AMCP and FormularyDecisions® Webinar: Breaking Down the Complexities of Product Evaluation in the Digital Era

February 28, 2022

2:00-3:00 pm ET

AMCP

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Improving lives.

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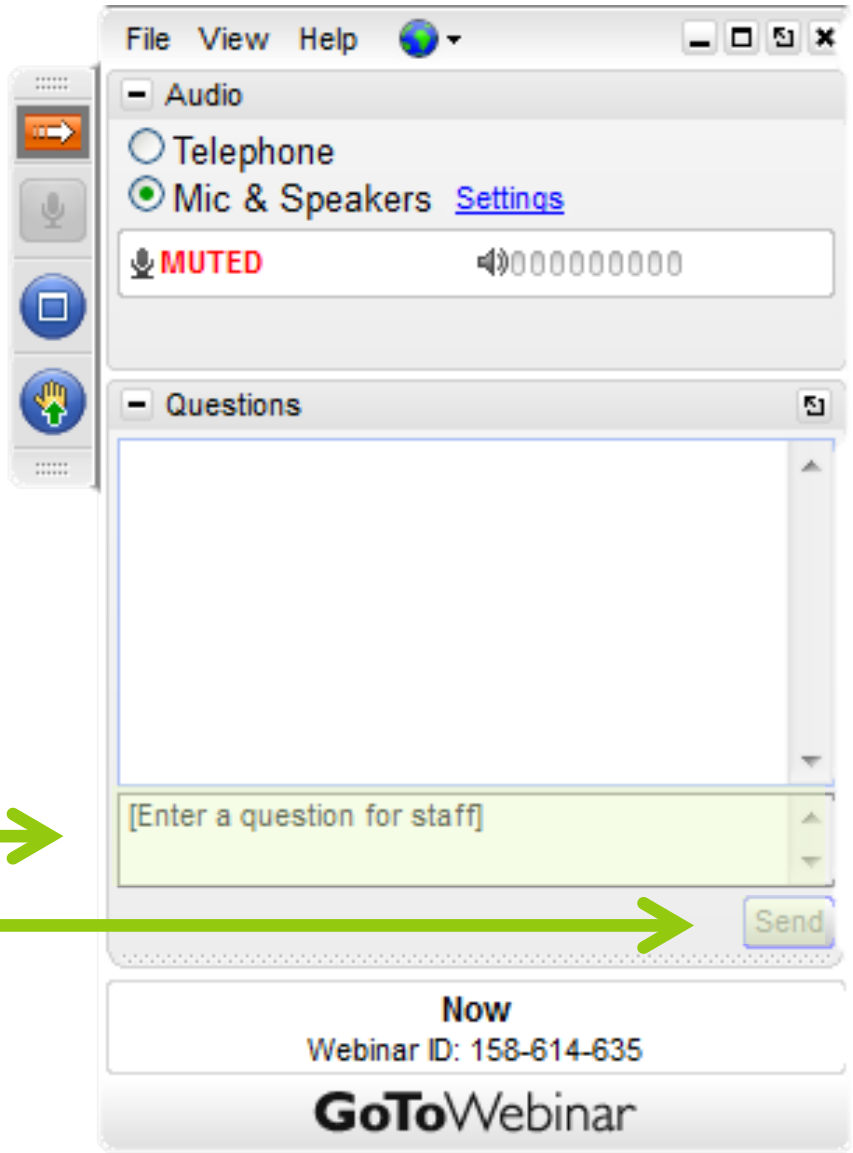
How to ask a question

Type your question in the "Questions" area, then click "Send"



Panelists

Moderator

Tasmina Hydery, PharmD, MBA, BCGP

Associate Director,
Digital Solutions
AmerisourceBergen/Xcenda

Sara Linnerooth, PharmD

Assistant Director,
Commercial Consulting
AmerisourceBergen/Xcenda

Jenny Craven, PharmD, BCPS

Senior Emerging Therapies
Pharmacist
UC Davis Health

Evelyn Sarnes, PharmD, MPH

Senior Director,
Health Economics &
Outcomes Research
Esperion

Disclaimers

- The speakers have no disclosures to report
- Anything discussed in this presentation represents the opinions of the speakers and does not reflect the opinions of the organizations
- The presentation is not intended to opine on FDA actions or legislation
- The presentation may not address all the nuances that exist in the formulary process or within organizations
- FormularyDecisions is owned and operated by Xcenda, LLC, which is a subsidiary of AmerisourceBergen

Webinar overview

In this session, you will learn:

- The steps involved in conducting a product review
- Common challenges in conducting reviews and review of a test scenario for a sample product launch
- Potential strategies to mitigate these challenges and opportunities to incorporate digital tools

Pre-webinar survey

Click on the link that has been included in the chat or enter the following URL in your web browser:

