Session 113 OF, Pharmacy Outcomes Based Contracting

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Denise Wolff
Value-based Contracting Opportunities with Pharmaceutical Manufacturers

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Vice President, Actuarial Consulting
Optum Consulting
Pharmacy Drug Spend Trend Rates

Forecasted PMPM Net Drug Spend Across the Pharmacy and Medical Benefit for Commercial Plan Sponsors

Can Value-Based Contracts with Pharmaceutical Manufacturers Mitigate or Justify this Rate of Increase in Net Drug Spend?

Artemetrx, “An Evaluation of Specialty Drug Pricing Under the Pharmacy and Medical Benefit”, March 2014
Prevalence of Outcomes-based Pricing and Reimbursement Arrangements

Historically, there have been very few outcomes-based pricing and reimbursement arrangements in the United States

Source: Nazareth et al, Outcomes-Based Pricing and Reimbursement Arrangements (PHP 175), ISPOR
Types of Global Risk Sharing Schemes

Risk sharing agreements are a way for payers to reduce risk through financial or outcomes-based schemes

**Financial-based Schemes**
- Focused on the financial arrangements between the manufacturer and purchaser; not tied to specific performance metrics
- Includes traditional rebates/discounts, price-volume agreements, quantity limits and treatment initiation

**Outcomes-Based Schemes**
- Schemes tied to specific performance metrics such as biomarkers, clinical outcomes, or other metrics (e.g., hospitalizations)
- Includes coverage with evidence development and “guarantee” type schemes

- Outcomes-based agreements are becoming an increasingly popular topic of discussion as the US health system moves to a pay for performance model
- However, a 2015 study found only 12% of global risk sharing agreements were in the US, what is holding the US back?

Source: “Private Sector RSAs in the United States”, September 2015 issue of American Journal of Managed Care, Vols. 21, No. 9
Potential Barriers to Risk Share Agreements in the United States

There are far less risk share agreements between pharmaceutical manufacturers and payers/PBMs in the US for a variety of complex reasons:

1. Significant additional effort required to establish / execute RSAs (e.g. compared to traditional rebates / discounts)
2. Challenges in identifying / defining meaningful outcomes
3. Challenges in measuring relevant real-world outcomes
4. Data infrastructure inadequate for measuring / monitoring relevant outcomes
5. Difficulty in reaching contractual agreement (e.g. on the selection of outcomes, patients, data collection methods)
6. Implications for federal best price (Medicaid)
7. Payer concerns about adverse patient selection
8. Fragmented multi-payer insurance market with significant switching among plans
9. Challenges in assessing risk upfront due to uncertainties in real-world performance
10. Lack of control over product use
11. Significant resource and / or costs associated with ongoing adjudication

Source: “Private Sector RSAs in the United States”, September 2015 issue of American Journal of Managed Care, Vols. 21, No. 9
Recently Announced Risk Share Agreements in United States

1. Gilead and Cigna for Harvoni
2. Amgen and Harvard Pilgrim for Repatha
3. Novartis and Aetna for Entresto
4. Novartis and Cigna for Entresto
What Drives Payers to Implement Outcomes-Based Contracts?

Figure 2: Payer Drivers for OBC Implementation

- Reduce costs
- Increase pharmacy discount/rebate level
- Reduce financial risks

As reported by payers:
- Reduce costs: 30%
- Increase pharmacy discount/rebate level: 11%
- Reduce financial risks: 17%
- Provide faster access to innovative medicines: 4%
- Internal or external goal: 13%
- Avoid providing access to an overly broad patient population: 5%
- Improve patient outcomes: 21%

As reported by manufacturers:
- Reduce costs: 21%
- Increase pharmacy discount/rebate level: 17%
- Reduce financial risks: 24%
- Provide faster access to innovative medicines: 9%
- Internal or external goal: 13%
- Avoid providing access to an overly broad patient population: 5%
- Improve patient outcomes: 19%

Source: Nazareth et al, Outcomes-Based Contracting for Pharmaceutical Products in the United States
AMCP 27th Annual Meeting, April 7-10, 2015
What Drives Manufacturers to Implement Outcomes-Based Contracts?

