Navigating Market Access With Magnolia

Prescription Drug Affordability Boards: The Potential Impact on Patients

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Magnolia Market Access: Today's Moderator and Speakers

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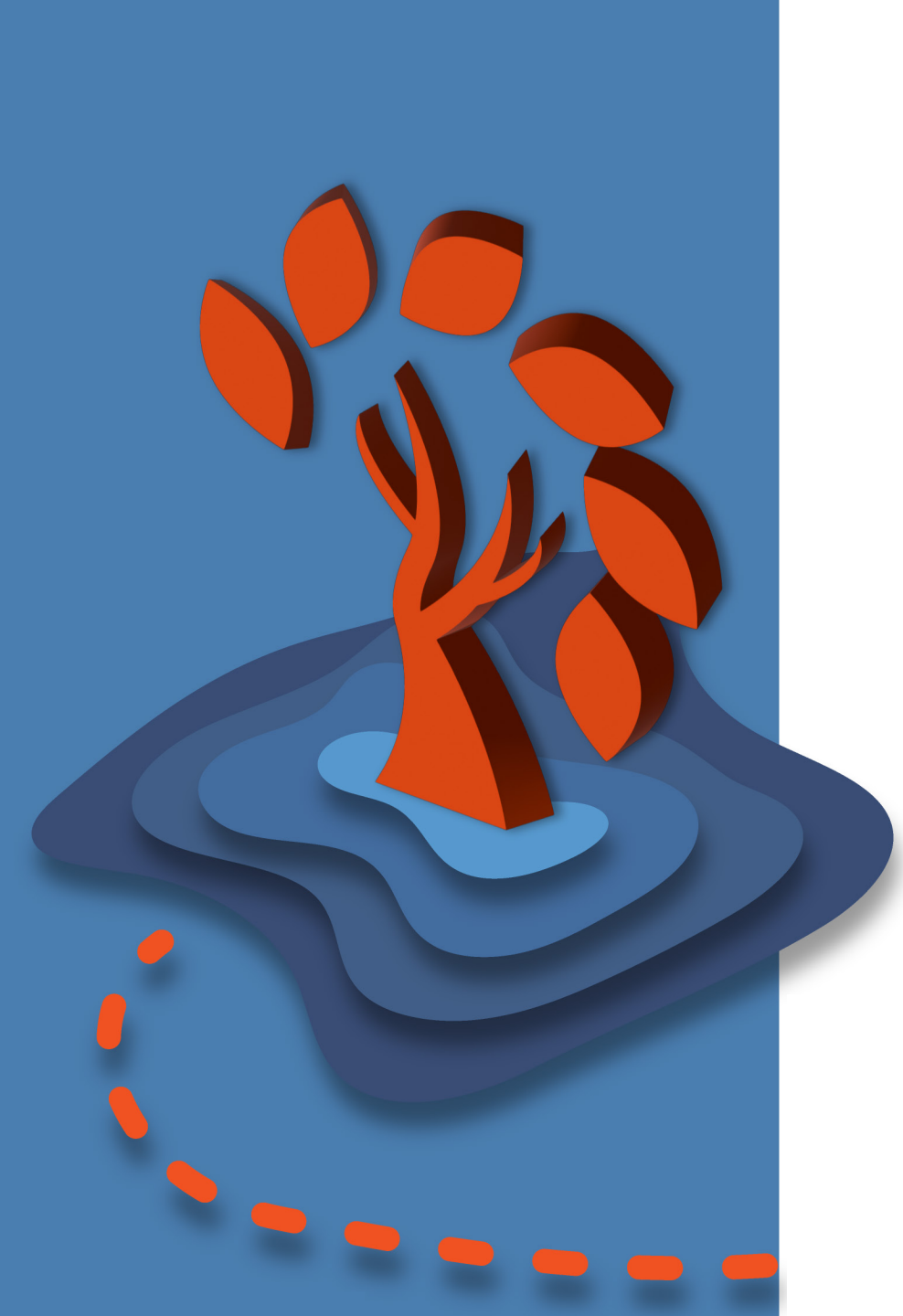

Agenda

1. Overview of Prescription Drug Affordability Boards (PDABs)
2. PDAB Process Flow
3. Examples of State Drug Reviews
4. Potential Impacts on Healthcare Stakeholders and Patients
5. Considerations to Increase Awareness and Action

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Overview of PDABs

What Are Prescription Drug Affordability Boards (PDABs)?

