



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

January 28, 2020



# 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:

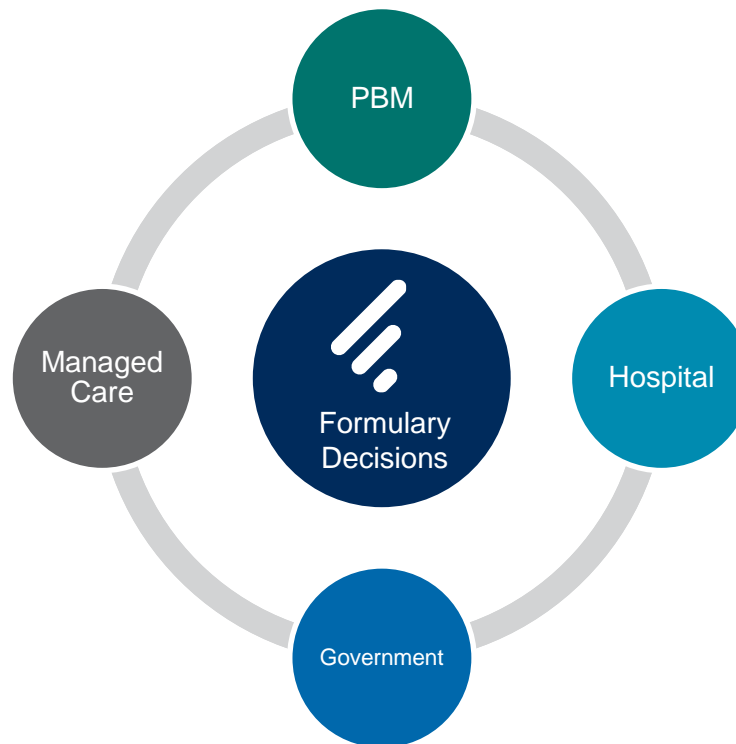
- *Lisa Cashman, PharmD, Director, Clinical Account Services, MedImpact Healthcare Systems*
- *Curtis Wander, PharmD, BCPS, Clinical Pharmacy Manager, SelectHealth*
- *Evelyn Sarnes, PharmD, MPH, VP, Medical Communications, Xcenda*

# 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.

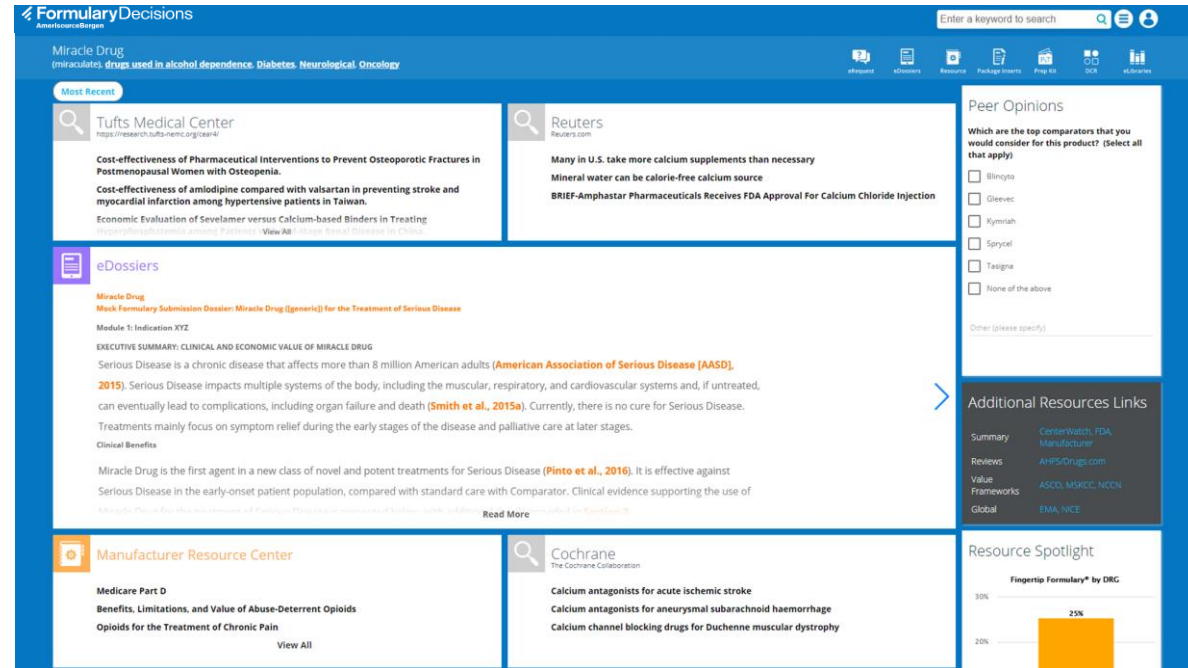
A closed payer only environment.