Figure 3: Manufacturer Drivers for OBC Implementation®

Source: Nazareth et al, Outcomes-Based Contracting for Pharmaceutical Products in the United States
AMCP 27th Annual Meeting, April 7-10, 2015
Variety of Potential Risk-Share Strategies

1. Guarantees to supplement traditional competitive pricing approach
   - Aggressive price and rebates combined with:
     - Price protection guarantee
     - PMPM cost trend guarantee minimum market share % guarantee
     - Price-volume agreements (PVAs)/budget impact schemes
   - Can be effective strategy short term; long term risk of commoditizing the product or more aggressive competition lowering overall margin

2. Financial risk share guarantees for patients who become hospitalized (or who incur different appropriately defined negative outcomes)
   - Pay for impacted members’ rx costs related to your product alone
   - Pay for impacted members’ total rx cost of all utilized products related to this condition
   - Pay for hospitalization costs for your product’s patients
Variety of Potential Risk-Share Strategies (continued)

3. Guarantee Clinical outcomes metrics; performance based/outcome-based approach

4. Member based insurance policy rider for hospitalization cost for your product’s patients

5. Total cost of care guarantee for your product’s patients (can be adjusted for differences in risk characteristics)
   - Guarantee the bending of total cost curve on a per episode basis (illustrated in subsequent slides)
   - Guarantee total cost of care PMPM
   - Guarantee total cost of care for your product’s patients is less than total cost of care for those using competitor products
1. Use ETGs to group historic episode costs (BY1, BY2, BY3)
2. Actuarially project future episode costs (PY1, PY2, PY3)
3. Apply outcomes evidence to episode costs to calculate guaranteed savings for PY1, PY2 and PY3
4. If actual savings are less, reimburse payer negotiated % of shortfall
5. If actual savings are more, share in the negotiated % of excess savings
Constructing Win-Win Risk Share Agreements

A systematic approach to designing and implementing risk share agreements:

<table>
<thead>
<tr>
<th>Research</th>
<th>Design</th>
<th>Pilot</th>
<th>Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Target patient?</td>
<td>• Agreement model simulation results?</td>
<td>• How well does it work?</td>
<td>• Final agreement structure?</td>
</tr>
<tr>
<td>• Current real-world outcomes?</td>
<td>• Proposed structure(s)?</td>
<td>• Opportunities to improve?</td>
<td>• Roll out plan?</td>
</tr>
<tr>
<td>• Historical agreement structure strengths and weaknesses?</td>
<td>• Accompanying interventions?</td>
<td>• Considerations for scale?</td>
<td>• Adjudication process?</td>
</tr>
<tr>
<td>• Target performance measures?</td>
<td>• How do we collect data and how frequently?</td>
<td></td>
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<tr>
<td></td>
<td>• What could go wrong and how do we avoid?</td>
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</tbody>
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Oversight checkpoints after each phase

Source: “Private Sector RSAs in the United States”, September 2015 issue of American Journal of Managed Care, Vols. 21, No. 9
Putting Together the Puzzle Value-based Contracting

Design, contract manage and adjudicate value-based contracts.

- Better outcomes
- Better satisfaction
- Better cost
## Components of a “GOOD” value-based contract

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Benefit</th>
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<tbody>
<tr>
<td>1</td>
<td>Creates value for all stakeholders</td>
<td>Beneficial</td>
</tr>
<tr>
<td>2</td>
<td>Balances short-and long-term opportunities and risks — want more than a one-year deal</td>
<td>Meaningful</td>
</tr>
<tr>
<td>3</td>
<td>Employs a patient/physician engagement program to <strong>drive outcomes</strong> and <strong>compliance</strong></td>
<td>Clinically Appropriate</td>
</tr>
<tr>
<td>4</td>
<td>Leverages a predefined adjudication criterion that is <strong>simple to execute</strong></td>
<td>Easy</td>
</tr>
<tr>
<td>5</td>
<td>Leverages claims and select clinical data to <strong>ensure understanding</strong> of outcomes and patient segments</td>
<td>Clinically Appropriate</td>
</tr>
<tr>
<td>6</td>
<td>Leverages a “pilot” to <strong>test uncertainties</strong> if there are significant unknowns</td>
<td>Beneficial</td>
</tr>
<tr>
<td>7</td>
<td><strong>Results reported quarterly</strong>, but reconciles annually</td>
<td>Easy</td>
</tr>
</tbody>
</table>
Total cost of care curve approach using episodes of care has the potential to address many of the current barriers to risk share agreements in the United States.

