Academy of Managed Care Pharmacy Dossiers: Use in Health Care Decision Making

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BACKGROUND

- The Academy of Managed Care Pharmacy (AMCP) dossier format was introduced in 2000.
- The dossier format guides manufacturers in presenting evidence for new pharmaceuticals, biologics, and vaccines to gain reimbursement and/or formulary placement in the United States (US) health care system.
- Limited information has been published on the role of these dossiers in health care decision making.

OBJECTIVE

- To characterize decision makers' use of AMCP dossiers in granting reimbursement and formulary placement for new health technologies.

METHODS

- We reviewed the published literature and third-party websites to identify how health care decision makers employ AMCP dossiers.
- We then developed a discussion guide for use in one-on-one interviews.
- Participants included 7 medical directors and 3 pharmacy directors who were voting members or chairs of Pharmacy and Therapeutics (P&T) committees at a range of US health plans (national, regional, integrated) (Table 1).
- Interviews focused on how AMCP dossiers inform decision making and the usefulness of each dossier section.
- US payers were asked to rate the usefulness of each section of the AMCP dossier on a scale of 0 to 10, where 0 is not useful at all and 10 is extremely useful.
- US payers were then asked specific questions about each section of the AMCP dossier.

Table 1. Profiles of Participating US Payers

Participant	Geographic Coverage Area	Covered Lives			
		Total (Millions)	Commercial (%)	Medicare (%)	Medicaid (%)
Medical Director A	Regional	1.0	100	0	0
Medical Director B	Integrated	2.0	60	30	10
Medical Director C	Regional	37	80	5	15
Medical Director D	Regional	36	77	17	6
Medical Director E	Regional	3.0	50	10	40
Medical Director F	National	8.0	70	30	0
Medical Director G	Regional	0.6	85	1	14
Pharmacy Director H	National	35	90	6	2
Pharmacy Director I	Regional	1.8	75	10	15
Pharmacy Director J	National	37	75	20	5

