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FormularyDecisions℠ AmerisourceBergen

Embracing Format v4.1 for Early, Effective Exchange of Information with Payers

January 28, 2020

Science & INNOVATION THEATER WEBINARS

Developed for Managed Care Pharmacy by AMCP Corporate Members

AmerisourceBergen

AMCP

Agenda

This webinar will include:

- An overview of key changes to the AMCP Format v4.1 that impact preapproval information exchange
- Payer perspective on current practices and how receiving earlier, more robust information will enhance decision making
- Best practices for manufacturers, including consideration of preapproval dossiers and use of payer and competitive insights from the FormularyDecisions platform to inform strategy

Speakers

Moderator:

- *Elizabeth Sampsel, PharmD, MBA, BCPS, Senior Director, Payer, Provider and Partner Alliances, Xcenda*

Speakers:

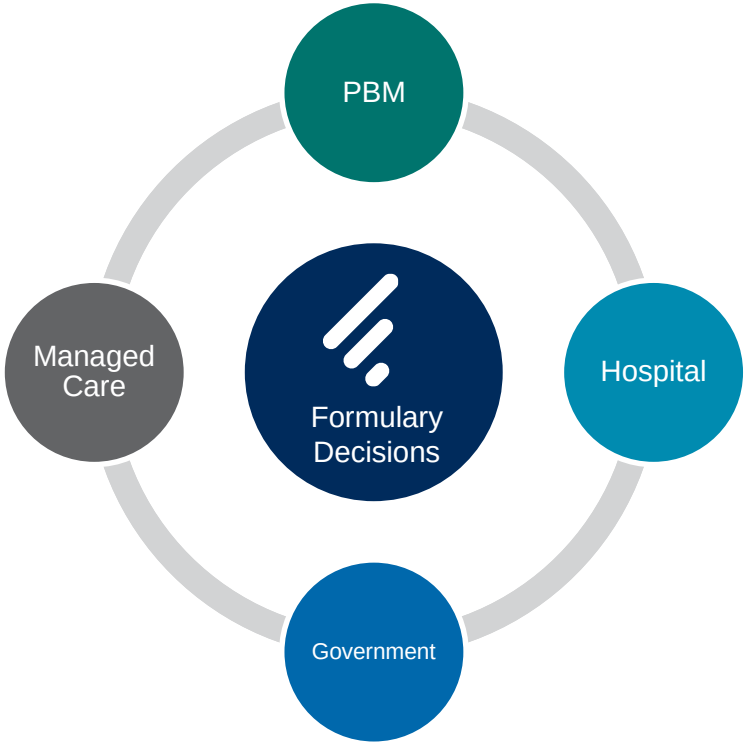
- *Lisa Cashman, PharmD, Director, Clinical Account Services, MedImpact Healthcare Systems*
- *Curtis Wander, PharmD, BCPS, Clinical Pharmacy Manager, SelectHealth*
- *Evelyn Sarnes, PharmD, MPH, VP, Medical Communications, Xcenda*

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:

- 2400+ US PAYERs/HCDMs
- 900+ organizations
- 86% of covered lives (MCO)
- Includes all top PBMs
- 520,000 + evidence links
- 3000 + products (including 400-500 preapproval products)



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

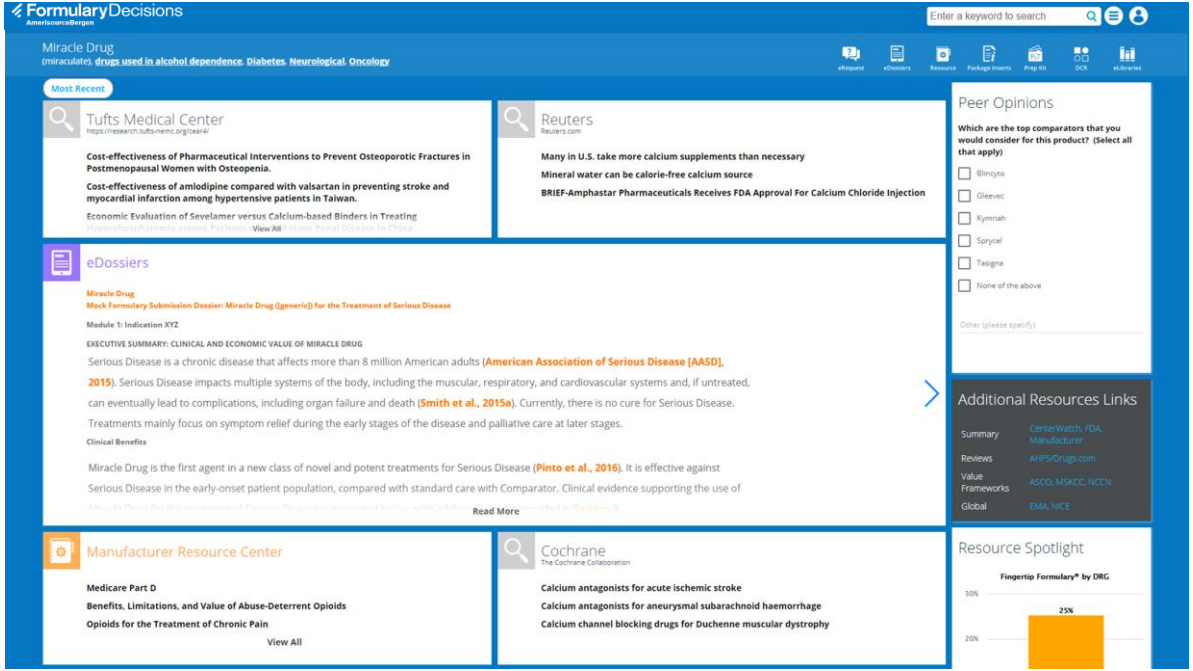
A closed payer only environment.

