BACKGROUND

The Academy of Managed Care Pharmacy (AMCP) dossier format was introduced in 2000. The objective format guides manufacturers in presenting evidence for new pharmaceuticals, biologics, and vaccines to gain approval for and to appear favorably on the formularies of the United States’ health care system.

Limited evidence 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 evaluated 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).

Interviewees focused on how AMCP dossiers inform decision making and the usefulness of each section of the AMCP dossier.

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.

RESULTS

Nine of the 10 health plans represented requested AMCP dossiers.

All 10 health plans requested an electronic version.

Three of 8 health plans also requested an electronic version and a hard copy.

Figure 1 outlines how P&T Committees at US health plans place in therapy (6) and the therapy would be more or less effective.

The majority of AMCP dossiers are rarely used for decision making; rather, health plans pull out the sections considered most important.

Participants indicated that the following sections of the AMCP dossier are most important to P&T committee decision makers:

- Clinical studies—Icty, efficacy, and safety
- Comparative effectiveness
- Complete monograph
- Potential patient populations
- Model validation 1 year later
- Results published in credible peer-reviewed journal
- Model fits the therapy
- Industries, and partnerships with third-party KOLs.

Payers want to see more independent, third-party evaluations for Section 3: Product Information and Disease Description—Comparators.

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–related)
- Companion testing, if applicable
- Checklists
- Treatments or options
- Comparators
- Biomarkers or any information that define the target audience

US payers expect Section 2 to provide accurate and appropriate information on real-world comparator treatments, including off-label medications.

US payers find that appropriate comparators are provided 50% to 75% of the time.

The AMCP dossier prepares monograph

Monograph is not useful at all and 10 is extremely useful.

Additional Information

US payers were open to the inclusion of additional information, if relevant.

- It’s unlikely that the inclusion of relevant additional data would be difficult for payers.

- 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.)
  - Direct cost data
  - Links and particularly for chronic diseases
  - PubMed abstracts
  - Value proposition for the plan, not just for the patient
  - Model validation 1 year later

DISCUSSION AND CONCLUSIONS

AMCP dossiers are widely used by US health plans; however, plans use them in different ways.

- There is a need for improved trust and collaboration among the “right” stakeholders (e.g., integrated plan data, real-world effectiveness data) are highly valued by US payers.

- Payers present evidence and the value proposition for the plan, and 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.

- Comparison of indications, rare diseases, and therapies, with new data on action that support the complete dossier and all the comparator data in the dossier.

- Comparative effectiveness data and follow-up studies.

- Health care decision makers 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 independent, third-party evaluations for Section 3 that support the unmet need and how the new health technologies fill those gaps, including those pertaining to the economic model.

- Inclusion of all relevant data for decision making is important in order to maintain credibility and transparency. If payers are unable to make sense of the data, then it will not be considered important.

- Payers want to see more transparency from manufactures 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

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

Susan L Hogue, Andrew P Brogan, Stephanie R Earmsaw, Shahnaz Khan, Shannon Nelson

RTI Health Solutions, Research Triangle Park, NC, United States

Figure 1. Flow Diagram of the Information Flow from an AMCP Dossier to Typically Elected P&T Committees at US Health Plans

Figure 2. Standard of Accuracy in a Scale of 0 to 10, Where 0 Is Not Useful at All and 10 Is Extremely Useful

Figure 3. Evaluation of the Accuracy of Information Provided in the AMCP Dossier to P&T Committees at US Health Plans

Table 1: Profile of Participating US Payers

<table>
<thead>
<tr>
<th>Payer Type</th>
<th>National</th>
<th>Regional</th>
<th>Integrated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Director H</td>
<td>35</td>
<td>90</td>
<td>6</td>
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<tr>
<td>Pharmacy Director I</td>
<td>9</td>
<td>90</td>
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</tr>
<tr>
<td>Medical Director E</td>
<td>3.0</td>
<td>50</td>
<td>10</td>
</tr>
<tr>
<td>Medical Director D</td>
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<tr>
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<tr>
<td>Medical Director C</td>
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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).

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