PAY-FOR-PERFORMANCE: THE PROMISE AND CHALLENGES OF OUTCOMES-BASED PHARMACEUTICAL CONTRACTING

Sam Peasah PhD, MBA RPh.
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- Dr. Peasah has no conflicts of interest to disclose.
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Initial release date is 3/3/2018.
Outline/Objectives

• Discuss the political dynamics driving outcomes-based Pharmaceutical contracting (OBPC)

• Understand the concept of OBPC

• Analyze the promises and challenges of OBPC
Economic and political factors

- There is a push to move from volume to value in our payment/reimbursement models
- CMS has been at the forefront of the value-based purchasing drive
  - Move from fee-for-service
  - Penalty for non-performance
    - Hospital-acquired conditions (hospital value-based purchasing program)
    - Hospital readmissions reduction program
    - Physician value modifier program
    - Physician quality reporting system
  - Medicare shared savings
    - Goal to reduce cost, improve quality and hence improve efficiency
- Bundled payment
- Global capitation
Summary of Value-Based Programs

VALUE-BASED PROGRAMS

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<td>ACA: Affordable Care Act</td>
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<td>MACRA: Medicare Access &amp; CHIP Reauthorization Act of 2015</td>
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<td>MIPPA: Medicare Improvements for Patients &amp; Providers Act</td>
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<td>PAMA: Protecting Access to Medicare Act</td>
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Program Implemented

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<td>APMs: Alternative Payment Models</td>
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<td>ESRD-QIP: End-Stage Renal Disease Quality Incentive Program</td>
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<td>HACRP: Hospital-Acquired Condition Reduction Program</td>
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<td>HRRP: Hospital Readmissions Reduction Program</td>
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<td>HVBP: Hospital Value-Based Purchasing Program</td>
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<td>MIPS: Merit-Based Incentive Payment System</td>
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<td>VM: Value Modifier or Physician Value-Based Modifier (PVBM)</td>
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<tr>
<td>SNF-VBP: Skilled Nursing Facility Value-Based Purchasing Program</td>
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Total U.S. prescription drug spending, in $ billions

Source: Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group. For definitions, sources, and methods for NHE categories, see CMS.gov.
National Health Expenditure Accounts methodology paper, 2017
According to the National Business Group on Health (2016)

**Top Cost Drivers of Rising Health Care Costs**

- Specialty pharmacy: 31% (Highest), 26% (Second), 23% (Third)
- High cost claimants: 32% (Highest), 25% (Second), 16% (Third)
- Specific diseases or conditions (i.e., musculoskeletal claims): 17% (Highest), 20% (Second), 24% (Third)
- Overall medical inflation: 11% (Highest), 9% (Second), 9% (Third)
- Hospitalization (i.e., inpatient care): 7% (Highest), 9% (Second), 2% (Third)
- Outpatient procedures: 2% (Highest), 5% (Second), 5% (Third)
- Traditional pharmacy: 4% (Highest), 5% (Second), 2% (Third)
- ACA compliance: 1% (Highest), 1% (Second), 2% (Third)
- Geographic variation in cost/utilization: 3% (Highest), 2% (Second), 2% (Third)
- Outpatient care (i.e., physician visits): 1% (Highest), 1% (Second), 2% (Third)
- Other: 1% (Highest), 2% (Second), 2% (Third)

**Note:** Other responses included: inefficient use of the health care system (e.g., inappropriate use of the emergency room).
## Prices Climb
The cost of drugs is rising, especially for rare disorders.

A selection of some of the most expensive drugs, annual cost in the U.S.

<table>
<thead>
<tr>
<th>Drug (company)</th>
<th>Treats</th>
<th>Typical/Annual Cost</th>
<th>Target patient population</th>
</tr>
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<tbody>
<tr>
<td>Soliris (Alexion)</td>
<td>Type of blood disease and also a kidney disorder</td>
<td>$440,000</td>
<td>10,000-12,000 world-wide</td>
</tr>
<tr>
<td>Naglazyme (BioMarin)</td>
<td>Rare enzyme disorder</td>
<td>$400,000</td>
<td>1,100 in developed countries</td>
</tr>
<tr>
<td>Elaprase (Shire/Sanofi)</td>
<td>Rare enzyme disorder</td>
<td>$375,000</td>
<td>2,000 world-wide</td>
</tr>
<tr>
<td>Cinryze (Shire)</td>
<td>Hereditary Angioedema</td>
<td>$350,000</td>
<td>6,000 in U.S.</td>
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<tr>
<td>Gattex (NPS)</td>
<td>Short Bowel Syndrome</td>
<td>$295,000</td>
<td>3,000-5,000 in U.S.</td>
</tr>
<tr>
<td>Harvoni (Gilead)</td>
<td>Hepatitis C</td>
<td>$94,500</td>
<td>3.2 million in U.S.</td>
</tr>
</tbody>
</table>