Relationships

AMCP phactMI ISPOR

Opportunities to Address Payer needs Preapproval

- Preapproval 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



Updated *Format* Version 4.1

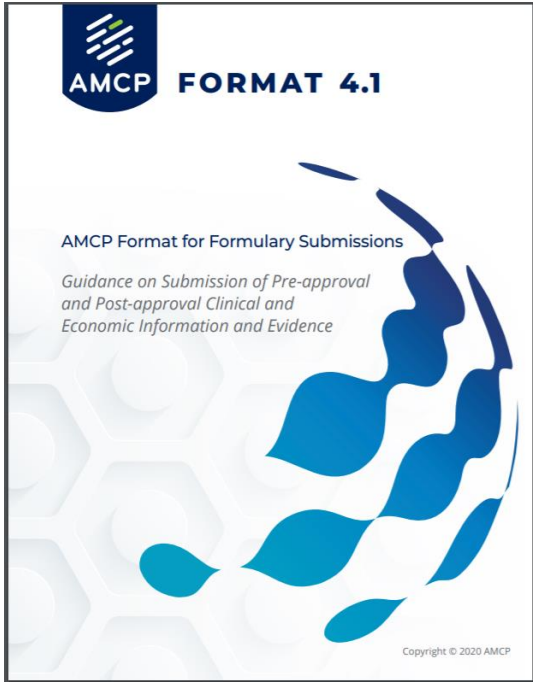
Lisa Cashman, Pharm.D.
Director, Clinical Account Services
MedImpact

MedImpact
Independent, Trend-Focused Pharmacy Benefit Manager™

Development of Version 4.1

- June 2018, FDA Final Guidance on manufacturer communications with payers, formulary, and similar entities was released[1]
- In Q3'18, the FEC decided to update V4.0 to V4.1 to build upon the *Format's* guidance on the communication of pre-approval information using dossiers as a communication mechanism
- Format 4.1 was released on December 23rd, 2019 and is posted here:

  https://www.amcp.org/Resource-Center/format-formulary-submissions/AMCP-Format-for-Formulary-Submissions-4.1



Challenges:

- Aligning with, referencing and interpreting the FDA Final Guidance
- Update the *Format* or develop a separate *Format*-like guidance document?
- Do we call the pre-approval information a dossier or something else?
- Opposing manufacturer and health care decision maker's (HCDM) perspectives, e.g., pricing information
- How to communicate pre-approval information, e.g., proactive or reactive?

1. Food & Drug Administration (FDA). Drug and device manufacturer communications with payors, formulary committees, and similar entities – questions and answers: guidance for industry and review staff. June 2018; Available at: https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537347.pdf. Accessed 1/31/19.

Dossier Information Before FDA Approval in Version 4.0

- Clinical trial information from Phase 1, Phase 2, and Phase 3 studies
  - Peer-reviewed publications
  - Medical congress abstracts, posters, presentations
  - Medical information or medical communication departments' response letters
- Information from clinicaltrials.gov
- Pre-clinical studies
- Data on file per manufacturer's discretion
- Disease state information, e.g., disease description, epidemiology, clinical presentation, currently available therapies, clinical practice guidelines, etc.
- Pipeline product information, e.g., proposed mechanism of action
- Any other information that a manufacturer deems relevant to the request and allowable according to the manufacturer's policies and procedures
- Some manufacturers may consider providing certain information under a confidentiality agreement

1.. Academy of Managed Care Pharmacy (AMCP) *Format for Formulary Submissions*, Version 4.0. April 2016. Available at:http://www.amcp.org/sites/default/files/2019-03/AMCP-Format-V4.pdf. Accessed 9/12/19