1. Significant additional effort required to establish / execute RSAs (e.g. compared to traditional rebates / discounts) ✓
2. Challenges in identifying / defining meaningful outcomes ✓
3. Challenges in measuring relevant real-world outcomes ✓
4. Data infrastructure inadequate for measuring / monitoring relevant outcomes ✓
5. Difficulty in reaching contractual agreement (e.g. on the selection of outcomes, patients, data collection methods) ✓
6. Implications for federal best price (Medicaid) ✓
7. Payer concerns about adverse patient selection ✓
8. Fragmented multi-payer insurance market with significant switching among plans ✓
9. Challenges in assessing risk upfront due to uncertainties in real-world performance ✓
10. Lack of control over product use ✓
11. Significant resource and / or costs associated with ongoing adjudication ✓

Source: “Private Sector RSAs in the United States”, September 2015 issue of American Journal of Managed Care, Vols. 21, No. 9
Thank you!
INNOVATIVE, CUSTOM CLIENT SOLUTIONS: OUTCOMES PERFORMANCE INITIATIVES

Denise L. Wolff, PharmD
National Account Manager
Market Access & Customer Solutions
EMD Serono, Inc.
Agenda

1. Overview of Outcomes-Based Contracts
2. Considerations and Key Factors for Success
3. Collaborative Approaches for Outcomes-Based Contracting Opportunities
4. Questions / Discussion
OVERVIEW OF OUTCOMES-BASED CONTRACTS
What is Outcomes-based Contracting?

Neumann et al defines an outcomes-based contract as:\(^1\)

A contract between a payer and a manufacturer in which the reimbursement for a drug is tied to the health outcomes achieved with “real-world” use.

Other examples may include:

- Supplemental rebates
- Discounts
- Other contract components

Outcomes-based Contracts Reflect a Shift to Real-World Demonstration of Effectiveness

Most of the activity in the US has centered on the use of coverage for evidence development (CED) arrangements at CMS.

Due to the diversity of US payers, performance-based risk-sharing arrangements occur in various forms & at various levels.

Arrangements address fundamental uncertainties that exist when products enter the market.

The pace of adoption appears to be slowing but still has traction in many health systems and remain a viable coverage and reimbursement mechanism for a wide range of products.

Primarily for oncology therapies.

Focus on high-cost diseases:
- 40% for chronic diseases
- 52% for oncology products
- 8% for devices & diagnostics

2 CONSIDERATIONS AND KEY FACTORS FOR SUCCESS
Key Operational Considerations

- Establishing an Outcomes-Based Contract is a collaborative process

**Administrative**
- Agree to contract details
- Identify data collection and adjudication protocols
- Establish monitoring process

**Outcomes Measurement**
- Define which outcome(s) will be measured
- Establish time horizon of measurement period
- Identify baseline period or comparator for assessment of outcomes

**Technology Requirements**
- Access to data systems
- Determine ability to capture pharmacy and/or medical claims

Current Healthcare Trends

Aligned with healthcare’s focus on performance measurement

Multiple HEDIS measures are related to the effectiveness of care and resource utilization

Affordable Care Act includes multiple pay-for-performance initiatives
- Accountable Care Organizations
- Hospital Value-Based Purchasing Program
- Medicare Physician Quality Reporting System

CMS 5-Star Quality Ratings System for Medicare Advantage plans emphasizes measurement of health outcomes and patient experience

The CMS Value-Based Insurance Design (VBID) Model will begin January 1, 2017 and run for five years. CMS will test the model in 7 states: Arizona, Indiana, Iowa, Massachusetts, Oregon, Pennsylvania, and Tennessee. Eligible Medicare Advantage plans in these states can offer varied plan benefit design for enrollees who fall into certain clinical categories identified and defined by CMS through 4 approaches.

- eliminate or reduce cost-sharing for evidence-based services and drugs;
- eliminate or reduce cost-sharing for “high-value” hospitals, doctors, skilled-nursing facilities and other providers;
- reduce cost-sharing for members who participate in disease-management programs; or
- provide full coverage for “supplemental benefits,” such as nonemergency transportation to primary-care visits.