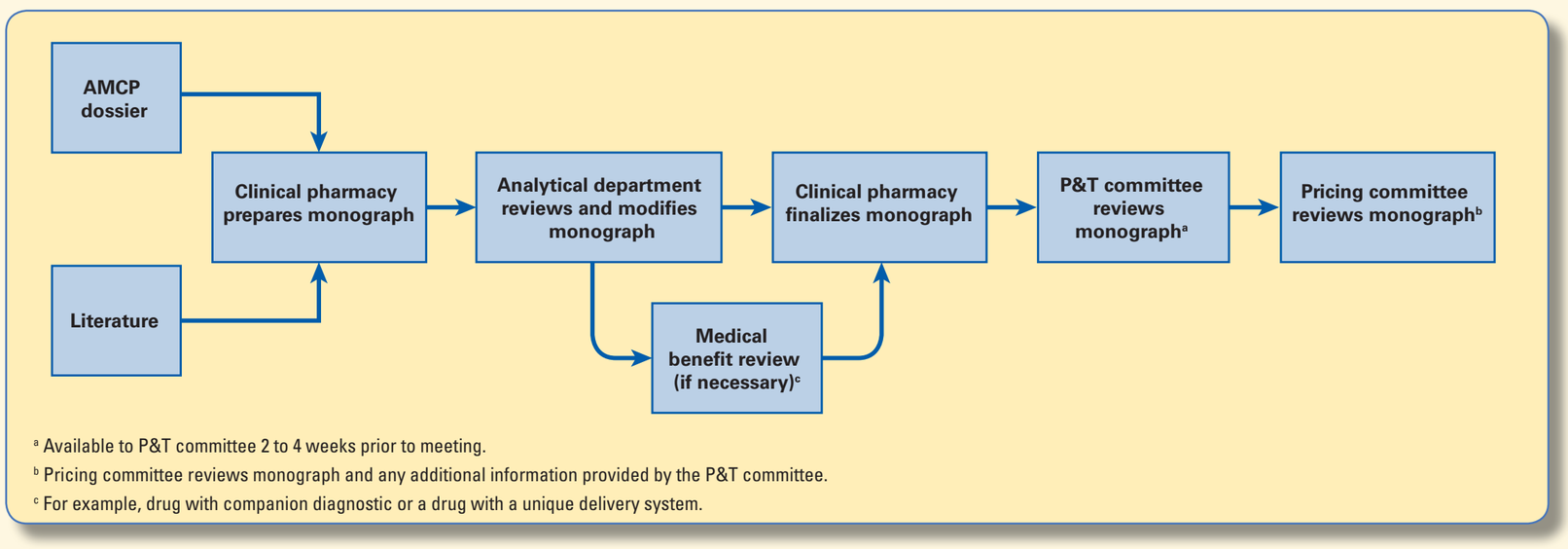
RESULTS

- Nine of the 10 health plans represented requested AMCP dossiers.
  - All 9 of these health plans requested an electronic version.
  - Three of 9 health plans requested both an electronic version and a hard copy.
- Figure 1 outlines how P&T Committees at US health plans typically use an AMCP dossier.
  - Complete AMCP dossiers are rarely used for decision making; rather, health plans pull out the sections considered most pertinent.
- Participants indicated that the following sections of an AMCP dossier are most important to P&T committee decision makers:
  - Clinical studies (efficacy and safety)
  - Comparators and head-to-head data
  - Subpopulations where the therapy would be more or less effective
  - Place in therapy
- Health plans may consult with outside experts if deemed necessary (e.g., orphan indications and rare diseases, specialty drugs, protected classes, and drugs with a new mechanism of action).
- Pharmacy Director J noted that the high degree of variability in the quality of AMCP dossiers they receive: "You would be amazed at what we see manufacturers submit that they consider to be a dossier. [This is not the norm] and is usually for a me-too drug that is not going to get a full review."
- Payers want to see more publications that support the unmet needs and how the medication fills those gaps, including those pertaining to the economic models.

Section 1: Executive Summary

- US payers were generally satisfied with the content in Executive Summaries and considered this to be a useful section of the AMCP dossier (Figure 2).
- US payers are looking for a concise summary.
  - Information can be presented in bullet points, and extraneous information can be omitted.
  - For example, Medical Director E stated, "The last thing I want is another summary of diabetes care."
- The level of information in the Executive Summary can vary depending on the disease area, mechanism of action, and whether the drug is first to market or a follow-on drug.
  - More information should be included if the drug has a new mechanism of action or is for an orphan indication or rare disease with which payers are less familiar.
  - When describing a follow-on drug in a familiar disease area, the focus should be on differences from the first-to-market drug.
  - For a follow-on drug, the Executive Summary may be the only information used to develop the monograph for the P&T committee meeting.

Figure 1. Flow Diagram of How Information From an AMCP Dossier Is Typically Used by P&T Committees at US Health Plans



[a] Available to P&T committee 2 to 4 weeks prior to meeting.
[b] Pricing committee reviews monograph and any additional information provided by the P&T committee.
[c] For example, drug with companion diagnostic or a drug with a unique delivery system.

Figure 2. Usefulness of the Executive Summary on a Scale of 0 to 10, Where 0 Is Not Useful at All and 10 Is Extremely Useful

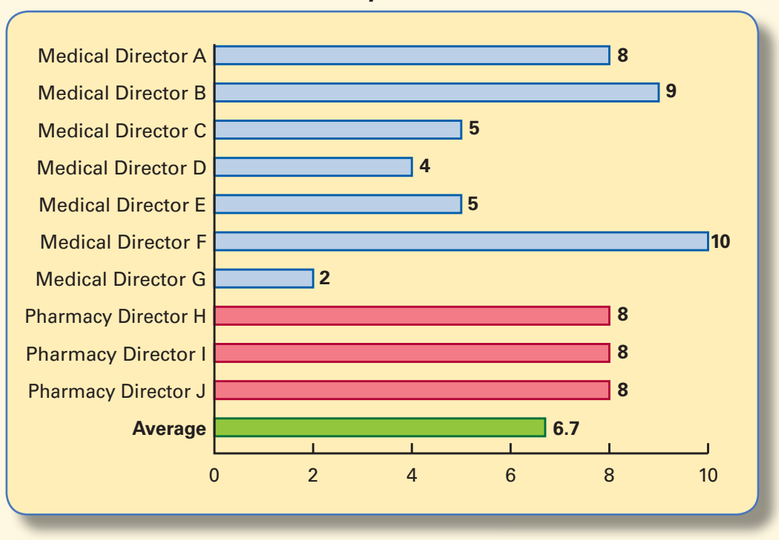
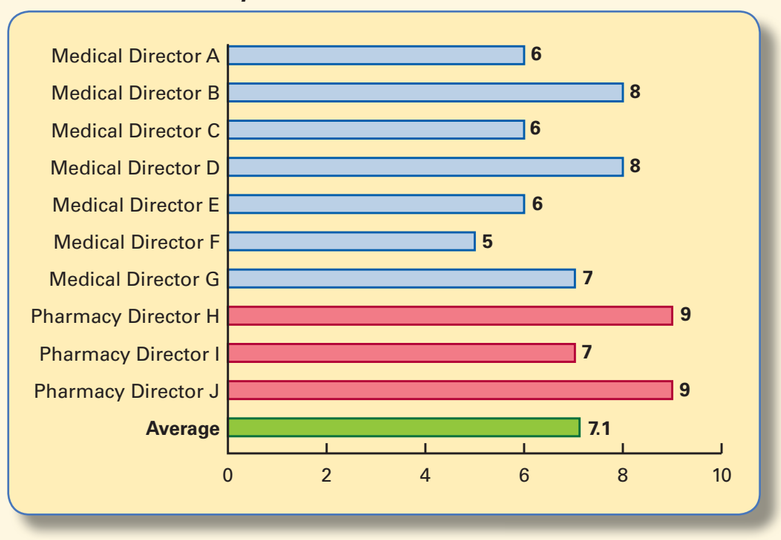


