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FormularyDecisions.com
Pre-approval Products – Supporting Payer Needs and the Information Exchange
June 13, 2019
Science & INNOVATION THEATER
Developed for Managed Care Pharmacy by AMCP Corporate Members
WEBINARS

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Xcenda
AmerisourceBergen
Dymaxium now a part of Xcenda!
FormularyDecisions.com ® is Dymaxium's leading platform that uniquely supports the information exchange between payers and manufacturers.
Xcenda recently acquired Dymaxium and FormularyDecisions.com ® to advance and accelerate the vision of the platform and aligns with their mission to generate and communicate credible, impactful evidence to support informed market access and reimbursement decisions.
AmerisourceBergen

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Speakers and Agenda

Speakers:

Elizabeth Sampsel, VP Payer Strategy and Relations, Dymaxium

Laurie Fazio, SVP, Market Access Technologies, Dymaxium

Amy M. Duhig, PhD, VP, Strategic Market Access and Intelligence, Xcenda

This webinar will include:

Active payer insights from the FormularyDecisions.com® community

- Features that support pre-approval review for Payers
- Payer needs for proactive and reactive resources and the timing requirements
- What Payers are using and what that means to manufacturers
- Case examples on the impact of supporting the exchange of information with Payers

Recommendations for manufacturers to support payers during their pre-approval review

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Active Payer Perspective

Elizabeth Sampsel, PharmD, VP, Payer Strategy and Relations, Dymaxium

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Pre-Approval Information Exchange
Current Landscape

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Strict FDA policy concerning the provision of information that is either 'unsolicited' or 'off label'

AMCP Format 4.0 has provision for making pre-approval information available (2016)

534: Pharmaceutical Information Exchange (PIE) Act proposed to Congress to codify the provision of pre-approval information to bona fide payers and healthcare decision makers

534; FDA final guidance provided to outline HCEI that can be shared prior to FDA approval. AMCP Format 4.1 planned with anticipated updates to further define requirements for pre-approval dossiers

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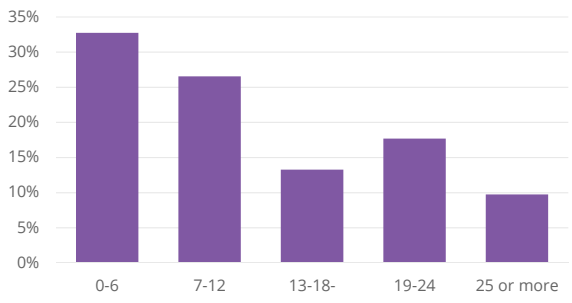
Pre-Approval Needs of PAYERS
Facilitating Formulary and Benefit Decision Making

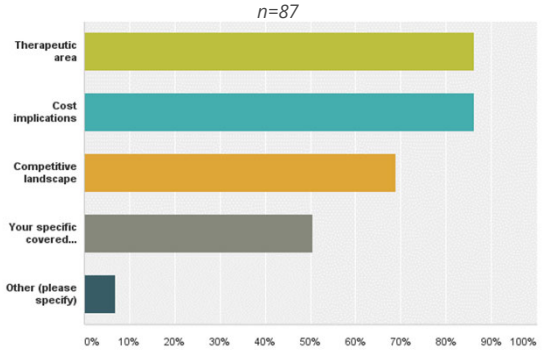
AMCP eDossier system @ FormularyDecisions.com® FormularyDecisions.com®

Payers are conducting product reviews earlier and require product information pre-approval to prepare for their budget and formulary requirements.

Payer Initiation of Pre-approval Product Research[1]
n=113



Factors Affecting Timing of Pre-approval Research[2]
n=87



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1 Dymaxium Surveys – average of responses 2016 & 2018 2 Dymaxium Survey 2016

