Payer Preferences Around Manufacturer Provided Evidence and Engagements in the US

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Introduction

To standardize and support communication of evidence, different regulations and guidance have been put into place in the US, such as the Pre-approval Information Exchange (PIE) Act of 2022. The PIE Act was enacted in an effort to improve communication of evidence on the value of new pharmaceuticals in the US, allowing manufacturers to proactively provide US payers with health care economic and scientific information about products with health payers prior to US Food and Drug Administration (FDA) approval. As both manufacturers and payers continue to adapt to this new mechanism for information sharing, uncertainties around how payers' views of manufacturer-submitted information is changing. With this, traditional manufacturer approaches to evidence and associated engagements often no longer fit the needs of payers, and additional research is required to better understand these evolving needs.

Objective

The objective of this primary research study was to evaluate diverse payer organization stakeholder perspectives around manufacturer-provided evidence and information-sharing engagements.

Methods

In May 2024, we recruited experienced stakeholders from US payer organizations via our Petauri Payer Network, inviting them to participate in an online quantitative and qualitative survey. Inclusion criteria for the survey included: Currently based in US, current or former US payer, at least 5 years of experience as payer or actuary, and a current or former voting member or participant on their organizations' Pharmacy and Therapeutics (P&T) committee. Within the survey, we explored 12 key themes, consisting of 53 questions. We conducted descriptive statistics and contextual analyses. Participants were provided with an honorarium for participation in the 30-minute survey based on fair market value.

Figure 1: Value of information from a manufacturer prior to formal drug approval

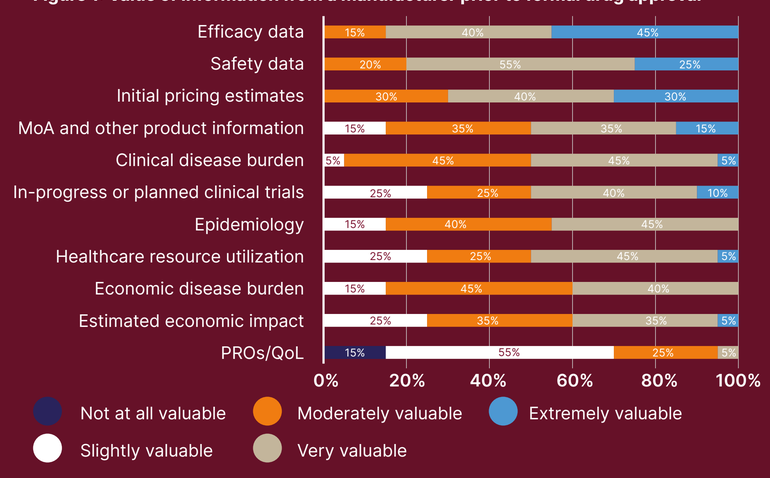


Figure 2: Preferred method(s) of receiving PIE from manufacturers

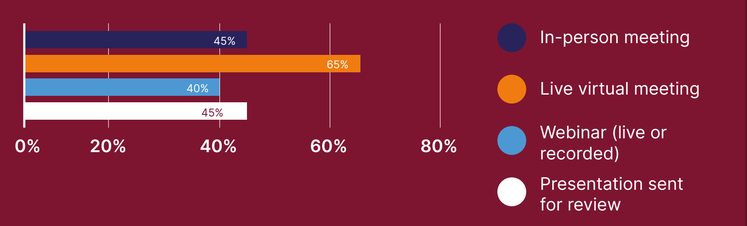


Figure 3: Perceived importance of types of evidence from a manufacturer following FDA approval in supporting coverage determinations and formulary placement