Function & Goals

- Identify certain **high-cost, high-spend drugs** in the state
- **Evaluate affordability** of drugs using set criteria
- Improve the **accessibility** and **affordability** of drugs deemed "unaffordable"

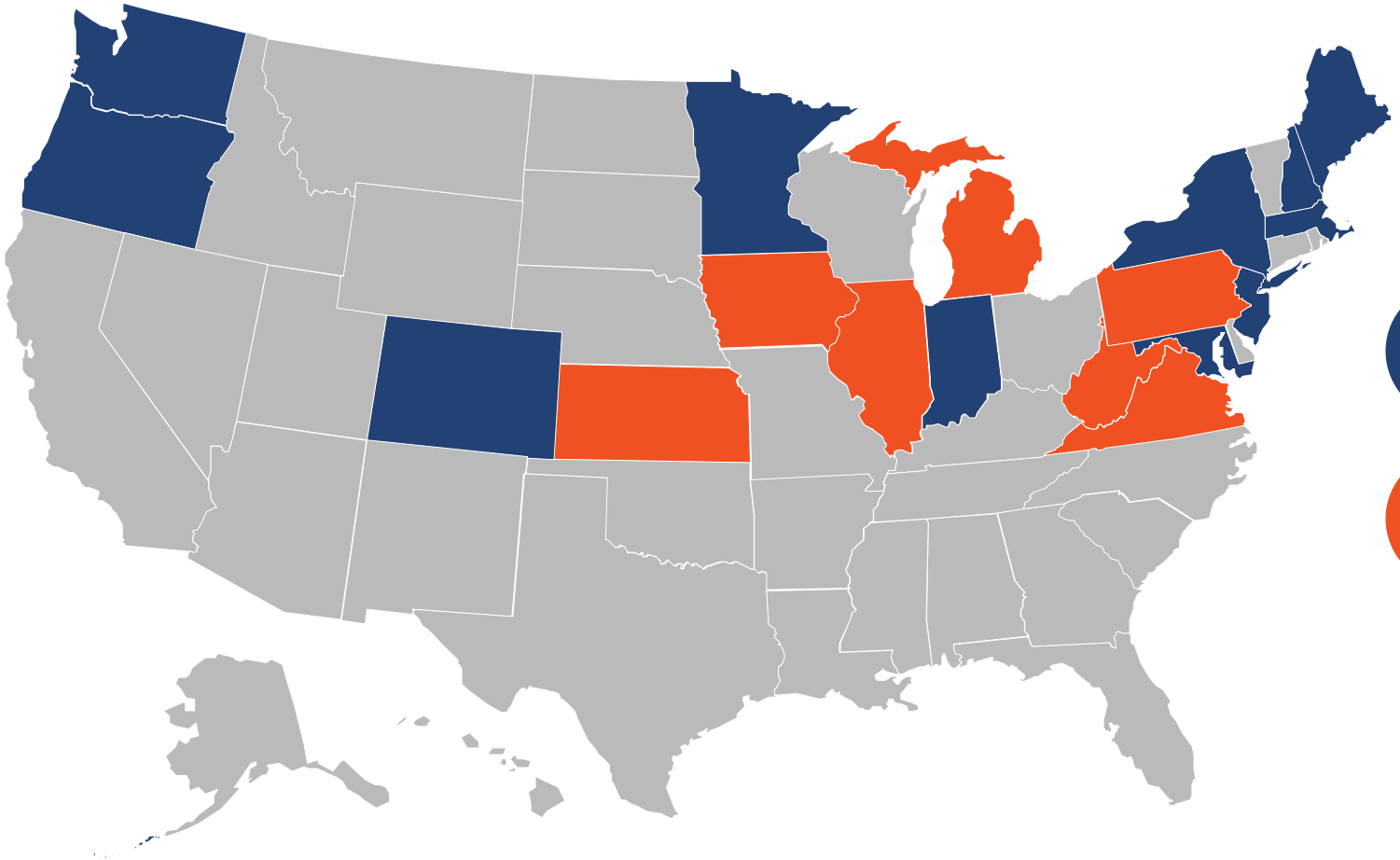
Structure

- Typically consists of **5-9 members** with expertise in medicine, healthcare economics, pharmacology, etc.
- May consult an **advisory council** of patients, providers, and other stakeholders on additional drug affordability and access issues

Reach

- Recommend policy measures to **lower drug costs** and **limit spending**
- In some cases, establish **upper payment limits (UPLs)** to cap drug costs
- Decisions may impact some (eg, Medicaid) or all consumers in **state-regulated plans**

PDAB Influence: Since 2019, 18 States Have Established or Are Currently Considering Establishing PDABs to Control Drug Costs



11 States With Established PDABs

7 States With Active Legislation to Establish PDABs

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PDAB Process Flow

PDAB Process Flow: Eligible Drugs Are Identified Based on Price and Marketing Thresholds Identified in Statute