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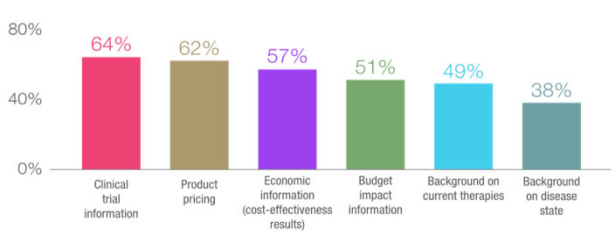
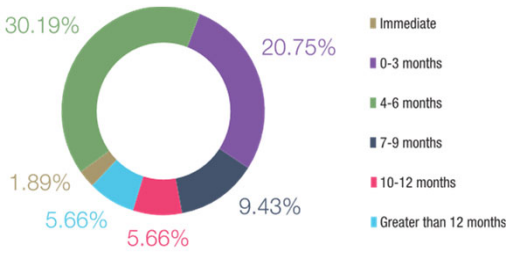
Pre-Approval Needs of PAYERS
Facilitating Formulary and Benefit Decision Making

Payers want pre-approval clinical trial information, product pricing and economic information *n=53*





79% of payer respondents request pre-approval information from manufacturers

60% of payer respondents want to meet with manufacturers within 9 months of product launch

Dymaxium Survey –payer attendees AMCP Conference 2018

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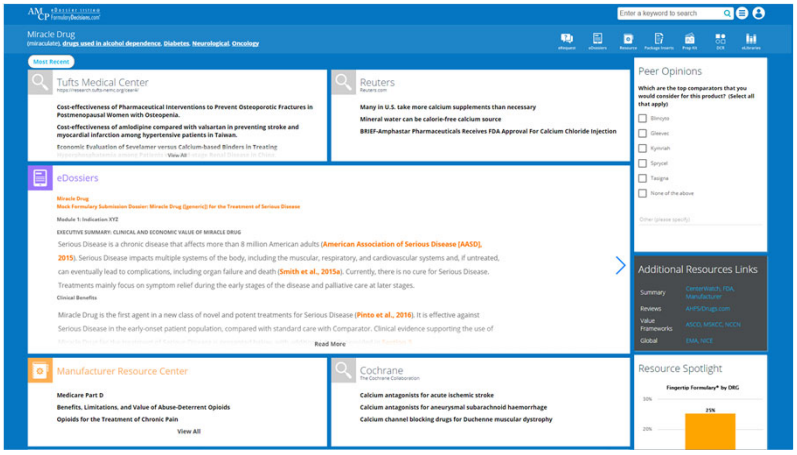
Opportunities to Address Payer needs Pre-approval

- Pre-approval dossiers
- P&T Prep Kits – analyst-driven, pharmacist reviewed
- Product Pages – accessible as early as 12, 18, 24 months on the platform (updated daily)
- Manufacturer Resource Center – manufacturers with pre-approval subscriptions can place information that does not require an unsolicited request – disease information, published clinical trials etc)
- PIE Webinars (together with AMCP)
- Global resources



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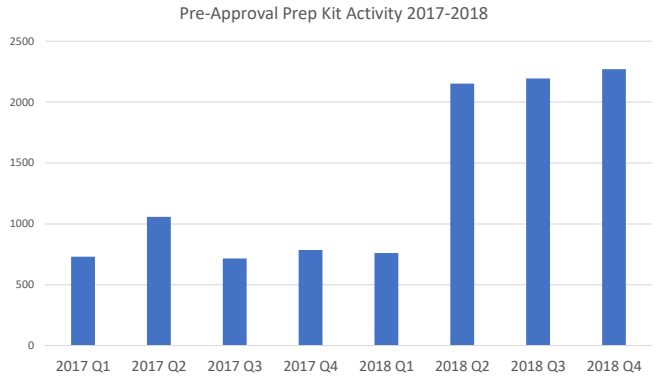
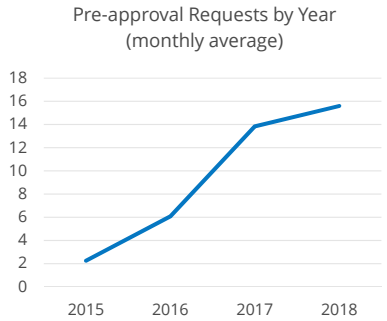
Timing Trends of Pre-approval Payer Activity





