Changes to Medical Benefit Reimbursement and Implications for Drug Contracting and Pricing

Trinity Partners
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CBI Reimbursement & Contracting
February 29, 2017
Philadelphia
Trinity Partners
Founded in 1996, Trinity Partners has over 140 professionals that specialize in the life sciences industry.

Trinity provides a range of strategy consulting services that run the gamut from strategic to tactical in nature, drawing on best-in-class capabilities in primary market research and advanced analytics.

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- Brand
- Market Access
- Strategic Customer Group / Trade
- Sales Ops
- Finance
Example Service Offerings

Services range from strategic research, advice, and insights to operational tools, analytics, & support

## SAMPLE PROJECTS

### Strategic

<table>
<thead>
<tr>
<th>Global Pricing Strategy</th>
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<tbody>
<tr>
<td>Price Corridor Strategy (Reference Price Planning)</td>
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<td>Price Sensitivity Research</td>
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<tr>
<td>Payer Control Assessment</td>
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<tr>
<td>Specialty Pharmacy &amp; Distributor Strategy</td>
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<tr>
<td>Coding Strategy &amp; Opportunity Assessment</td>
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<td>Value Proposition Development</td>
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<td>Contracting Strategy Payer</td>
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<td>Contract Competitive Intelligence</td>
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<td>Strategic Account Planning</td>
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### Tactical

<table>
<thead>
<tr>
<th>Price Increase Impact Assessment</th>
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<tbody>
<tr>
<td>ASP &amp; GTN Modeling</td>
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<tr>
<td>PAP, Co-Pay Program, and Cost Share Analysis</td>
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<tr>
<td>Coding Support</td>
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<tr>
<td>Practice Economics Analysis</td>
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<tr>
<td>AMCP and Global Dossier Development</td>
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<tr>
<td>Contract Dashboards &amp; Data Management</td>
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<tr>
<td>Contract Impact Analytics</td>
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<tr>
<td>Strategic Customer Reporting &amp; Targeting</td>
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<tr>
<td>Operational Rebate Management</td>
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<tr>
<td>Contract Awareness Campaign Design</td>
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</table>
Agenda

- Recent Changes to Medical Benefit Reimbursement
- The **Oncology Care Model** (OCM): Case Studies in Value
- Reimbursement & Contracting for **Biosimilars** in the US
  - Implications of Interchangeability
  - Reimbursement Economics: Impact of the Shared HCPCS Code
  - What’s Next?
The Value Shift: Medicare Fee For Service (FFS) Evolution
January 2015 HHS goals for value-based payments

Source: U.S. Department of Health and Human Services
With 70+ Medicare payment and care reform programs in effect or active development, the pace of CMS innovation is accelerating.

The 2015 Medicare Access and CHIP Reauthorization Act (MACRA), for which final rules were issued in October 2016, ties all Medicare Part B provider payments to value and/or quality.
Recent MACRA legislation introduced a new value-based reimbursement system with two participation tracks: MIPS and APMs.

**Quality Payment Program**

**Merit-Based Incentive System (MIPS)**

- **Automatic Enrollment**
  - Payment adjustments based on publicly available Composite Performance Score
  - Score measures overall care delivery quality (not limited to Medicare, no measure of cost)
  - Medicare reimbursement impact as much as +/- 4% in 2019 and +/- 9% in 2022
  - Payments in 2019 based on data collected in 2017 & 2018

**Alternative Payment Models (APMs)**

- **Opt-In by Program**
  - Includes:
    - CMS innovation models
    - Medicare Shared Savings Programs
    - Health Care Quality Demonstration Program
    - Advanced APMs (next slide)
  - 5% annual lump sum payment to physicians who participate at qualifying thresholds
  - Exempt from MIPS reporting & penalties

**Implications for Manufacturers**

- Complicates provider revenue cycle → complicates contracting
- Differential messaging for APM-participating providers/payers
- Unclear impact on novel therapeutics → where do your drugs fit?
Several Advanced APMs continue to evolve, including the accountable care and episode-based care models

