the difference (starting PY 2 [grace period for repayments in year 1])

*Data not yet submitted for publication*
Outcomes Linked to Payment

- **Composite Score Methodology**
  - The quality composite score is based on the three quality measures and how the hospital ranks on the program’s quality measures relative to other CJR hospitals in the program.
    - THA/TKA Complications (NQF #1550): 50%
    - HCAHPS Survey (NQF #0166): 40%
    - Patient Reported Outcomes Data (Reporting Only): 10%
      - PROMIS Global, Veterans Rand, HOOS Jr, HOOS, KOOS Jr
  - The composite quality score is based out of 20 total points.

<table>
<thead>
<tr>
<th>Percentile Rank</th>
<th>Points for THA/TKA Complications</th>
<th>Points for HCAHPS Survey</th>
<th>Points for submitting PRO Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥90th</td>
<td>10</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>&gt;80th and &lt;90th</td>
<td>9.25</td>
<td>7.4</td>
<td>“</td>
</tr>
<tr>
<td>≥70th and &lt;80th</td>
<td>8.5</td>
<td>6.8</td>
<td>“</td>
</tr>
<tr>
<td>≥60th and &lt;70th</td>
<td>7.75</td>
<td>6.2</td>
<td>“</td>
</tr>
<tr>
<td>≥50th and &lt;60th</td>
<td>7</td>
<td>5.6</td>
<td>“</td>
</tr>
<tr>
<td>≥40th and &lt;50th</td>
<td>6.25</td>
<td>5</td>
<td>“</td>
</tr>
<tr>
<td>≥30th and &lt;50th</td>
<td>5.5</td>
<td>4.4</td>
<td>“</td>
</tr>
<tr>
<td>&lt;30th</td>
<td>0</td>
<td>0</td>
<td>“</td>
</tr>
</tbody>
</table>
Outcomes Linked to Payment

- If the overall composite score is “below acceptable,” the hospital will be ineligible to receive reconciliation payments regardless of their performance on the cost measures.

- The composite score will determine the “effective discount percent” for both reconciliation payments (in PYs 1-5) and repayments (PYs 2-5 only). If a hospital performs very well on the quality composite score, their effective discount percent to the episode target price will be reduced to 1.5%. Conversely, if a hospital does poorly on the quality composite score, the effective discount percent will be increased to 3%.

<table>
<thead>
<tr>
<th>Quality Composite Score Range out of 20</th>
<th>Quality Category</th>
<th>Eligible for Reconciliation Payment</th>
<th>Effective Discount % for Reconciliation Payment</th>
<th>Effective Discount % for Repayment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;13.2</td>
<td>Excellent</td>
<td>Yes</td>
<td>1.5%</td>
<td>PY1: N/A * PY2-3: 0.5% PY4-5: 1.5%</td>
</tr>
<tr>
<td>≥6 and &lt;13.2</td>
<td>Good</td>
<td>Yes</td>
<td>2%</td>
<td>PY1: N/A PY2-3: 1% PY4-5: 2%</td>
</tr>
<tr>
<td>≥4 and &lt;6</td>
<td>Acceptable</td>
<td>Yes</td>
<td>3%</td>
<td>PY1: N/A PY2-3: 2% PY4-5: 3%</td>
</tr>
<tr>
<td>&lt;4</td>
<td>Below Acceptable</td>
<td>No</td>
<td>3%</td>
<td>PY1: N/A PY2-3: 3% PY4-5: 3%</td>
</tr>
</tbody>
</table>

*CMS.gov, AHA.org
Gain and Loss Limits

- **Stop-Loss and Stop-Gain Policies**
  
  CMS will limit how much a hospital can gain (in reconciliation payments from Medicare) or lose (in repayments back to Medicare) based on its actual episode payments relative to the target prices. Both stop-gain and stop-loss limits gradually increase over the course of the CJR program.

<table>
<thead>
<tr>
<th>Year</th>
<th>Stop-Gain Limit</th>
<th>Stop-Loss Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>PY 1 (Apr-Dec 2016)</td>
<td>5%</td>
<td>N/A</td>
</tr>
<tr>
<td>PY 2 (CY 2017)</td>
<td>5%</td>
<td>5%</td>
</tr>
<tr>
<td>PY 3 (CY 2018)</td>
<td>10%</td>
<td>10%</td>
</tr>
<tr>
<td>PY 4 (CY 2019)</td>
<td>20%</td>
<td>20%</td>
</tr>
<tr>
<td>PY 5 (CY 2020)</td>
<td>20%</td>
<td>20%</td>
</tr>
</tbody>
</table>

*Example 1*: A hospital treats 10 LEJR episodes in PY 1 with a target price of $10,000 each, for a total of $100,000. Actual spending across all 10 episodes was only $85,000, leaving a difference of $15,000. The stop-gain limit in PY 1 is 5%, so the hospital would receive a $5,000 reconciliation payment.