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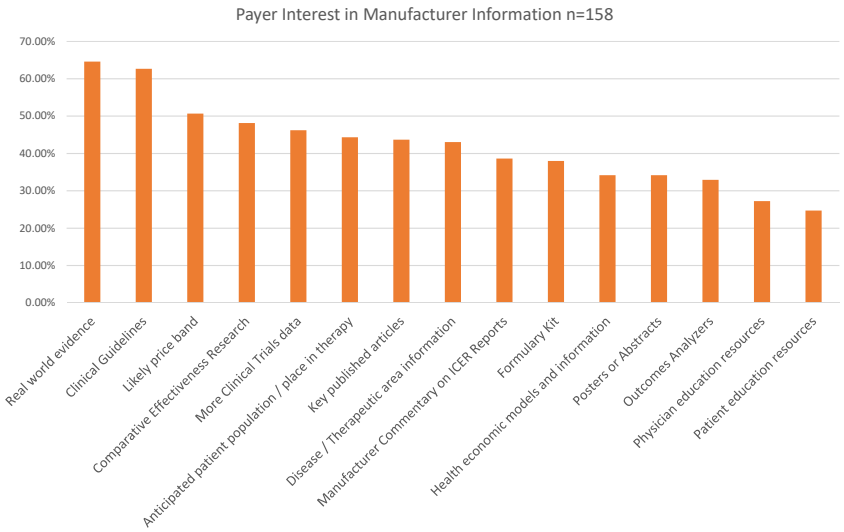
Active Payers – What they want to see "Proactive"



Dymaxium Syndicated Payer Survey Results June 2019

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FormularyDecisions.com® Active Payer Insights

Laurie Fazio, SVP, Market Access Technologies, Dymaxium

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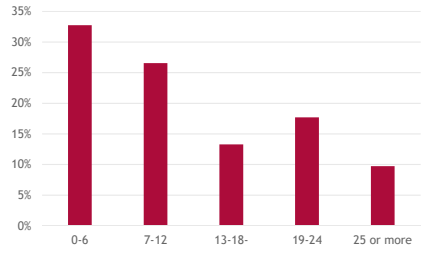
Pre-Approval Needs of PAYERS

Facilitating Formulary and Benefit Decision Making

Payers are conducting product reviews earlier and require product information pre-approval to prepare for their budget and formulary requirements.

Payer Initiation of Pre-approval Product Research[1] n=113



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Factors Affecting Timing of Pre-approval Research[2]

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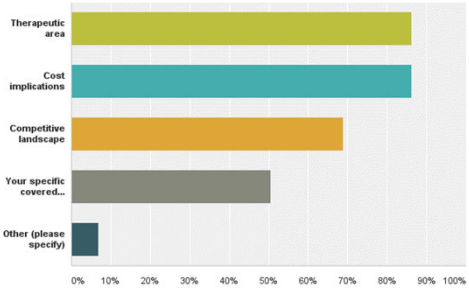

1 Dymaxium Surveys – average of responses 2016 & 2018 - 2 Dymaxium Survey 2016 3 Dymaxium Manufacturer Survey Feb/Mar 2019

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Manufacturer Approach to Pre-approval Information Exchange

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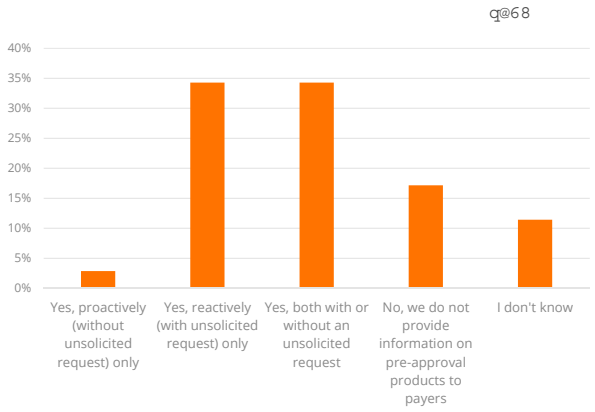
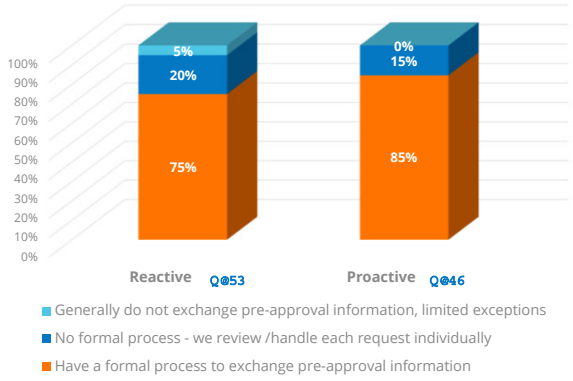
Manufacturer Engagement in Pre-approval Information Exchange (Proactive/Reactive)