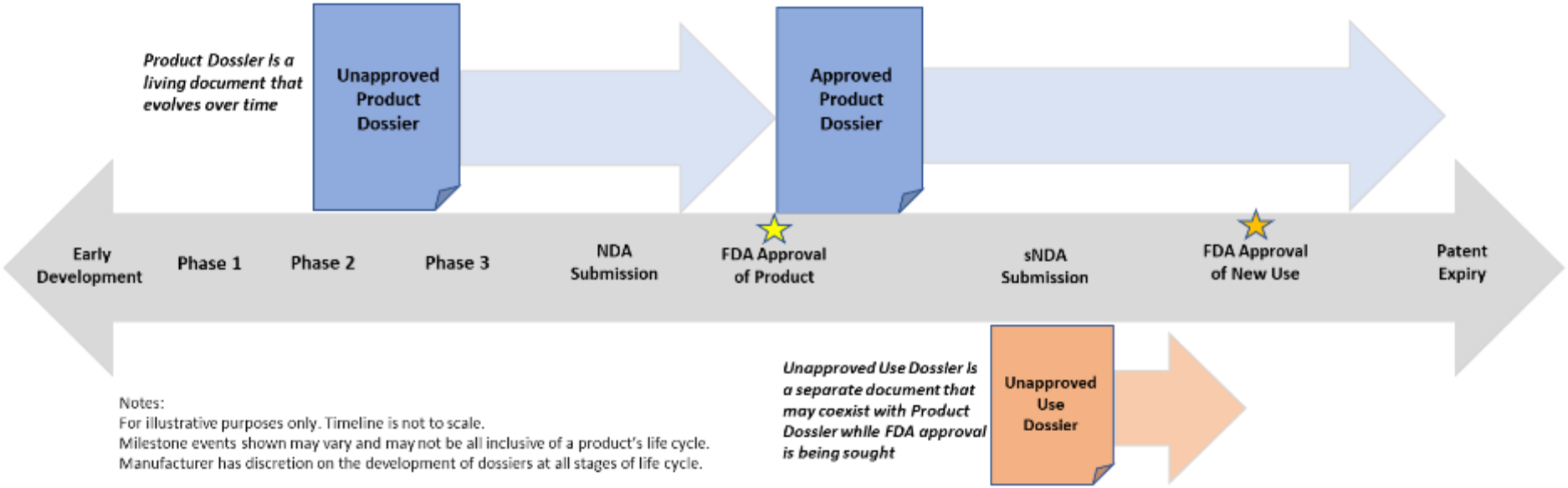
Types of Dossiers

Dossier	Description
Unapproved Product	• Contains information about an unapproved product for which initial FDA approval is being sought • Used to communicate information about an unapproved product
Approved Product	• Contains clinical and economic evidence about an approved product • Used to respond to unsolicited requests from HCDMs after FDA approval of the product
Unapproved Use	• Contains information about an unapproved use of an approved product for which FDA approval is being sought • Used to communicate information about an unapproved use of an approved product for which FDA approval is being sought

Academy of Managed Care Pharmacy (AMCP). The AMCP Format for Formulary Submissions, Version 4.1. October

AMCP Dossier Relative to Product Life Cycle

Figure 1. AMCP Dossier Relative to Major Milestone Events of a Product's Life Cycle



Notes:
For illustrative purposes only. Timeline is not to scale.
Milestone events shown may vary and may not be all inclusive of a product's life cycle.
Manufacturer has discretion on the development of dossiers at all stages of life cycle.

NDA = New Drug Application; sNDA = Supplemental New Drug Application

Academy of Managed Care Pharmacy (AMCP). The AMCP Format for Formulary Submissions, Version 4.1. October 2019

Regardless of Dossier Type:

Recipients

Recipients of dossiers include HCDMs, payers, and entities that make or influence formulary, coverage, policy, and reimbursement decisions

Updates

Updates to dossiers should occur when new information becomes available; at the discretion of manufacturer

Guidance

The *Format* is a guidance, not a mandate

Development

Development of dossiers is at the discretion of the manufacturer

Content of Dossiers

	Approved Product Dossier	Unapproved Product & Unapproved Use Dossiers
Value Proposition	Can communicate value that is grounded on clinical and economic evidence and information	No characterizations/conclusions beyond factual evidence should be made regarding the safety or effectiveness of the unapproved product/unapproved use of approved product
Clinical Information	Clinical evidence and information regarding an approved product, including any off-label uses supported by evidence	Factual presentation of clinical evidence for unapproved product/unapproved use that is available at the time of communication
Economic Information	Product price; health economic and outcomes research; economic models on budget impact and cost-effectiveness	AMCP Format Executive Committee recommends providing anticipated product price or anticipated product price reflected as a range

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Communication of Dossiers

	Approved Product Dossier	Unapproved Product & Unapproved Use Dossiers
How should manufacturer provide dossier to HCDMs?	Upon unsolicited request only	Manufacturers' discretion
Who from manufacturer should communicate or provide dossier?	Personnel with appropriate medical/clinical/scientific credentials, expertise, and responsibilities	AMCP Format Executive Committee strongly recommends personnel with appropriate medical/clinical/scientific credentials, expertise, and responsibilities

Academy of Managed Care Pharmacy (AMCP). The AMCP Format for Formulary Submissions, Version 4.1. October 2019

Unapproved Product Dossier

How is it used?