*Example 2*: A hospital treats 10 LEJR episodes in PY 3 with a target price of $10,000 each, for a total of $100,000. Actual spending across all 10 episodes was $120,000, leaving an average of $20,000. The stop-loss limit in PY 3 is 10%, so the hospital would be required to pay back Medicare a total of $10,000.
CJR “Sharing”

- Hospitals may have certain financial relationships with collaborators (they can share reconciliation payments and internal cost savings with collaborators who furnish care during the episode)

- Collaborators may include:
  - Physicians and non-physician practitioners
    - Home health agencies
    - Skilled nursing facilities
    - Long-term care hospitals
    - Physician group practices
    - Inpatient rehabilitation facilities
    - Providers or suppliers of therapy services

- Sharing Limits
  - A CJR hospital must retain at least 50 percent of its total risk
    » It cannot share more than 50 percent of that repayment responsibility with Collaborators
    » It cannot share more than 25 percent of its responsibility with any single CJR Collaborator
    » Providers cannot receive more than 50% of the original fee rate

*CMS.gov, AHA.org*
CMS Waivers Under CJR

- The SNF 3-day rule can be waived if SNF is rated 3 stars or higher on Nursing Home Compare.

- The “incident to” rule for physician services can be waived to allow clinical staff of a physician to furnish home visits.

- Originating-site requirements for telehealth may be waived to allow services to be originated in patient’s home.

*CMS.gov
Bundled Payments Care Improvement (BPCI)

- Voluntary
- Consists of 4 models of varying involvement (Model 2 is very similar to CJR)
- The cost of an episode of care is standardized, and providers / hospitals share in the savings or losses
- Target prices are set by same-hospital and regional standards
- Consists of over 48 types of care / procedures
- Gains / Losses capped at 20%, based on final cost compared to target pricing
- 3 year time period (What happens after this period)
- Lower extremity joint replacement was the most popular of all BPCI procedures

*CMS.gov*
Gainsharing

- BPCI and CJR participants may share incentive payments they receive with partners, including physicians and post-acute providers. Physician gainsharing cannot exceed 50 percent of the regular Medicare fees that they receive in CJR / BPCI episodes.

- For both CJR and BPCI, CMS and the HHS Office of Inspector General have waived the physician self-referral and anti-kickback laws with respect to financial arrangements that otherwise comply with the programs’ requirements.

*CMS.gov, AHA.org
CJR Bottom Line

- We have no choice
- Physician and hospital alignment is crucial to success
- The financial burden rests with the hospital (unless the hospital decides to contract with other stakeholders)
- The main target for efficacy in this model seems to be post-discharge care
- Patient experience and satisfaction is important to success under this model

*CMS.gov, AHA.org
CJR Subjective Thoughts

- No risk stratification (except for hip fracture pts)
- The “Target Prices” and benchmark will likely only get lower with time
- Margaret Thatcher:
  - “The problem with socialism is that eventually you run out of other people’s money.”
- Private insurance will follow suit
Opportunities to Excel Under CJR

- Patient satisfaction
- Decreased readmissions
- Decreased complications (wound problems and surgical site infections)
- Decreased cost of post-discharge care

SURGICAL WOUND CARE
Occlusive Dressings

- Improved re-epithelialization
- Increase in collagen synthesis by 2-6x compared to wounds open to the air
- Lower rate of wound infection (Hutchinson et al. 1990)
  - With occlusive dressing 2.6%
  - With non-occlusive dressing 7.1%

AQUACEL® Ag Surgical Dressing

Advantages

- Barrier to pathogen transmission
- Microbicidal effects of silver ion
- Dressing may be left in place for 7 days (or longer based on provider preference)
  - Less environmental exposure
  - Improved patient comfort
  - Decreased manpower / resources
- Patient satisfaction
  - Immediate showering

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Advanced Dressings
Hydrofiber® Technology

- Basic component is cellulose
- Carboxymethylation* process alters the absorption capacity
- Hydrofiber® technology allows for fluid to be absorbed directly into the fibers
- A bond is formed with the absorbed fluid to hold it within the fiber