## Relationships



# 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



**FormularyDecisions**  
AmerisourceBergen

Enter a keyword to search

**Most Recent**

- Tufts Medical Center**  
Cost-effectiveness of Pharmaceutical Interventions to Prevent Osteoporotic Fractures in Postmenopausal Women with Osteopenia.  
Cost-effectiveness of amlodipine compared with valsartan in preventing stroke and myocardial infarction among hypertensive patients in Taiwan.  
Economic Evaluation of Sevelamer versus Calcium-based Binders in Treating Hyperphosphatemia among Patients with End-Stage Renal Disease in China.
- Reuters**  
Many in U.S. take more calcium supplements than necessary  
Mineral water can be calorie-free calcium source  
BRIEF-Amphastar Pharmaceuticals Receives FDA Approval For Calcium Chloride Injection

**eDossiers**

**Miracle Drug**  
Mock Formulary Submission Dossier: Miracle Drug (generic) for the Treatment of Serious Disease  
Module 1: Indication XYZ  
EXECUTIVE SUMMARY: CLINICAL AND ECONOMIC VALUE OF MIRACLE DRUG  
Serious Disease is a chronic disease that affects more than 8 million American adults (American Association of Serious Disease [AASD], 2015). Serious Disease impacts multiple systems of the body, including the muscular, respiratory, and cardiovascular systems and, if untreated, can eventually lead to complications, including organ failure and death (Smith et al., 2015a). Currently, there is no cure for Serious Disease. Treatments mainly focus on symptom relief during the early stages of the disease and palliative care at later stages.  
Clinical Benefits  
Miracle Drug is the first agent in a new class of novel and potent treatments for Serious Disease (Pinto et al., 2016). It is effective against Serious Disease in the early-onset patient population, compared with standard care with Comparator. Clinical evidence supporting the use of Miracle Drug for the treatment of Serious Disease is presented below, with additional information available in Executive Summary.

**Manufacturer Resource Center**

**Medicare Part D**  
Benefits, Limitations, and Value of Abuse-Deterrent Opioids  
Opioids for the Treatment of Chronic Pain

**Cochrane**  
The Cochrane Collaboration  
Calcium antagonists for acute ischemic stroke  
Calcium antagonists for aneurysmal subarachnoid haemorrhage  
Calcium channel blocking drugs for Duchenne muscular dystrophy

**Peer Opinions**  
Which are the top comparators that you would consider for this product? (Select all that apply)  
☐ Brinto  
☐ Gleevec  
☐ Kymriah  
☐ Sprycel  
☐ Tasigna  
☐ None of the above  
Other (please specify):

**Additional Resources Links**

- Summary: CenterWatch, FDA, Manufacturer
- Reviews: AVP/Drugs.com
- Value Frameworks: ASCO, MSKCC, NCCN
- Global: EMA, NICE

**Resource Spotlight**  
Fingertip Formulary® by DEG  
30%  
25%  
20%

# Updated *Format* Version 4.1

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



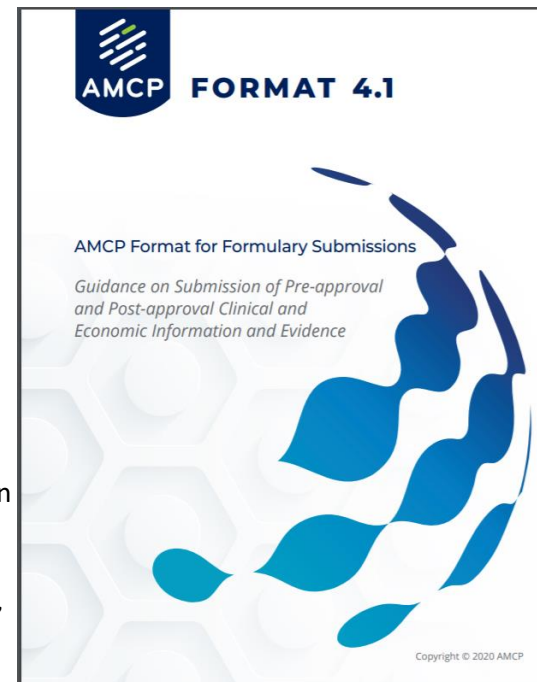
# Development of Version 4.1

- June 2018, FDA Final Guidance on manufacturer communications with payers, formulary, and similar entities was released<sup>1</sup>
- 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 23<sup>rd</sup>, 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](http://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