https://forms.microsoft.com/r/0qipAu64FS

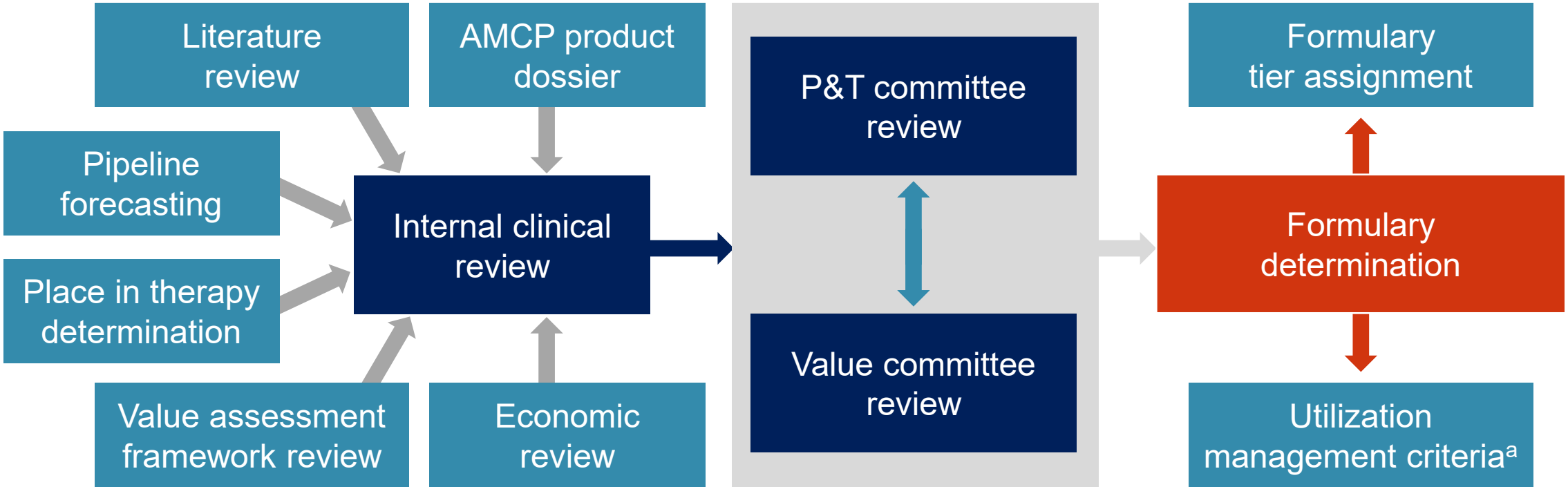
Learning objectives

- Summarize the processes and key similarities and differences involved in reviewing a product pre- and post-FDA approval in a managed care setting
- Discuss common challenges and gaps in the clinical and economic data available and how stakeholders can overcome these barriers
- Discuss opportunities to incorporate digital tools into the formulary review process
- Identify methods through which healthcare technology is shaping formulary management

FDA = Food and Drug Administration.

Overview on formulary management: Processes, roles, and timeline overview

Formulary process: Overview



P&T = pharmacy and therapeutics.

[a] Types of utilization management may include prior authorization, step therapy, quantity limits, or site-of-service steering.

Figure adapted from Hogue SL, et al. Academy of Managed Care Pharmacy dossiers: Use in health care decision making. Poster presented at: ISPOR; 2014.

Formulary process: Definitions

Formulary: A continually updated set of preferred products supported by current evidence and practicing physician (and other health professional) judgment.[1] Formularies encourage the use of safe, effective, and affordable medications

P&T committee: Composed primarily of practicing physicians, pharmacists, and other healthcare professionals, with multiple specialties represented, to review evidence to determine whether products are placed on the formulary[2]

Value-based committees: A group generally composed of internal employees (pharmacists, analysts, contracting) who are responsible for evaluating economic information to determine the overall value of a drug. This committee makes recommendations for placement and utilization management strategies that were voted on by the P&T committee

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P&T = pharmacy & therapeutics.

1. AMCP. Formulary management. https://www.amcp.org/about/managed-care-pharmacy-101/concepts-managed-care-pharmacy/formulary-management 2. AMCP partnership forum: principles for sound pharmacy and therapeutics (P&T) committee practices: what's next? *J Manag Care Spec Pharm*. 2020;26(1):48-53.

Formulary process: Pre- and post-approval

Pre-approval → FDA approval → Post-approval

- Pre-approval reviews
  - Review before FDA approval
  - Coverage decisions can be made immediately upon approval[1]
  - Drivers for identifying upcoming launches to be prioritized may include:
    - Pipeline reports, forecasting, orphan drugs, FDA priority reviews, and value assessment framework publications
- Post-approval review
  - Generally reviewed within 6 months of FDA approval[2,a]
    - CMS protected classes are reviewed within 90 days of approval[2]

[a] Dependent on the organization's P&T schedule and frequency of P&T meetings.

CMS = Centers for Medicare & Medicaid Services; FDA= Food & Drug Administration; P&T = pharmacy & therapeutics.

1. AMCP. Pre-approval Information exchange (PIE). https://www.amcp.org/policy-advocacy/legislative-regulatory-issues/pre-approval-information-exchange
2. CMS. Medicare Modernization Act of 2007: Final guidelines – formularies. https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/cy07formularyguidance.pdf

Prioritizing products for review

- In general, products expected to have high utilization, a significant economic impact, or anticipated use immediately following approval may warrant either pre-approval review or prioritization for post-approval review

Rare/orphan conditions, oncology, cell and gene therapies, etc

- Example: Zolgensma (onasemnogene abeparvovec-xioi) was approved in May 2019,[1] but due to the unprecedented cost of therapy, MCOs reviewed it in advance of approval. ICER also published a report in advance of FDA approval[2]

New mechanism, dosing, or formulation likely to cause significant disruption

- Examples: Oral agents for hepatitis C, PCSK9s

- A need for utilization management may also prompt for an urgent or prioritized review

Unforeseen risk of misuse/abuse or drug shortages

- Example: GLP-1s for weight loss

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GLP-1 = glucagon-like peptide 1; ICER = Institute for Clinical and Economic Review; MCO = managed care organization; PCSK9 = proprotein convertase subtilisin/kexin type 9 inhibitor

1. FDA. Zolgensma. https://www.fda.gov/vaccines-blood-biologics/zolgensma
2. ICER. https://icer.org/wp-content/uploads/2020/10/ICER_SMA_Final_Evidence_Report_110220.pdf

Components included in product reviews

Clinical evaluation

- Review of efficacy and safety
  - Assessment of endpoints and study population
  - Evaluation of adverse events and severity
- Place in therapy
  - Review of other products in the same class or that treat the same indication to compare efficacy and safety (direct or indirect)

Contracting

- Economic/value evaluation
  - Modeling (cost calculators, BIMs, CEAs, etc)
  - Value assessment frameworks (eg, ICER, NCCN Evidence Blocks, ASCO)
  - Place in therapy
    - Compare cost of other products within the same class or that treat the same condition to understand the economic impact