Manufacturer Practices for Pre-approval Information Exchange with Payers



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Dymaxium Manufacturer Survey Feb/March 2019

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Use of Available Resource in Pre-approval

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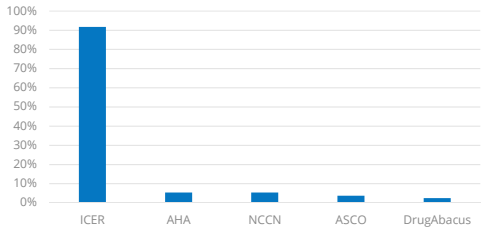
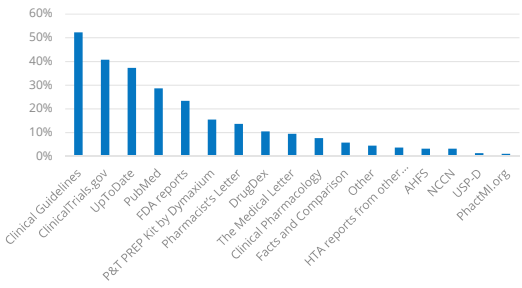
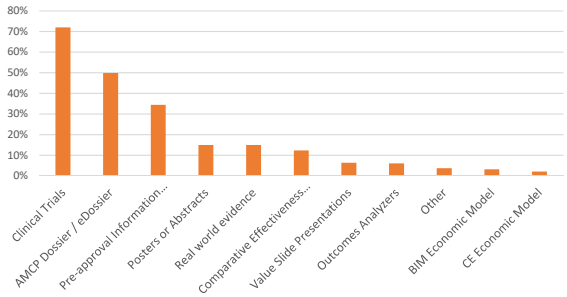
Use of Value Frameworks in Pre-approval Product Evaluations n=242



3rd Party Evidence Sources in Pre-approval Product Evaluations



Use of Manufacturer Provided evidence Sources in Pre-Approval Product Evaluations n=381



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Proactive Information Exchange - Manufacturers

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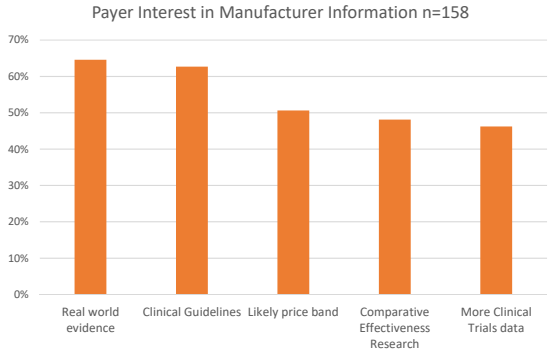

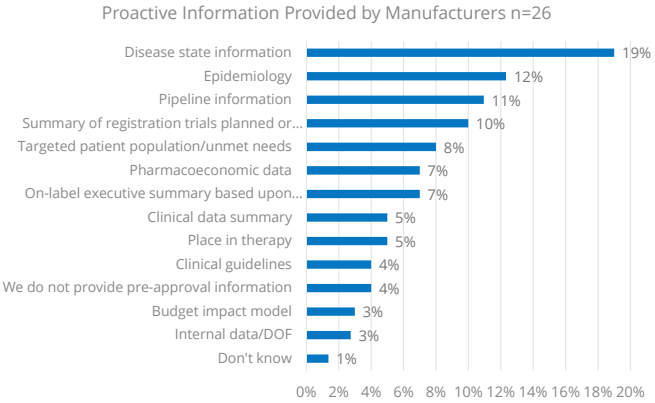

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Dymaxium Manufacturer Survey Feb/March 2019