<table>
<thead>
<tr>
<th>Advanced APM*</th>
<th>Payment Model</th>
<th>Status</th>
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<tbody>
<tr>
<td><strong>Accountable Care</strong></td>
<td></td>
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<tr>
<td>Comprehensive ESRD Care Model</td>
<td>• Large dialysis organization eligible for <strong>shared savings</strong>, liable for <strong>shared losses</strong></td>
<td>• 37 ESRD Seamless Care Organizations</td>
</tr>
<tr>
<td>Next Generation ACO Model</td>
<td>• Allows higher exposure to financial risk / reward than available under Shared Savings Program</td>
<td>• 45 Next Gen ACOs</td>
</tr>
<tr>
<td><strong>Episode-Based Care</strong></td>
<td></td>
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</tbody>
</table>
| Oncology Care Model | • **$160** monthly Enhanced Oncology Service (MEOS) payments for duration of episode  
• Variable **performance-based payment** | • 195 Practices  
• 17 payers |
| Comprehensive Care for Joint Replacement (CJR) | • Year-end comparison of spending vs. target for joint replacements → **incentive / penalty** | • 67 MSAs |
| **Primary Care Transformation** | | |
| Comprehensive Primary Care Plus (CPC+) | • Care **Management Fee**  
• **Performance-Based Incentive**  
• Payment under Medicare Physician Fee Schedule | • 2,893 primary care practices  
• 54 aligned payers in 14 regions |

*Note: Medicare Shared Savings Program Track 2 & 3 and Vermont All-Payer ACO Model are also approved Advanced APMs*
(A Failed) 2016 Medical Benefit Reimbursement Experiment: The Medicare Part B Demonstration → ASP Add-On

March 8th
Medicare announces 102.5% + $16.80 “experiment”

March 9th
Community Oncology Alliance promises to pursue “every legal legislative and related option to stop the CMS Medicare Part B Drug Payment Model, which is nothing more than a perverse experiment on cancer care provided to seniors”

April 7th
MedPAC discusses 103.5% +$5 option

April 28th
Republican senators write CMS to withdraw proposal entirely

May 9th
Responses due to proposed rule; over 600 responses were received, the vast majority were negative

December 16th
Program Halted

“All new therapies would be cost-prohibitive, and some standard support therapies would also be out of reach. Our physicians would be forced, by financial realities, to prescribe older therapies or go out of business.”

-- Suanne Gersdorf, CEO of the Oklahoma Cancer Specialists and Research Institute

"I was named in a Change.org petition where I got email about every 20 seconds from patients saying their doctor said they wouldn't get their medicine" under this plan. As a practicing physician, it bothered me personally; it was clear that was not what this proposal is intended to do."

-- Patrick Conway, MD, CMS Chief Medical Officer

STOP THE MEDICARE EXPERIMENTS!

Call Congress Today @ 202-683-7977
## Agenda

- Recent Changes to Medical Benefit Reimbursement

- The **Oncology Care Model (OCM)**: Case Studies in Value

- Reimbursement & Contracting for **Biosimilars** in the US
  - Implications of Interchangeability
  - Reimbursement Economics: Impact of the Shared HCPCS Code
  - What’s Next?
Today’s OCM Section Objectives: Understand the “Real World” Case Study Observations and Implications of the July OCM Roll Out

CMS Innovation Center Models Goals:

- Better care
- Smarter spending
- Healthier people
**Oncology Care Model**

**Overview**

- New 2016 CMS payment and delivery model designed to improve Oncology Care
- **195** Practices enrolled
- **17** commercial insurers enrolled
- Provide higher quality, better coordinated care at the same or lower cost
- Oncology FFS payments tied to financial and care **quality** accountability for **6 month episodes of cancer patients care**
- Commit to providing **enhanced services** to Medicare beneficiaries (e.g. care coordination, navigation)
- **Pharma** uncertain about OCM impact on participants’ drug choice decisions

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CMS
Oncology
Care
Model

Jul 1 2016 –
Jun 30 2021

- What is OCM?
  - More practices than expected, but fewer payers

- Goal
  - Provide higher quality, better coordinated care at the same or lower cost

- How OCM works
  - Oncology FFS payments tied to financial and care **quality** accountability for **6 month episodes of cancer patients care**
  - Commit to providing **enhanced services** to Medicare beneficiaries (e.g. care coordination, navigation)

- Why it matters
  - **Pharma** uncertain about OCM impact on participants’ drug choice decisions
## Oncology Care Model

### Overview

OCM model designed to evolve oncology clinics towards enhanced coordinated care with a focus on value-based treatment aligned with national guidelines.

