
Xcenda
AmerisourceBergen
Effectively Communicating Pipeline Information to Drive Payers' Attention
AmerisourceBergen

Agenda

Contributors:

- Matt Mitchell, PharmD, MBA, MHP, FAMCP, Director, Pharmacy Services, SelectHealth
- Laurie Fazio, Head, Market Access Solutions & Growth Strategies, FormularyDecisions
- Amy M. Duhig, PhD, Vice President, Strategic Market Access and Intelligence, Xcenda

This presentation will include:

- Payer perspective – Current pre-approval needs
- Active payer insights on what payers are using, what they want for pre-approval product reviews – From the FormularyDecisions.com℠ community
- Manufacturers' role in pre-approval information exchange

Payers Need Pre-approval Information

PRE-APPROVAL

Formulary
Planning
Budget
Forecasting

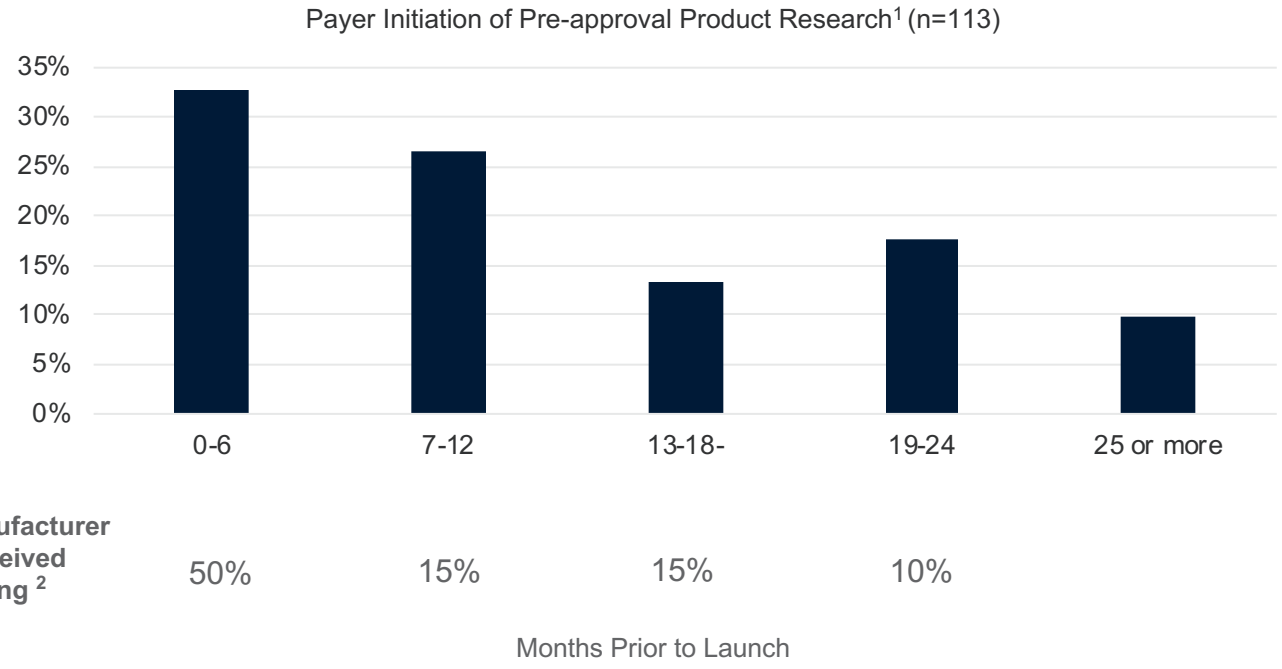
POST-FDA APPROVAL

Evaluate for
Formulary
Reimbursement
and Coverage
Decisions

NEW INDICATION

Formulary
Planning
Budget
Forecasting

Payers are conducting product reviews and require information earlier to prepare for their budgetary and formulary decision making