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Case Example: Supporting Payers During Pre-approval Product Review

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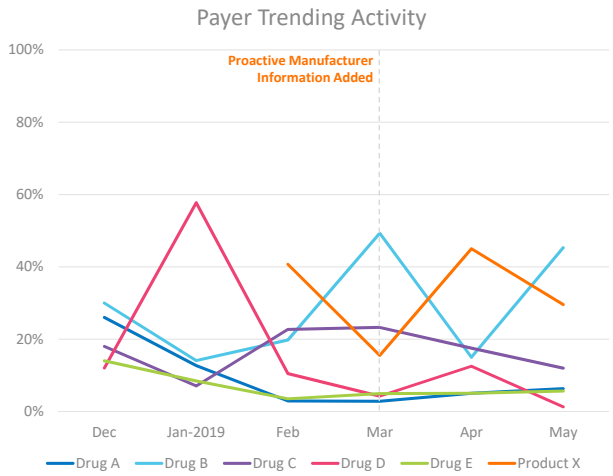
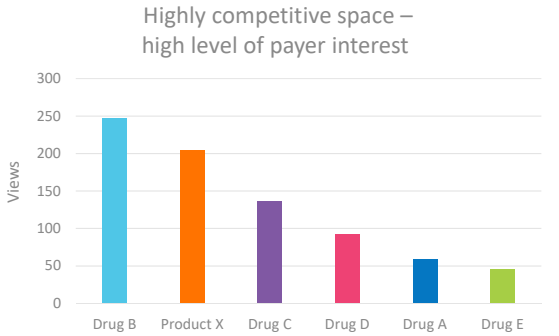
24+ months from launch



Payers are spending on average **50%** more time on Product X vs major competitors. **(23 min vs 16)**



Within the last 30 days activity increased by **28%**	**22%** Share of competitor activity	**39%** Comparative requests	**38** Unique visitors	**30** Unique Payers providing feedback	**6** Following product

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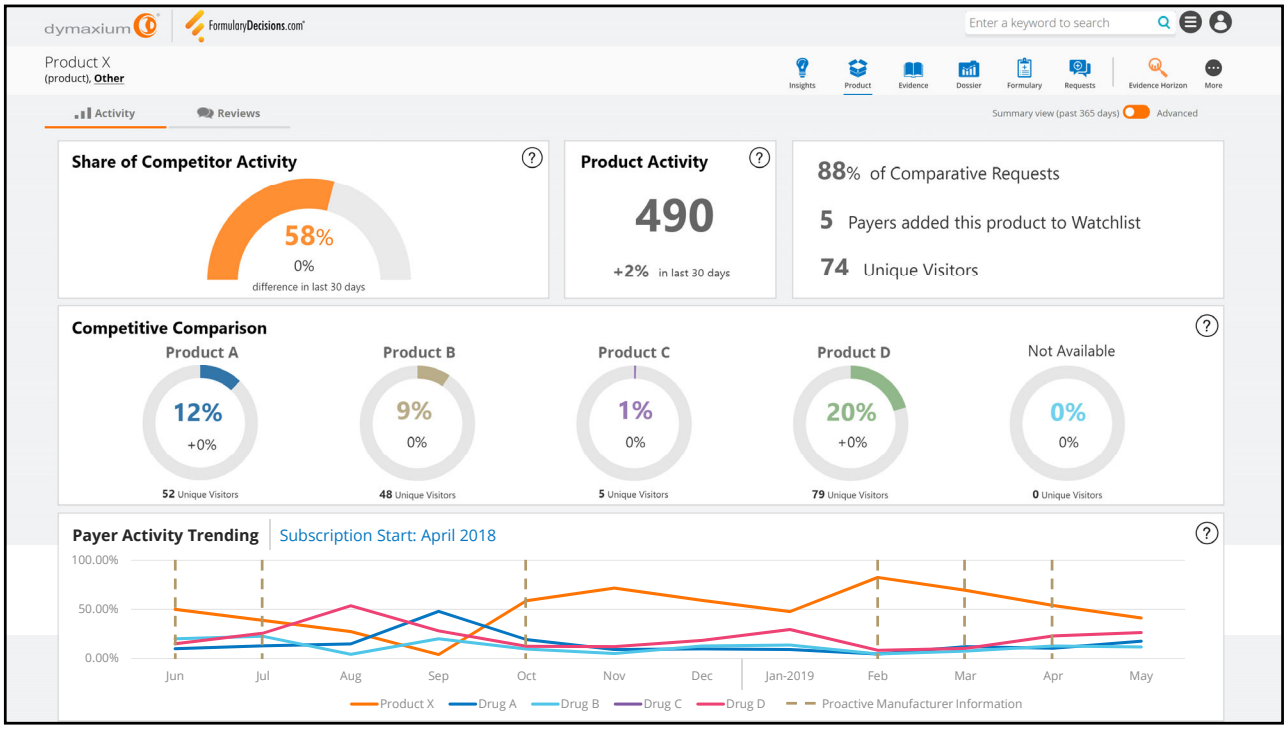
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Enter a keyword to search
Product X
(product), Other
Insights
Product
Evidence
Dossier
Formulary
Requests
Evidence Horizon
More
Activity
Reviews
Summary view (past 365 days)
Advanced
Share of Competitor Activity
58%
0%
difference in last 30 days
Product Activity
490
+2% in last 30 days
88% of Comparative Requests
5 Payers added this product to Watchlist
74 Unique Visitors
Competitive Comparison
Product A
12%
+0%
52 Unique Visitors
Product B
9%
0%
48 Unique Visitors
Product C
1%
0%
5 Unique Visitors
Product D
20%
+0%
79 Unique Visitors
Not Available
0%
0%
0 Unique Visitors
Payer Activity Trending
Subscription Start: April 2018
100.00%
50.00%
0.00%
Jun
Jul
Aug
Sep
Oct
Nov
Dec
Jan-2019
Feb
Mar
Apr
May
Product X
Drug A
Drug B
Drug C
Drug D
Proactive Manufacturer Information