Figure 3 Usefulness of Section 2 on a Scale of 0 to 10, Where 0 Is Not Useful at All and 10 Is Extremely Useful



Section 2: Product Information and Disease Description

- US payers generally found Section 2 to be useful and were satisfied with the layout and content (Figure 3).
- US payers defined the most important parts of Section 2 as follows:
  - Disease description (especially if orphan indication or rare disease)
  - Extensive details on new mechanism of action or first-to-market drug
  - Unmet need
  - Treatment options
  - Treatment sequencing
  - Comparators
  - Biomarkers or any information that defines the appropriate patient
  - Any issues with this drug class
- US payers expect Section 2 to provide accurate and appropriate information on real-world comparator treatment options, including off-label medications.
  - US payers find that appropriate comparators are provided 50% to 75% of the time.
  - Pharmacy Director H stated that defining comparators is "the meat and potatoes of what is useful from the dossier and crucial to the evaluation [of the treatment]."
  - US payers find that comparator evaluations in the AMCP dossier can have manufacturer bias, and this information is validated independently.
  - Medical Director C stated that "if you are going to [provide a comprehensive overview of comparator data], then do a good job. This is like testifying in court. There is a duty to tell the court things they should know, and you look bad if your opponent points it out instead of declaring it yourself. This is the right and ethical thing to do."

Section 3: Clinical Evidence

- US payers consistently found Section 3 to be the most useful portion the AMCP dossier.
  - US payers are looking for an outcome measure that will have an impact on the health plan's bottom line (e.g., fewer hospitalizations).
  - Medical Director D stated, "I am looking for a good outcome endpoint to hang my hat on."
- US payers indicated that more information could be provided on the following:
  - Comparative effectiveness
  - Meta-analysis
  - Orphan indications and rare diseases
  - Companion testing, if applicable

Section 4: Economic Model

- US payers indicated that the most important information in Section 4 is as follows:
  - Medical cost offsets, particularly identifying big cost drivers and particularly for chronic diseases
  - Compliance and adherence tied to real-world and daily average consumption
  - Outcomes measures that may affect quality measures (e.g., Medicare Star Ratings pay-for-performance program)[1]
- US payers would like to use the economic model section; however, they repeatedly indicated that this section contains a lot of manufacturer bias.
- To build more trust between the health plans and manufacturers, US payers suggested the following improvements for Section 3:
  - Greater transparency
  - Consistent rigor in development
  - Results published in credible peer-reviewed journal
  - Endorsement from independent third-party KOLs and "promotion" of these partnerships in discussions with payers and with field-based staff who discuss the economic data
  - Real-world data to validate the model
  - Model validation 1 year later

Additional Information

- US payers were open to the inclusion of additional information, if relevant.
  - It is unlikely that the inclusion of relevant additional data would negatively impact the evaluation.
- Payers are particularly looking for the following:
  - Comparative effectiveness data
    - Head-to-head data (One health plan has a comparative effectiveness requirement for manufacturers, and the Food and Drug Administration label is not sufficient.)
    - Meta-analyses
  - Properly vetted, rigorous observational studies (Real-world data from an integrated plan would be particularly useful.)
  - Direct cost analysis and links between medical and pharmacy benefit utilization
  - Value proposition for the plan, not just for the patient and provider

DISCUSSION AND CONCLUSIONS

- AMCP dossiers are widely used by US health plans; however, plans use them in different ways.
- Brevity, accuracy, and containing the "right information" and the "right sources" (e.g., integrated plan data, real-world data, comparative effectiveness data) are highly valued by US payers.
  - Dossiers present evidence and the value proposition for the health technology; they should not be considered simply a sales tool.
- Although there are formal guidelines for AMCP dossiers, health care decision makers seek information tailored to the disease and technology.
  - Orphan indications, rare diseases, and therapies with new mechanisms of action warrant the inclusion of detailed information.
  - Concise summaries are sufficient for common diseases and follow-on drugs.
- Health care decisions are not made in a vacuum, and payers are seeking more comparative effectiveness data to better inform decision making.
- There are opportunities for manufacturers to build trust and stronger relationships with US payers through robust development of the dossier, economic model, model publications, and partnerships with third-party KOLs.
  - Payers want to see more publications that support the unmet needs and how the new health technologies fill those gaps, including those pertaining to the economic models.
  - Inclusion of all relevant data for decision making is important in order to maintain credibility and transparency. If US health plans discover relevant missing information, the entire AMCP dossier may receive additional scrutiny.
  - Payers want to see more transparency from manufacturers with respect to the economic models used in the AMCP dossiers.
  - Payers would like to see more independent, third-party KOLs included on the models and model publications, and manufacturers should actively "promote" these partnerships.

REFERENCE

1. National Committee for Quality Assurance. Continued improvement in Medicare. Available at: https://www.ncqa.org/Directories/HealthPlans/StateofHealthCareQuality.aspx Accessed March 20, 2014.

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