### Payment System

<table>
<thead>
<tr>
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<th>2H 16</th>
<th>1H 17</th>
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<th>2H 18</th>
<th>1H 19</th>
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<td><strong>Traditional FFS</strong></td>
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<td><strong>MEOS Payment</strong></td>
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<td><strong>“Enhanced Services”</strong></td>
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<tr>
<td><strong>Performance-based Payment</strong></td>
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<td><strong>Variable vs discounted baseline period costs of care</strong></td>
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<tr>
<td>Shared Savings: 4.0% discount – Must qualify by 1H 19 to maintain eligibility</td>
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<tr>
<td>Shared Risk - Opt-in: 2.75% discount</td>
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Informal discussions with Community Oncology Practice Managers and Pharmaceutical clients

<table>
<thead>
<tr>
<th>Participating Practices (n=5)</th>
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<tbody>
<tr>
<td>Enhanced Services + MEOS is the current focus</td>
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<tr>
<td>“We think CMS’s commitment to enhanced coordination, navigation, and quality is OCM’s #1 tenet. The MEOS payment provides great incentive to improve our processes and communications for these services”</td>
</tr>
<tr>
<td>– Mid-size Oncology Practice Manager</td>
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<tr>
<td>PBP Analysis is Too Complex</td>
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<tr>
<td>“The financial math for performance based payment (PBP) is just too much to think about. Our Oncologists have collectively agreed to just keep practicing good medicine.</td>
</tr>
<tr>
<td>– Large Multi-site Oncology Practice</td>
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</tbody>
</table>
Informal discussions with Community Oncology Practice Managers and Pharmaceutical clients

Participating Practices (n=5)

Default to Guidelines, Pathways, and EOS

“Our current perspective is that, if quantification of drug-vs.-drug total cost of care savings is even possible, our practitioners will defer to guidelines and pathways organizations to ‘do that math’ and make recommendations. It’s likely that level of guidance will be a few years down the road before good data is available to inform active decision making on the performance-based payment side”
- National Community Oncology Practice Manager

Supportive Care “Investment”

“In supportive care, there are obvious risks and tradeoffs of trying to find savings in certain regimens. We feel there is too much unknown risk and exposure to office visits and hospitalizations with that approach, so we’re not going to there to find savings
- Small Midwest Oncology Practice Manager
Informal discussions with Community Oncology Practice Managers and Pharmaceutical clients

<table>
<thead>
<tr>
<th>Pharmaceutical Clients (N=2)</th>
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<tr>
<td><strong>OCM Exposure Is Unknown</strong></td>
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<tr>
<td>“When this started, we have no idea how much of our historical usage was through the 195 practices which signed up for OCM and therefore potentially at risk if practices started focusing on the cost cutting as a first step.”</td>
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<tr>
<td>– Part B Oncology Supportive Care Manufacturer</td>
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<tr>
<td><strong>Contracts Remain Influential</strong></td>
</tr>
<tr>
<td>“We have a strong focus on ensuring the community practices using our drug are not losing $ after Medicare reimbursement – through GPO-based contracts. It seems the waters are muddled in the field between uncertain upside of OCM vs a known quantity of our contract which also helps lower ASP and drug costs to the system in the long run”</td>
</tr>
<tr>
<td>– Part B Oncology Therapeutic Manufacturer</td>
</tr>
</tbody>
</table>
OCM Enrollee Summary and Approximate Exposure Estimates