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FormularyDecisions.com
FormularyDecisions.com® Active Payer Insights
Amy M. Duhig, PhD, VP, Strategic Market Access and Intelligence, Xcenda

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What Are We Trying to Accomplish?

Improve access to emerging therapies for patients

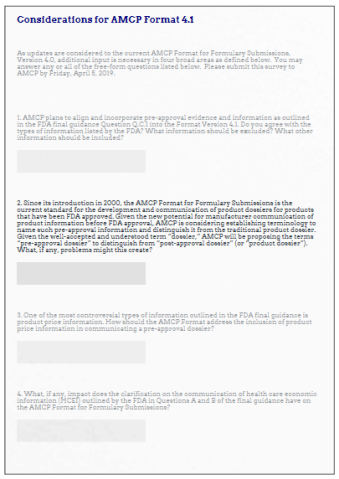
Provide unbiased, factual, accurate, and non-misleading information on products or indications not yet approved

Communicate product information earlier to assist payers with forecasting

Become a better partner for your payer customers as you develop and launch new products and line-extensions

What Are The Current Barriers?

- PIE legislation not approved and FDA guidance does not address HCEI
- Organizational awareness is inconsistent
- Companies have a lack of plan and process to deliver PIE
- AMCP Format does not address (4.1 update is planned)



Considerations for AMCP Format 4.1

As updates are considered to the current AMCP Format for Formulary Submissions, Version 4.0, additional input is necessary in four broad areas as defined below. You may answer any or all of the Free-form questions listed below. Please submit this survey to AMCP by Friday, April 5, 2019.

1. AMCP plans to align and incorporate pre-approval evidence and information as outlined in the FDA final guidance "Question Q+A I into the Format Version 4.1. Do you agree with the types of information listed by the FDA? What information should be excluded? What other information should be included?