Eligibility criteria vary by state but may include the following:

- **Brand-Name Drugs and Biologics:** Meet a specific WAC amount ($3000 to $60,000+)
- **Price Increases:** Annual WAC increase of $300-$3000 or more and/or cumulative increase over 3 years of 15%-200%
- **Biosimilars:** Eligible if price is <15% off reference product price
- **Generics:** Eligible if WAC is >$100 or has increased by a specified amount
- **Time on Market:** Some PDABs only consider drugs that have been on the market for at least 7 years

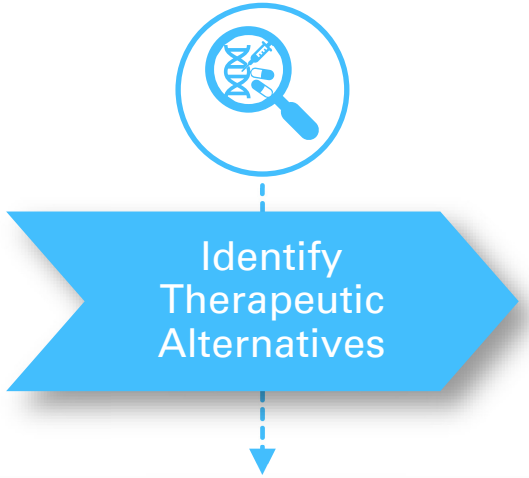
WAC, wholesale acquisition cost

PDAB Process Flow: Selection Criteria Is Applied to Eligible Drugs to Identify Candidates for Affordability Reviews

Selection criteria may also depend on the state, though typically include the following:

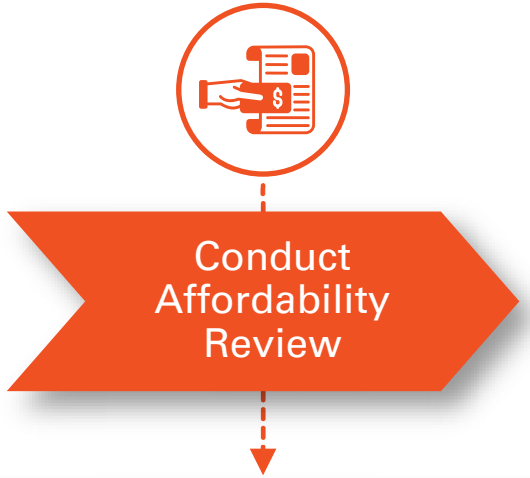
- **Patient Impact:** Out-of-pocket cost (average and total); utilization
- **Health Plan Impact:** Total plan spend per drug and average price paid per prescription
- **Availability of Alternatives:** Therapeutic equivalents or generic availability
- **Stakeholder Input:** PDABs may consult with advisory councils for insights on patient impact