Source: Sector & Sovereign Research (price changes); Needham & Co. (drugs, patient population); Centers for Disease Control and Prevention (patient population)

*Adjusted for inflation*
Change in Commercial Payer Drug Spending, Traditional vs. Specialty Drugs, by PBM, 2016

- CVS Health (Caremark)
- Express Scripts
- Medimimpact
- Prime Therapeutics

Traditional (non-specialty)  Specialty  Overall

n.a. = CVS Health did not report separate figures for traditional and specialty drugs.
Source: Pembroke Consulting analysis of company drug trend reports. Figures represent commercially insured beneficiaries only.

Published on Drug Channels (www.DrugChannels.net) on March 21, 2017.
7 IN 10 SAY INSURANCE SHOULD ALWAYS PAY FOR HIGH-COST DRUGS; 6 IN 10 SAY INSURERS SHOULD ONLY PAY IF PROVEN EFFECTIVE

A recent Kaiser Family Foundation poll shows many in the public think health insurance companies should cover prescription drugs, even if it means higher premiums for everyone. However, they also believe effectiveness of the drug should factor into coverage.

If a doctor recommends an expensive new drug to treat an illness when no lower-cost alternative exists, do you think...

- **71%**: Health insurance should always pay for it, even if it eventually leads to higher premiums for everyone
- **17%**: Individuals should be required to cover the cost themselves
- **11%**: DK/Ref.

- **37%**: Health insurance companies should always pay for it
- **58%**: Insurance companies should pay only if it has been proven to be more effective than existing treatments
- **5%**: DK/Ref.

*Source: Kaiser Family Foundation Health Tracking Poll (conducted June 2-9, 2015). Used with permission.*

What Pharma Leaders Consider their Main Market Assess Priorities Going Forward

- Demonstrating value in the real-world: 70%
- Generating adequate economics/outcomes data: 60%
- Improving the value proposition/story: 50%
- Showing commercial value in clinical development: 40%
- Securing access to payers: 30%
- Shifting policy environment: 20%
- Setting up risk sharing agreements: 10%
- Monitoring value in the real world: 5%
What is outcome-based contracting?

- An agreement or scheme between healthcare payers and medical product manufacturers in which the price, level, or nature of reimbursement are tied to future measures of clinical or intermediate endpoints ultimately related to patient quality or quantity of life (Carlson et al 2010)

- It is a rebate/discount contract (between manufacturers and payers) based on the outcomes at the patient level, of expensive pharmaceutical products

- The goal is to pay-for-value leading to a tiered payment system where you pay more if it works and less if it doesn’t

- Has several names in the literature
  - Performance-based health outcomes scheme
  - Performance-based risk-sharing arrangements
Outcomes-Based Risk Model

Payers

Access

Risk Sharing Agreements

Reimbursement

Providers

Manufacturers

Manufacturers as solution providers

Value-added services, e.g.:
- Patient Hubs
- Disease / medication mgmt.
- Adherence support programs
- Homecare services
- Specialty product support
- Contract support

Patients/caregivers

Treatment

Supply

Pharmacies

Distribution

Source: adapted from “Risk Sharing – a Driver to Achieve Better Outcomes,” Dr. Urs C.H. Wiedemann, Euroform Rethinking Healthcare conference, Berlin, (October 2013)
Features of OBC according to Garrison et al (2013)

• There is a program of data collection agreed to between manufacturer and payer

• This data collection is typically initiated during the time period following the regulatory approval

• The price, reimbursement, and/or revenue for the product are linked to the outcome of this program of data collection either explicitly or implicitly

• The data collection is intended to address uncertainty about one or more of the following
  • Efficacy or effectiveness either per phase 3 or broader more heterogeneous
  • Adverse events or adherence issues
  • Healthcare providers management of the patient
  • Size and value of cost-offsets such as fewer hospital visits
  • Type and proportion of patients who respond

• These arrangements provide a different distribution of risk than the historical manufacturer-payer relationship
# Contract Terms Template

**Contract definition**: Manufacturer will refund the **hospitalization costs** for patients who require hospitalization due to serious adverse event (SAE) while on therapy, **in excess of baseline SAE rate**

