ABSTRACT

Objectives: To assess and analyze the number, type, and extent of risk-sharing agreements worldwide that based on outcomes.

Methods: A structured literature review using predefined search criteria was conducted to identify references to, or descriptions of, health-outcomes-based risk-sharing arrangements within peer-reviewed and trade publications between the years of 2000-2009. The identified publications were categorized by strength of evidence (i.e., systematic or non-systematic), and then stratified by type of agreement, technology, and companies involved within the agreement. Analysts have completed to demonstrate commonalities among identified agreements in order to design unique success strategies.

Results: A total of 61 abstracts were reviewed of these articles. The review literature suggests that many risk-sharing arrangements are not published and that few are very similar in design, scope, and intent. The search resulted in 61 abstracts which identified 8 individual published risk-sharing schemes. While all identified agreements involved sharing (effectiveness) and expense (costs), specific outcomes varied widely in design, scope, and intent. The search literature will contribute to the trajectory of best practices will be of interest to all future outcome and cost analyses for similar agreements.

Conclusions: Health outcomes-based reimbursement agreements offer the potential for both benefit and limitation to manufacturers and payers alike. The ability to cross-country within this field to-date and attempt to offer trends towards best practices will be of interest to all future outcome and cost analyses for similar agreements.

RESULTS (CONT'D)

1. All identified schemes showed a link between improvements in health outcomes with cost-savings for the payer.
2. Definition of what was considered an improved health outcome, as well as the type of analysis, varied from one to improve the provision of clinical data and/or for the aggregation.
3. A list of these agreements by country is included in Table 1. Four examples are explored.

Table 1. Summary of Published Risk-sharing Schemes, by Manufacturer, Drug, and Country

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Drug</th>
<th>Outcome</th>
<th>Agreement Type</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biogen Idec</td>
<td>Janumet</td>
<td>Diabetes</td>
<td>Performance-based</td>
<td>US (CIGNA)</td>
</tr>
<tr>
<td>Merck</td>
<td>Januvia &amp; Janumet</td>
<td>Diabetes</td>
<td>Performance-based</td>
<td>US (CIGNA)</td>
</tr>
<tr>
<td>Pfizer</td>
<td>Rebif</td>
<td>Multiple Sclerosis</td>
<td>Performance-based</td>
<td>US (CIGNA)</td>
</tr>
<tr>
<td>Genentech</td>
<td>Erbitux</td>
<td>Multiple Myeloma</td>
<td>Performance-based</td>
<td>US (CIGNA)</td>
</tr>
</tbody>
</table>

REFERENCES

5. Merck entered into a more unusual arrangement with CIGNA for the diabetes drugs Januvia and Januvia. Merck agreed to pay a bigger discount if...
6. Patients were adherent and persistent with Janumet and Januvia.
7. Patients who failed to benefit from biologic therapies were expected to be offered an increase in volume sales, thereby making the agreement economically advantageous.
8. Novartis proposed taking on payment for bone fractures occurring while the patient is taking Actonel.
9. Qualifying patients (non-comorbid, no prior fractures, etc.) that have taken Actonel for six months could continue their treatment for another six months if annual bone density scan showed no further bone loss.
10. The manufacturers agreed to pay for any injections of Lucentis (ranibizumab) for wet macular degeneration (AMD) that exceeded the predicted 1.25 injections of the annual injection plan.

CONCLUSIONS

Risk-sharing agreements offer the opportunity for payers and manufacturers to share the cost of developing and post-approval trials to the benefit of the patients.

Linking outcomes to payments ensures that patients and payers are getting the most value possible for their money by paying for what works pharmaco-economic analyses are able to enter a marketplace while proving their drug's value in real-world settings.

Patient outcomes are not necessarily the same across the globe and manufacturers should consider other factors besides cost and effectiveness when evaluating the success of these agreements.

The literature has demonstrated that this trend is already growing in Europe and North America. Whether further understanding of the advantages of the schemes, they may also become more popular among those paying for new technologies.

The objectives of this study were to assess and analyze the number, type, and extent of risk-sharing arrangements worldwide that published an agreement.

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The literature review suggests that many risk-sharing agreements are not published and that few are very similar in design, scope, and intent. The search resulted in 61 abstracts which identified 8 individual published risk-sharing schemes. While all identified schemes involved sharing (effectiveness) and expense (costs), specific outcomes varied widely in design, scope, and intent. The search literature will contribute to the trajectory of best practices will be key to the long-term viability of these cost-outcome reimbursement efforts. Despite the heterogeneity of agreement type, methods, and goals, successful utilization of these agreements has been achieved and could potentially offer a guide for replication in future cases.

Examples

- Biogen Idec entered into an agreement with the US NHS for Lucentis for treat Age-related Macular Degeneration (AMD).
- Merck entered into a more unusual arrangement with CIGNA for the diabetes drugs Januvia and Januvia. Merck agreed to pay a bigger discount if...
- Patients were adherent and persistent with Janumet and Januvia.
- Patients who failed to benefit from biologic therapies were expected to be offered an increase in volume sales, thereby making the agreement economically advantageous.

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