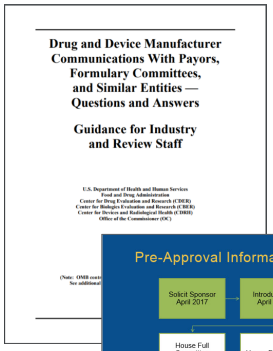
2. Since its introduction in 2000, the AMCP Format for Formulary Submissions is the current standard for the development and communication of product dossiers for products that have been FDA approved. Given the new potential for manufacturer communication of product information before FDA approval, AMCP is considering establishing terminology to name such pre-approval information and distinguish it from the traditional product dossier. Given the well-accepted and understood term "dossier," AMCP will be proposing the terms "pre-approval dossier" to distinguish from "post-approval dossier" (or "product dossier"). What, if any, problems might this create?

3. One of the most controversial types of information outlined in the FDA final guidance is product price information. How should the AMCP Format address the inclusion of product price information in communicating a pre-approval dossier?

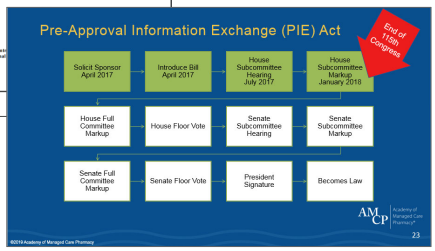
4. What, if any, impact does the clarification on the communication of health care economic information (HCEI) outlined by the FDA in Questions A and B of the final guidance have on the AMCP Format for Formulary Submissions?

What Is your Role?

- Understand FDA Guidance and PIE Act
- Ensure organizational awareness
- Understand what information payers are seeking (MCO, IDN, PBM, etc)
- Create a plan and process to deliver PIE

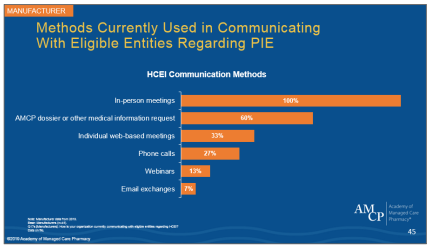

Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities — Questions and Answers

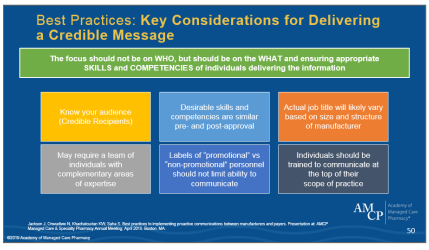
Guidance for Industry and Review Staff



PIE Delivery Considerations

- In-person/web-based meetings
  - Medical science liaison
  - Health outcomes liaison
  - Account manager
- Focus on core skills and competencies for delivering PIE





PIE Delivery Considerations

	Proactive	Reactive
Document Source	P&T PREP Kit PLUS	Pre-approval AMCP Format Dossier
Timing relative to FDA approval	12-24 months before approval	6-12 months before approval
Method of dissemination	Proactive (no request required)	Reactive (unsolicited HCDM request required)
Approximate length of document	20 – 30 pages	60 – 80 pages
Type of information provided	▪ Product information ▪ Current disease landscape for the indication(s) being sought (epidemiology, societal/economic burden) ▪ Current treatment landscape ▪ Overview of clinical studies (study design and results)	▪ Follows AMCP Format v4.0 (2016) for 'Dossier Information Before FDA Approval' ▪ Additional HCEI component

Integrate Insights from FormularyDecisions.com® With Other Market Access Activities for Pre-Approval

Pre-approval insights on payer perception of your product – by payer type – MCO vs PBMs

Early competitive intelligence – payer perception of competitors, activity metrics for competitors.

- Disease state/therapeutic categories, competitive barriers, maximize patient access

Utilize insights to help to refine market access strategy:

- Identify issues that can be explored in more detail through focus groups, advisory boards, or surveys
- Identify clinical, real world data or studies that have a particular resonance with payers
- Identify priority materials that should be posted on FormularyDecisions.com, or made available to payers through other mechanisms
- Identify issues and topics of particular interest to payers, on which the company can engage in the field or digitally

Summary

There's more that you can be doing

One size does not fit all

Consider your payer-manufacturer partnership goals

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Pre-approval Products – Supporting Payer Needs and the Information Exchange

For more information contact

Laurie Fazio - lfazio@dymaxium.com

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Liz Sampsel - esampsel@dymaxium.com

Science & INNOVATION THEATER WEBINARS

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