PDAB Process Flow: Therapeutic Alternatives Are Utilized in Clinical and Economic Comparisons With the Selected Drug



- Determination of therapeutic alternatives may be conducted by the PDAB, their advisory council, or support staff
- Process is **variable** by state: Alternatives may be limited to pharmacologic class or more expansive to include all therapeutic treatment options for an identified disease or condition

PDAB Process Flow: Various Factors May Be Assessed During Reviews to Determine Affordability and Accessibility to Patients

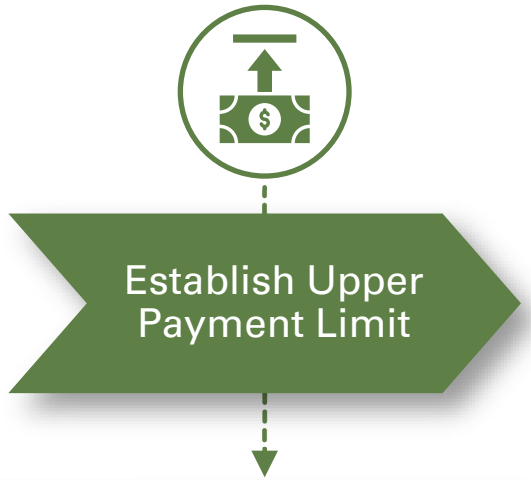


In order to determine if the selected drug poses an affordability challenge, PDABs may review the following factors:

- **Cost Analysis:** Drug WAC and average discounts provided to plans and PBMs
- **Patient Access:** Impact of price on access and adherence; financial burden on patients
- **Market Dynamics:** Availability and pricing of alternative treatments and market competition
- **Stakeholder Input:** Feedback from advisory councils, patient advocates, healthcare professionals, and public comments

PBM, pharmacy benefit manager

PDAB Process Flow: For States With the Authority, an Upper Payment Limit (UPL) May Be Established Following a Negative Review



States have different approaches to setting UPLs, which vary based on factors including the following:

- **Maximum Number of UPLs:** No limit in some states; 12-18 per year in others
- **Methodology:** Various options may be considered or selected by states, including aligning with Medicare MFP or benchmarking to prices in other states/countries
- **Exceptions:** Some states include exceptions for drugs on FDA's shortage list or that treat rare diseases
- **Applicability:** UPLs may apply broadly across all consumers in state-regulated plans; only to public plan or Medicaid enrollees

FDA, US Food and Drug Administration; MFP, maximum fair price

UPL Authority: Four States Have UPL-Setting Authority, Though No PDABs Have Established UPLs to Date

State	Drugs Selected for Review	Drugs Reviewed	Drugs to Be Considered for UPL
Colorado[1]	Cosentyx Enbrel Stelara Genvoya Trikafta	Cosentyx Enbrel Stelara Genvoya Trikafta	Cosentyx Enbrel Stelara
Maryland[2]	Dupixent Farxiga Jardiance Ozempic Skyrizi Trulicity		
Minnesota	No drugs selected		
Washington	No drugs selected		

Note: Oregon's PDAB was tasked with developing a methodology for establishing a UPL before it would be granted the authority to set a UPL.

