

Devising Outcomes-Based Contracts. Is the devil in the detail?

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Objectives

To discuss:

- The evolving landscape of outcomes-based contracting and a discussion of currently what is working or not
- US payer survey results - based on responses from the AMCP eDossier System @FormularyDecisions.com community
- Payer perspective of working with outcomes-based contracting and lessons learned
- Manufacturer perspective of accommodating the growing payer interest in outcomes-based contracting and lessons learned
- Discussion of barriers to outcomes-based contracting and potential solutions

Devising Outcomes-Based Agreements: Is the Devil in the Detail?

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Centre for Health Economics
University of York, UK
and
Board Member, Dymaxium

THE UNIVERSITY *of York*



Outline of Presentation

- Advantages and disadvantages of outcomes-based agreements to payers and manufacturers
- Issues in the design and conduct of outcome-based agreements
- Conclusions

Perceived Benefits of Outcomes-Based Agreements

- Potential to enhance coverage decisions and strengthen existing evidence bases on the benefits and costs of new technologies.
- Enable payers to participate in the research process.
- Allow hospitals and clinicians to monitor more closely procedures being performed and manage costs until benefit is substantiated.
- Encourage industry to generate the data needed to support the value claims of their innovations.
- Allow earlier access for patients to potentially valuable treatments than they might otherwise be granted.

Garrison *et al* *Value in Health* 2013:703-29

Key Challenges

- Establishing a clear framework for applying outcomes-based agreements (e.g. deciding when they are appropriate).
- Identifying and applying appropriate research methods (e.g. RCTs, observational studies).
- Involving all the relevant parties (e.g. manufacturers, health providers, professional groups).
- Funding and conducting the research.
- Determining appropriate coverage arrangements based on the research findings.

When Should we Consider Outcomes-Based Agreements?

- Outcomes-based schemes are most useful when there is uncertainty in clinical or economic outcomes
- Sources of uncertainty include:
 - long term clinical outcomes (eg maintenance of clinical effect or to validate a surrogate endpoint)
 - performance of the technology in different patient sub-groups
 - clinical or organizational response to the new technology

Note: If the main issue concerns the cost or affordability of a technology, outcome-based schemes are a wasteful way of addressing this issue

Can Observational Studies Help Us Estimate Relative Treatment Effect?

- Writing in the context of the revisions to the Cancer Drugs Fund in the UK, Grieve et al argue that simple randomized clinical trials, using routinely collected data are required

Grieve R et al British Medical Journal 2016;354:i5090

- However, the ISPOR Task Force on Prospective Observational Studies argue that 'well-designed and well-executed observational studies can provide evidence of causal relationships'

Berger M et al Value in Health 2012;15: 217-230

Clearly Defining and Measuring Outcomes

- The most successful arrangements have a clear (often single) outcome measure (eg Velcade for multiple myeloma in the UK)
- The method for measuring the outcome needs to be unambiguous or independently determined
- Achievement of the desired outcome needs to be related to use of the technology and not influenced by other factors (eg finasteride in Canada)

Velcade(Bortezomib) for Multiple Myeloma

- In the course of a NICE technology appraisal, an 'outcome guarantee' scheme was suggested by the manufacturer.
- The NHS agreed to ensure that 'all suitable patients' would have access to the drug.
- In return, the manufacturer agreed to refund treatment costs for patients who failed to respond (based on M-protein).
- Widely regarded as a success

Complexity and Cost of Arrangements

- Complexity and cost is a common reason for outcomes-based agreements not being pursued
- In most jurisdictions the manufacturer is expected to bear the cost of data collection and monitoring (although this is up for discussion)
- More complex schemes may result in less transparency about the price being paid for the drug or other health technology

Timelines for Outcomes-Based Agreements

- Many arrangements fail due to the time required to get alignment among all the stakeholders (eg attempts by CMS in the US to establish 'coverage with evidence development' schemes for procedures)
- In Italy, a common consistent process was established to facilitate outcomes based schemes
- Once agreed, arrangements with data collection lasting longer than 2-3 years tend not to be successful (eg MS Monitoring Scheme in the UK)
- The longer the timespan of an agreement, the greater the likelihood that other factors could change, such as the launch of a rival product (eg bosentan agreement in Australia)

Connecting Decisions to the Outcomes Obtained

- A common concern of manufacturers is that there is often uncertainty regarding the policy decisions following outcomes-based schemes
- Agreements are more likely to succeed if the consequences for pricing and reimbursement are set out clearly in advance, preferably in a written agreement

Conclusions on Outcomes-Based Agreements

- They are clearly worth considering when the conditions are right
- However, the devil is in the detail, so payers and manufacturers need to consider carefully whether an outcomes-based agreement is the best way forward