1. Dymaxium Surveys – Average of responses 2016 & 2018; 2. Dymaxium Manufacturer Survey Feb/Mar 2019.

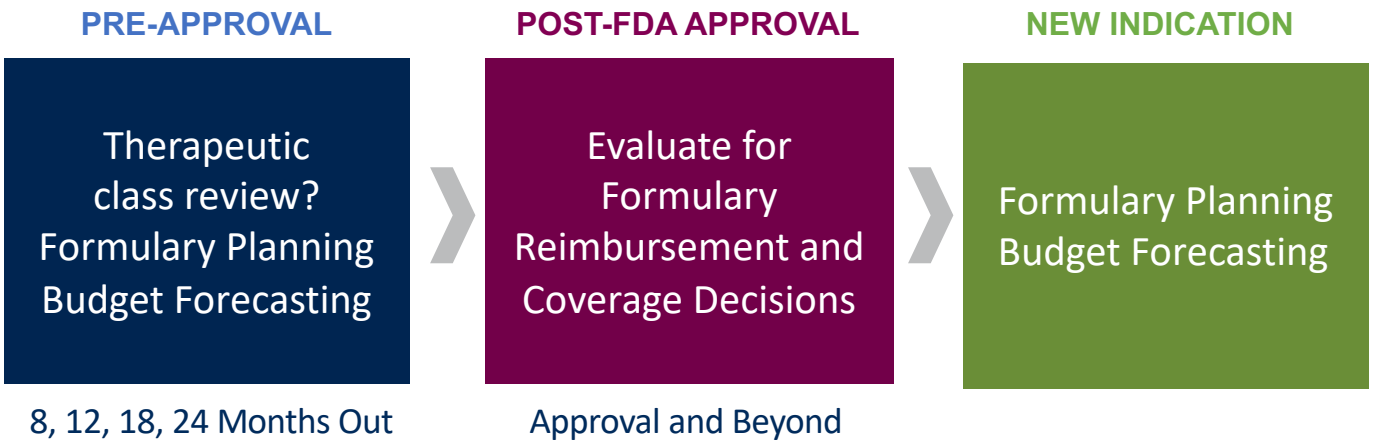
Payer Perspectives on Pre-approval Information

Matt Mitchell, PharmD, MBA, MHP, FAMCP

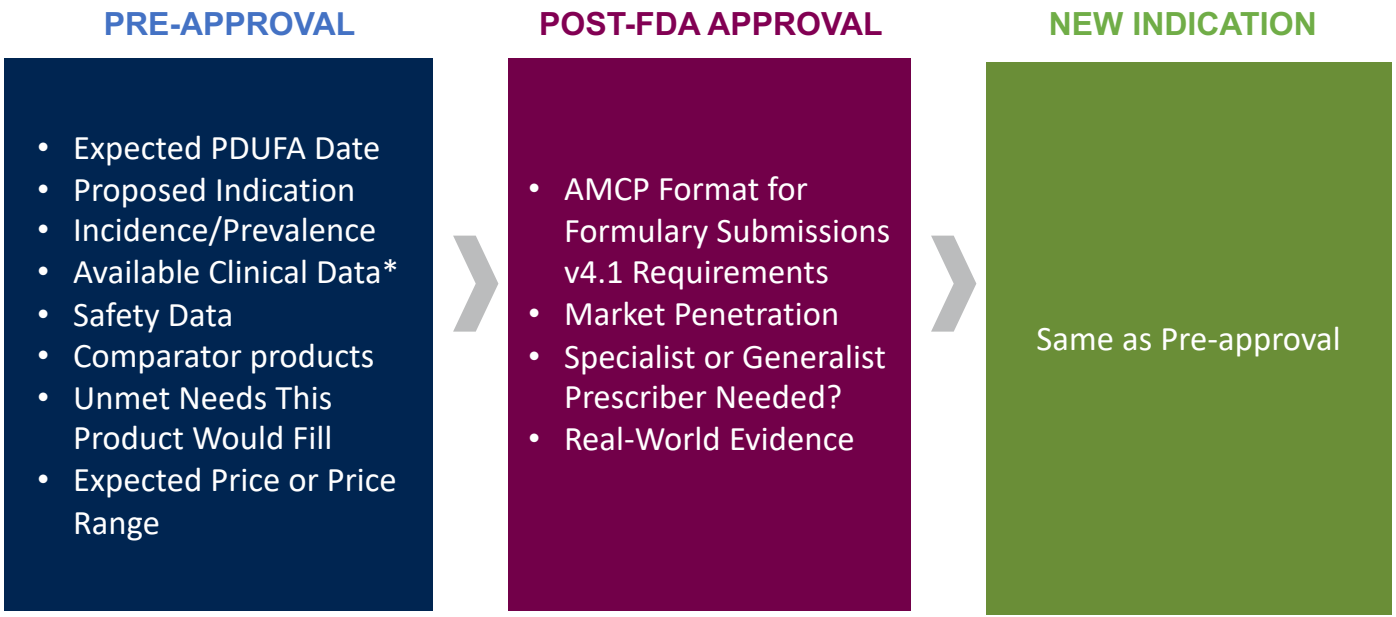
Director, Pharmacy Services

SelectHealth

When do payers need information?