Used by manufacturers to communicate information to HCDMs before FDA approval of the product

Planning and budgeting

When should dossier be ready for use?

Any time before FDA approval of product; at the discretion of manufacturer. Typically 6-12+ months prior to FDA approval

Evidence Recommendations for Unapproved Product Dossier

Section 1.0: Highlights and Overview

- Note: no executive summary (no value proposition due to inability to draw conclusions regarding safety and effectiveness of approved product)
- Single table of key information about an unapproved product

- Manufacturer Name
- Unapproved Product Name
- Drug Class
- Disease or Anticipated Indication
- Special FDA Designations
- NDA/BLA Submission Date
- FDA Advisory Committee Meeting
- PDUFA or FDA Approval Date
- Product Launch Data
- Phase 2/3 Trials Completed/In Progress
- Anticipated Dosing/Routes of Administration
- Product Pricing Information
- Anticipated Distribution Strategy
- Anticipated Patient Support Programs
- Anticipated Setting of Administration

Academy of Managed Care Pharmacy (AMCP). The AMCP Format for Formulary Submissions, Version 4.1. October 2019

Evidence Recommendations for Unapproved Product Dossier

Section 2.0: Product Information and Disease Description

- Section 2.1A Product Description
  - Statement that the unapproved product is not FDA approved, and that the safety or effectiveness of the unapproved product has not been established
  - Product Information *(*e.g., drug class, device description and features)
- Section 2.2A Disease Description
  - Manufacturers are requested to provide as much information as possible about the medical condition or disease state for which the unapproved product is being studied and FDA-approval being sought without making characterizations or conclusions about the safety or effectiveness of the product

Section 3.0: Clinical Evidence

- All clinical studies that support the unapproved product
- Manufacturers may use discretion to provide information in the form of study summaries only or evidence tables only or both

Section 4.0 Economic Information

- Manufacturers encouraged to provide as much product pricing information as possible.
- Cost-effectiveness models and budget impact models may not be feasible due to inability to draw conclusions about product safety and efficacy

Academy of Managed Care Pharmacy (AMCP). The AMCP Format for Formulary Submissions, Version 4.1. October 2019

Unapproved Use Dossier

How is it used?

- Used by manufacturers to communicate information to HCDMs about an unapproved use(s) of an approved product for which the manufacturer is seeking FDA approval
- Planning and budgeting

When should it be ready for use?

Any time while manufacturer is seeking FDA-approval for the unapproved use of approved product

Evidence Recommendations for Unapproved Use Dossier

Section 1.0: Highlights and Overview

- Note: no executive summary (no value proposition due to inability to draw conclusions regarding safety and effectiveness of approved product)
- Single table of key information about an unapproved product

- Manufacturer Name
- Unapproved Use
- Approved Use and Indication
- Special FDA Designations
- sNDA/sBLA Submission Date
- FDA Advisory Committee Meeting
- PDUFA or FDA Approval Date
- Approval Dates in Other Countries
- Anticipated Setting of Administration
- Anticipated Dosing/Routes of Administration
- Incidence/Prevalence of Condition
- Product Pricing Information
- Anticipated Distribution Strategy
- Anticipated Patient Support Programs
- Phase 2/3 Trials Completed/In Progress related to Unapproved Use

Academy of Managed Care Pharmacy (AMCP). The AMCP Format for Formulary Submissions, Version 4.1. October 2019

Evidence Recommendations for Unapproved Use Dossier

Section 2.0: Product Information and Disease Description

- Section 2.1A Product Description
  - Statement that the unapproved use of an approved product is not FDA approved, and that the safety or effectiveness of the unapproved use has not been established
  - Product Information *(*e.g., drug class, device description and features)
- Section 2.2A Disease Description
  - Manufacturers are requested to provide as much information as possible about the medical condition or disease state for which the unapproved use is being studied and FDA-approval being sought without making characterizations or conclusions about the safety or effectiveness of the unapproved use

Section 3.0: Clinical Evidence

- All clinical studies that support the unapproved product
- Manufacturers may use discretion to provide information in the form of study summaries only or evidence tables only or both

Section 4.0 Economic Information

- The price of the product should be known for the approved product and should be included in the Unapproved Use Dossier.
- Cost-effectiveness models and budget impact models may not be feasible due to inability to draw conclusions about product safety and efficacy

