

How Do Payers Utilize the AMCP eDossier System for Pre-Approval Information and Could it Qualify as a Safe Harbor?

Jackie Gladman, Dymaxium, Elizabeth Sampsel, PharmD, Dymaxium, Michael Drummond, PhD, University of York, Dymaxium, Laurie Fazio, Dymaxium

Currently there is no accepted FDA-sanctioned safe harbor for the exchange of truthful and non-misleading information for payers. Payers review products 18 months or more in advance of approval to meet budget/formulary approval timelines. Since 2010, the AMCP eDossier System has been supporting the exchange of manufacturer-provided approved dossier information. The AMCP eDossier System within FormularyDecisions.com® is a secure platform specifically designed for qualified US health care decision makers to support their efficient assessment of evidence via an FDA-compliant unsolicited request. The FDA is currently reviewing safe harbor options. This research explores how the AMCP eDossier System is used in the exchange of information between manufacturers and payers before product approval.

Methodology

- 1500+ US health care decision makers
- Online survey
- 29 questions
- November 16-30, 2016
- 172 surveys completed
- AMCP eDossier System @FormularyDecisions.com® is a secure, web-based system to support US payer P&T recommendations and formulary decision making

Respondents by Organization*

| | |
|-----------------------------|-----|
| Managed Care Organization | 61% |
| Pharmacy Benefit Management | 14% |
| Hospital/Other Providers | 14% |
| Academia | 10% |

*as identified by respondent status

Recommendation

The research indicates the System could be a safe harbor mechanism for the exchange of pre-approval information between payers and manufacturers. Overall, payers indicated System usage for this purpose and believe the System supports the process. There are opportunities to increase manufacturer participation, provided identified barriers could be overcome.

Efficiency of the AMCP eDossier System

80%

Indicated the System's ease of use in the exchange of information pre-approval

86%

Felt the System met or exceeded the needs for pre-approval product review

62%

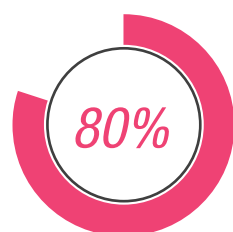
Indicated the System's unsolicited request process supports the information exchange between manufacturers and decision makers pre-approval

67%

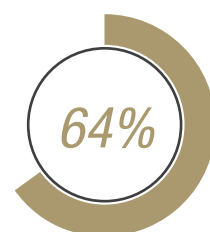
Responded that manufacturers participating in the System have a better response rate than those who do not participate

100% of all payers asked indicated having ready access to a manufacturer curated information repository within the AMCP eDossier System **is helpful**

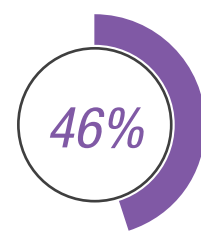
How does the AMCP eDossier System support the exchange of information pre-approval?



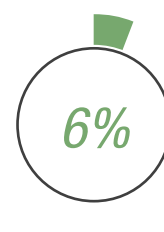
Easy to Use



Easy to Specify Exactly What I Need From Manufacturers

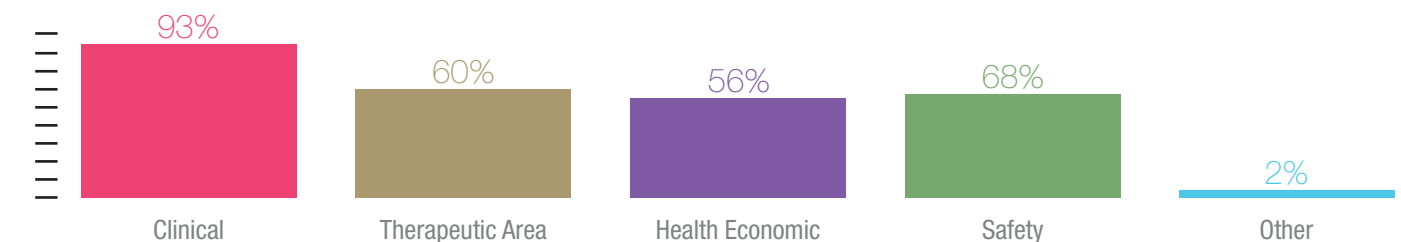


Manufacturers Respond



Other

Information generally asked of manufacturers to support pre-approval product review



Key Points

- ◆ 75% of survey respondents were directly involved in or aware of (53% / 22% respectively) the process for pre-approval decisions
- ◆ In the past year, 85% requested pre-approval information 1-10 times; 15% requested it 10-20+ times
- ◆ 45% felt the exchange of information was better since AMCP Format Version 4.0 77% thought the System can better support the information exchange by making it easier to understand what manufacturer information is available
- ◆ 68% wanted to ensure more manufacturer participation
- ◆ 64% are using manufacturer content for pre-approval product reviews. #1 resource – FDA pipeline information (77%)