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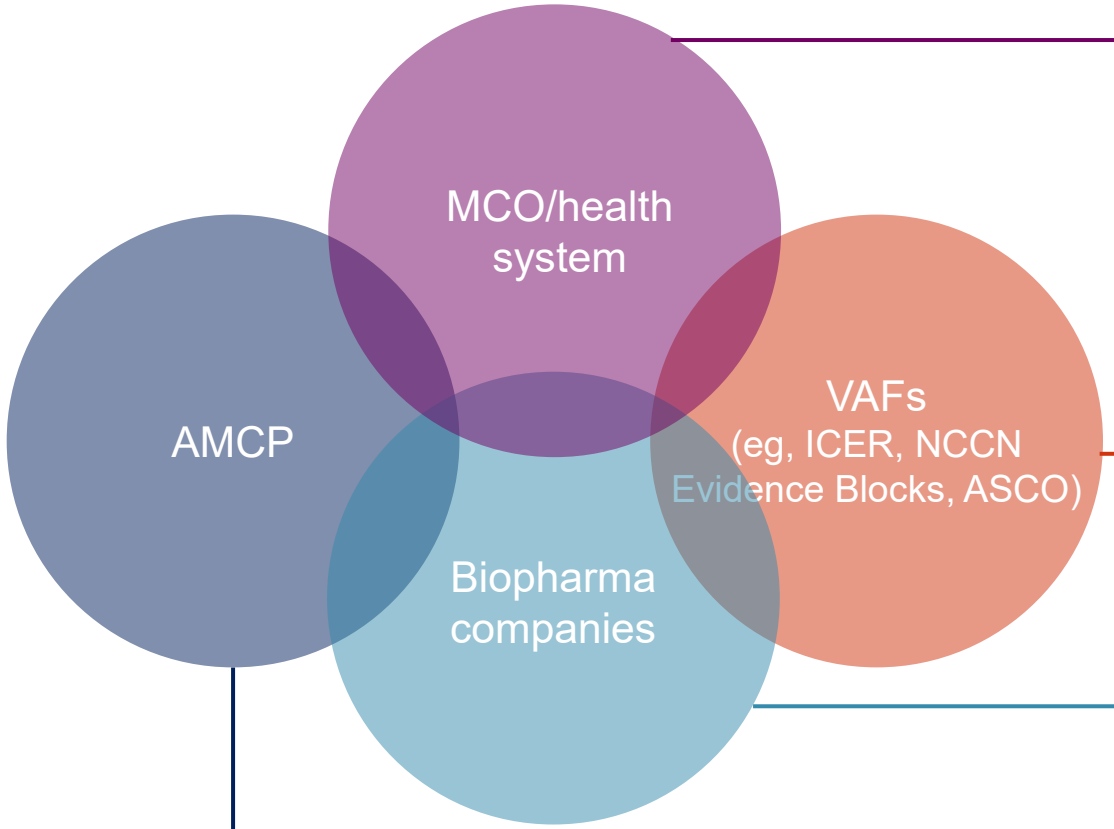
ASCO = American Society of Clinical Oncology; BIM = budget impact model; CEA = cost-effectiveness analysis; ICER = Institute for Clinical and Economic Review; NCCN = National Comprehensive Cancer Network

Re-evaluation

- Products are generally re-evaluated when:
  - New evidence becomes available
    - New clinical trials (existing indication)
    - Expanded indications
    - New guidance is published that changes the treatment pathway
  - As part of a scheduled cadence with the drug class
    - Reviewed at least annually
    - May have economic/value focus if there are no recent changes to the product or class
  - Upon contract negotiation with a biopharma company
  - A generic launches within a class

Roles in formulary management



MCOs and health systems generally have 2 groups of internal teams that are integral to the product review process

- Clinical team gathers information to evaluate safety and efficacy, creates monograph, and presents to P&T committee
- Value/economic review team evaluates economic information and VAFs

VAFs are independent organizations that review evidence and determine the value of a product. MCOs may use these reports to support formulary decision making. Manufacturers submit information to VAFs when their products are evaluated

Biopharma companies share data on their products, including clinical trials, dossiers, and economic models, that might be needed by an MCO/health system to perform a review

AMCP supports the exchange of information between biopharma companies and MCOs

ASCO = American Society of Clinical Oncology; ICER = Institute for Clinical and Economic Review; MCO = managed care organization; NCCN = National Comprehensive Cancer Network; VAF = value assessment framework.

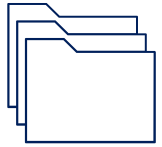
1. AMCP. Value frameworks. https://www.amcp.org/policy-advocacy/policy-advocacy-focus-areas/where-we-stand-position-statements/value-frameworks

Addressing common barriers in the product review process

Types of barriers in the review process

Operational barriers	Organizational barriers	Other barriers
		
Obstacles that are specific to obtaining the necessary information needed to conduct a product review	Obstacles experienced in the review process due to the structure of the organization itself	Obstacles such as external forces, including legislative changes that affect/disrupt the current formulary management process

Operational barriers

Common barriers	MCO barriers	Biopharma barriers	Possible solutions
Locating necessary data to conduct a comprehensive review	• Unpublished data • No active comparator or potentially inappropriate active comparator • Small clinical trials or absence of phase 3 trials	• Ability to identify the appropriate individuals/teams involved in formulary management • Constrained resources	• Open lines of communication
Lack of standardization in review process and cycle between organizations	• Review cycle is unique to each organization and cadence of P&T meetings • Prioritization of products may change review times for other products	• May cause hesitation regarding when information should be shared • Potential for a missed opportunity to engage in contract discussions	• Discuss review calendars and anticipated data timings

MCO = managed care organization; P&T = pharmacy & therapeutics.

