Risk-Sharing Agreements in the U.S.: Trends, Barriers & Prospects
Speakers

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How to Ask a Question

To Submit Questions

Submit questions and comments via the Questions section in the Control Panel
In the News

“The Pink Sheet” Daily

Amgen's Repatha Pricing Deal With Harvard Pilgrim Hinges On Results, Utilization
By Scott Steinke  Posted: November 9 2015 4:55 PM
Additional discounts kick in if patients don't achieve same LDL cholesterol reduction seen in clinical trials and if utilization is excessive.

HHS.gov

HHS Announces Forum on Pharmaceutical Innovation, Access, Affordability and Better Health
The forum will include a discussion of possible new payment models that pay for a drug based on how effective it is shown to be.
# Risk-Sharing Agreements Can Be Win-Win

<table>
<thead>
<tr>
<th>Category</th>
<th>Benefits</th>
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<tbody>
<tr>
<td>Payers</td>
<td>• Reduce uncertainty regarding clinical value, performance and financial impact of a new product</td>
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<tr>
<td>Manufacturers</td>
<td>• Differentiate and demonstrate the value and effectiveness of their product</td>
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<td>Consumers</td>
<td>• May gain earlier/easier access to treatments</td>
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<td>Society</td>
<td>• Moves towards value-based purchasing</td>
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Findings

• There is limited RSA activity in the U.S.
• Interest among payers and manufacturers is strong
• Numerous barriers exist
• Changing environment may lead to more RSAs
Study Components

- University of Washington Database Review
- Literature Review of Taxonomies
- Interviews
- Brief Online Survey on Barriers
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Performance-Based Risk-Sharing Arrangements: A Variety of Names

- Risk-sharing Agreements
- Managed Entry Agreements (MEA)
- Outcomes-Based Schemes
- Coverage With Evidence Development (CED)
- Access With Evidence Development
- Patient Access Schemes (PAS)
- Conditional Licensing
- Pay-for-Performance Programs (P4P)
- And Others?
PBRSA/Risk-Sharing Agreements—Five Key Elements

1. There is a program of data collection.
2. This data collection is typically initiated during the time period following the regulatory approval.
3. The price, reimbursement, and/or revenue are linked to the outcome of this program of data collection (explicitly or implicitly).
4. The data collection is intended to address uncertainty.
5. These arrangements provide a different distribution of risk.

Source: Garrison et al., 2013
Performance-Based Schemes by Year

Total Schemes: 292

Source: UW PBRSA Database, Oct. 2015
Performance-based Schemes by Country

Total Schemes: 292

Source: UW PBRSA Database, Oct. 2015
Taxonomy

Performance-based schemes between health care payers and manufacturers

Non-outcomes based schemes
- Population level
  - Market share
  - Price volume
  - Utilization caps
  - Manufacturer funded treatment initiation
- Patient level

Health outcomes-based schemes
- Conditional coverage
  - Coverage with evidence development (CED)
  - Conditional treatment continuation (CTC)
- Performance-linked reimbursement (PLR)
  - Outcomes guarantee
    - Only in research
    - Only with research
      - Clinical Endpoint
      - Intermediate Endpoint
  - Pattern or process of care
Junuvia and Janumet (Merck) and CIGNA for Diabetes

- Scheme has three core components:
  1. CIGNA assesses the blood sugar levels (A1c lab values) for patients on any oral antidiabetic medications.
     - If the A1c values, in aggregate, improve by the end of the agreement period, the discounts will increase by a pre-agreed amount.
  2. CIGNA uses claims data to determine if patients are taking Januvia and Janumet as prescribed.
     - Merck will further increase the discounts.
  3. Better placement on CIGNA’s formulary + lower copayment versus that for other branded drugs.
Junuvia and Janumet (Merck) and CIGNA for Diabetes

• In 2010, CIGNA announced positive outcomes from the diabetes support program:
  – patients’ blood sugar levels were reduced by more than 5%.
  – individuals who participated were more likely to control their blood sugar than those who did not participate in the program, 87% of patients who took Januvia or Janumet took their medications correctly.

• According to Dr. Jeffrey Kang, CIGNA’s Chief Medical Officer, “what makes this unique approach so successful is that everyone’s incentives line up behind helping customers keep their diabetes under control”
Risedronate (Proctor & Gamble, Sanofi-Aventis) and Health Alliance for Osteoporosis

• Clinical trials of risedronate failed to show a statistically significant reduction in non-spinal fractures, whereas some competitors have demonstrated this benefit in their trials.
• Two companies agree to reimburse the insurer for the costs of treating non-spinal fractures suffered by patients who consistently take their medications.
• First published example of a manufacturer agreeing to cover the cost of disease-related sequelae as opposed to discounting or refunding the cost of their product.
• Hip and wrist fractures cost approximately $30,000 and $6,000, respectively.