Approach
- Matched CMS-published OCM Enrollment List to “Ship-to” distributor data for several key oncology supportive care products used per guidelines in a range of chemotherapy protocols
- **Auto-matching process** used ‘fuzzy logic’ on site address / names at a threshold to minimize false positive matches; Auto matches manually inspected to remove false matches; Remaining non-matched OCM sites were matched through manual review with appropriate ‘Ship-to” sites
- For True Community Oncology practices, OCM Flag was pushed out to all sibling sites

Matching Success Rate: # Practices

- **~178 of the 195** practices were matched
- Only 125 of the 195 practices enrolled in OCM fall into the traditional “Community Oncology Clinic” segment (serviced by traditional community oncology GPOs and contracts offered through these GPOs)
- Unmatched accounts are primarily health systems / hospitals where address match was not possible vs available ship-to addresses
- “Hospital”-oriented accounts include major health systems, academic centers, etc. → scope of inclusion for these organizations is unclear
OCM Exposure in Community Oncology Clinics nears 27% for a blended Supportive Care Market Basket

Volume exposure to OCM by “segment”

<table>
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<tr>
<th>CLINICS</th>
<th>HOSPITALS - SYSTEMS</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>73%</td>
<td>92%</td>
<td>84%</td>
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<tr>
<td>27%</td>
<td>8%</td>
<td>16%</td>
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Distribution of all OCM-exposed product volume

- Clinics: 76%
- Hospitals - Systems: 24%

Of the ~180 matched accounts…
- 100 were among “Top 8” Decile accounts in supportive care use
- 85 Clinics + 15 Hospitals / Health Networks
Implications for Pharmaceutical Manufacturers

Part B drug pricing and contracting are likely to maintain traditional evaluation criteria and usage to guidelines as pathways organizations evaluate how to incorporate total cost of care into the quality and performance measures.

Part B Oncology
Chemotherapy Therapeutics

- Continue to drive traditional “Value” efforts through Health Economics Value Proposition, cost avoidance, and total cost of care focused data and communications.
- Evaluate Risk Share-based contracting where traditional economics justification is difficult to establish.

Part B Oncology Supportive Care

- Supportive care products with similar efficacy / safety profiles will likely continue to follow a practice level ‘pick the winner’ model in key community oncology practices.
- Practice economics will continue to drive adoption and use in these settings well into 2018 unless better economic / outcomes evidence is developed to shift use or drive use towards equally effective but less expensive options.
Recent Changes to Medical Benefit Reimbursement

The Oncology Care Model (OCM): Case Studies in Value

Reimbursement & Contracting for Biosimilars in the US
  - Implications of Interchangeability
  - Reimbursement Economics: Impact of the Shared HCPCS Code
  - What’s Next?
US Loss of Exclusivity Timeline
Major Biologic Therapeutics

Sources: EvaluatePharma, Cortellis
Since 2015, there have been two approvals for major anti-TNF biosimilars, along with the publication of key CMS/FDA guidance.

Select US Biosimilar Events

- **2012**
  - FDA publishes draft guidance on demonstrating biosimilarity
  - Finalized in 2015

- **2015**
  - Feb. 2015
    - Zarxio Approved by the FDA
  - April 2015
    - Inflectra Approved by the FDA

- **2016**
  - Sept. 2016
    - Amjevita Approved by the FDA*
    - Inflectra Marketed in the US

- **2017**
  - January 2017
    - Interchangeability draft guidance published in Federal Register
  - January 2017
    - All new regulation and guidance suspended for 60 days

*Note that there is a mandatory 180 day notification period between the approval of a biosimilar and when the biosimilar can launch, though Amjevita is expected to be delayed for longer due to unsettled litigation.
Interchangeability:
The biological product may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product.

Requirements

- Submit data from at least one switching study evaluating results in two or more switch intervals with two products in US clinical setting.
- Demonstrate that the risk – in terms of safety or diminished efficacy of switching between use of the interchangeable product and reference product – is not greater than the risk without alternating in any given patient.