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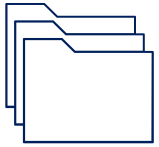
Organizational barriers

Common barriers	MCO barriers	Biopharma barriers	Possible solutions
Resources dedicated to formulary management	• Size = resources for formulary management • Smaller organizations also more likely to experience cost-prohibitive barriers such as accessing primary literature or subscription-based solutions	• Limitations on publishing all available trials • Enrolling a population reflective of an MCO's covered lives	• Open lines of communication
Book of business (lines covered) may greatly affect the formulary management process	• Commercial plans have the most flexibility • Medicare and Medicaid plans are less flexible with CMS oversight	• One size does not fit all	• Develop and leverage a contact to understand unique needs/ capabilities

CMS = Centers for Medicare & Medicaid Services; MCO = managed care organization.

Previous legislation affecting MCOs and biopharma

Medicare Modernization Act of 2007[1]

- CMS protected classes: **Part D** formularies to include "all or substantially all" drugs in 6 drug classes and require an expedited review (**within 90 days**)
- Antidepressants, antipsychotics, anticonvulsants, immunosuppressants to prevent rejection of organ transplants, antiretrovirals, and antineoplastics (chemotherapy drugs not covered under **Part B**)

Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA)[2]

- **Prevents** group health plans and insurers from imposing less favorable benefits for mental health or substance abuse disorders than benefits to treat other conditions
- Increased state auditing to ensure health plans are **compliant**
- Includes formulary process, placement, and utilization management on these products

Affordable Care Act (ACA) of 2010[3]

- Expanded Medicaid and established the health insurance market (**exchange plans**)
- Requires plans to cover people with **pre-existing conditions**
- **Coverage of preventive health services**, including medications,[4] at no cost-share

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1. CMS. Medicare Modernization Act 2007 final guidelines -- formularies. https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/cy07formularyguidance.pdf 2.CMS. The Mental Health Parity and Addiction Equity Act (MHPAEA). https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/mhpaea_factsheet 3. 111th Congress. H.R. 3590 Patient Protection and Affordable Care Act. https://www.congress.gov/bill/111th-congress/house-bill/3590/text 4. USPSTF. A & B Recommendations. https://uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations

Recent legislation affecting MCOs and biopharma

Inflation Reduction Act of 2022[1]

- Max out-of-pocket cap for Medicare beneficiaries under Part D beginning in **2025**
- CMS is required to negotiate the prices of certain brand drugs beginning in **2026**
- Biopharma companies are required to issue rebates to CMS for brand drugs that cost **$100** or more per year per individual
- Insulin copays capped at **$35** for Medicare Part D as of 2023

Note: Some states passed legislation prior to the Inflation Reduction Act to cap the copay cost of insulin. These laws may also extend to applicable commercial plans

Pre-approval Information Exchange Act of 2022[2]

- Provides additional clarification to previous guidance issued in **2018** around healthcare economic information prior to a product gaining FDA approval[3]

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CMS = Centers for Medicare & Medicaid Services; FDA = Food and Drug Administration.

1. 117th Congress. H.R.5376. Inflation Reduction Act of 2022. https://www.congress.gov/bill/117th-congress/house-bill/5376 2. 117th Congress. H.R. 7008. Pre-approval Information Exchange Act of 2022. https://www.congress.gov/bill/117th-congress/house-bill/7008/text 3. AMCP. Pre-approval information exchange (PIE). https://www.amcp.org/policy-advocacy/legislative-regulatory-issues/pre-approval-information-exchange

Digital tools: Utilizing technology to help streamline product reviews

The increasing role of technology in conducting product reviews

Digital platforms

- Utilized to gather/access credible information, including primary literature
- Can be subscription-based (eg, UptoDate, Micromedex, Clinical Pharmacology) or free resources (PubMed, FormularyDecisions)

Pipeline insights

- Subscription-based (eg, IPD Analytics, Biomedtracker)
- Some organizations may also have a PBM that will send regular pipeline reports

Monographs for P&T

- AMCP monograph template
- Leverage monographs through subscription-based platforms (eg, FormularyDecisions Product Snapshots)

P&T = pharmacy & therapeutics.

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The increasing role of technology in conducting product reviews (cont.)

Access to dossiers	Ability to view information on how other HCDMs/organizations are managing products

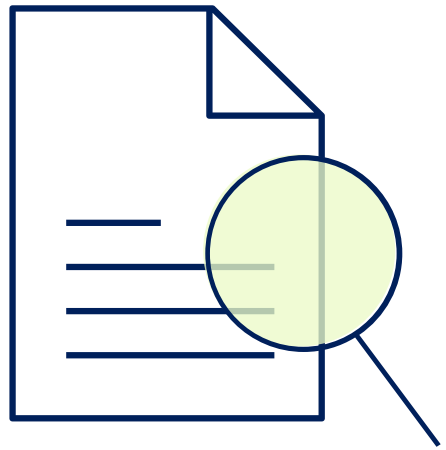
• FormularyDecisions houses eDossiers and allows registered HCDMs to request dossiers that are not available electronically	• Coverage Insights via FormularyDecisions
	  • Uses weekly data from MMIT
	  • Provides information on coverage by benefit type (pharmacy or medical) and line of business
	  • Includes whether UM strategies (prior authorization, step therapy, quantity limit) were deployed and the percentage of plans using a particular strategy

HCDM = healthcare decision maker; MMIT = Managed Markets Insight & Technology.

Case study

Case study: Background

- Sample drug was approved on January 2, 2023
- Breakthrough therapy
- Indication: NASH
- Formulation: Oral (2 tablets daily)
- Cost: ~$150K annually per member
- VAFs: ICER is expected to review NASH in late April 2023
- Prevalence is roughly 5% of Americans



ICER = Institute for Clinical and Economic Review; NASH = nonalcoholic steatohepatitis; VAF = value assessment framework.