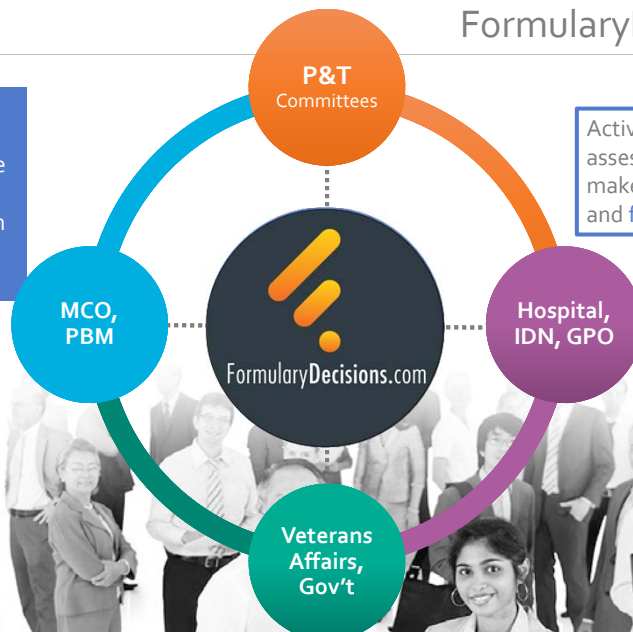
Environmental Scan - Payer Perspective

Elizabeth Sampsel, Pharm.D, MBA, BCPS
Vice President, Payer Strategy and Relations
Dymaxium

The central platform that connects PAYERS/health care decision makers (HCDM) to the **evidence, resources**, and their **peer community**, helping them work more effectively and collaboratively.

Active evidence review and assessment of product value to make informed reimbursement and formulary decisions.

A closed payer only environment.



**1600+ US
PAYERs/HCDMs**

3rd party Product Reviews
and HTA Insights

150K+ Evidence Links

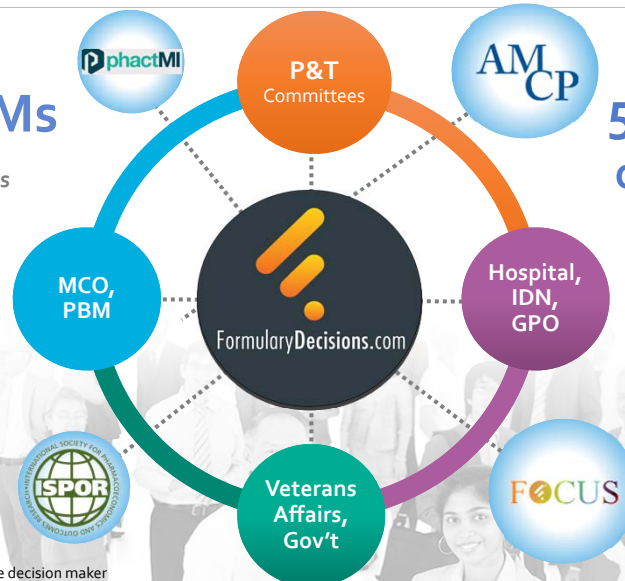
Newly approved products
and Pipeline analysis

**86% Covered
lives**

Manufacturer eDossiers

Modeling Tools

HCDM= health care decision maker



**500+ PAYER
organizations**

P&T Formulary Tools

P&T Monographs
and Presentations

**3000+
future
PAYERS/
industry**

DCR and Evidence
Comparison

- Purpose: To better understand the payer perspective on the current landscape of outcomes-based contracting.
- N = 128
- Survey timeline: 3/21/2018 to 4/19/2018
- Respondents:
 - Managers/Supervisors, Directors and above (39%).
 - Represent health plans and PBMs (72%)
 - Organization covers greater than 1 million lives (44%).
 - Primarily represent Commercial (73%), Medicare (63%) and Medicaid (52%).

Contract Operations – Payer Perspective

- 68% said that their organization would consider entering into an outcomes-based contract (OBC) with a manufacturer. (N=127)
- 1/3 of respondents have direct experience with OBCs (N=112)



(N=33)

Contract Operations – Payer Perspective

- Respondents thought that the criteria that should be included in OBCs are: (N=110)
 - clinical (99%)
 - cost (93%)
 - savings (80%)
- 63% thought that both manufacturers and payers should be responsible for administrative costs involved with the set up and/or monitoring of OBCs. (N=110)

Pros and Cons – Payer Perspective

- Major attractions of outcomes-based contracts for payers included: (N=100)