Differences vs. “Biosimilarity”

- For biosimilarity, sponsors may use data from animal or clinical studies comparing a proposed product with a non US-licensed comparator product.
- In a switching study, the comparator product must be US-licensed and used in both the active switching arm and the control non-switch arm, rather than being used only as a control.
Due to concerns regarding misapplication of existing generics rules and legislation, there is a movement to **amend state laws to more explicitly address biosimilars and interchangeable products** (e.g., to limit or carefully regulate automatic substitution).
Remicade Biosimilar Case Study:
Inflectra (infliximab-dyyb)

- **Reference Drug:** Remicade (Janssen)
- **Manufacturer:** CELLTRION, Inc.
- **Marketer:** Pfizer (Hospira)
- **Price:** $946/vial
- **Indications:** Crohn’s Disease (including pediatric), Ulcerative Colitis, Rheumatoid Arthritis (in combination with methotrexate), Ankylosing Spondylitis, Psoriatic Arthritis, Plaque Psoriasis
- **Licensed Markets:** Europe*, United States, Canada, Australia, and New Zealand
- **EMA Approval:** October 2013
- **FDA Approval:** April 2016
- **Marketed in US:** October 2016
- **Inflectra has not yet sought an interchangeability designation**

*Sold in Europe as Remsima*
In a hypothetical example where JNJ offers a ~10% rebate to a payer…
Biosimilars: The Provider Perspective
Illustrative Infliximab Provider Net Cost Recovery (NCR) Example

Net Cost Recovery

- Provider “Net Cost Recovery” = Reimbursement minus net effective acquisition cost
- For Medicare patients: dictated by the CMS allowable: ASP+6% (~4.3% under sequestration)
- 6% cushion is **not** 6% of the biosimilars’ ASP but rather 6% of the reference product’s ASP

<table>
<thead>
<tr>
<th>Product</th>
<th>WAC</th>
<th>ASP</th>
<th>Share of Code Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remicade</td>
<td>$1,113</td>
<td>$782</td>
<td>100%</td>
</tr>
<tr>
<td>Inflectra</td>
<td>$946</td>
<td>$800</td>
<td>33%</td>
</tr>
<tr>
<td>Rem BS2</td>
<td>$850</td>
<td>$700</td>
<td>33%</td>
</tr>
<tr>
<td>Rem BS3</td>
<td>$750</td>
<td>$600</td>
<td>33%</td>
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</table>
At the close of 2015, there were 41 biosimilars under development for four key biologics going off patent.

Source: IMS Institute for Health Informatics
The impact of biosimilars in the US will likely be delayed due to various postponements, litigation, and clinical uncertainty


Despite the launch of Inflectra late in 2016, J&J states it has yet to have “observed any significant impact to-date” from the product.

‘Facility Inspections Delay Sandoz’ Filing For Humira Biosimilar in US’

Sandoz pushed the filing into the first half of 2017 based on discussions with the FDA and ongoing capacity upgrades at their product site to align with the timing of regulatory inspections.

‘Enbrel biosimilar Erelzi won’t launch before 2018, delayed by legal battle’

Nearly 5 months since receiving FDA approval for Erelzi, product launch is not likely until 2018 due to the outstanding patient litigation between Sandoz and Amgen.

‘Supreme Court Takes Up Amgen, Sandoz’ Market-Defining Biosimilars Dispute’

The Supreme Court agreed to hear a case regarding the six-month waiting period required after a biosimilar company notifies the original developer about the rival drug and when that notification can take place.
Value-based care models are not going away
Manufacturers should continue to monitor the impact of medical benefit evolution on customers and offer innovative contracts to match

The Oncology Care Model (OCM) doesn’t change much, for now
Part B drug pricing and contracting likely to maintain traditional evaluation criteria and usage until organizations can incorporate total cost of care into quality and performance measures

The impact of biosimilars may be delayed (in the US), but not forever
As a flood of major biologics lose US exclusivity in the coming years, biosimilars will become an increasingly relevant piece of the pharma puzzle

Biosimilar medical benefit reimbursement offers contract opportunities
Manufacturers of both innovator and biosimilar products should consider the unique reimbursement dynamics of biosimilars (e.g., the shared HCPCS code) and adjust pricing & contracting strategies accordingly to adapt
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