Case study: Gathering evidence

You are managing a population of approximately 1 million covered commercial lives.

Question 1: What would be a useful starting point for gathering all information available for this product?

A. Use a tertiary resource to understand NASH treatment
B. Do a primary literature search for the product
C. Obtain the dossier or pull the package insert to identify all clinical trials
D. I work on the biopharma side, and my team would be actively engaging payers
E. I work on the biopharma side, and we would wait to engage payers

NASH = nonalcoholic steatohepatitis.

Case study: Identifying gaps

When reviewing the data, you notice only phase 2 studies were published (N=68). Additionally, there were some topline results posted for a phase 3 trial, and there are results included in the dossier requested from the biopharma company

Question 2: What would your next step be to begin the product review?

A. Reach out to my rep to start a request for more information
B. Review the phase 3 trial design on ClinicalTrials.gov
C. Proceed with the review with available published data
D. A, B, and C
E. N/A; I work for a biopharma company

Case study: Creating solutions

The biopharma company was able to share some additional data that were presented at a recent conference. Data were statistically significant; however, it is unknown whether this will translate into clinically meaningful outcomes

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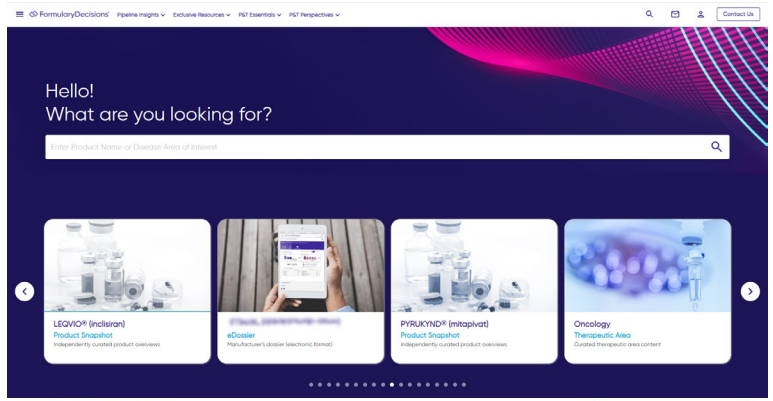
Question 3: What would your next step be in moving this product to P&T review?

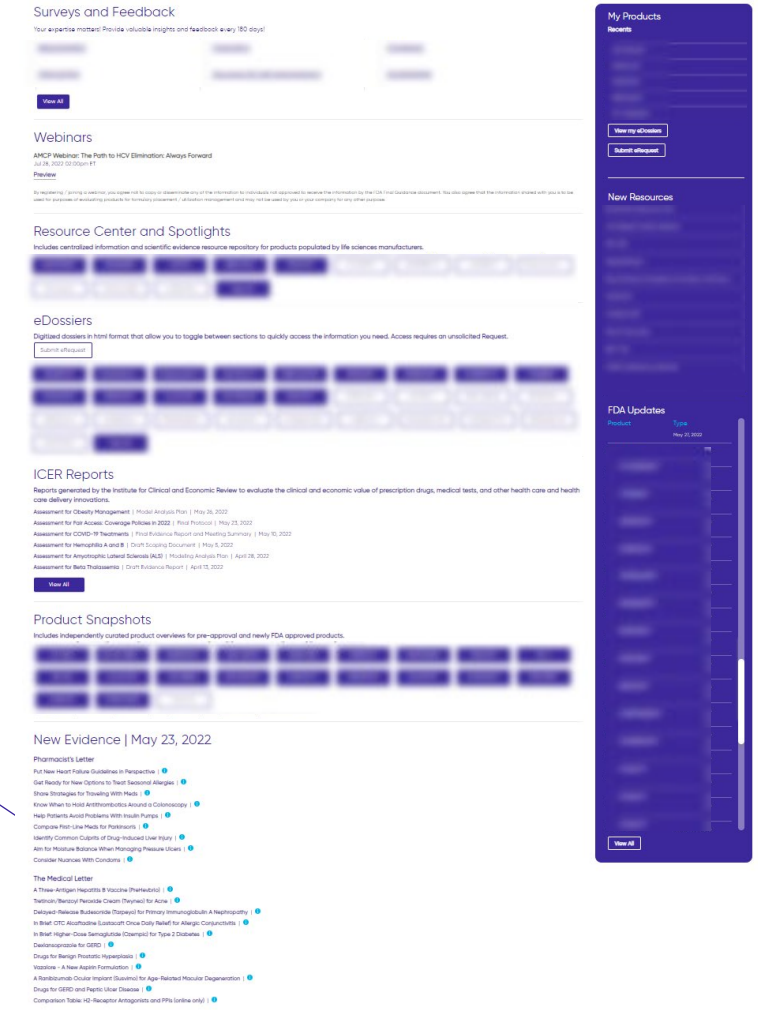
A. Discuss findings and gaps, and ask about the clinical significance of the endpoints with the P&T committee
B. Propose that the P&T committee waits to review this product until the ICER report becomes available in a few months
C. I would feel comfortable with the data to make a recommendation
D. I would recommend an early review; however, I would recommend re-review if new evidence becomes available
E. N/A; I work for a biopharma company

ICER = Institute for Clinical and Economic Review; P&T = pharmacy & therapeutics.

FormularyDecisions capabilities

FormularyDecisions homepage





Home Page

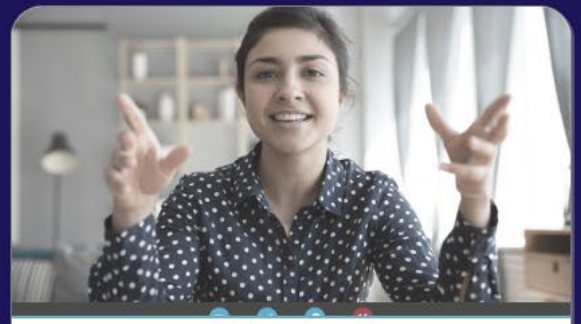
FormularyDecisions Pipeline Insights Exclusive Resources P&T Essentials P&T Perspectives Contact Us

Hello!
What are you looking for?