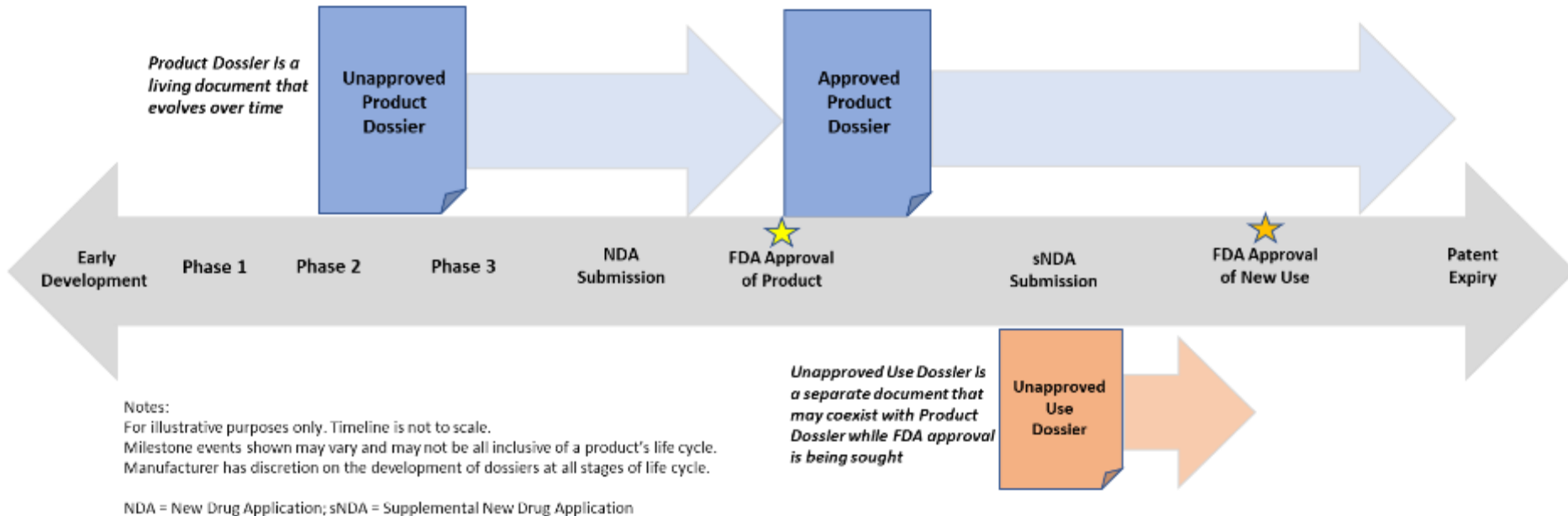
# Types of Dossiers

Dossier	Description
Unapproved Product	<ul style="list-style-type: none"><li>• Contains information about an unapproved product for which initial FDA approval is being sought</li><li>• Used to communicate information about an unapproved product</li></ul>
Approved Product	<ul style="list-style-type: none"><li>• Contains clinical and economic evidence about an approved product</li><li>• Used to respond to unsolicited requests from HCDMs after FDA approval of the product</li></ul>
Unapproved Use	<ul style="list-style-type: none"><li>• Contains information about an unapproved use of an approved product for which FDA approval is being sought</li><li>• Used to communicate information about an unapproved use of an approved product for which FDA approval is being sought</li></ul>

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**



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

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### Updates

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

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### Guidance

The *Format* is a guidance, not a mandate

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### Development

Development of dossiers is at the discretion of the manufacturer

# Content of Dossiers

	Approved Product Dossier	Unapproved Product & Unapproved Use Dossiers
<b>Value Proposition</b>	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
<b>Clinical Information</b>	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
<b>Economic Information</b>	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
<b>How should manufacturer provide dossier to HCDMs?</b>	Upon unsolicited request only	Manufacturers' discretion
<b>Who from manufacturer should communicate or provide dossier?</b>	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

