US PIE and AMCP dossiers: Payer preferences, best practice, and a comparison with global evidence dossiers

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Introduction

The US healthcare system is becoming increasingly complex, driven by a rapidly changing policy landscape, the emergence of innovative, high-cost therapies, and a shift towards value-based care.

As engagement between manufacturers and US population health decision-makers (PHDMs) evolves, it is important for manufacturers to understand payer perspectives on best practice for the development and dissemination of communication materials, including pre-approval information exchange (PIE) and Academy of Managed Care Pharmacy (AMCP) dossiers, from pre- to post-launch.

Our previous research highlighted that manufacturer pre- and post-approval AMCP dossiers are key evidence sources used by US PHDMs to inform formulary and coverage decision-making (1). Our current research builds on these insights, exploring US payer preferences and best practice for pre-approval product information.

We also expanded on our initial research to compare US and global communication materials, with the goal of highlighting considerations for global strategy.

Objectives

1. **Explore US payer perspectives on manufacturer-provided pre-approval product information and evidence to support formulary and coverage decision-making**
2. **Compare key features and requirements of US communication materials with those of global dossiers**

Methodology

In March 2025, stakeholders from US payer organisations were recruited. Eligibility criteria included current/former US payers currently based in the US, with at least 5 years' experience as a payer, and a current or former voting member or participant in their organisation's Pharmacy and Therapeutics (P&T) committee.

Participants completed a 30-minute online quantitative and qualitative survey that explored key themes around PIE and AMCP dossier timing and use, value, evidence priorities, and factors contributing to dossier impact and quality. Participants were provided with an honorarium for survey participation based on fair market value. Results were aggregated and descriptive statistics conducted.

Current and previous survey findings were used to inform a narrative comparison of key features and requirements of US pre- and post-approval materials, with those of global evidence dossiers.

Results

Survey respondents

The survey included 18 participants (4 medical directors, 11 pharmacy directors, and 3 industry/trade relations professionals) who represented national and regional managed care organisations (MCOs), national pharmacy benefit managers (PBMs), and integrated delivery networks (IDNs). Within respondents' organisations, covered members were distributed across Commercial, Managed Medicaid, Medicare Advantage, Exchange, Medicare Fee-for-Service (FFS), and Medicaid FFS.

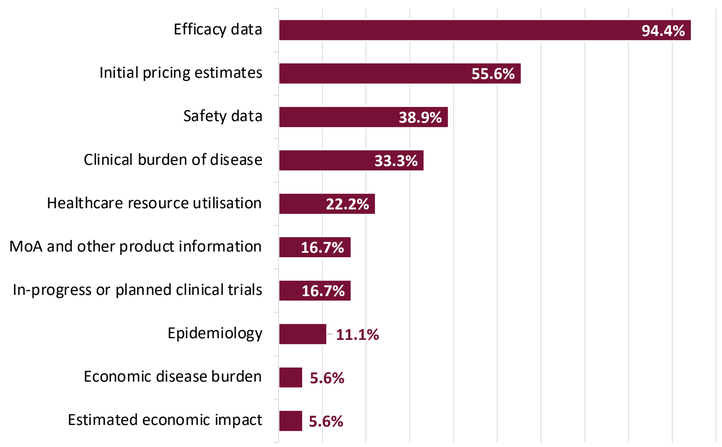
17 respondents had ≥15 years' experience at US payer organisations. 15 were currently in role, with the remaining 3 being former payers or working as non-US payers. 14 of the medical and pharmacy directors were voting members in their organisation's P&T committee; the remaining one served as a non-voting member.

Payer perspectives on PIE

When asked about the ideal timing for receiving pre-approval information from manufacturers, payers reported a preference for early engagement (up to 6 months before product launch, 50%; 6–12 months before launch, 33%) (data not shown).

The most important types of manufacturer-provided pre-launch information were efficacy data (94%), initial pricing estimates (56%), and safety data (39%) (Figure 1). Regarding preferred format, the majority (56%) wanted to receive both a pre-approval AMCP dossier and a PIE deck to review (data not shown).