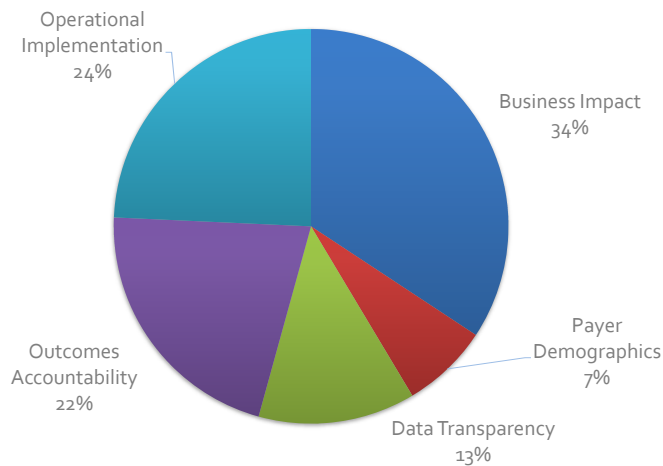
Benefit Formulary Reduced Monitoring Results Increased Rebate
Effective Guaranteed Rebates Value Money Cost Healthcare
Outcomes Performance Drugs Hold Manufacturers Risk
Return on Investment Products Appropriate Therapies Quality

- Major concerns of outcomes-based contracts for payers included: (N=100)

Reporting Management Increased Metrics Patient Providers
Data Collection Resource Contracts Results
Outcomes Risk Cost Market Share Administrative Hard
Track Money Drug

Manufacturer Considerations – Payer Perspective

- What is the most important thing for a manufacturer to consider? (N=100)



Environmental Scan – Payer Respondents

- Key takeaways:

- Payers are anticipating entering into more outcomes-based contracts with manufacturers in 2018, yet not all payers have experience in this area.
- While payers feel that these contracts can be attractive (such as paying for value), they also express concerns (such as data monitoring and reporting).
- Payers identified these important factors for manufacturers to consider when proposing an outcomes-based contract: business impact, operational implementation and outcomes accountability.

Outcomes-Based Contracting

Lessons Learned

James T. Kenney, RPh, MBA
Manager, Specialty and Pharmacy Contracts
Harvard Pilgrim Health Care

Key Drivers for Health Plans

- Proof of Efficacy with Outcomes Performance
- Appropriate Product Access
 - Limit Products to a Specific Population
 - Reduce Financial Risk
- Increase Rebates/Savings
- Reduce Overall Costs
- Achieve Desired Outcomes



Measurement Challenges

- Metrics – Medical and Pharmacy Claims
- Realistic Timelines – 3 months - 2 years
- Data Collection Method
 - Plan to Manufacturer
 - Third Party Vendor
- Validation Options/Analytics
 - Density of Data
 - Timing for Claims Adjudication
- Health Insurance Portability and Accountability Act (HIPAA)

Barriers to Success

- Information Technology Limitations
- Transaction/Administrative Costs
- Agreement on the Outcomes Measure
- Poor Adherence Rates
- Lack of Sufficient Outcome Results
 - Lab Value Limitations
 - Number of Valid Patients
- Realization of Financial Savings/Benefits

Success Metrics

- Event Avoidance
 - ER Visits/Hospitalizations
 - Office Visits
 - Ancillary Resource Utilization
- Reduction in Medical or Pharmacy Expenses Long Term
- Reduced Disability Claims
- Decreased Absenteeism

Long Term Goals

- Multiple Outcomes Contracts for Competing Therapies
- Use Results to Make Formulary Decisions/Changes
- Assess True Benefit of Treatments
- Get Value in Return for Pharmaceutical Dollar Spend

AMCP | Academy of
Managed Care
Pharmacy*

CASE STUDY: AMGEN AND HARVARD PILGRIM OUTCOMES-BASED CONTRACT

TOM RICE
VICE PRESIDENT, VALUE & ACCESS

AMCP WEBINAR

AMGEN
Pioneering science delivers vital medicines™

SPECIALTY DRUGS REPRESENT ABOUT ~43% OF ALL DRUG SPENDING; BUT GROWTH IS OUTPACING TRADITIONAL MEDICINES

In 2017, specialty spend is growing at 9.3% while traditional is declining at 4.0%



Source: IQVIA, National Sales Perspectives, March 2018

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INNOVATIVE MEDICINES: PART OF THE SOLUTION

UNITEDHEALTH GROUP

Study: New Cancer Care Payment Model Reduced Health Care Costs, Maintained Outcomes

Journal of Oncology Practice publishes results of UnitedHealthcare pilot of new cancer care payment model that rewards quality, not quantity, achieving lower costs while maintaining excellent patient care

MINNETONKA, Minn. (July 08, 2014) — A new cancer care payment model that rewards physicians for focusing on best treatment practices and health outcomes rather than the number of drugs they prescribe resulted in significant cost savings without affecting the quality of care.