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

# 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



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

# 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

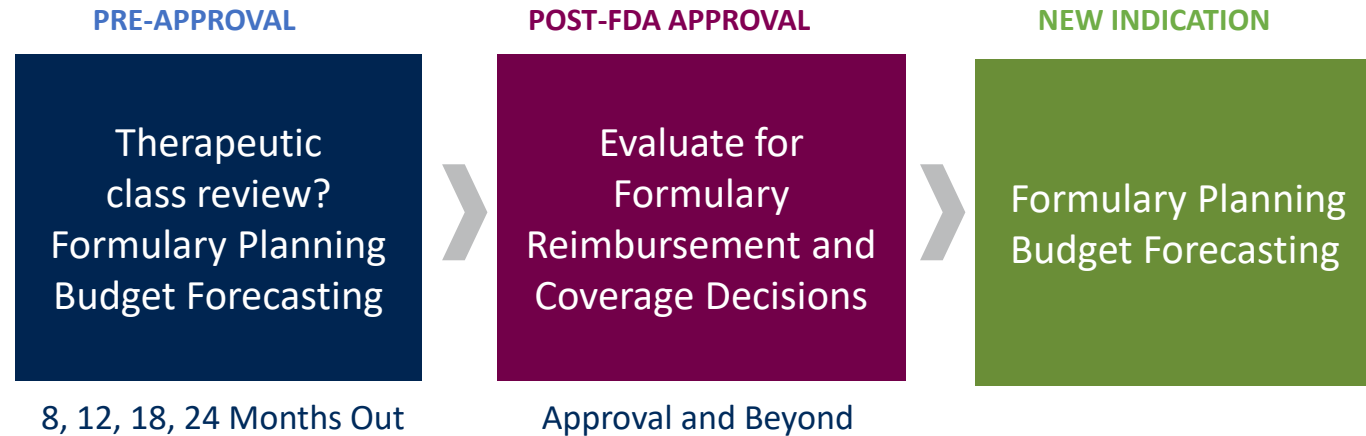
- The price of the product should be known for the approved product and should be included in the Unapproved Use Dossier.
- Cost-effectiveness models and budget impact models may not be feasible due to inability to draw conclusions about product safety and efficacy

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

## PRE-APPROVAL

- Expected PDUFA Date
- Proposed Indication
- Incidence/Prevalence
- Available Clinical Data\*
- Safety Data
- Comparator products
- Unmet Needs This Product Would Fill
- Expected Price or Price Range

## POST-FDA APPROVAL

- AMCP Format for Formulary Submissions v4.1 Requirements
- Market Penetration
- Specialist or Generalist Prescriber Needed?
- Real-World Evidence

## NEW INDICATION

Same as Pre-approval

\*With appropriate disclaimers for trials still in process.

# Challenges to Receiving Information

## PRE-APPROVAL

- Manufacturer Compliance Department Concerns
- Fast Track or Abbreviated Review Process
- Budget Impact/Financial Impact Regionally



## POST-FDA APPROVAL

- Unknown Financial Impact Post-FDA Approval
- Patient Warehousing
- Lag in Receiving RWE
- Adherence Measuring Could Take up to 1 Year
- Limited Network



## NEW INDICATION

Same as Pre-approval

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

## Best Practices for Manufacturers

*Evelyn Sarnes, PharmD, MPH*

*VP, Medical Communications*

*Xcenda*



*Delivery*

**TIMING**

**Content**

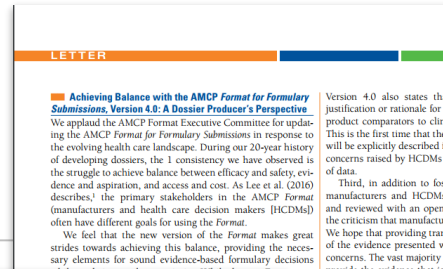
Ambiguity in the Format provides flexibility as the industry is still evolving around preapproval information exchange

# Informed recommendations

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



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



Version 4.0 also states that justification or rationale for the product comparators to clinical. This is the first time that the rationale will be explicitly described in the concerns raised by HCDCMs regarding data.

Third, in addition to fostering manufacturers and HCDCMs, the new version of the AMCP Format will be reviewed with an open mind to the criticism that manufacturers. We hope that providing transparent evidence-based formulary decisions will provide the evidence that is required to support evidence-based formulary decisions.

All of these changes move to communication between manufacturers and producers, we often see the disparate stakeholders. We will cross this gap and look forward