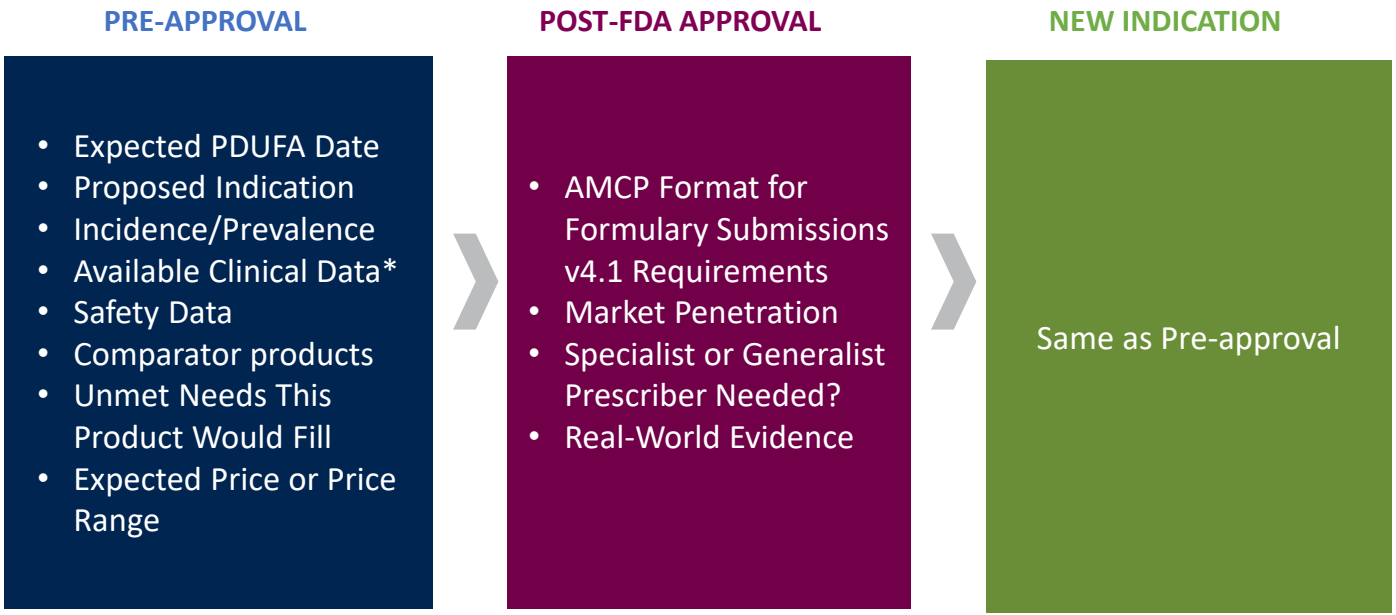
Academy of Managed Care Pharmacy (AMCP). The AMCP Format for Formulary Submissions, Version 4.1. October 2019

Payer Perspectives on Pre-approval Information

Curtis Wander, PharmD, BCPS
Clinical Pharmacy Manager
SelectHealth

When do payers need information?

Payer Information Requirements



*With appropriate disclaimers for trials still in process.

Challenges to Receiving Information

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Best Practices for Manufacturers

Evelyn Sarnes, PharmD, MPH

VP, Medical Communications

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Ambiguity in the Format provides flexibility as the industry is still evolving around preapproval information exchange

Informed recommendations

Grounded in HCDM needs and understanding of the PIE guidance and history (FDAMA 114)

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Forums & Webinars on FDAMA 114, Section 3037, and PIE

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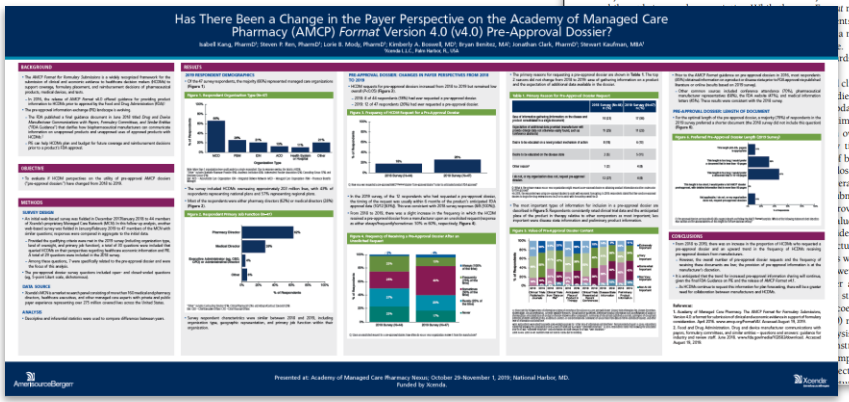
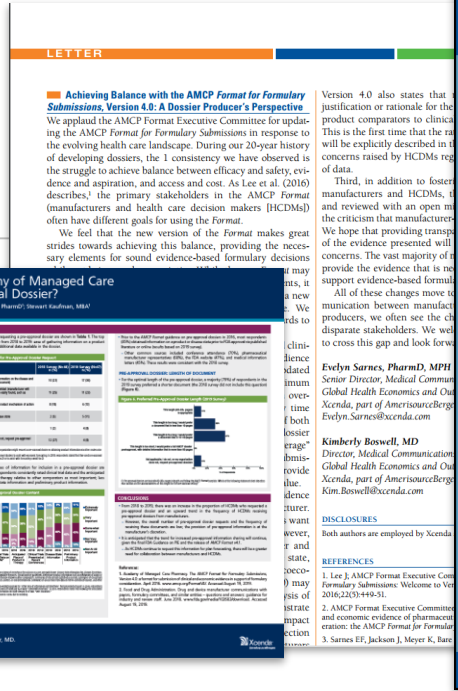
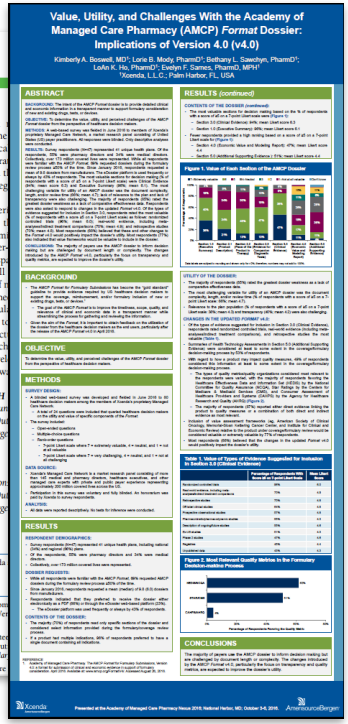