Sources: 1. Roebuck C, et al. Medication Adherence Leads to Lower Health Care Use And Costs Despite Increased Drug Spending. *Health Affairs*. 2011;30(1):91-99. 2. Congressional Budget Office. Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services. Report, November 29, 2012. www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf. Accessed 7/17/17.

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BALANCING SCIENTIFIC INNOVATION & AFFORDABILITY

By engaging in value-based programs with stakeholders across healthcare systems, we can identify mutually beneficial opportunities to reduce costs, improve care and enhance patient experiences worldwide.

What are value-based programs?



Partnerships & Projects

Collaborations that evaluate data and science to gain insights to better inform, and potentially improve, patient outcomes and experiences



Contracts

Product-specific financial arrangements that may lower the net price of the product based on specified performance, outcomes or risk-sharing



Globally, Amgen is engaged in about 75+ distinct value-based programs.

These programs span disease state collaborations, risk-sharing, cost-cap guarantee, pay-for-performance and outcomes-based agreements. We're building a core capability in this area to use international and local experience to create more value-based partnerships in the future.

REPATHA® OUTCOMES-BASED REBATE (OBR) CONTRACT PLATFORM



Patient-focused risk-based contracts

- Contract requires both medical and pharmacy inputs:
 - Time on therapy
 - Event for the patient



Simple value proposition for the plan

- Offers employer groups and downstream plans access to innovative medicines and potentially manage costs

AMGEN AND HARVARD PILGRIM AGREE TO FIRST CARDIOVASCULAR OUTCOMES-BASED REBATE CONTRACT



Harvard Pilgrim Refines the Utilization Management Criteria to Help High-Risk Cardiovascular Patients Access Repatha; First-of-its-Kind Contract Will Demonstrate Value to Harvard Pilgrim Plans for Cardiovascular Patients



Michael Sherman,
Chief Medical
Officer, Harvard
Pilgrim Health
Care

"Repatha has been shown to have a significant outcome on reducing cardiovascular morbidity for high risk individuals with elevated LDL cholesterol... **We hope to negotiate more contracts of this type, in which a pharmaceutical company truly has 'skin in the game'** going forward. This agreement is the first we have signed in which there is a full refund of all costs related to the medication if the patient experiences a heart attack or stroke while taking it."¹



Joshua Olman,
SVP, Global
Value, Access &
Pricing, Amgen

"Given the urgency to reduce LDL cholesterol in patients at high risk of cardiovascular events, we value our relationship with leading health plans like **Harvard Pilgrim who have worked with us to refine their utilization management criteria to accelerate access for their high-risk patients.** We look forward to partnering with other payers to create similar outcomes-based contracts for Repatha."²

Sources: 1. Harvard Pilgrim Health Care. (2017). *Harvard Pilgrim signs second groundbreaking contract with Amgen for Repatha* [Press release]. Retrieved from <https://www.harvardpilgrim.org/publicnews-detail?nid=1471912937208>. 2. Amgen. (2017). *Amgen and Harvard Pilgrim agree to first cardiovascular outcomes-based refund contract for Repatha® (Evolocumab)* [Press release]. Retrieved from <http://www.amgen.com/media/news-releases/2017/05/amgen-and-harvard-pilgrim-agree-to-first-cardiovascular-outcomes-based-refund-contract-for-repatha-evolocumab>.

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ADDRESSING CHALLENGES; DEPENDS ON SITUATION

Challenges

Defining appropriate goals, objectives and performance benchmarks

Data insufficiency, challenging to capture timely, accurate and reliable clinical data on membership

Shorter vs. longer time horizons

Population dynamics

Account team's fear of false starts

Getting comfortable with potentials risks and failure

Managing input and feedback across multiple internal workstreams and functional groups

Cost and resource to establish contracts

Solutions

Repatha endpoints are clear

Contract only requires measurable inputs: time on therapy and event for the patient

Repatha data supports a 1-2 year timeframe

Clear patient target: diagnosis, LDL and treatment history

Senior level engagement; timeframe

Clear internal champion and financial impact profiled

Early identification of internal quarterback

Recognize this is incremental work

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SUMMARY AMGEN OBJECTIVE: ENSURE ACCESS FOR PATIENTS TO OUR MEDICINE

- Align around advanced methods and approaches to value-balanced conversation
- Outcomes contracts can be part of the discussion, but early days
- Challenges are real, engage your functional partners early and often
- Choose your partner thoughtfully, be ready to solve problems together



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Discussion & Questions

AMCP eDossier System
FormularyDecisions.com

dymaxium 



Thank you for participating!

For any questions, contact esampsel@dymaxium.com