Enter Product Name or Disease Area of Interest

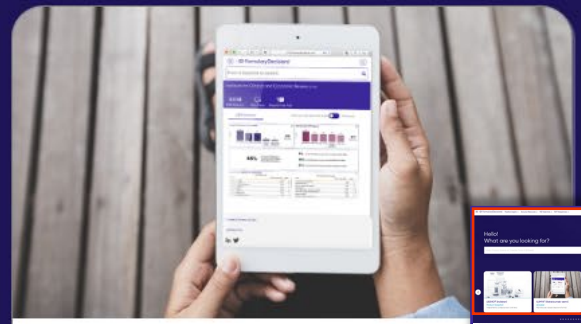
The carousel includes tools and resources that were most recently updated, including eDossiers, Product Snapshots, newly added video tutorials, and upcoming webinars

KB-103 (beremagene geperpavec)
Product Snapshot
Independently curated product overviews

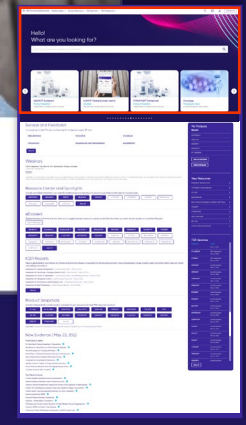


AMCP PIE Webinar: The Path to HCV Elin
Webinar
Registration Open

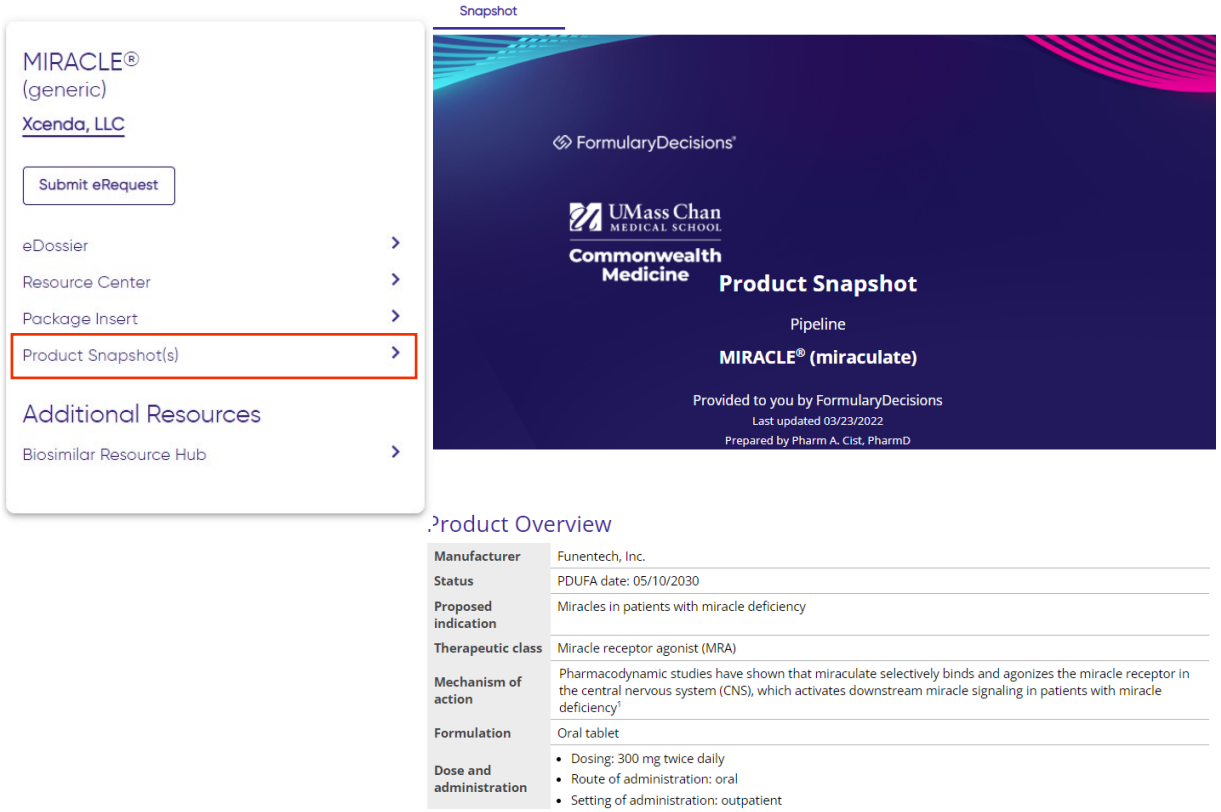
[redacted]
Product Snapshot
Independently curated product overviews



[redacted]
eDossier
Manufacturer's dossier (electronic format)