Risedronate (Proctor & Gamble, Sanofi-Aventis) and Health Alliance for Osteoporosis

• Reimbursement rate for non-spinal fractures was 79% lower than the maximum outlined in the agreement in the first nine months.

• *Christina Barrington, Health Alliance’s pharmacy director, stated,* “the Fracture Protection Pilot Program was launched to highlight the effectiveness of Actonel through medical outcomes reimbursement. Initially, we had hoped that this program could lower insurance costs not only for Health Alliance, but for our subscribers as well. As a result, Health Alliance independently chose to help our subscribers by lowering their costs. We look forward to continuing and building upon this successful pilot."

• *Raulo Frear, Pharmacy Director of Regence Health Plan, stated,* “we have reviewed the Fracture Protection Program and are enthusiastic about the opportunity to partner with the makers of Actonel to tie expected outcomes to drug utilization in our patient population. This program is an example of an innovative way plans and pharmaceutical manufacturers can partner and bring value to our plan sponsors.”
U.S. Results

- **CMS and CED:**
  - Data used to inform two policy decisions
  - Other studies failed to be designed, funded, or implemented due to costs, measurement issues, and legal challenges

- **Cigna and Januvia/Janumet:**
  - Blood glucose levels improved by more than 5 percent
  - Adherence was 87 percent for patients taking Januvia or Janumet

- **Health Alliance and Actonel**
  - Reimbursement rate 79% at 9 months
  - Lower than contract maximum
  - Incidence of non-spinal fractures consistent with clinical trial data
U.S. Database Review: Take-Home Points

• Most likely to target high-cost disease areas and expensive drugs.
• CED is a mechanism to compel additional data generation to resolve existing uncertainty.
• Successful arrangements can provide benefits for payers, manufacturers, and patients. Example: Januvia/Janumet
• Arrangements should address an agreed-upon uncertainty. Example: Actonel and non-spinal fractures
• Arrangements may link to disease and/or treatment related costs to avoid issues related to drug price. Example: Actonel
• Arrangements should use existing data systems when possible. Example: Januvia/Janumet
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Key Themes from Interviews (1)

- 14 one-hour—semi-structured interviews—manufacturers, payers, experts
  - 5 US Pharma, 2 EU Pharma
  - 4 US Payer, 1 EU Payer
  - 2 Experts

- RSA Types and Trends:
  - There is an increasing interest in financial deals and mixed interest in outcomes-based deals. Outcomes-based agreements are difficult to execute and transaction costs are high, whereas financial agreements are easier to implement. Simple agreements work well.
Key Themes from Interviews (2)

Logistics:

• Payers only have the bandwidth to do a few outcomes-based deals simultaneously due to burden of data collection.

• Payers are willing to have multiple agreements with companies for competing products (more likely to be feasible for bigger plans).

• Medium-term deals (2-4 years) are necessary if making an investment in evidence development.

• Data collection is typically the responsibility of payers.
Key Themes from Interviews (3)

Reasons to Use RSAs:

- Depends on the product, disease area, and data infrastructure.
- Differentiate their product and demonstrate product value.
  - Usually done for newly launched products.
  - Some challenges exist but where there is still evidence of clinical benefit.
  - Draw the link between efficacy and effectiveness, and/or demonstrate comparative effectiveness.

“If somebody can help reduce risk, take some of the variability out of the equation, or can actually help you manage some of those medical costs, then that's very attractive and that's more attractive than just getting a discount. It allows us to actually get experience using the medication or our members using the medication but it takes some of the risk off us.” - US Payer
Key Themes from Interviews (4)

What works:

• It may be easier to measure outcomes for drugs that are administered in settings where there are more immediate clinical data available (e.g., hospital settings) or where drugs are administered in person. Complex outcomes might require an active provider (e.g., patient-centered medical home) to measure.

• Clinical outcomes deals are most successful where the infrastructure is robust to collect clinical data (e.g., single payer/closed settings - hospitals, Kaiser, integrated delivery networks).

• Manufacturers should be able to predict the outcomes of the agreement and assess the risk they are taking on (e.g., what level of compliance is required, to what extent clinical trial population differs from the real-world population).

“There are very few disease areas where these make sense. Need a very severe, acute condition where you can then see response within 3-6 months.” – EU Pharma
Key Themes from Interviews (5)

What doesn’t work:

• Having multiple products as part of a single agreement is a challenge: difficult to track and execute.

• Payers often do not have the systems/data to support agreements in which the manufacturer pays for non-pharmaceutical expenditures.

• Population-based agreements are risky for manufacturers because there are many unknowns around compliance, prescribing, etc. Don’t want to take on risk when you cannot control how the drug is being prescribed/used.

• It is critical that both parties trust the data; if one party tries to poke holes in the data after it is collected, this will affect the ability to have future arrangements.