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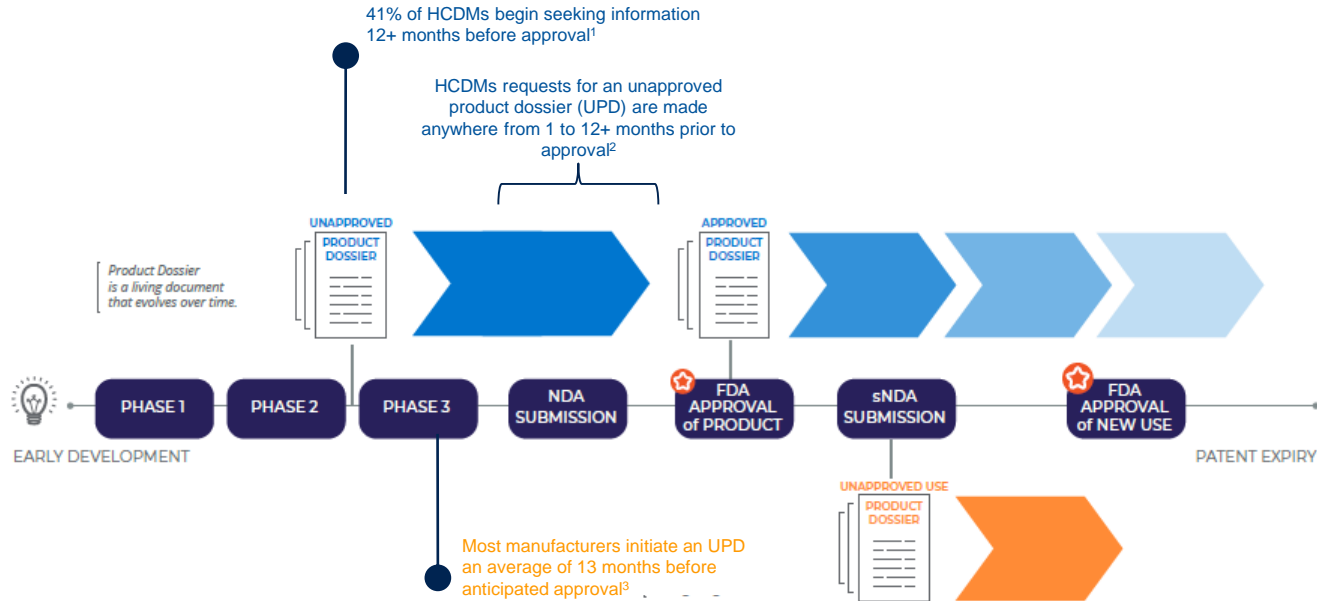
DISCLOSURES  
Both authors are employed by Xcenda.