<table>
<thead>
<tr>
<th>Patient Eligibility</th>
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<tbody>
<tr>
<td>Must be taking manufacturer’s drug and compliant with therapy</td>
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<td>Must be admitted with one or more specific ICD9 codes: TBD</td>
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<tr>
<th>Performance Baseline (and other assumptions)</th>
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<tr>
<td>Baseline rate of serious adverse event = 3% (per label)</td>
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<tr>
<td>Avg. cost of hospitalization for therapy-related SAE = $19,000</td>
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## Payment to Plan (Example)

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<th>Payment to Plan (Example)</th>
<th>Low SAE Scenario</th>
<th>High SAE Scenario</th>
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<tbody>
<tr>
<td>Patients Started on Therapy</td>
<td>100% 1,000 patients</td>
<td>100% 1,000 patients</td>
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<tr>
<td>Eligible Patients</td>
<td>90% * 1,000 = 900 patients</td>
<td>90% * 1,000 = 900 patients</td>
</tr>
<tr>
<td>Rate of AEs vs. Baseline Rate</td>
<td>3% - 3% = Same rate</td>
<td>6% - 3% = 3% excess</td>
</tr>
<tr>
<td>Eligible Patients Hospitalized</td>
<td>N/A</td>
<td>3% * 900 = 27 patients</td>
</tr>
<tr>
<td>Total Manufacturer Refund</td>
<td>N/A</td>
<td>$19,000 * 27 = $513,000</td>
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## Manufacturer Terms

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<th>Manufacturer Terms</th>
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<td>Exclusive position on Tier 2 of formulary</td>
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*Source: Adapted from “Making Risk-Sharing and Clinical Performance Contracts Win-Win,” Andrew Parece, Risk Sharing and Value-Based Pricing Conference, NextLevel Pharma, (October 2009)*
FIGURE 2  Publicly Disclosed Pharmaceutical OBCs in the United States and EU-5 (1994-2014)

EU-5 = France, Germany, Italy, Spain, and the United Kingdom; OBC = outcomes-based contract.
Uptake of OBC in the US

OBC Uptake
(Shown: All payers)

Have an OBC in place: 24%

- 8% One
- 4% Two to Five
- 12% More than Five
- 30% None, but we are in negotiations for one or more now
- 29% None, as we are not planning to undertake OBCs
- 16% Not sure
Examples of OBC

- Amgen-Harvard Pilgrim Healthcare
  - Evolocumab (Repatha) 2015
    - Compare patients LDL to clinical trial outcomes which triggers additional discounts
    - Utilization above pre-determined level triggers rebate
    - LDL not lowered enough triggers additional rebate

- Evolocumab (May, 2017)
  - Reimbursement for eligible patients who has heart attack or stroke while on medication

- Enbrel (Feb., 2017)
  - Based on 6 Rx inputs to an algorithm scale for effectiveness
    - Patient compliance
    - Switching or adding drugs
    - Dose escalation
    - Steroid interventions
Examples of OBC cont’d

• Astra Zeneca- Harvard Pilgrim Healthcare
  • Brilinta
    • To reduce risk of repeat heart attacks following discharge after ACS hospitalization
    • Reduction in repeat ACS events compared to other antiplatelet therapy
  • Bydureon
    • To reduce blood glucose levels in Type 2 diabetics
    • Predetermined HbA1C goal for patients who adhere

• Novartis-different payers (Including Harvard Pilgrim, CIGNA, AETNA)
  • Entresto (Sacubitril/valsartan) in 2016
    • Based on reduction in proportion of patients hospitalized due to heart failure (RRR 20%)
  • Kymriah in 2017 (with CMS)
    • A $475,000 IV infusion to treat patients with acute lymphoblastic leukemia (ALL)
    • Will receive payment only if significant improvement after one month of therapy
### Other Examples

#### Major value-based drug deals

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<tr>
<th>Insurer/PBM</th>
<th>Manufacturer</th>
<th>Drug</th>
<th>Metrics</th>
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<tbody>
<tr>
<td><strong>Cigna and Aetna</strong></td>
<td>Merck &amp; Co.</td>
<td>Januvia and Janumet (diabetes)</td>
<td>Stabilizing blood glucose levels, glycated hemoglobin</td>
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<td><strong>Express Scripts</strong></td>
<td>AbbVie</td>
<td>Viękira Pak (hepatitis C)</td>
<td>Adherence (patient takes 100% or plan gets refund)</td>
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<tr>
<td><strong>Cigna and Aetna</strong></td>
<td>Novartis</td>
<td>Entresto (heart failure)</td>
<td>Reduction in hospitalization rate</td>
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<tr>
<td><strong>Harvard Pilgrim</strong></td>
<td>Amgen</td>
<td>Repatha (cholesterol)</td>
<td>Reduction in cholesterol levels</td>
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<td>Health Care and Cigna</td>
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<tr>
<td><strong>Humana</strong></td>
<td>Eli Lilly and Co.</td>
<td>Effient (anti-coagulant)</td>
<td>Reduction in hospitalization rate</td>
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*Source: Modern Healthcare reporting*
An Example: Genentech-Priority Health Pilot Design