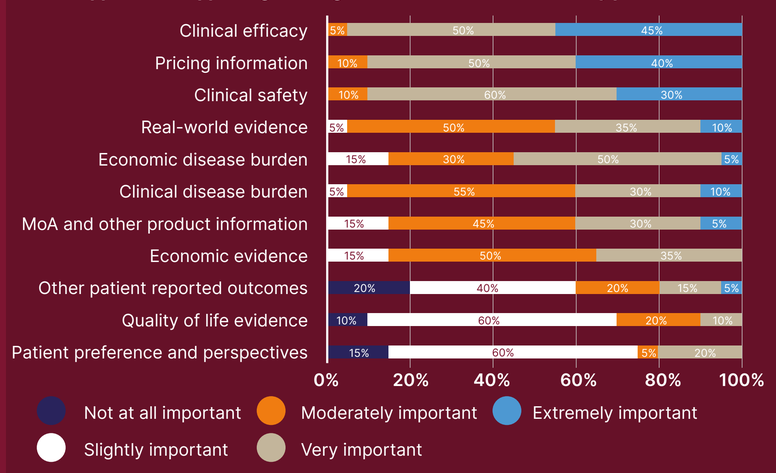


Figure 4: Reasons for low level of trust in manufacturer-developed health economic models

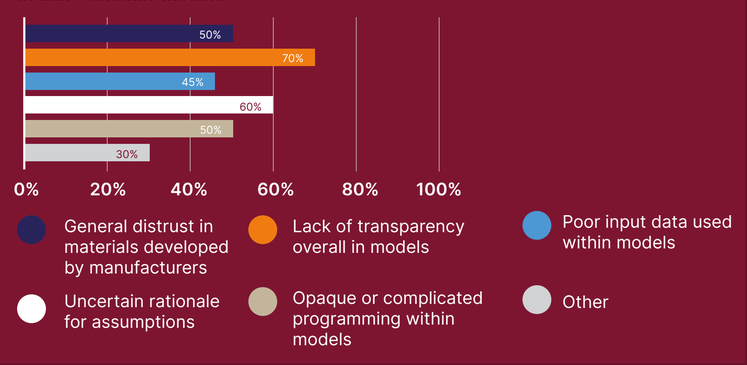
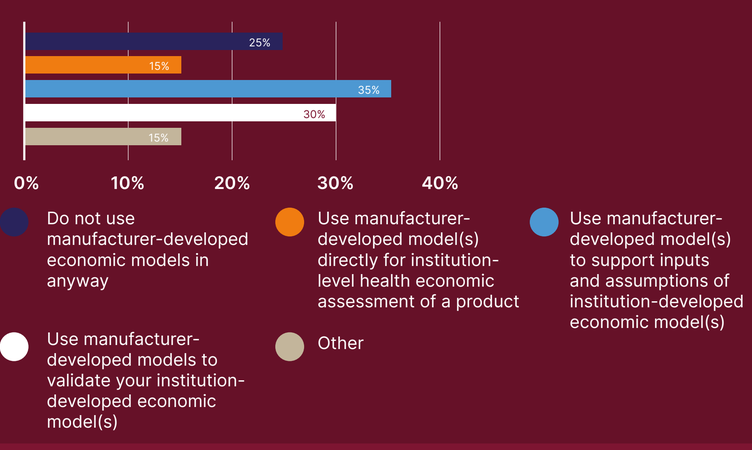


Figure 5: Cited uses of manufacturer-developed health economic models



Results

The survey included 20 participants (4 medical directors, 11 pharmacy directors, 4 industry/trade relations professionals, and 1 actuary), who Participants represented national and regional Managed Care Organizations (MCOs), Pharmacy Benefit Managers (PBMs), and Integrated Delivery Networks (IDNs). Overall, 80% of participants reported 15 or more years at payer organizations, with 75% of participants were currently in role. Most (87%) of the pharmacy and medical directors were voting members in their organization's P&T committee, with the remaining 13% serving as non-voting P&T members.

Within the survey, we explored payer preferences in manufacturer engagement leading up to, and after product launch. Before product launch, the most valuable manufacturer-provided evidence for payers was efficacy (weighted average: 4.30/5.0), safety (4.10), and initial pricing estimates (4.0) (Figure 1).