Payer Information Requirements



*With appropriate disclaimers for trials still in process.

Challenges to Receiving Information

Payer Insights from FormularyDecisions

Laurie Fazio

Head, Market Access Solutions & Growth Strategies, FormularyDecisions

Xcenda

FormularyDecisions

Central platform connecting health care decision makers to the **evidence**, **resources**, and their **peer community**, so they can work more effectively and collaboratively.

Data collected on:

- 2,100+ US PAYERs/HCDMs
- 900+ organizations
- 86% of covered lives (MCO)
- Includes all top PBMs
- 500,000 + evidence links
- 2,500 + products

Active evidence review and assessment to make informed formulary and reimbursement decisions.

A closed payer only environment.

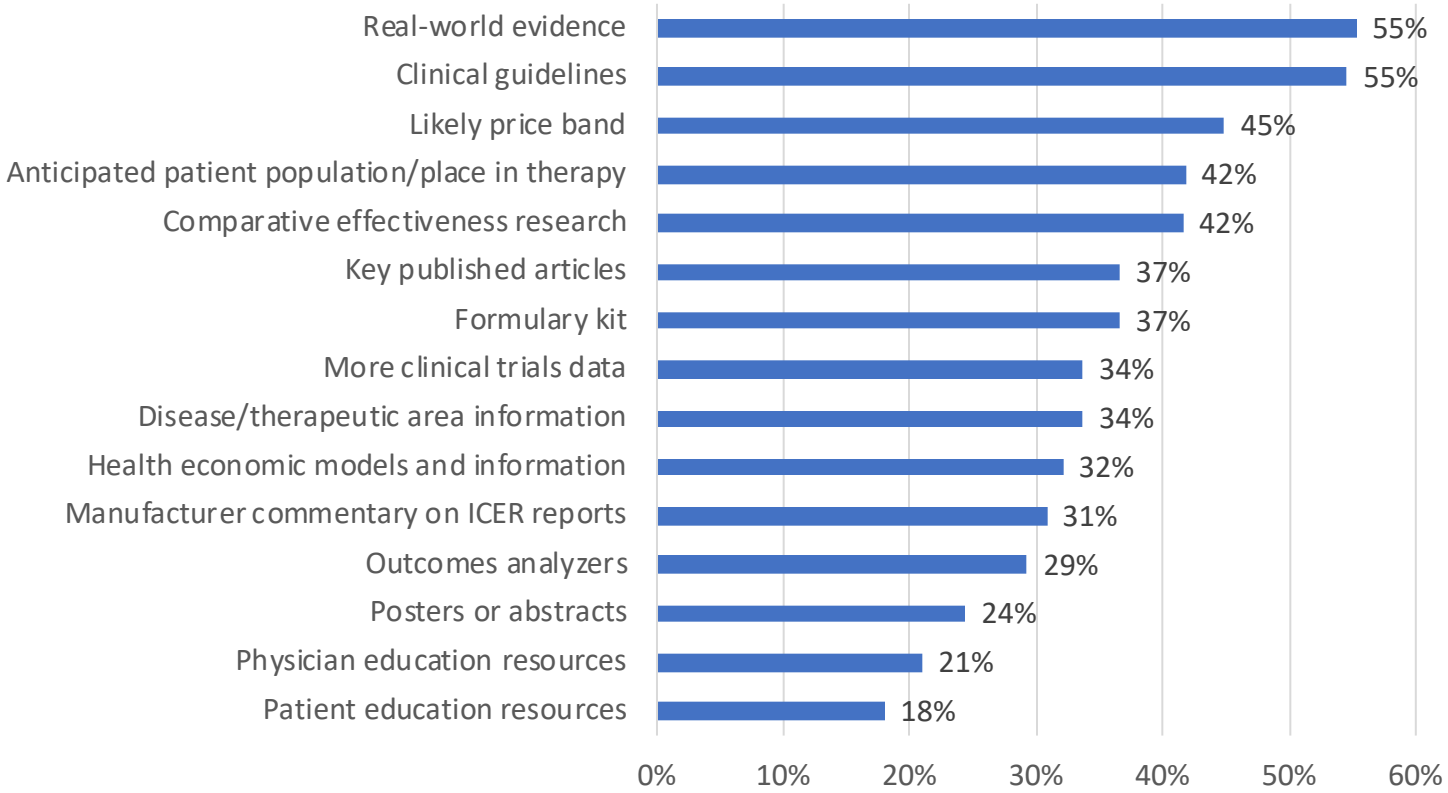
ISPOR

AMCP

PhactMI

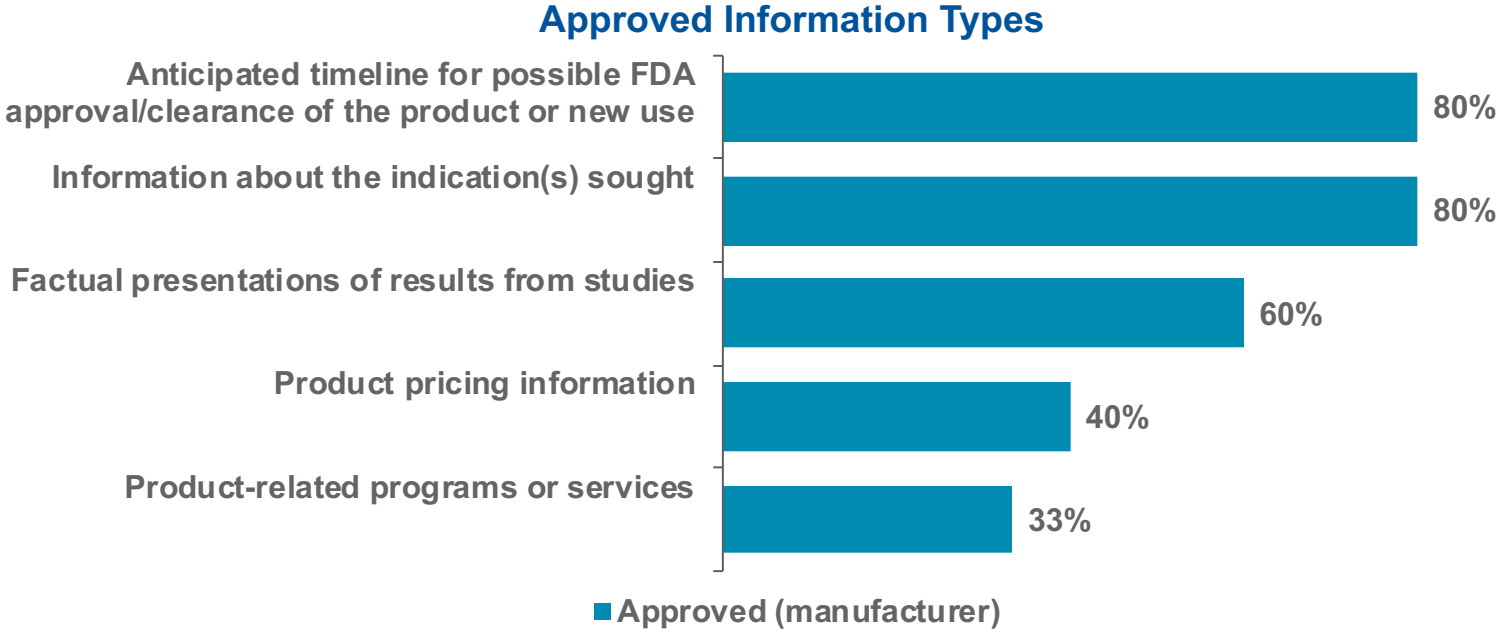
Relationships

What payers are seeking…



FormularyDecisions Syndicated Survey Results: 12 months ending Oct 2019 (N=1346)

What manufacturers are delivering…



Note: Manufacturer data from 2018. Base: Subset of 41 manufacturers who engaged in pre-approval information exchange (n=15). Q20 [Manufacturers]: Which, if any, of the following types of information about investigational products are approved in your organization for PIE discussions with eligible entities? Data on file; Xcenda.