Product Snapshots



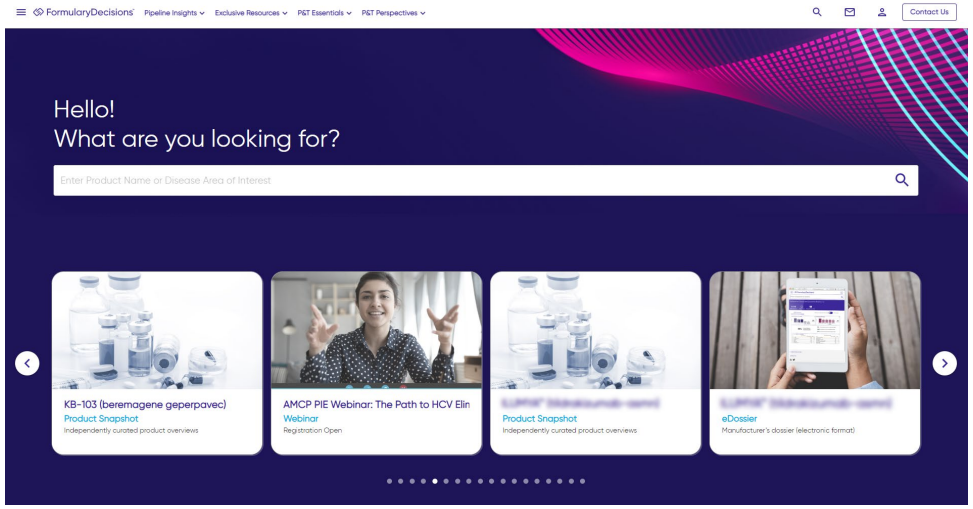
Curated by clinical pharmacists, **Product Snapshots** include product information to help HCDMs jumpstart the review process. With a focus on pre-approval products, **Product Snapshots** contain the following key information:

- Life sciences manufacturer
- PDUFA date
- Approved indication(s)
- Therapeutic class
- Mechanism of action
- Dose and administration
- Epidemiology of disease
- Distinguishing factors of product
- Relevant disease background and treatment guidelines
- Key comparators
- Clinical trials overview
- P&T considerations

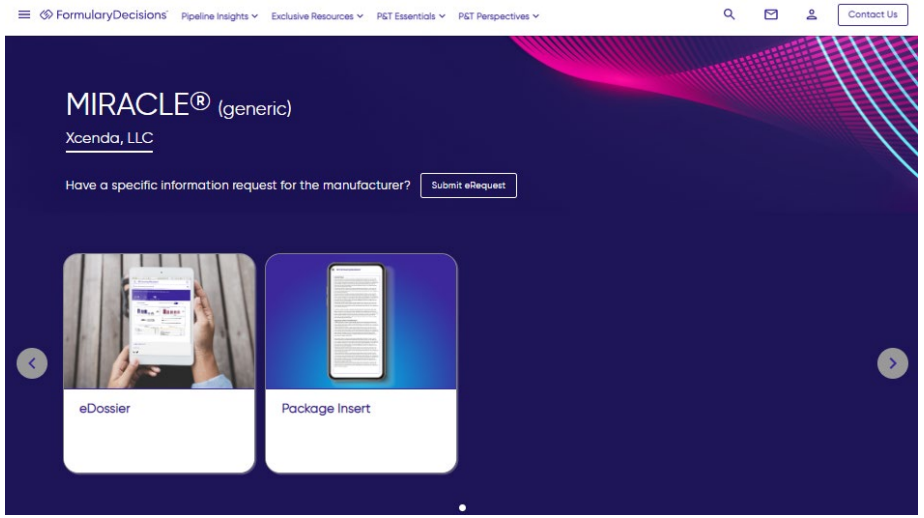
HCDM = healthcare decision maker; P&T = pharmacy and therapeutics; PDUFA = Prescription Drug User Fee Act.

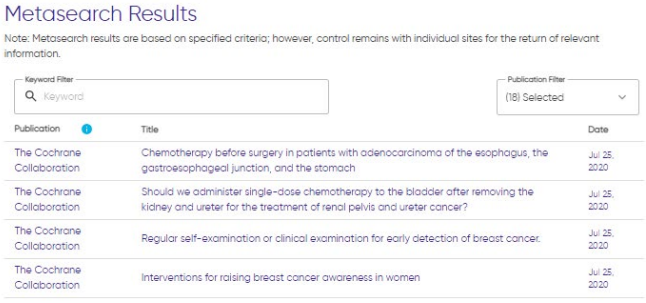
Search by product name or topic of interest

(Search for “MIRACLE drug” to view a sample product page)

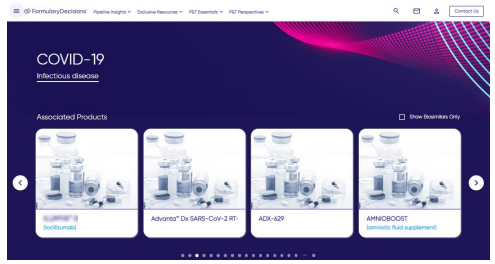


MIRACLE





COVID-19



Product Page: Miracle Drug

MIRACLE® (generic)

Xcenda, LLC

Have a specific information request for the manufacturer? Submit eRequest

eDossier

Package Insert

Send an unsolicited request to any life sciences manufacturer, and detail the information you are seeking

Navigate to information and resources available for a product using the Key Information Links

Resource Center

Content in this section curated by manufacturer

FormularyDecisions Focus Newsletter

Preapproval Information Exchange (PIE) Information on Miracle

Soaring with MIRACLE

View All

Repository of life sciences manufacturer-curated information related to the specific product

Spotlight

MIRACLE® (generic)

Xcenda, LLC

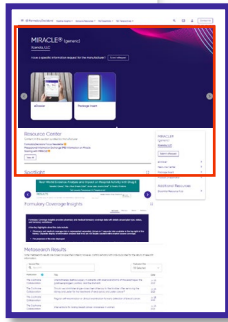
Submit eRequest

eDossier

Resource Center

Package Insert

Product Snapshot(s)



Product Page: Miracle Drug

Key visual information highlighted by the life sciences manufacturer

Spotlight

Read More

Formulary Coverage Insights

Review pharmacy and medical coverage data and formulary restrictions for products

Formulary Coverage Insights provides pharmacy and medical formulary coverage data with details around plan type, status, and formulary restrictions.

Metasearch Results

Note: Metasearch results are based on specified criteria; however, control remains with individual sites for the return of relevant information.