Regarding preferences around timing of pre-approval information from manufacturers, 45% of payers surveyed preferred receiving this information 0–6 months prior to launch, and 40% preferred to receive this information 6–12 months prior to launch. With this, some payers noted that longer time is more important if the product will have a large market impact (e.g., large patient population or large budget impact).

When asked about method of delivery of pre-approval information, most payers (65%) shared a preference for receiving this information via live virtual meetings, with others sharing interest in in-person meetings, presentation sent for review, and/or webinars (live or recorded) (Figure 2).

Most payers (85%) shared that PIE with manufacturers 'often' or 'sometimes' meets their needs for information prior to formal product approval. On opposite ends of the spectrum, no payers surveyed believed that these 'always' or 'never' meet their needs, highlighting that these presentations can vary in their level of support toward addressing pre-launch informational needs.

Payers were also asked about the importance of different types of manufacturer evidence post-FDA approval in coverage determinations. Post-FDA approval, the most valuable manufacturer-provided evidence was efficacy (weighted average: 4.4/5.0), pricing information (4.3), and clinical safety (4.2) (Figure 3). This was largely consistent with perspectives shared about information shared prior to approval.

Evaluating perspectives around economic evidence and use in decision making processes, viewpoints also varied widely among respondents. With regard to manufacturer-provided health economic models, most participants had a low level of trust (45%) or moderate level of trust (35%).

Of those who answered no level of trust, low level of trust, or moderate level of trust in manufacturer provided economic models, the most common reasons cited were: lack of transparency overall in models (70%), uncertain rationale for assumptions in models (60%), opaque or complicated programming within models (50%), and a general distrust in materials developed by manufacturers (50%) (Figure 4).

Only 10% of participants shared that they 'frequently' or 'always' use manufacturer models, while only one-fifth of those surveyed stated they 'never' use manufacturer models.

When asked about how manufacturer-developed economic models are used, the most common utilization cited was to support inputs and assumptions of their own institution-developed economic models (35%), or to validate their own institution developed economic models (30%) (Figure 5).

Shifting from economic impact to pricing and negotiation strategies, payers shared mixed perspectives regarding level of interest in pursuing innovative contracting with manufacturers, ranging from low level of interest (25%) to moderate level of interest (45%) to high level of interest (30%).

The most significant limitations to innovative contracting were 'availability of evidence to track outcomes' (80%), 'availability of resources to analyze outcomes' (70%), 'uncertainty around perceived value' (65%), and 'concern with level of potential risk' (50%).

Conclusion

While payer trust in engagements and materials from biopharmaceutical manufacturers varies, there is a demonstrated and consistent need for high-quality evidence. Overall, both pre- and post-launch, payers are most interested in clinical efficacy and safety data, as well as pricing information.

Payers are open to engagement with manufacturers, especially when they can gain insights around potential product impact prior to launch. The importance of pre-launch engagement is elevated in products that may have a larger financial impact or larger eligible patient population.

Regarding evidence transparency, concerns still exist around manufacturer-developed health economic models. While these models have enormous potential to support discussions of economic impacts of a new product, US payers generally have a low level of trust due to perceived lack of transparency and unclear rationale for assumptions. Manufacturers need to continue to evolve their approach to support transparent and scientifically robust communication around not only the clinical value of products, but the economic impact as well.

Transparency, timeliness, and quality of information remain critical in payer-manufacturer engagements to facilitate patient access. Both manufacturers and payers must show flexibility and adapt to growing evidence needs to take advantage of the opportunities provided by evolving dynamics in the US, such as the PIE Act of 2022. It is critical to continue to evolve evidence transparency and communication between payers and manufacturers.

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Abbreviations

FDA: Food and Drug Administration
IDN: Integrated Delivery Network
MCO: Managed Care Organization
MoA: Mechanism of Action
P&T: Pharmacy and Therapeutics
PBM: Pharmacy Benefit Manager
PIE: Pre-approval Information Exchange