1. Colorado PDAB Affordability Reviews. https://drive.google.com/drive/folders/13_pKCoRLYkvr7A94SPbmLikQvpak4UNJ. **2.** Maryland PDAB Cost Review Study Process Updates. https://pdab.maryland.gov/Pages/cost_review_process.aspx#Drug

PDAB Processes: Concerns and Limitations

1. Broad drug selection and aggregation
2. Consideration of multiple perspectives in review
3. Variable resources for therapeutic alternatives identification
4. Combined clinical and economic review
5. Limited consultation with key stakeholders
6. Available methodologies for setting UPLs

Examples of State Drug Reviews

Colorado Review of Stelara® (ustekinumab)

Stelara Identified

- Identified using statutory criteria
- PDAB maintains an eligible drug dashboard (n=604)[1]

Stelara Selected

One of 5 drugs selected with the following rationale[2]:

- WAC increased greater than the increase in inflation
- 63% of carriers reported it as one of the top 15 drugs that raised premiums for all covered lives
- Appeared in other states' assessments

Therapeutic Alternatives Identified

- Multi-step process including WHO-ATC classification, FDA Prescribing Information, clinical practice guidelines, tertiary references
- Cost and utilization data not available for all identified alternatives

Stelara Determined "Not Affordable"

- Also determined separately that Cosentyx® and Enbrel® are not affordable

Stelara Rulemaking Needed

- Stelara UPL not set
- Enbrel UPL rulemaking begins April 11, 2025, and will take place over 3 meetings before initiating rulemaking for Stelara or Cosentyx

WHO-ATC, World Health Organization Anatomical Classification System

1. CO PDAB 2023 Eligible Drug Dashboard. **2.** Affordability Review Summary Report: Stelara. June 7, 2024.

Oregon Review of Humulin® R U-500 KwikPen®

Humulin R U-500 KwikPen Identified

- Utilization and cost data for insulin products available from Oregon Health Authority's All Payer All Claims reporting program

Humulin R U-500 KwikPen Selected

- PDAB is required to select 9 prescription drugs and at least 1 insulin product

Therapeutic Alternatives Identified

- Regular insulin: U-500 vial, U-100 vial and pen, 70/30 vial and pen[1]

Humulin R U-500 KwikPen Affordability Determination

- May create affordability challenges for healthcare systems or high out-of-pocket costs for patients in Oregon[2]

PDAB Not Authorized to Set UPL

- PDAB submitted a plan for implementing UPLs in December 2024 to the Oregon legislature[3]

*As of June 26, 2024, the Oregon PDAB voted to pause its affordability reviews for 2024.

1. Oregon PDAB. Humulin R U-500 KwikPen Affordability Review (version 2). **2.** Oregon PDAB. January 26, 2024 Minutes. 3. Oregon PDAB. Prescription Drug Affordability Board (PDAB) Upper Payment Limit (UPL) Report to Legislature. December 2024.

Potential Impacts on Healthcare Stakeholders and Patients

PDABs and UPLs: Potential Impact on Healthcare Stakeholders

Pharmaceutical/Biotech Manufacturers

- UPL drug may be unavailable for sale in certain states
- Impacts to other prices/pricing metrics (Medicaid best price, 340B double dipping)
- Disincentive to research additional clinical uses or improve formulations of drugs

Pharmacies

- Reduced reimbursement rates; uncertain margin
- Decreased pharmacy access
- Increased administrative burden and operational challenges (eg, different pricing structures)

Payers

- Changes to benefit design and increased utilization management
- Increased administrative burden (eg, contracting)
- Impact on overall cost of care uncertain

Providers

- Reduced reimbursement for provider-administered therapies
- Fewer therapeutic options for patients
- Increased administrative burden due to payer plan design change

PDABs and UPLs: Potential Impact on Patient Care and Access

Limited Treatment Options

- Reduced access at the pharmacy or their provider
- UPLs on rare disease products could lead to no alternative
- May result in worse clinical outcomes and increases in other healthcare costs

Changes in Benefit Design

- No requirement to lower the tier or prefer the UPL product could increase patient costs
- Increased utilization management requirements could decrease access

Lack of Medical Necessity/Appeal Process

- No solutions for patients to overcome barriers to access their medically necessary medicines (eg, medical exception or prior authorization review or an appeals process)

Decreased Innovation

- Diminished incentives for development of new therapies and biosimilars
- Limited ongoing research that supports expanded use or new indications