Supporting Payers via FormularyDecisions

Top 25 pre-approval products (based on overall activity)

IV Meloxicam	Ursodeoxycholic acid
ALKS 3831	Ketanest
CSL112	Rova-T
ITCA 650	AR101
Valtoco	Ongentys
Tralokinumab	Remoxy
Vumerity	Viaskin Peanut
Remune	Ozanimod
Golodirsen	Brixadi
Ampion	A-101
Talzenna	Coversin
Zynquista	Ubrogepant
	CT-P6

Driving interest and activity

- Top 25 products had an average of over 60 unique payers' access information on their product
- Subscribing products that utilized the Manufacturer Resource Center to provide product information that did not require an unsolicited request had a 20% increase in overall activity

Payer Review Activities: FormularyDecisions

Top 25 pre-approval products

- 50% had payers accessing a drug class review
- 60% had requests for information (71 payers requested)
- 70% are being followed by payers (83 payers are following)
- 80% of products had payers searching for that specific product; 20% had exposure indirectly via evidence sources
- 100% of products with relevant ICER reports were accessed by payers

Payer Insights via the FormularyDecisions Platform Can Provide a Feedback Loop for Pre-Approval Product Information

> *I think there's definitely 'potential' for value with 'new product,' but it's just a little early to say for sure without understanding the full clinicals. In general, however, there is definitely an unmet need in improving outcomes in people with cardiovascular issues. The PCSK-9 inhibitors were supposed to be huge blockbuster drugs, but never really took off that way due to high pricing and perhaps limited efficacy in improving CV outcomes. 'New product' is interesting as it has a new mechanism and preliminary info suggests it can significantly improve outcomes... but certainly we will need much more clinical info to know the value of this product.*

> *Product Y coming in at around 7% less than Product Z was a welcome finding and I would hope 'new product' would come in even less than both (time will tell!). Once again the more competition the lower drug prices (hopefully at least).*

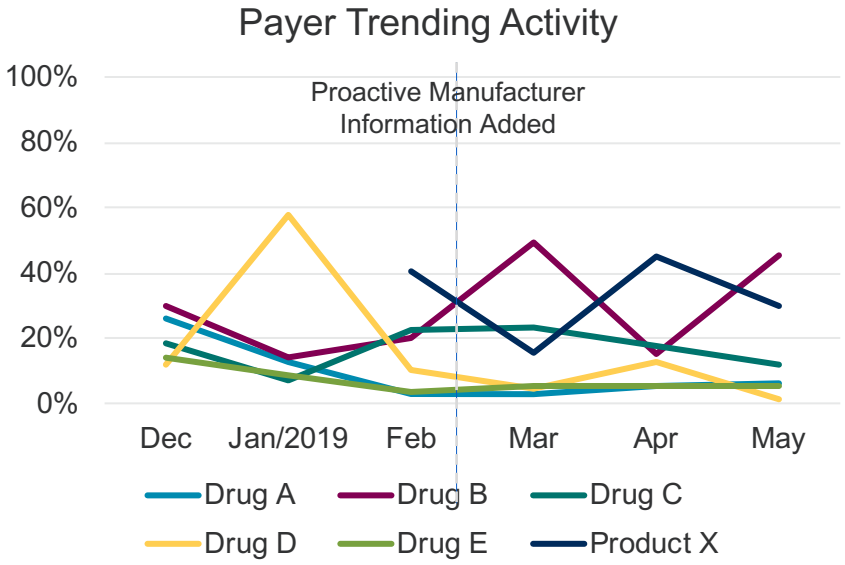
> *I think there's potential value for 'new product' as an additional MOA on the market will only increase treatment options for physicians. However, I don't see an obvious gap in therapy this product is looking to solve. Existing products are already on the market with many years' worth of data supporting their use.*

> *Similar efficacy to other oral agents listed; potentially more favorable than Product X.*

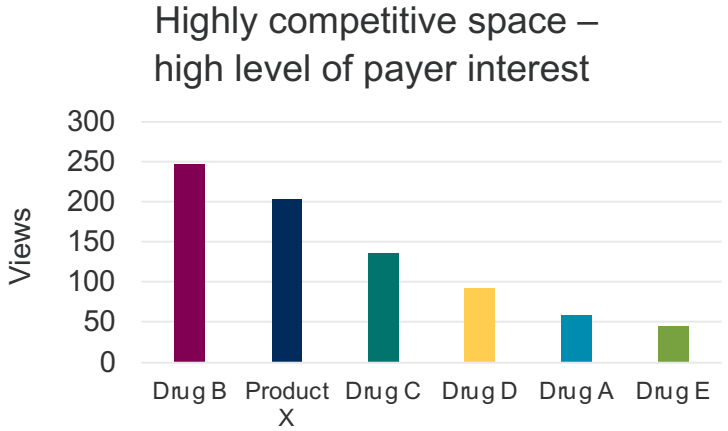
> *Good because it's a head-to-head study with a competitor product.*

Supporting Payers During Pre-approval Product Review

24+ months from launch



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



Within the last 30 days activity increased by **28%**

22% Share of competitor activity | **39%** Comparative requests | **6** Payers added this product to Watchlist | **38** Unique visitors

Manufacturers' Role in Pre-approval Information Exchange

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

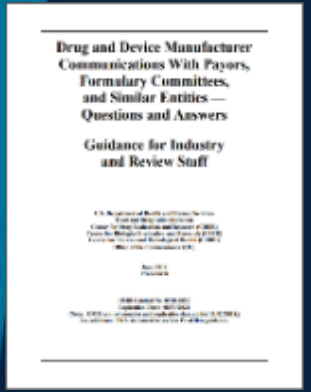
What is Your Role?

