AMCP Dossier Format v5.0: US Payer Preferences and Utilization to Support Formulary Decision Making

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ISPOR poster acceptance code: HTA16
Abstract ID: 5076

Introduction

The AMCP Format for Formulary Submissions provides a comprehensive dossier framework for manufacturers to share clinical and pharmacoeconomic evidence with US PHDMs as they consider new products for coverage and formulary placement (1). In April 2024, the AMCP released Version 5.0 of the Format, which included guidance on developing PIE documents, DTx, real-world evidence, health disparities, and the need for brevity to streamline dossiers (2).

As engagement between manufacturers and PHDMs in the US continues to evolve, it is important to understand payer perspectives on best practice for the development and dissemination of AMCP dossiers, as well as the role of dossiers in facilitating timely product assessment and reimbursement.

Objectives

The aim of this primary research study was to explore US payer perspectives, preferences, and utilization of AMCP dossiers to support formulary, coverage, and policy decision making. As this research comes one year on from the release of v5.0 of the AMCP Format, we also aimed to understand respondents' level of familiarity with the updates made since the previous version (v4.1).

Methodology

In March 2025, we recruited experienced stakeholders from US payer organizations via our Petauri Payer Network, to participate in a 30-minute online quantitative and qualitative survey. Eligibility criteria included current or former US payers who are currently based in the US, have at least 5 years of experience as a payer, and are a current or former voting member or participant in their organization's P&T committee.

Within the survey, we explored key themes around AMCP dossier use, value, evidence priorities, and the factors contributing to dossier impact and quality. We conducted descriptive statistics and contextual analyses. Participants were provided with an honorarium for survey participation based on fair market value.

Results

The survey included 18 participants, of whom 4 (22%) were medical directors, 11 (61%) were pharmacy directors, and 3 (17%) were industry/trade relations professionals. Participants represented national and regional MCOs, national PBMs, and IDNs. Within respondents' organizations, covered members were distributed across Commercial, Managed Medicaid, Medicare Advantage, Exchange, Medicare FFS, and Medicaid FFS programs.

Overall, 17 (94%) respondents had 15 or more years of experience at US payer organizations. Fifteen (83%) were currently in role, with the remaining three (17%) being former payers or working as non-US payers. Fourteen of the medical and pharmacy directors reported that they were voting members in their organization's P&T committee; the remaining one reported serving as a non-voting member.

Results (continued)

When asked about the value that AMCP dossiers provide, 89% of payers perceived post-approval Approved Product Dossiers to be 'moderately' to 'extremely' valuable, compared with 61% of payers for pre-approval Unapproved Product Dossiers (Figure 1). Reasons for the ratings varied; for example, respondents commented that post-approval dossiers provide a detailed, transparent repository of information that forms the basis of P&T discussions and is "invaluable for comparative evaluations of therapeutic alternatives, budget impact modeling, and [for] justifying formulary placement or tiering decisions". For pre-approval dossiers, some payers felt it useful to receive information early for proactive planning purposes, whilst others noted limitations such as incomplete clinical data or pricing information.

In line with these findings, 28% of payers reported using post-approval dossiers as a primary source of information or evidence, compared with 11% for pre-approval dossiers. Overall, almost all payers shared that they use dossiers as either a primary or secondary information source (100 and 94% for post- and pre-approval dossiers, respectively) (Figure 2). When later asked about their preferred format of pre-approval information, the majority of payers (56%) wanted to receive both a dossier and a PIE deck (data not shown).

Figure 1: Perceived level of value of pre- and post-approval AMCP dossiers

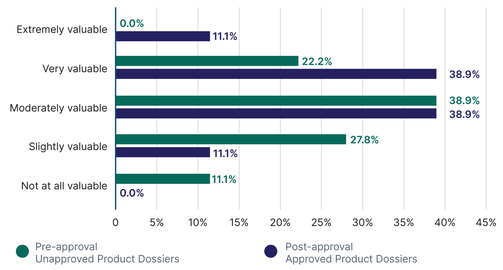
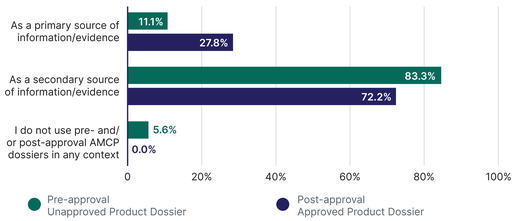


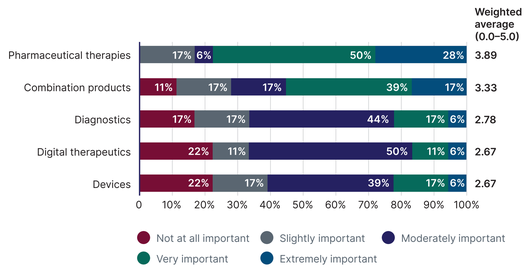
Figure 2: Most common use of pre- and post-approval AMCP dossiers†



† For pre-approval, respondents were asked about the use of dossiers to inform advance budget and formulary planning. For post-approval, respondents were asked about the use of dossiers to inform new product assessment and P&T committee review.