REFERENCES

1. Lee J. AMCP Format Executive Committee Formulary Submissions: Welcome to Version 2016/2017/2018/2019/2020/2021/2022/2023/2024/2025/2026/2027/2028/2029/2030/2031/2032/2033/2034/2035/2036/2037/2038/2039/2040/2041/2042/2043/2044/2045/2046/2047/2048/2049/2050/2051/2052/2053/2054/2055/2056/2057/2058/2059/2060/2061/2062/2063/2064/2065/2066/2067/2068/2069/2070/2071/2072/2073/2074/2075/2076/2077/2078/2079/2080/2081/2082/2083/2084/2085/2086/2087/2088/2089/2090/2091/2092/2093/2094/2095/2096/2097/2098/2099/2100/2101/2102/2103/2104/2105/2106/2107/2108/2109/2110/2111/2112/2113/2114/2115/2116/2117/2118/2119/2120/2121/2122/2123/2124/2125/2126/2127/2128/2129/2130/2131/2132/2133/2134/2135/2136/2137/2138/2139/2140/2141/2142/2143/2144/2145/2146/2147/2148/2149/2150/2151/2152/2153/2154/2155/2156/2157/2158/2159/2160/2161/2162/2163/2164/2165/2166/2167/2168/2169/2170/2171/2172/2173/2174/2175/2176/2177/2178/2179/2180/2181/2182/2183/2184/2185/2186/2187/2188/2189/2190/2191/2192/2193/2194/2195/2196/2197/2198/2199/2200/2201/2202/2203/2204/2205/2206/2207/2208/2209/2210/2211/2212/2213/2214/2215/2216/2217/2218/2219/2220/2221/2222/2223/2224/2225/2226/2227/2228/2229/2230/2231/2232/2233/2234/2235/2236/2237/2238/2239/2240/2241/2242/2243/2244/2245/2246/2247/2248/2249/2250/2251/2252/2253/2254/2255/2256/2257/2258/2259/2260/2261/2262/2263/2264/2265/2266/2267/2268/2269/2270/2271/2272/2273/2274/2275/2276/2277/2278/2279/2280/2281/2282/2283/2284/2285/2286/2287/2288/2289/2290/2291/2292/2293/2294/2295/2296/2297/2298/2299/2300/2301/2302/2303/2304/2305/2306/2307/2308/2309/2310/2311/2312/2313/2314/2315/2316/2317/2318/2319/2320/2321/2322/2323/2324/2325/2326/2327/2328/2329/2330/2331/2332/2333/2334/2335/2336/2337/2338/2339/2340/2341/2342/2343/2344/2345/2346/2347/2348/2349/2350/2351/2352/2353/2354/2355/2356/2357/2358/2359/2360/2361/2362/2363/2364/2365/2366/2367/2368/2369/2370/2371/2372/2373/2374/2375/2376/2377/2378/2379/2380/2381/2382/2383/2384/2385/2386/2387/2388/2389/2390/2391/2392/2393/2394/2395/2396/2397/2398/2399/2400/2401/2402/2403/2404/2405/2406/2407/2408/2409/2410/2411/2412/2413/2414/2415/2416/2417/2418/2419/2420/2421/2422/2423/2424/2425/2426/2427/2428/2429/2430/2431/2432/2433/2434/2435/2436/2437/2438/2439/2440/2441/2442/2443/2444/2445/2446/2447/2448/2449/2450/2451/2452/2453/2454/2455/2456/2457/2458/2459/2460/2461/2462/2463/2464/2465/2466/2467/2468/2469/2470/2471/2472/2473/2474/2475/2476/2477/2478/2479/2480/2481/2482/2483/2484/2485/2486/2487/2488/2489/2490/2491/2492/2493/2494/2495/2496/2497/2498/2499/2500/2501/2502/2503/2504/2505/2506/2507/2508/2509/2510/2511/2512/2513/2514/2515/2516/2517/2518/2519/2520/2521/2522/2523/2524/2525/2526/2527/2528/2529/2530/2531/2532/2533/2534/2535/2536/2537/2538/2539/2540/2541/2542/2543/2544/2545/2546/2547/2548/2549/2550/2551/2552/2553/2554/2555/2556/2557/2558/2559/2560/2561/2562/2563/2564/2565/2566/2567/2568/2569/2570/2571/2572/2573/2574/2575/2576/2577/2578/2579/2580/2581/2582/2583/2584/2585/2586/2587/2588/2589/2590/2591/2592/2593/2594/2595/2596/2597/2598/2599/2600/2601/2602/2603/2604/2605/2606/2607/2608/2609/2610/2611/2612/2613/2614/2615/2616/2617/2618/2619/2620/2621/2622/2623/2624/2625/2626/2627/2628/2629/2630/2631/2632/2633/2634/2635/2636/2637/2638/2639/2640/2641/2642/2643/2644/2645/2646/2647/2648/2649/2650/2651/2652/2653/2654/2655/2656/2657/2658/2659/2660/2661/2662/2663/2664/2665/2666/2667/2668/2669/2670/2671/2672/2673/2674/2675/2676/2677/2678/2679/2680/2681/2682/2683/2684/2685/2686/2687/2688/2689/2690/2691/2692/2693/2694/2695/2696/2697/2698/2699/2700/2701/2702/2703/2704/2705/2706/2707/2708/2709/2710/2711/2712/2713/2714/2715/2716/2717/2718/2719/2720/2721/2722/2723/2724/2725/2726/2727/2728/2729/2730/2731/2732/2733/2734/2735/2736/2737/2738/2739/2740/2741/2742/2743/2744/2745/2746/2747/2748/2749/2750/2751/2752/2753/2754/2755/2756/2757/2758/2759/2760/2761/2762/2763/2764/2765/2766/2767/2768/2769/2770/2771/2772/2773/2774/2775/2776/2777/2778/2779/2780/2781/2782/2783/2784/2785/2786/2787/2788/2789/2790/2791/2792/2793/2794/2795/2796/2797/2798/2799/2800/2801/2802/2803/2804/2805/2806/2807/2808/2809/2810/2811/2812/2813/2814/2815/2816/2817/2818/2819/2820/2821/2822/2823/2824/2825/2826/2827/2828/2829/2830/2831/2832/2833/2834/2835/2836/2837/2838/2839/2840/2841/2842/2843/2844/2845/2846/2847/2848/2849/2850/2851/2852/2853/2854/2855/2856/2857/2858/2859/2860/2861/2862/2863/2864/2865/2866/2867/2868/2869/2870/2871/2872/2873/2874/2875/2876/2877/2878/2879/2880/2881/2882/2883/2884/2885/2886/2887/2888/2889/2890/2891/2892/2893/2894/2895/2896/2897/2898/2899/2900/2901/2902/2903/2904/2905/2906/2907/2908/2909/2910/2911/2912/2913/2914/2915/2916/2917/2918/2919/2920/2921/2922/2923/2924/2925/2926/2927/2928/2929/2930/2931/2932/2933/2934/2935/2936/2937/2938/2939/2940/2941/2942/2943/2944/2945/2946/2947/2948/2949/2950/2951/2952/2953/2954/2955/2956/2957/2958/2959/2960/2961/2962/2963/2964/2965/2966/2967/2968/2969/2970/2971/2972/2973/2974/2975/2976/2977/2978/2979/2980/2981/2982/2983/2984/2985/2986/2987/2988/2989/2990/2991/2992/2993/2994/2995/2996/2997/2998/2999/3000/3001/3002/3003/3004/3005/3006/3007/3008/3009/3010/3011/3012/3013/3014/3015/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# Recommendations on the dossier development timeline