Has There Been a Change in the Payer Perspective on the Academy of Managed Care Pharmacy (AMCP) *Format* Version 4.0 (v4.0) Pre-Approval Dossier?


LETTER

Achieving Balance with the AMCP *Format for Formulary Submissions*, Version 4.0: A Dossier Producer's Perspective


Value, Utility, and Challenges With the Academy of Managed Care Pharmacy (AMCP) *Format* Dossier: Implications of Version 4.0 (v4.0)

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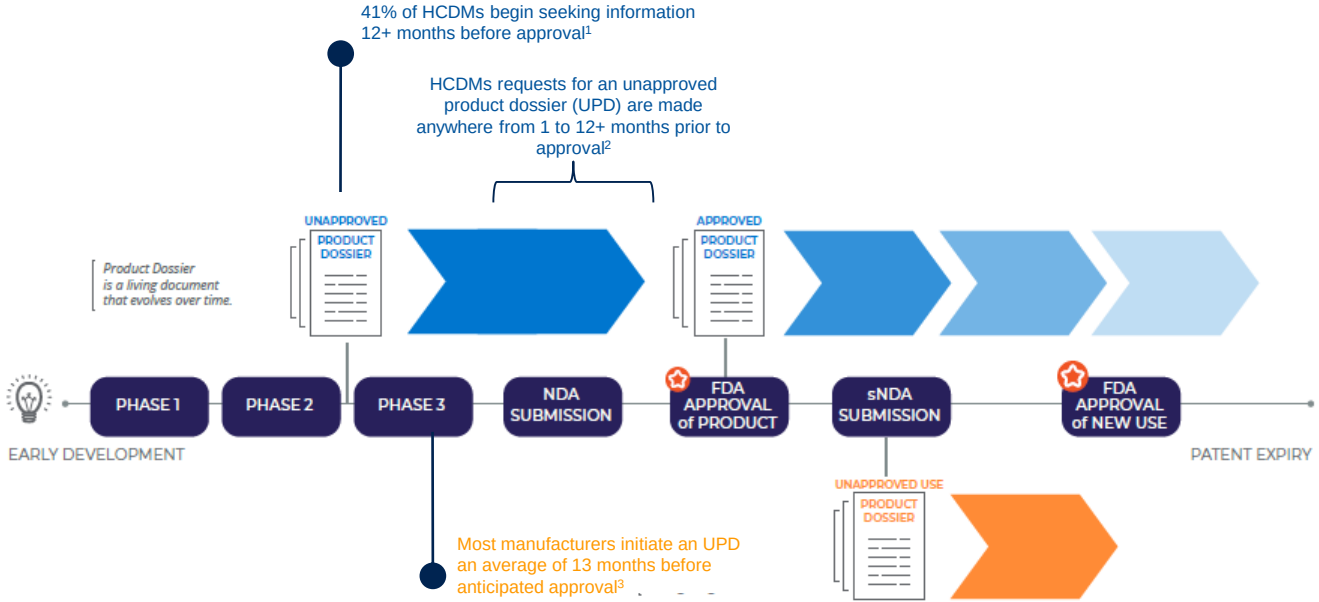
Recommendations on the dossier development timeline

AMCP dossier development relative to major product lifecycle events



Key: AMCP – Academy of Managed Care Pharmacy; FDA – Food and Drug Administration; HCDM – health care decision maker; mos – months; NDA – New Drug Application; sNDA – Supplemental New Drug Application; UPD – unapproved product dossier

1. Dymaxium Internal Data: Survey; Average of 2016 and 2018 response. 2. Mody L, et al. Payer perspective on the AMCP *Format* v4.0 preapproval dossier in a Managed Care Network [poster]. Presented at AMCP Annual Meeting; April 23-26, 2018: Boston, MA. 3. Xcenda internal data.