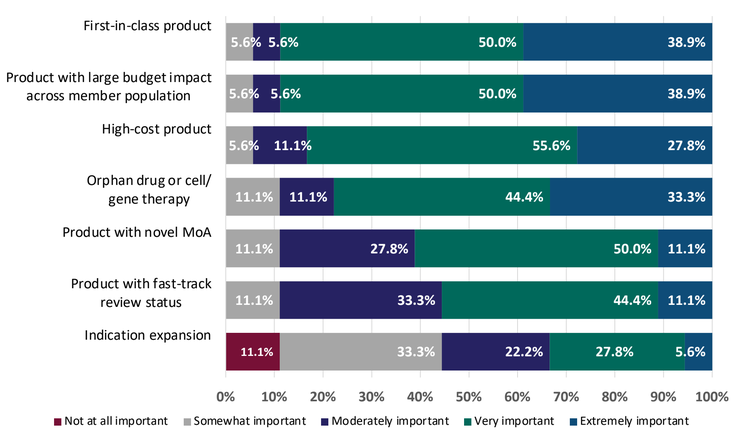
Figure 1: Importance of the different types of pre-approval product information or evidence



Respondents were asked to select the three most important types of information/evidence.

The importance of PIE in different scenarios and for different product types was also explored (Figure 2). First-in-class, large budget impact, high-cost, and orphan drug or cell/gene therapy products were deemed at least very important by 89, 89, 83, and 78% of payers, respectively.

Figure 2: Importance of PIE in different scenarios and for different product types



Payers also indicated how frequently PIE materials or manufacturer engagements supported their needs. Only 33% responded 'often', with the majority (67%) feeling that their needs are only met 'sometimes' or 'rarely' (data not shown).

Payers made the following suggestions for increasing the benefit of PIE discussions ahead of launch:

- Ensuring information is relevant and concise
- Clearly explaining how the product differs from standard of care, impacts outcomes, and is expected to change the treatment paradigm
- Providing "more cost information"
- Updating PIE materials as new data and information (e.g. Food and Drug Administration [FDA] approval timeline updates) become available

> ***"It is essential to establish a collaborative and strategic approach [to PIE]. Initiating these discussions early allows for comprehensive evaluations and informed planning… ensuring preparedness for market entry and decision-making"***
> – US Regional MCO Medical Director, 2025

Comparison of US and global communication materials

The narrative comparison showed that, while both US and global materials serve as tools for manufacturers to consolidate clinical and pharmacoeconomic evidence, differences emerge for document purpose, audience, timing, and structure (Table 1).

Table 1: Comparison of key features and requirements of US and global communication materials

	US AMCP dossiers and PIE materials	Global evidence dossiers (GVDs/GRDs)
Purpose	Pre-and post-approval communication between manufacturers and US HCDMs to support new product evaluation	Comprehensive 'master' document to support market access activities, and national reimbursement submissions
Audience/end users	US HCDMs making or influencing formulary, coverage, or policy decisions†	Internal resource for manufacturer's global and affiliate teams
Timing of development	PIE (including pre-approval dossier): Typically 6–12 months before expected FDA approval Approved product AMCP dossier: Available by FDA approval	Early dossier: Typically 18–24 months pre-launch Full dossier: Approximately 6–12 months pre-launch
Structure and content	AMCP dossiers: Aligned with the AMCP Format for Formulary Submissions 5.0 (2) PIE slide decks: Flexible structure; non-promotional content includes available clinical data, expected positioning, and pricing estimates	Moderately flexible structure; content supports full product value story and may be aligned with HTA information requirements (for GRDs)
Key considerations/ success factors	Early engagement (for PIE), transparency, clear value proposition, brevity and concision	Story flow and messaging, comprehensiveness, ease of navigation and adaptation for local materials
Frequency of updates	In line with new data and label changes	Living document, to be updated as new data become available and new indications are added

† For example, MCOs, PBMs, IDNs, and P&T committee members.

Conclusion

This study builds on our previous research (1), providing further US payer insights into best practice for the development of PIE materials and AMCP dossiers. Our results highlight the importance of early manufacturer engagement with PHDMs, and of clearly communicating available clinical and cost information ahead of market entry. This research also highlights potential efficiencies for manufacturers to consider when developing these tools as part of a coordinated global communication strategy.

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References

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Abbreviations

AMCP, Academy of Managed Care Pharmacy
FDA, Food and Drug Administration
FFS, Fee-for-Service
GRD, global reimbursement dossier
GVD, global value dossier
HCDM, healthcare decision-maker
HTA, health technology assessment
IDN, integrated delivery network
MCO, managed care organisation
MoA, mechanism of action
P&T, Pharmacy and Therapeutics
PBM, pharmacy benefit manager
PHDM, population health decision-maker
PIE, pre-approval information exchange