AMCP dossier development relative to major product lifecycle events



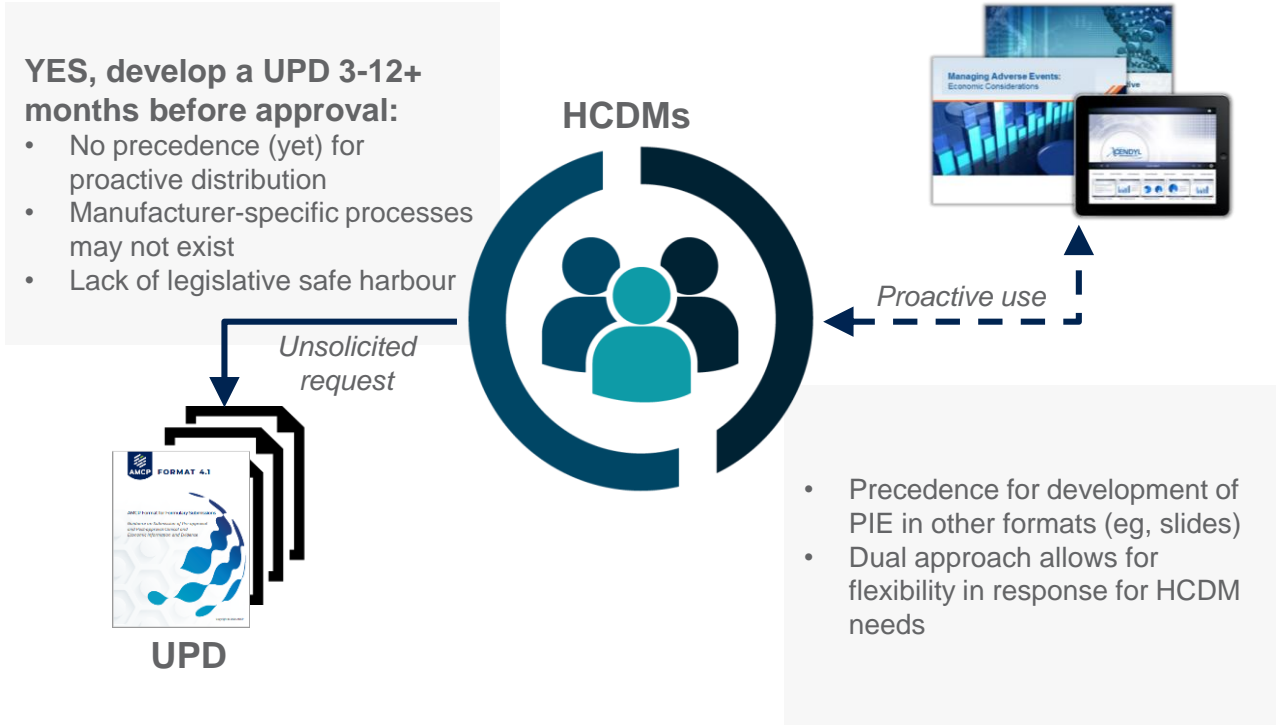
Key: AMCP – Academy of Managed Care Pharmacy; FDA – Food and Drug Administration; HCDM – health care decision maker; mos – months; NDA – New Drug Application; sNDA – Supplemental New Drug Application; UPD – unapproved product dossier

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.

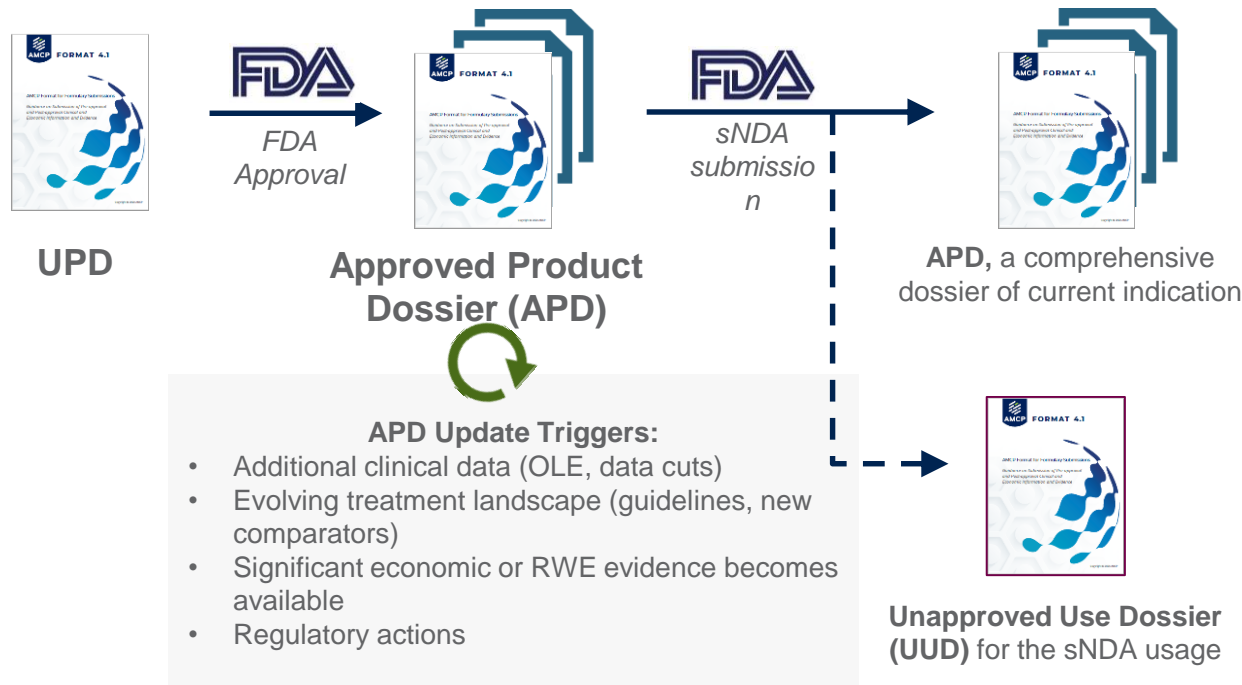
# How should an unapproved product dossier be delivered?