Figure adapted from the AMCP Format for Formulary Submissions v4.1. Copyright 2020 AMCP.

How should an unapproved product dossier be delivered?

Our best practices recommendations to developing a unapproved product dossier (UPD)

YES, develop a UPD 3-12+ months before approval:

- No precedence (yet) for proactive distribution
- Manufacturer-specific processes may not exist
- Lack of legislative safe harbour

PIE Deck

HCDMs

Proactive use

Unsolicited request

UPD

- Precedence for development of PIE in other formats (eg, slides)
- Dual approach allows for flexibility in response for HCDM needs

Key: APD – approved product dossier; HCDM – health care decision maker; PIE – preapproval information exchange; UPD – unapproved product dossier

How do I make sure the dossier is a living document?

Practical considerations for the unapproved, approved, and unapproved use dossier

UPD

FDA

FDA Approval

Approved Product Dossier (APD)

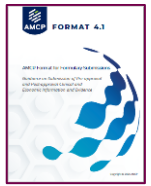
FDA

sNDA submission

APD, a comprehensive dossier of current indication

APD Update Triggers:

- Additional clinical data (OLE, data cuts)
- Evolving treatment landscape (guidelines, new comparators)
- Significant economic or RWE evidence becomes available
- Regulatory actions

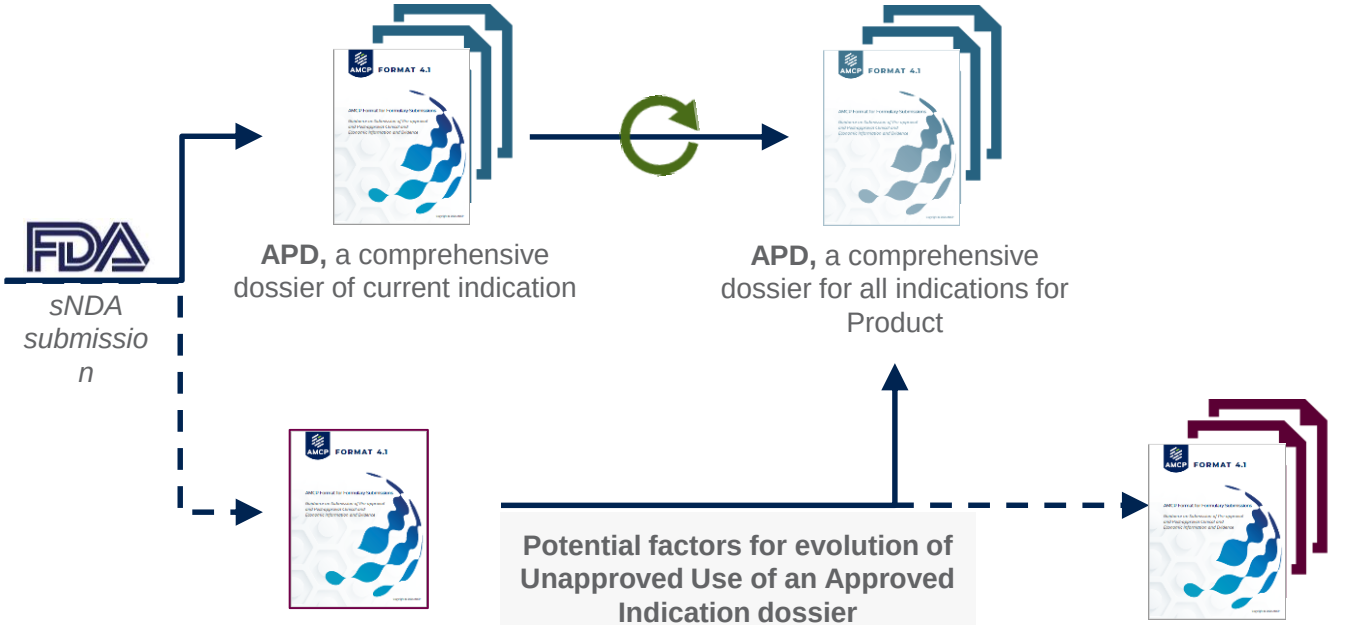


Unapproved Use Dossier (UUD) for the sNDA usage

Key: APD – Approved Product Dossier; FDA – Food and Drug Administration; OLE – open-label extension; RWE – real-world evidence; sNDA – Supplemental New Drug Application

How do I make sure the dossier is a living document? (cont'd)