FDA will not object if firms communicate the following:

- Product information
- Study design/results
- Information about the indication(s) sought
- Anticipated FDA approval/clearance/licensure timing
- Pricing information
- Patient utilization projections (eg, epi data projection on incidence and prevalence)
- Product-related programs or services (eg, patient support programs)

Other information:

- A clear statement that the product or use is not approved/cleared/licensed, safety or effectiveness has not been established
- Information about the stage of development
- A prominent statement disclosing the intended indication(s)
- Information must be accurate, factual, non-misleading, and unbiased
- Update payers on changes/new information


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

Guidance for Industry and Review Staff

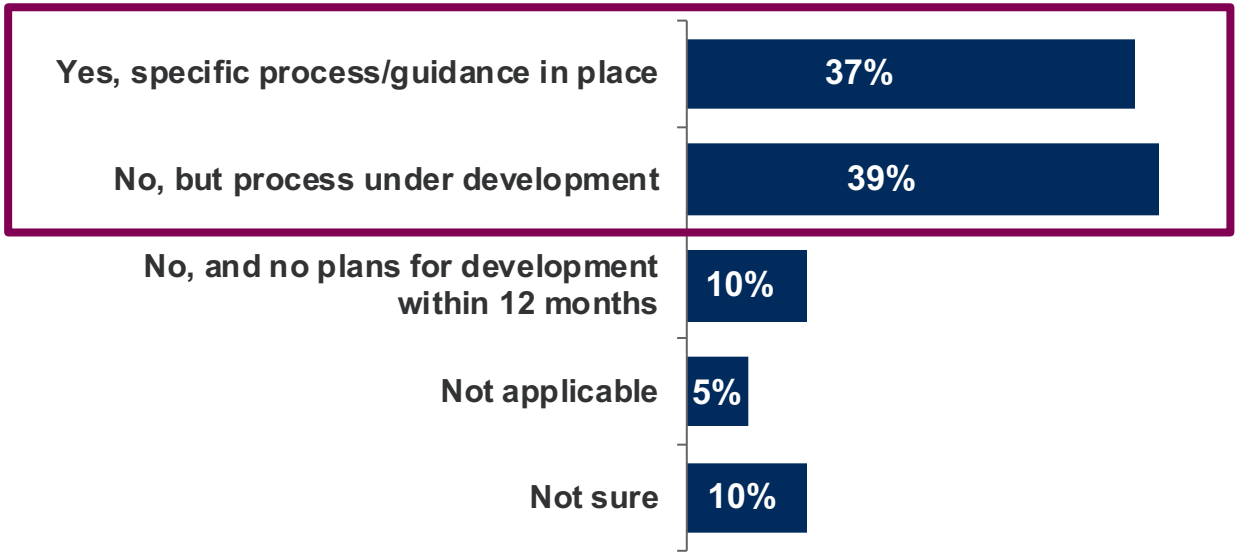
FDA. Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities – Questions and Answers: Guidance for Industry and Review Staff. June 2018.

What Is Your Role?

- Know legislative activities--Burr Amendment (PIE language looking for a bill)
- Ensure organizational awareness
- Understand what information payers are seeking by product (MCO, IDN, PBM, etc)
- Create a plan and process to deliver PIE