- Avastin (bevacizumab) for small-cell lung cancer

- Outcome: Progression free survival (PFS)

- Five key considerations for developing and executing an OBC agreement
  - Leadership commitment
  - Medicine selection
  - Definitions and metrics
  - Data issues
  - Government Price reporting
Benefits of OBC

• Improve access to innovative drugs to patients

• Risk-shifting to manufactures in cases where medication turns out to be less effective than in clinical trials

• Preferred status on formulary for manufacturers products
  • Provides alternatives to closed formularies in exchange for guaranteed outcomes

• Excellent public relation for manufacturers and payers

• Accelerate availability of new medications and treatments

• Quicker access to real world data for researchers and policy makers
Benefits in Italy (based on 2012 National Report. By Navarria et al)

- About 3.3% savings nationally from 2006 to 2012 (AIFA)

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<tr>
<th>Reimbursement scheme</th>
<th>Positive features</th>
<th>Negative features</th>
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<td>Cost sharing</td>
<td>Applied for all treatments; easy to apply (no follow-up required)</td>
<td>Not based on safety/efficacy outcome</td>
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<tr>
<td>Risk sharing</td>
<td>Based on efficacy outcome</td>
<td>Partial reimbursement of the cost for nonresponders; difficult to apply (requires follow-up and notification to the company); no incentive to start and follow up the refund procedure for prescribing centers (refund does not go to the prescribing center but to the hospital)</td>
</tr>
<tr>
<td>Payment by results</td>
<td>Based on efficacy outcome; theoretic total reimbursement of cost for nonresponders</td>
<td>Difficult to apply (requires follow-up and notification to the company); no incentive to start and follow up the refund procedure for prescribing centers (refund does not go to the prescribing center but to the hospital)</td>
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<tr>
<td>Success fee</td>
<td>Based on efficacy outcome; no cost for nonresponders; prescribing centers are more incentivized (money for nonresponders treatment remain within the center)</td>
<td>Difficult to apply (requires follow-up and notification to the company), but easier than other PBRSAs: no risk to pay for nonresponders; requires a tax bill to be provided by the company to give the drug with initial no payment (solved with a pro forma tax bill at the beginning of treatment, followed by proper tax bill only for responders)</td>
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PBRSA, performance-based risk-sharing arrangement.
Challenges for OBC

Risk Sharing: Top Challenges

Significant additional effort
Data infrastructure inadequate
Medicaid best price
Significant resources/costs of adjudication
Difficulty in reaching contractual agreement
Challenges in measuring relevant outcomes
Fragmented, multi-payer market
Challenges in identifying/defining outcomes
Challenges in assessing risk upfront
Lack of control over how product will be used
Require 3rd party payer; difficult to contract directly with providers

Number of Respondents (n=15)

Challenges Specific to Heart Failure

Heart Failure MCOs' Biggest Challenge in Negotiating/Engaging in Outcomes-Based Contracts

- Trusting and verifying the integrity of pharmaceutical company data (13.33%)
- Trusting and verifying the integrity of physician-supplied data (6.66%)
- Difficulty of data collection (6.66%)
- Dedicating MCO resources (staffing and financial) to the contracting process (6.66%)
- Difficulty in reaching consensus about metrics with pharmaceutical companies (6.66%)
- Collecting enough data to properly assess outcomes (6.66%)
- Requires prolonged data tracking over several years (53.33%)

Source: DR/Decision Resources, LLC
Limitations to the promise of OBC

• Outcomes measurable requirements limits scope of drugs to be included
  • Rheumatoid Arthritis, Oncology, Heart failure, Hepatitis C, Diabetes, LDL

• Monitoring or outcomes measure data collection can be expensive

• Rebates are based on initial price which are controlled by manufacturers
  • E.g. Repatha ($14,100/year) research shows risk of heart attack is 3.5% making effective
    price of $13,620 compared to suggested price by ICER of ($2,200 to $5,000/year)

• Does not necessarily result in lower co-payments or premiums

• Mostly in the private sector but CMS can be a major player
References

- https://www.ced.org/blog/entry/top-healthcare-stories-for-2016-pay-for-performance