Demystifying the U.S. Payer Mindset and Expectations

Our Rationale for this Study

A common question we hear in the pharmaceutical and biotech industry is:

Are manufacturers building the evidence that will allow them to succeed with payers? What do payers ultimately want to see in order to provide favorable access and reimbursement?

We also vividly remember panel discussions at industry conferences where manufacturers and payers were brought together for dialogue. It was evident that a major gap exists between what payers want and what manufacturers are willing and able to provide given the risks and costs involved!

As we stepped back and took a broader view, it became clear that there were some core issues that needed to be addressed by our industry as a whole. These are issues we encounter every day in our own work as we help our clients (manufacturers) develop the appropriate evidence they need to demonstrate the value of their products. We wanted to address these issues, holistically and candidly, to assess what payers truly want to see from manufacturers, across products and therapeutic areas. Our key questions were:

- What keeps payers up at night?
- What is the evidence – both clinical and economic – that payers want to see from industry?
- Are manufacturers meeting payer expectations?
- What risks, if any, do manufacturers face?
- Are payers interested in partnering with manufacturers to facilitate dialogue and the review process?
- What are best practices in manufacturer-payer collaboration as seen from the point of view of payers?

Energized by these questions, Trinity conducted quantitative and qualitative market research with U.S. payers, both commercial plan directors and advisors to the Centers for Medicare and Medicaid Services (CMS), to explore industry-wide trends. We were careful to position the work as unbiased, conducted by Trinity as a third party, and generalized across the industry. The results were enlightening. The findings validated many of our own internal hypotheses and also brought to light some new insights.

In this paper, we share some of the highlights from our research.

What Keeps Payers Up at Night?

When asked to describe their pain points and challenges, payers noted increasing costs (especially treatment costs), the Affordable Care Act (ACA), and specialty medications. Surprisingly, several payers said that determining coverage – their key function - is one of the major challenges for them!
Digging deeper, we found that payers’ concerns over increasing costs are comprised of several separate but related elements – the high cost of injectable biologics, increasing healthcare spend, and the increased costs associated with hospitalization. Changes brought about by the ACA – mainly the uncertainty about what it means for payers in the short-term – are a major issue.

Factors such as the aging U.S. population that drive costs up, or the limited availability of biosimilars, are not top concerns for payers as of yet.

What Evidence do Payers Want to See and How is Industry Performing?

Given this uncertainty and anxiety, payers say that they are turning to evidence. Payers report that large, head-to-head studies are of greatest value to them in assessing clinical outcomes, in addition to health economic models.

However, when it comes to delivering on these, payers believe that manufacturers fall short, making it hard for payers to make coverage decisions. Is the new product truly differentiated? What is its value add? How much better is it than currently available therapies? Are improvements medically meaningful? These are the questions with which payers are grappling.

While not performing poorly on any single dimension, manufacturers receive mediocre ratings from payers on average across all dimensions:

What Keeps Payers Up at Night?

In addition to rating the ACA as a significant concern, two-thirds of the payers interviewed report that the ACA has already had a major impact on their plan.

The nature of that impact (i.e., positive or negative and the degree of its effect) is still unclear to them, and that too is a source of stress. Their main concerns include:

- “Who is going to take care of the increasing number of patients with access to physicians?*
- “Who is going to pay for all of the patients who will have insurance?”

---

* Manufacturers did not score high marks on any of the items tested

**Neutral** Rating

While drug manufacturers invest significantly in KOLs and patient registries, payers note that they are less important.

**Important** Rating

Health economic modeling and clinical trial design elements are cited as the most important by payers.
Key concerns noted by payers in working with data from manufacturers include the perception of biased data, incomplete information, inappropriate comparators in clinical trials (placebo versus the standard of care) and the lack of differentiation.

With the cost of therapies and hospital readmission on the rise, payers express some frustration with the accuracy, thoroughness and transparency surrounding the data provided by manufacturers.

The Risk to Manufacturers: Unilateral Moves by Payers?