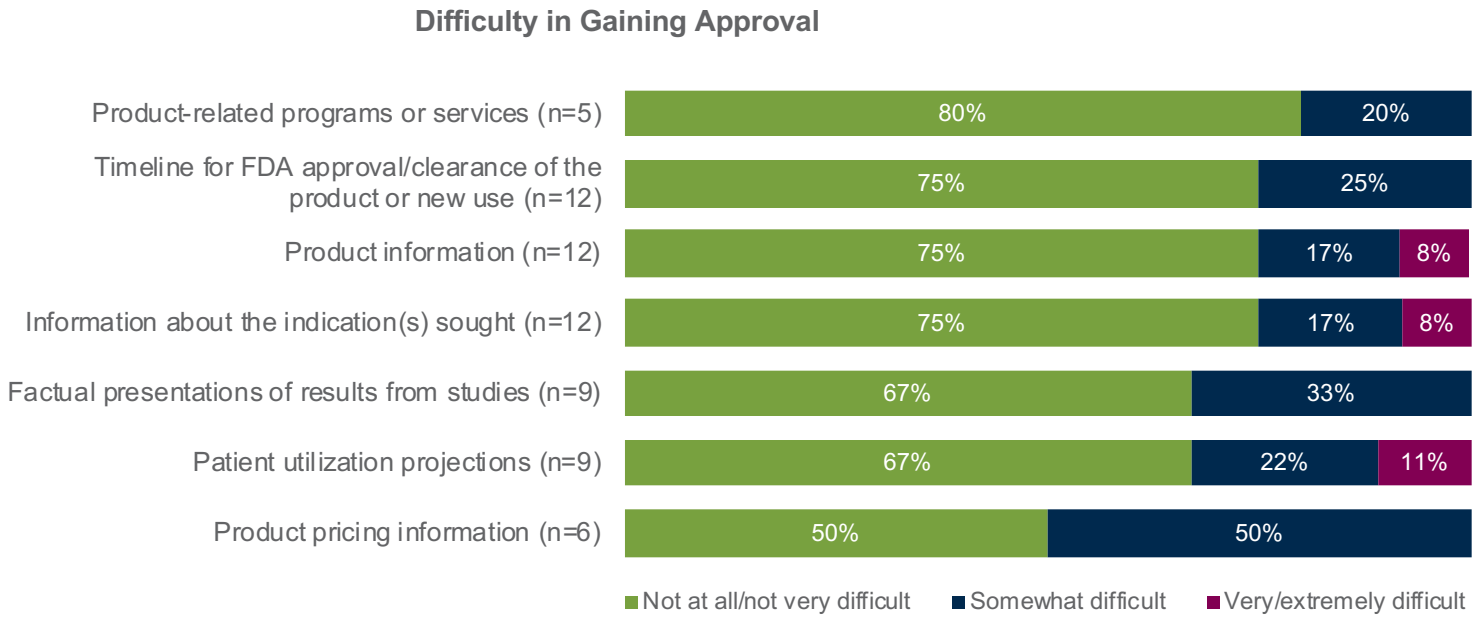
Most manufacturer respondents have a specific process in place or in the works for approving PIE materials

Existence of Process to Approve PIE Materials



Note: Manufacturer data from 2018. Percentages may not total 100% due to rounding.
Base: Manufacturers (N=41).
Q1 [Manufacturers]: Is there a specific process/guidance (eg, SOP, formal committee, etc) in place within your organization to approve materials intended for PIE?
Data on file; Xcenda.

Difficulty Experienced in Gaining Approval for Each Type of PIE Within Organization



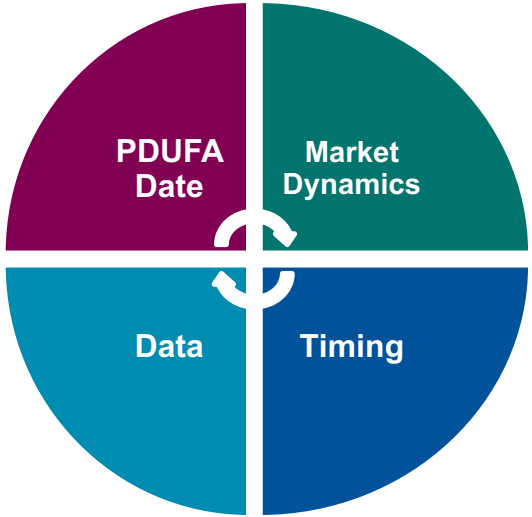
Notes: Ratings based on types of PIE used within respondent organizations; manufacturer data from 2018.
Base: Manufacturers who gave a rating (15 of 41 responses).
Q21a [Manufacturers]: For each type of PIE listed, please rate the level of difficulty experienced in gaining approval.
Data on file.