*Carboxymethylation: addition of sodium carboxymethyl cellulose fragment

**AQUACEL® Ag**

**Broad-spectrum Antimicrobial Activity**

### Aerobic Bacteria
- *Staphylococcus aureus* (NCTC 8532)
- *Staphylococcus aureus* (clinical isolate)
- *Pseudomonas aeruginosa* (clinical isolate, x2 strains)
- *Enterobacter cloacae* (clinical isolate)
- *Streptococcus pyogenes* (clinical isolate)
- *Klebsiella pneumoniae* (clinical isolate, x3 strains)
- *Enterococcus faecalis* (clinical isolate)
- *Escherichia coli* (NCIMB 8545)
- *Escherichia coli* (NCIMB 10544)
- *Acinetobacter baumannii* (NCIMB 9214)

### Antibiotic-resistant Bacteria
- MRSA (NCTC 10442)
- MRSA (NCTC 12232)
- MRSA (clinical isolate, x8 strains)
- VRE (NCTC 12201)
- VRE (clinical isolate, x2 strains)
- *Serratia marcescens* (clinical isolate)
- *Pseudomonas aeruginosa* (NTC 8506)

### Anerobic Bacteria
- *Bacteroides fragilis* (clinical isolate)
- *Peptostreptococcus anaerobius* (clinical isolate)
- *Clostridium ramosum* (clinical isolate)
- *Clostridium clostridioforme* (clinical isolate)
- *Clostridium cadaveris* (clinical isolate)
- *Clostridium perfringens* (clinical isolate)
- *Tissierella praecute* (clinical isolate)

### Yeasts
- *Candida albicans* (NCPF 3179)
- *Candida albicans* (NCPF 3265)

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Hydrofiber® Ag Dressing
Bacterial Sequestration & Bactericidal Activity

Confocal microscopy of *Pseudomonas aeruginosa* on hydrated Hydrofiber® Ag dressing fiber

Green = Alive
Red = Dead
T = Time in minutes

AQUACEL® Ag Surgical Dressing
CLINICAL RESULTS
Rothman Institute

- Retrospective study- Journal of Arthroplasty, 2014
- 1,778 patients undergoing primary THA/TKA
  - 875 standard gauze dressing
  - 903 AQUACEL® Ag Surgical dressing
- 76% reduction in incidence of surgical site infection in AQUACEL® Ag Surgical group
- Multivariate analysis
  - no other independent variables such as patient co-morbidities, age, or BMI impacted the reduction in infection

OrthoCarolina Prospective, Randomized Clinical Trial

- Prospective Randomized Study – American Journal of Orthopedics, 2015
- AQUACEL® Ag Surgical vs. Control
- 300 pts
- Midterm analysis of 150 TKA (AAOS 2013)
- Significant reduction in wound complications (p=0.009)
- Significantly less # dressing changes (p<0.001)
- Improved patient satisfaction, perception of hygiene

AQUACEL® Ag SURGICAL Dressing

Polyurethane film provides waterproof viral and bacterial barrier *3

Patented Hydrofiber® Technology absorbs and locks in fluid, including harmful bacteria. *2

Unique construction enhances extensibility and flexibility

Skin-friendly hydrocolloid technology flexes with the skin during body movement *1, 3

*As demonstrated in vitro

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1 Nelson Laboratories Report, Viral Penetration ASTM Method F1671, Procedure Number :ST0062 Rev07, Protocol Detail Sheet No. 200902139, Rev 1, Laboratory no. 483744, 7th August 2009,


3 WHRI 3264 Laboratory Test Comparison of AQUACEL® Surgical Dressing ‘New Design’ and the Jubilee Method of Dressing Surgical Wounds. 7th Oct 2009
Dressing With Hydrofiber® Technology *

- Locks in fluid*¹
- Sequesters bacteria²,³
- Traps harmful enzymes*⁴,⁵

Sequestration test: a simple experiment using fluids of different colors to demonstrate the ability of dressings to lock in fluid

*as demonstrated in vitro

Surgical Cover in Today’s Joint Replacement World

- **Patient satisfaction**
  - Immediate showering
  - Decreased dressing changes → increased comfort

- **Decreased readmissions**
  - Decreased surgical site infection rates

- **Decreased complications**
  - Surgical site infections
  - Wound complications

- **Decreased cost of post-discharge care**
  - Decreased need for trained medical wound care assistance

*Data not yet submitted for publication*
Additional CJR Resources

- CMS’ FAQ on CJR: https://innovation.cms.gov/Files/x/cjr-faq.pdf