Practical considerations for the unapproved, approved, and unapproved use dossier



Key: APD – Approved Product Dossier; FDA – Food and Drug Administration; sNDA – Supplemental New Drug Application

Other Key Changes in the AMCP Format v4.1

- Significant emphasis on early and open dialogue between manufacturers and HCDMs, including bidirectional feedback on the dossier itself

The AMCP Format Executive Committee updated the AMCP Format to Version 4.1 to focus and modernize the bidirectional communication between manufacturers and HCDMs specifically as it relates to communication of preapproval information

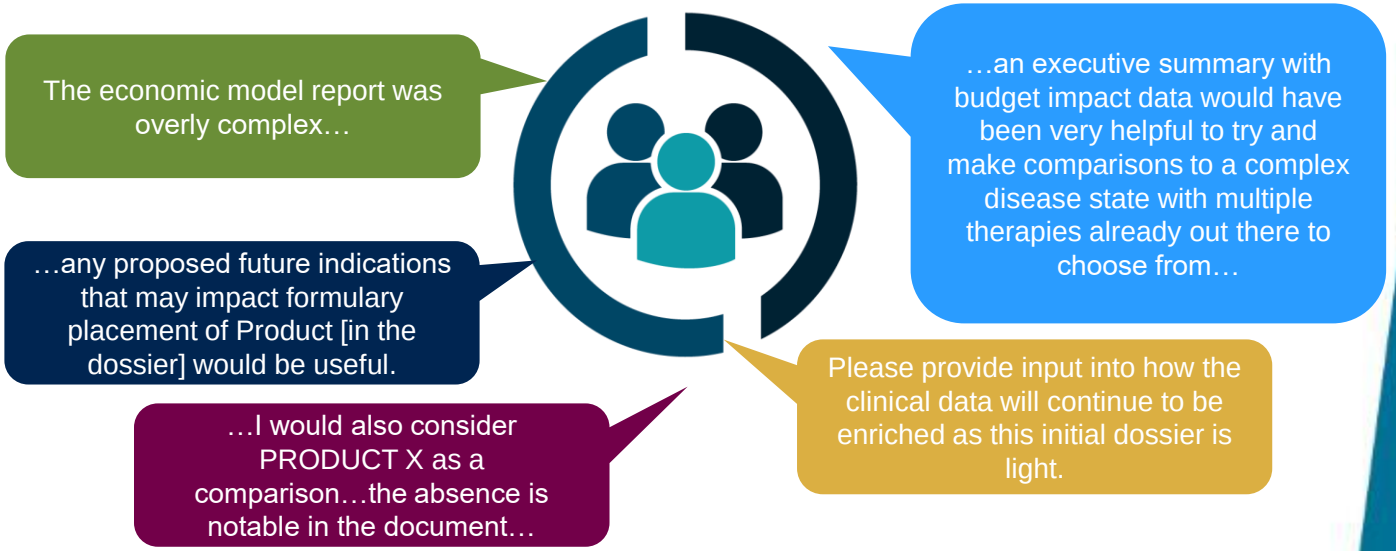
Substantial ongoing and bidirectional, rather than unidirectional, communication and feedback between the HCDM and manufacturer throughout the product evaluation process is critical to manage expectations and maximize the quality of available evidence

Key: AMCP – Academy of Managed Care Pharmacy; HCDM – health care decision maker

Value and Impact of Bidirectional Feedback

Examples of feedback for an AMCP eDossier

- Feedback received from HCDMs on an Approved Product AMCP dossier available on FormularyDecisions
- Received from the platform as survey responses and open-ended comments/feedback

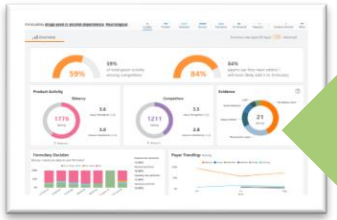


Key: AMCP – Academy of Managed Care Pharmacy; HCDM – health care decision maker

How to Encourage Early and Open Dialogue

- Many ways to solicit feedback exist and are used
  - Advisory boards and focus groups
  - Direct feedback during live meetings
  - Surveys

- An electronic platform like FormularyDecisions supports the exchange of information between manufacturers and active HCDMs



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Provides value and evidence communications, including the dossier, and ongoing feedback via surveys and comments

Manufacturers

HCDM Community

Key: HCDM – health care decision maker

Summary

Knowledge gaps on early product information exchange between HCDMs and manufacturers remain even with the updated AMCP Format v 4.1

It is up to each manufacturer to determine their own best practice for the optimal information, timing, and delivery of the dossier across a product's lifecycle

Early engagement between HCDMs and manufacturers, with ongoing bidirectional feedback, is critical to inform each parties' strategy

Key: AMCP – Academy of Managed Care Pharmacy; HCDM – health care decision maker

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Questions?

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Where knowledge,
reach and partnership
shape healthcare delivery.