In response, some payers plan to take a unilateral and insular approach to new product reviews and policy determination, closing the window of opportunity for dialogue with manufacturers. Payers signal that in the future, they will implement (or step up) restrictions targeted toward delaying therapy use and set even higher thresholds for usage. A few mechanisms they will utilize include step edits, prior authorizations, electronic medical record (EMR) tracking, and more clinical pathways and guidelines as noted below:

Likelihood of Implementation in Response to Market Challenges*

<table>
<thead>
<tr>
<th>Market Challenge</th>
<th>Likelihood Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased utilization requirements for expensive therapies (e.g., Prior Authorization, Step Edits, etc.)</td>
<td>7.2</td>
</tr>
<tr>
<td>EMR tracking to optimize healthcare utilization</td>
<td>7.1</td>
</tr>
<tr>
<td>Implementation of additional clinical pathways and guidelines</td>
<td>6.9</td>
</tr>
<tr>
<td>Partnering with a long-term care or medical home facility</td>
<td>5.6</td>
</tr>
<tr>
<td>Offering additional co-insurance to your members</td>
<td>5.5</td>
</tr>
<tr>
<td>Greater collaboration with manufacturers</td>
<td>5.4</td>
</tr>
</tbody>
</table>

*Ratings were given separately in response to 3 market challenges (i.e., changing healthcare environment, controlling expensive pharmaceutical therapies and biotech products, coverage of therapies for diseases with large patient populations) and are reported on aggregate above.

In interviews, payers also mention mandating additional paperwork and in general, creating a hassle-factor, as a tool to control utilization. The lowest ranking payer response to likely action in the future is greater collaboration with manufacturers, a response we find troubling. In conversation, payers explain that this is largely the result of the historical relationship, where manufacturers are not traditionally looked upon as partners. That said, they recognize the need for a partnership, or at least a two-way exchange given that these challenges will persist and will need solutions.

There has not been much dialogue because currently the message is not clear and poignant – but if it were, we would open our doors more readily!

We need to work on examples where everyone wins – industry, payers and the patient.
How Do Manufacturers Overcome These Formidable Barriers?

Trinity’s position as a consultant to leading biotech and pharmaceutical developers uniquely positions us to help our clients navigate these challenges and dilemmas and build the evidence payers need, while being cognizant of manufacturers’ resource challenges and appetite for risk. Through our work, and in this research, we have uncovered what payers want and what manufacturers can do to better engage with payers – both in terms of process and content. Payers in this research confirm our belief. They are looking for the following “best practices” from industry:

<table>
<thead>
<tr>
<th>The What</th>
<th>The How</th>
</tr>
</thead>
<tbody>
<tr>
<td>Craft a clear-cut and well defined story</td>
<td>Payers need to justify the value of new therapies. They want manufacturer input on the key benefits of a new product, its differentiation, and its placement in the clinical algorithm</td>
</tr>
<tr>
<td>Define the value proposition and the target audience</td>
<td>Payers are looking for the “hook” that gives novel entrants an edge; manufacturers need to focus on illustrating that key differentiation, in concise and transparent summaries</td>
</tr>
<tr>
<td>Commit to transparency</td>
<td>Payers explain they “don’t want to be sold” on a therapy; instead, they want to understand “where to use it and for whom.” Being the clinical expert and providing this information scientifically will elevate the status of manufacturers</td>
</tr>
<tr>
<td>Be an educator</td>
<td>Payers are receptive to engaging with clinical and scientific leads or medical science liaisons, more so than the traditional sales rep messenger</td>
</tr>
<tr>
<td>Communicate through a different messenger</td>
<td></td>
</tr>
</tbody>
</table>

By understanding the issues from the payers’ as well as the manufacturers’ perspective, Trinity can help manufacturers build the type of evidence that interests and motivates payers. Specifically, this entails finding that optimal common ground between what payers are looking for (how the new product will improve the clinical care they can offer to patients, at reasonable cost) and what manufacturers are looking for (how to position their product for success at an optimal risk-reward ratio).

About Trinity Partners

Trinity Partners is a global life sciences strategy consulting firm. We provide our clients with the vision, thoughtful groundwork and robust evidence they need for appropriate decision-making. In the past 5 years, Trinity has completed over 60 Payer / Market Access studies and dozens of Health Economic and Outcomes Research engagements to help clients generate the insights needed to appropriately position their products in the market as well as generate the evidence needed to support coverage and reimbursement for their products.

Contact Us

Please contact us the next time you need a partner for the following types of services:

- Systematic Literature Reviews
- HEOR Models
  - Burden of Illness
  - Cost-Effectiveness Analyses
  - Budget Impact Model
- Claims Database Analysis
- Chart Audit Studies
- Primary Market Research with Payers, Physicians and Patients
- Strategic Pricing and Contracting
- Value Presentation/Messaging

Please visit us at: www.trinitypartners.com

Herman Sanchez  
Partner  
hsanchez@trinitypartners.com

Neal Dunn  
Partner  
ndunn@trinitypartners.com

Fotios Kokkotos  
Partner  
fkokkotos@trinitypartners.com

Jillian Godfrey Scaife  
Principal  
jscaife@trinitypartners.com

Nandini Hadker  
Senior Consultant  
nhadker@trinitypartners.com