Considerations to Increase Awareness and Action

Provider Associations

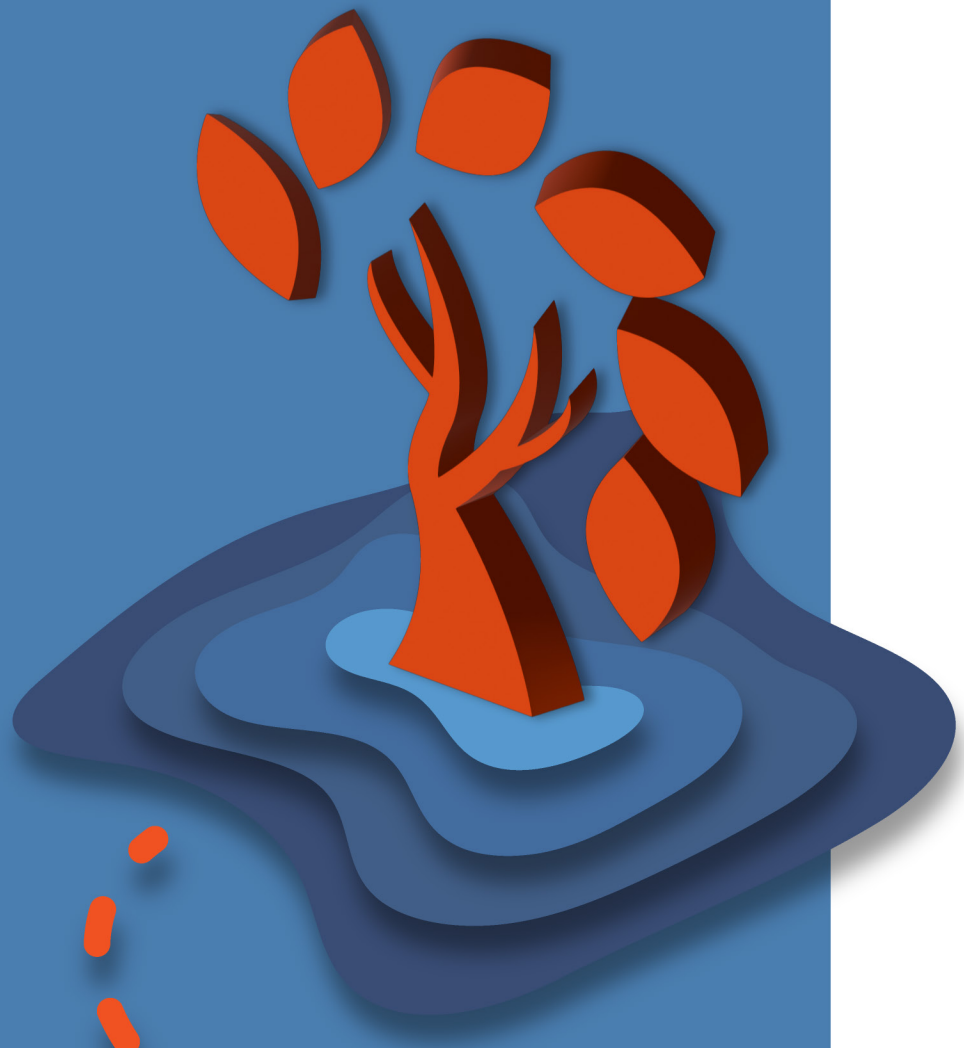
- Increase member awareness through state and national-level educational campaigns
- Conduct outreach to encourage providers to engage with PDABs through written comments or presentations to speak to patient impacts

Pharmaceutical/Biotech Manufacturers

- Increase patient and provider awareness through creation and dissemination of educational materials for applicable states
- Monitor PDAB activity and engage by providing comments either in writing or by presenting to the PDAB

Patient Advocacy Groups

- Increase patient awareness through educational campaigns
- Engage patient members in impacted states to advocate engagement in writing and in-person during open comment periods and meetings