Communication Timelines Must Be Flexible

Key factors to consider that may impact timing of information delivery:

- Anticipated PDUFA date
- Normal approval pathway vs faster approval pathway (Accelerated, Breakthrough, Priority, Fast Track)

- Availability of treatment options
- Novel therapy (eg, rare/ ultra rare)
- Curative or significant change in treatment landscape

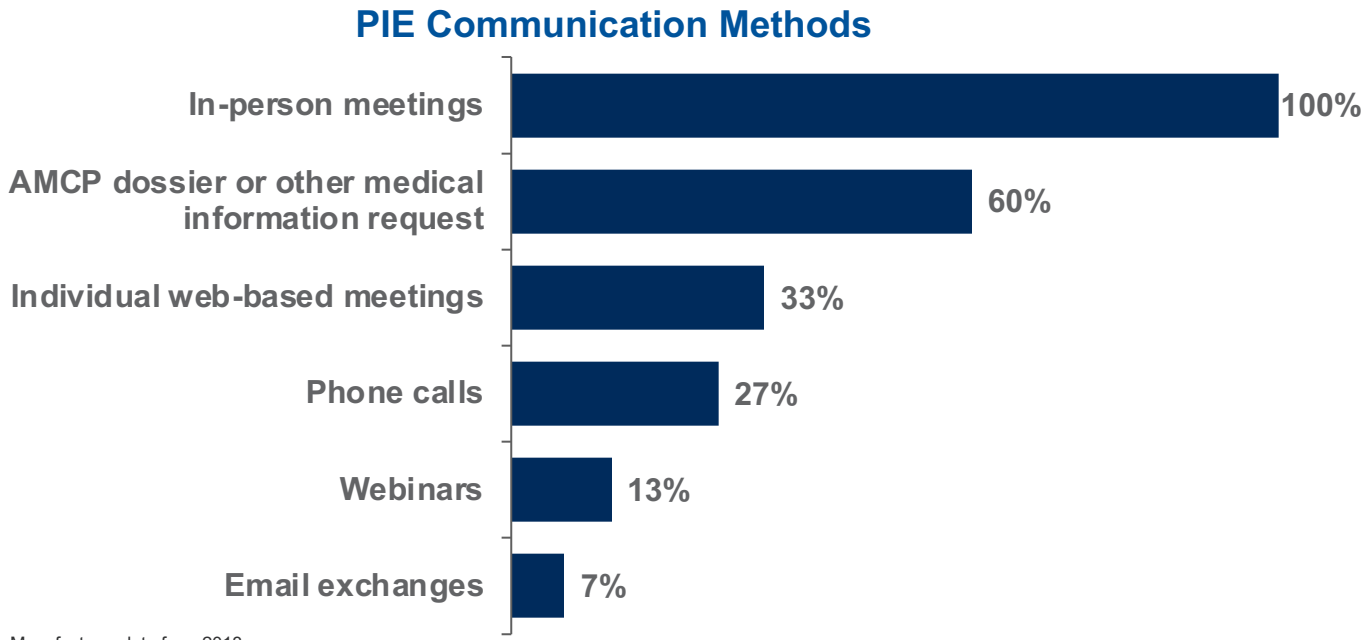


- Robustness of available data
- Type of data

- Payer budget, forecasting, and planning cycles
- Publication timing (embargoed)

Jackson J, Onwudiwe N, Khachatourian KW, Saha S. Best practices to implementing proactive communications between manufacturers and payers. Presentation at: AMCP Managed Care & Specialty Pharmacy Annual Meeting; April 2018. Boston, MA.

PIE is most likely to be communicated through in-person meetings, followed by reactive AMCP dossiers / other medical requests



Note: Manufacturer data from 2018.
Base: Manufacturers (n=15).
Q26 [Manufacturers]: How is your organization currently communicating with eligible entities regarding PIE?
Source: Data on file; Xcenda.

Key Considerations for Delivering a Credible Message in Person

The focus should not be on WHO, but should be on the WHAT and ensuring appropriate SKILLS and COMPETENCIES of the individuals delivering the information

- Know your audience (Credible Recipients)
- Desirable skills and competencies are similar pre- and post-approval
- Actual job title will likely vary based on size and structure of manufacturer
- May require a team of individuals with complementary areas of expertise
- Labels of “promotional” vs “non-promotional” personnel should not limit ability to communicate
- Individuals should be trained to communicate at the top of their scope of practice

Jackson J, Onwudiwe N, Khachatourian KW, Saha S. Best practices to implementing proactive communications between manufacturers and payers. Presentation at: AMCP Managed Care & Specialty Pharmacy Annual Meeting; April 2018. Boston, MA.

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Where knowledge,
reach and partnership
shape healthcare delivery.