“Setting up individual agreements with all these individual players, and without the benefit of large populations, economics of scale, or large datasets, it is very difficult to enact a financial agreement that makes sense without a straightforward rebate. Or if you try to get into the more complicated clinical outcomes-based agreements, payers just aren’t sophisticated enough at this point to have the kind of databases and track and follow patients with enough time to be able to make those agreements reasonable. It’s a combination of the fragmentation of the market but it’s also a very fluid market as well.” –US Pharma
Key Themes from Interviews (6)

Potential in the U.S.

- There are opportunities for RSAs in the U.S.
- The ACO setting could be appealing for risk-sharing. But maybe timing is not right for ACOs; it is too early as they are still being established.
- Medicaid best price is a limiting factor.
- In the U.S., the decentralized system poses a challenge: requires individual agreements with many payers. Agreements may be most likely with large, national payers and ACOs.

“They could evolve in an interesting way. If in fact systems of care and payment reform change, if the ACO concept catches on, if there are more and more integrated delivery networks, risk-bearing entities could change the landscape and make risk-sharing a much more appealing proposition, particularly if we are able to get past some of the constraints from both the compliance side of things as well as the best price issues.” – US Pharma
Potential Barriers to RSA Use in U.S. (1)

1. Significant additional effort required to establish/execute RSAs (e.g., compared to traditional rebates/discounts)

2. Challenges in identifying/defining meaningful outcomes
   1. Challenges in measuring relevant real-world outcomes
   2. Data infrastructure inadequate for measuring/monitoring relevant outcomes
   3. Difficulty in reaching contractual agreement (e.g., on the selection of outcomes, patients, data collection methods)

*Source: Garrison et al., 2015*
Potential Barriers to RSA Use in U.S. (2)

6. Implications for federal (Medicaid) best price

7. Payer concerns about adverse patient selection

8. Fragmented multi-payer insurance market with and significant patients switching among plans

9. Challenges in assessing risk upfront due to uncertainties in real-world performance

10. Lack of control over how product will be used

11. Significant resources and/or costs associated with ongoing adjudication

Source: Garrison et al., 2015
Survey Findings of Top Barriers to the Use of RSAs in the U.S.

Source: Garrison et al., 2015
Summary: U.S. Perspective

- There is continued and even growing interest on the part of both manufacturers and payers.
- Yet, the number of new agreements is still small—mostly exceptional situations.
- There is a lot of talk, but improved data systems and changed incentives (via health reform and ACOs) may generate more action.
ISPOR TASK FORCE REPORTS


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Conclusion: Findings and Recommendations (1)

1. PBRSAs are an understandable response to market forces.
2. In addressing a specific uncertainty, PBRSAs should consider two design options:
   – Utilization management at the patient-level
   – Research-based CED
3. PBRSAs using CED can be only *with* research (OWR) or only *in* research (OIR).
   – But should follow internationally relevant good research practices.
Conclusion: Findings and Recommendations (2)

4. Evidence from PBRSAs is a global public good.
   – Value is enhanced if good research practice is followed.

5. Evidence is costly.
   – Good research design should match the design to the key uncertainties.

6. There are substantial barriers to forming PBRSAs.
   – Costs of negotiation, evaluation, and monitoring can be high.
   – Good governance is essential
Conclusion:
Findings and Recommendations (3)

7. As a public good, PBRSAs are under-utilized. Public authorities should:
   – Disseminate research results
   – Incentivize private parties to use PBRSAs

8. Societal desirability of a PBRSA is a value-of-information question.
   – Evaluation should be multidimensional.
   – These investments in evidence generation affect static and dynamic efficiency.

9. There is a dearth of ex post evaluation of PBRSAs.
   – Good practice should include evaluation plans.
Dr. Ed Pezalla
Vice President, Pharmaceutical Policy and Strategy, Aetna

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What issues will Risk-Sharing Arrangements address?
- Uncertainty
- Place in Therapy

What are the primary barriers to implementing RSAs?
- Transaction Costs
- Data Availability
- Size of Impact
- Issue of Locus of Control
Addressing Uncertainty

Risk-sharing makes the most sense when it addresses issues of uncertainty

Types of Uncertainty
- Long-Term Safety
- Long-Term Outcomes
- Effect on Individual Patient
- Changes in Behavior (Adherence)
- Impact on Utilization And Costs
Addressing Barriers

Primary barriers

- Transaction costs
- Data Availability

Potential Solutions

- Re-usable platforms
- Cooperation with providers for data
- Policy to address Medicaid best price issues
- Economic and financial incentives to improve control
  e.g.
  - adherence/persistence
  - Proper use and dosing

- Size of Impact
- Issue of Locus of Control
Total Outcomes
Total Cost and Improvements in Care Involving Providers

Four Ps
- Patient
- Provider
- Payor
- Pharma

- Create partnerships
- Put enough money on the table
- Share data
- Address the big issues
Ask Away!

To Submit Questions

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Q&A Session

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Thank You!

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