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



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

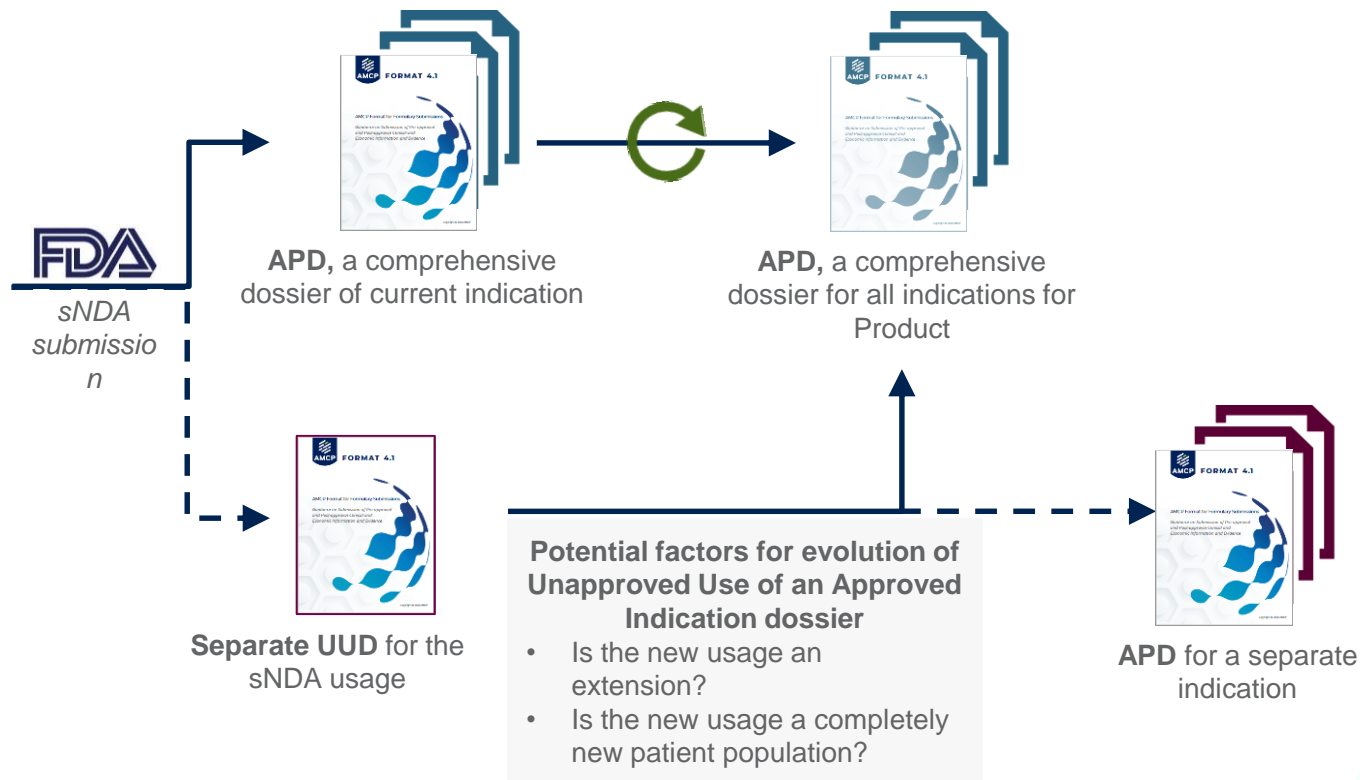
Practical considerations for the unapproved, approved, and unapproved use dossier



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*

# 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





# 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



Manufacturers

FormularyDecisions  
AmerisourceBergen

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



HCDM Community

## 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

# Questions?

For more information, please contact  
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shape healthcare delivery.