Benefits of a Collaborative System

• Demonstrates to stakeholders that the payer is an integral partner dedicated to achieving high-quality care for plan members
  o Highlights the payer as an innovator in healthcare quality
  o Supports company’s strategic value objectives
  o Aligns with core themes in the Affordable Care Act
  o Supports HEDIS metrics and CMS Star Ratings

• Provides a shared approach to optimizing patient outcomes

• Allows appropriate access to new drugs and technologies

3 COLLABORATIVE APPROACHES FOR OUTCOMES-BASED CONTRACTING OPPORTUNITIES
Key Factors for Successful Implementation

Selection of the appropriate product / therapeutic area
• Most contracts are for therapies in high-spend, high-impact disease states\textsuperscript{1}
• Potential benefits > implementation and transaction costs\textsuperscript{2}

Collaboration between the manufacturer and the payer on the outcomes measured
• “Objective, clearly defined, reproducible, and difficult to manipulate”\textsuperscript{3}
• Appropriate measurement period (1–2 years)\textsuperscript{3}

Access to adequate data and personnel
• Complexity of outcomes dictates the needs and level of IT\textsuperscript{3}
• Payment and reimbursement mechanisms are clearly established\textsuperscript{2}

Engagement of payer and manufacturer resources is critical to support tactics leading to desired patient outcomes

References:
QUESTIONS/DISCUSSION
Pharmacy Outcomes Based Contracting

Presented by:

Alex Cires, FSA, MAAA
Consulting Actuary
Agenda

- Types of Risk-Based Contracts
- Considerations for Risk-Based Contracts
TYPES OF RISK-BASED CONTRACTS
Outcomes-Specific Cost

- Pay for specific outcome
  - Risks that may be known/controlled
    - Hepatitis C
      - Sustained Viral Response
    - Oncology
      - Tumor size decrease
      - Survival
  - Risks with very little control
    - HA1C level
    - Emergency room usage
Indication-Specific Cost

- Oncology products
  - May have 20x dose for some types of cancer versus others
  - Do not wish to collect 20x dollars for a single patient
  - Common in some European countries
  - May impact Medicaid best price

- Contract structure
  - Determine equivalent discount based on population
  - May have rebate calculation on prospective basis instead of retrospective
Maximum Per Patient

- Can be in conjunction with compliance program
- Removes negative incentives for increasing adherence
- Removes payer concerns about increasing treatment rates
- Can be used for medications with different dosing variation
  - Can impact Medicaid best price
  - Can be similar to indication-specific contracting
Capitation Amount Per Member Per Month

- Single payment per member per month for unlimited supply of medications
- Can be based on single product or therapeutic class
- Allows manufacturer to increase market share with incentives for health plan to shift market share to products described in contract
- Removes negative incentives for health plans to promote adherence
CONSIDERATIONS FOR RISK-BASED CONTRACTS
Selecting a suitable partner is critical to contract success and future opportunities

Level of Pharmacy Risk

- Pharmacy claims volume impacted must be meaningful to payer or PBM
- Must be a desire to have more predictable pharmacy cost
- Payer or PBM must be willing to move market share to preferred choices for successful contract
- Some therapeutic classes may have impact on medical benefit costs
  - Must have visibility to medical claims to measure impact
Selecting a suitable partner is critical to contract success and future opportunities

Contract Administration

- Payer or PBM must have data available to administer contract
  - Ability to calculate payments
  - Ability to shift market share
- Systems must be in place to track therapeutic class spending and shift utilization
- Third party verification needed for most contracts
Selecting a suitable partner is critical to contract success and future opportunities

Customer Relationships

- Payer must be able to take advantage of physician relationships to leverage unique aspects of risk-based contracts
- PBM must have ability to “sell” contract to downstream entities
- A suitable partner for Pharma will have the ability to utilize the contract with a large portion of its business
- Pharma must “sell” the contract internally as well as externally
Selecting a suitable partner is critical to contract success and future opportunities

Clinical Sophistication

- Payer or PBM must have the ability to track clinical outcomes
  - Compliance
  - Lab results
  - Electronic medical records
- Payer or PBM must have ability to manage care in relevant therapeutic areas