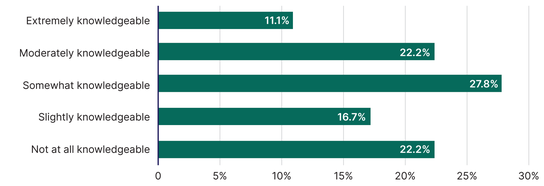
Payers were also asked about the importance of AMCP dossiers for different types of pharmaceutical and healthcare products (Figure 3). Dossiers are consistently deemed important for pharmaceutical therapies (weighted average: 3.9/5.0) and combination products such as those that comprise a drug and device (3.3/5.0). For diagnostics, DTx, and devices, weighted average scores ranged from 2.7–2.8/5.0, indicating that perceived importance is more varied for these interventions.

Figure 3: Importance of AMCP dossiers for different product types



One year on from the release of the AMCP Format v5.0, only 2 (11%) respondents reported being 'extremely knowledgeable' about the updates made since v4.1. Most (67%) had some knowledge of the updates, and 22% were not aware of the new version at all (Figure 4).

Figure 4: Level of knowledge of updates made to the AMCP Format for Version 5.0



The most important factors contributing to AMCP dossiers being impactful and/or high quality were the transparency of dossier evidence and methodology (reported by 89% of payers), communication of a clear product value proposition (78%), and overall brevity and concision (78%) (Figure 5). These findings were consistent with the most commonly reported limitations or shortcomings of manufacturer-provided AMCP dossiers, including "too long or cumbersome", "missing or insufficient evidence", "lack of clear value story or summary of key takeaways", and "lack of transparency in evidence and/or methodology" (data not shown).

Finally, we explored the potential implications of payers not receiving timely or high-quality AMCP dossiers from manufacturers (Figure 6). The most likely consequences shared by payers included an increased burden on the P&T committee (to find information from other sources), delays in formulary coverage, and deprioritization of the product review or assessment.

Figure 5: Factors that contribute to an AMCP dossier being impactful and/or of high quality

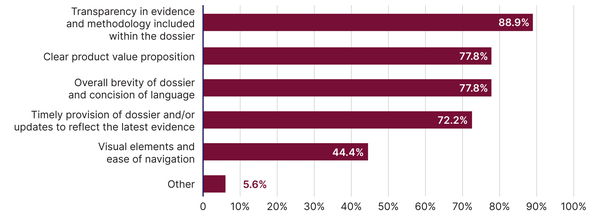
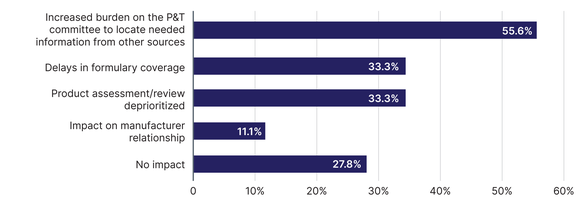


Figure 6: Potential implications of not receiving timely or high-quality AMCP dossiers from manufacturers



Conclusion

The results of this survey highlight the importance of timely, high-quality manufacturer AMCP dossiers, particularly post-approval dossiers, as a key source of evidence used by US PHDMs to inform new product access/coverage and formulary decision making.

Our findings confirm that dossier transparency, clear communication, and brevity are key success factors, and that dossiers are particularly important for pharmaceutical and combined products. For other health technologies, including diagnostics, DTx, and devices, further research is needed to gain insights into why perceived dossier importance varies. For example, the lack of consensus may reflect payer preferences for other information sources, and/or differences in payer awareness of updated guidance (e.g., for DTx) included in Format v5.0.

As the US healthcare landscape becomes increasingly more complex, manufacturers must create payer-facing resources that support impactful communication of value, while acknowledging payer preferences for this information. Failure to do so may result in delayed access, review deprioritization, or other negative impacts for critical therapies and innovations in the US.

ISPOR Global 2025,
May 14–16 2025,
Montreal, Canada

Booth no. 1115

References

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2. Journal of Managed Care & Specialty Pharmacy. AMCP Format for Formulary Submissions 5.0. JMCP. 2024;30(4-B).

Abbreviations

AMCP, Academy of Managed Care Pharmacy
DTx, digital therapeutics
FFS, Fee-For-Service
IDN, integrated delivery network
MCO, managed care organization
P&T, Pharmacy and Therapeutics
PBM, pharmacy benefit manager
PHDM, population health decision maker
PIE, pre-approval information exchange