Q&A

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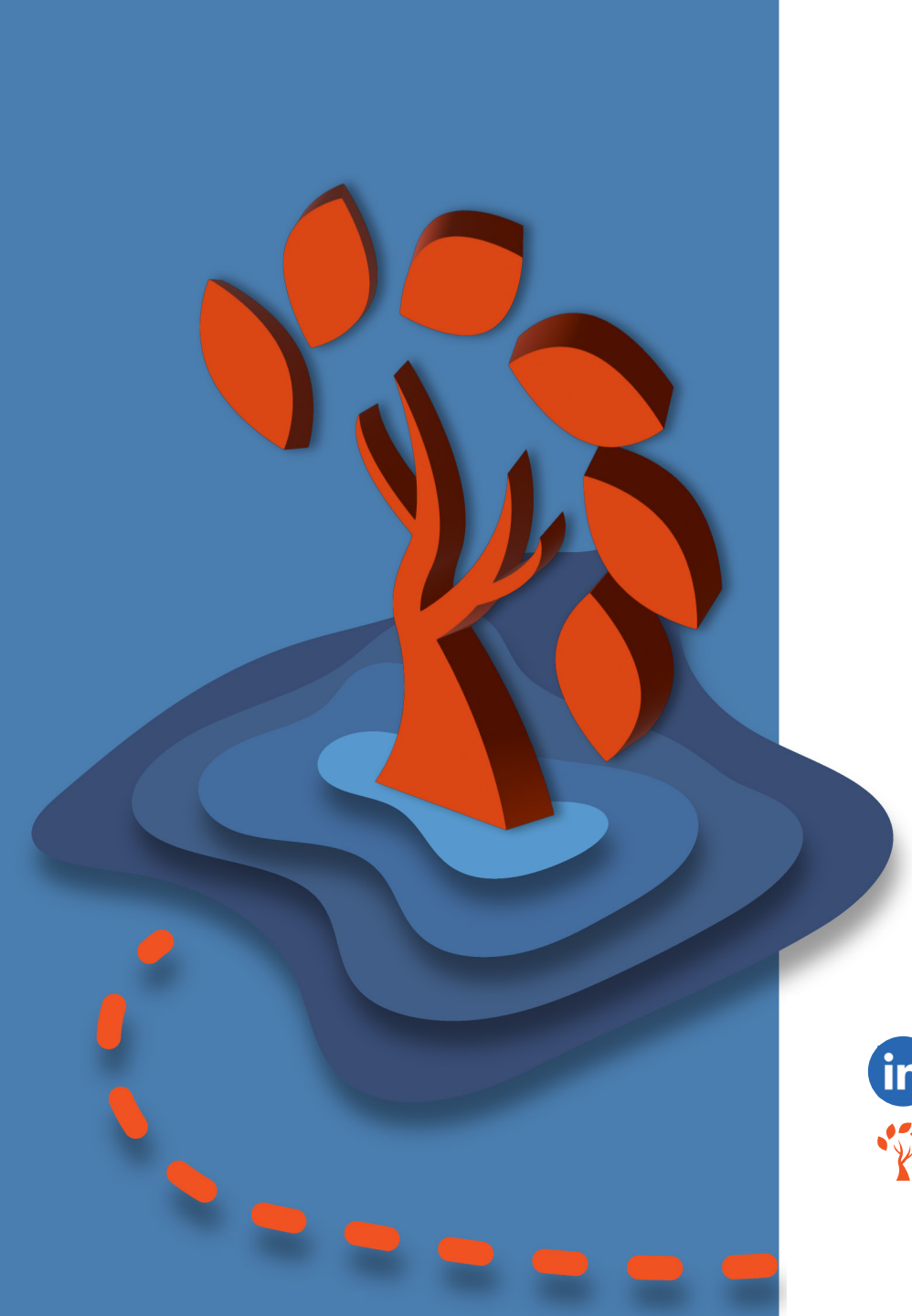

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Overview of Real-World Data in Vaccine Safety

Thursday, April 24, 2025
12:00 pm to 1:00 pm ET

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