Quickly navigate to the latest articles on a product or topic of interest pulled using a metasearch engine

Keyword Filter: Keyword

Publication Filter: (18) Selected

Publication	Title	Date
Reuters	In 'miracle' city Shenzhen, fears for China's economic future	Jun 13, 2022
ClinicalTrials	Miracle Friends Evaluation	Jun 11, 2022
The Journal of the American Medical Association	Considerations for Generic-to-Generic Levothyroxine Switching	Jun 08, 2022
The Journal of the American Medical Association	Considerations for Generic-to-Generic Levothyroxine Switching—Reply	Jun 08, 2022
The Journal of the American Medical Association	Considerations for Generic-to-Generic Levothyroxine Switching	Jun 08, 2022
The Journal of the American Medical Association	The Relation of Diseases of the Skin to General Conditions	Jun 08, 2022
The Journal of the American Medical Association	US Surgeon General Sounds Alarm on Health Worker Burnout	Jun 08, 2022
National Institutes of Health	The miracle drug - PMC	Jun 01, 2022
National Institutes of Health	Cortisone in Popular Culture: Roueché, Ray, and Hench - PMC	Jun 01, 2022
The Journal of the American Medical Association	Use of Machine Learning to Mine User-Generated Content From Mobile Health Apps for Weight Loss to Assess Factors Correlated With User Satisfaction	May 31, 2022

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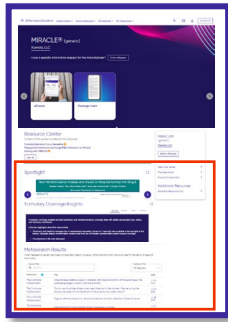
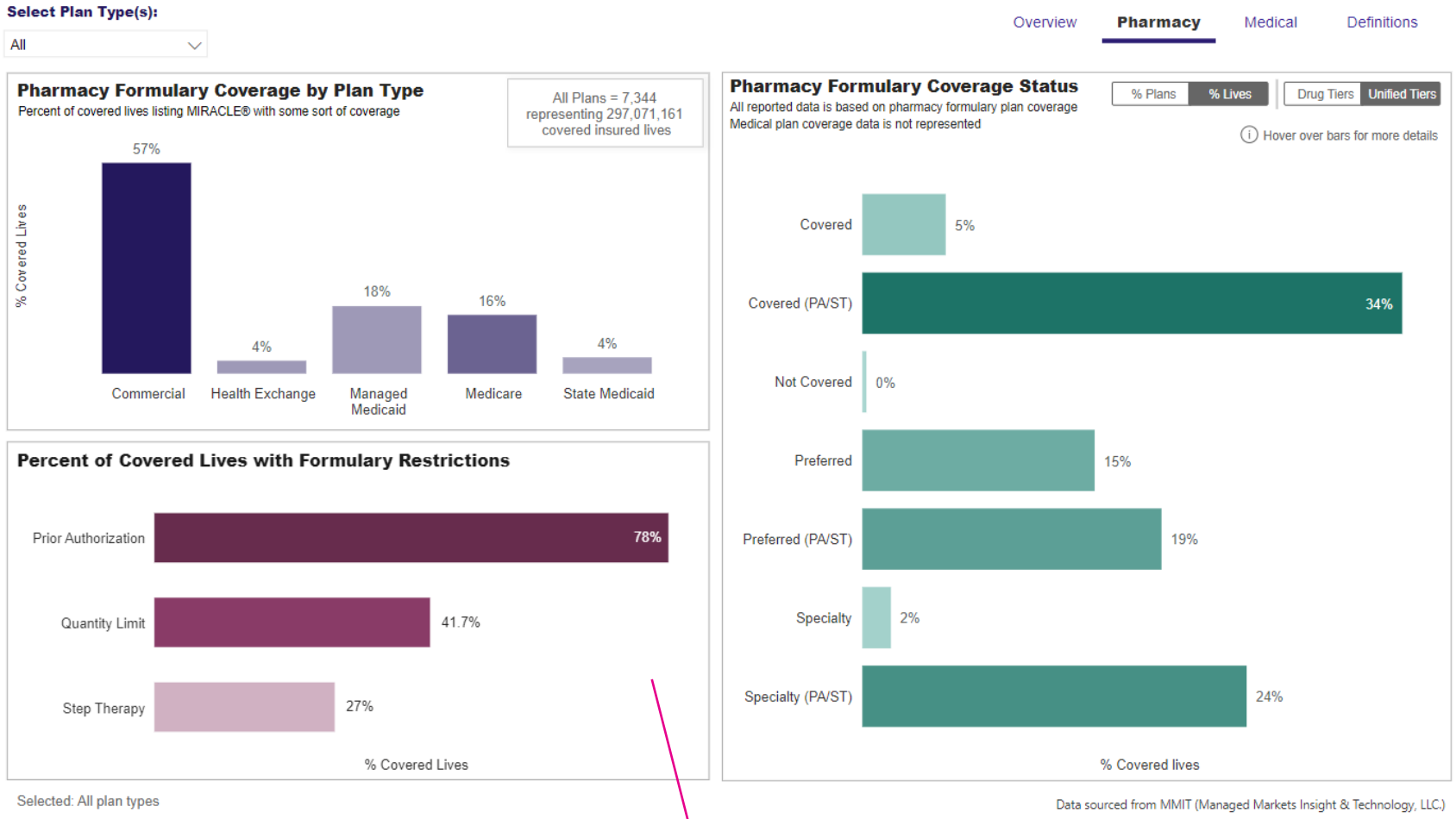


Formulary coverage insights and data



Obtain insights on how peer organizations are managing coverage and restriction of products

Find this tool on the Product Page of every FDA-approved product

Data are sourced from Managed Market Insight and Technology

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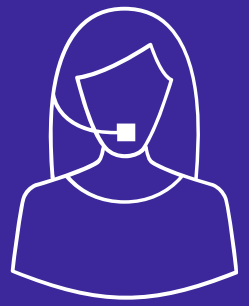

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