Objection Handling: How Should Manufacturers Evolve to Meet the Clinical and Contracting Demands of Payers?

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Objectives

Provide background on how the landscape continues to evolve and how payer expectations are becoming more complex to justify product coverage and adequate payment

Discuss what manufacturers should consider in their payer value proposition presentations, and how they should prepare to answer payer objections

Highlight key strategies and best practices in addressing payer objections and resolving issues to promote access

Review case study examples that identify opportunities for successful objection handling

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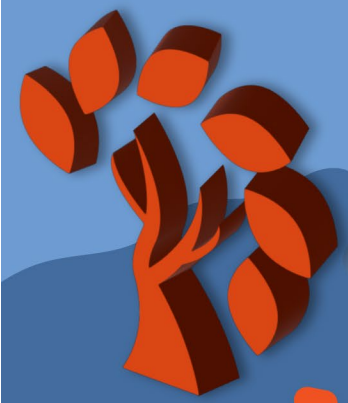
Challenge:
Consolidation and Integration



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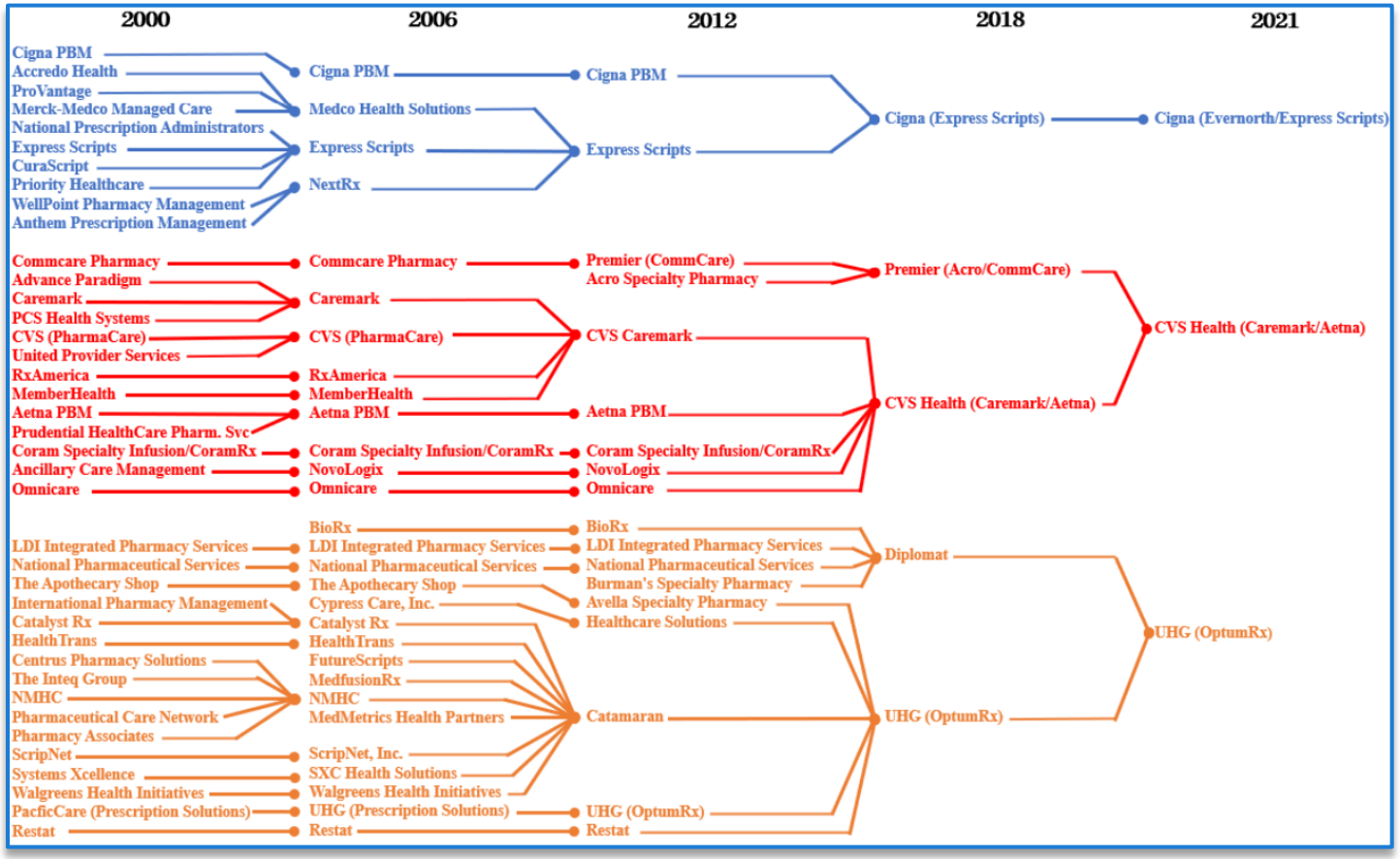
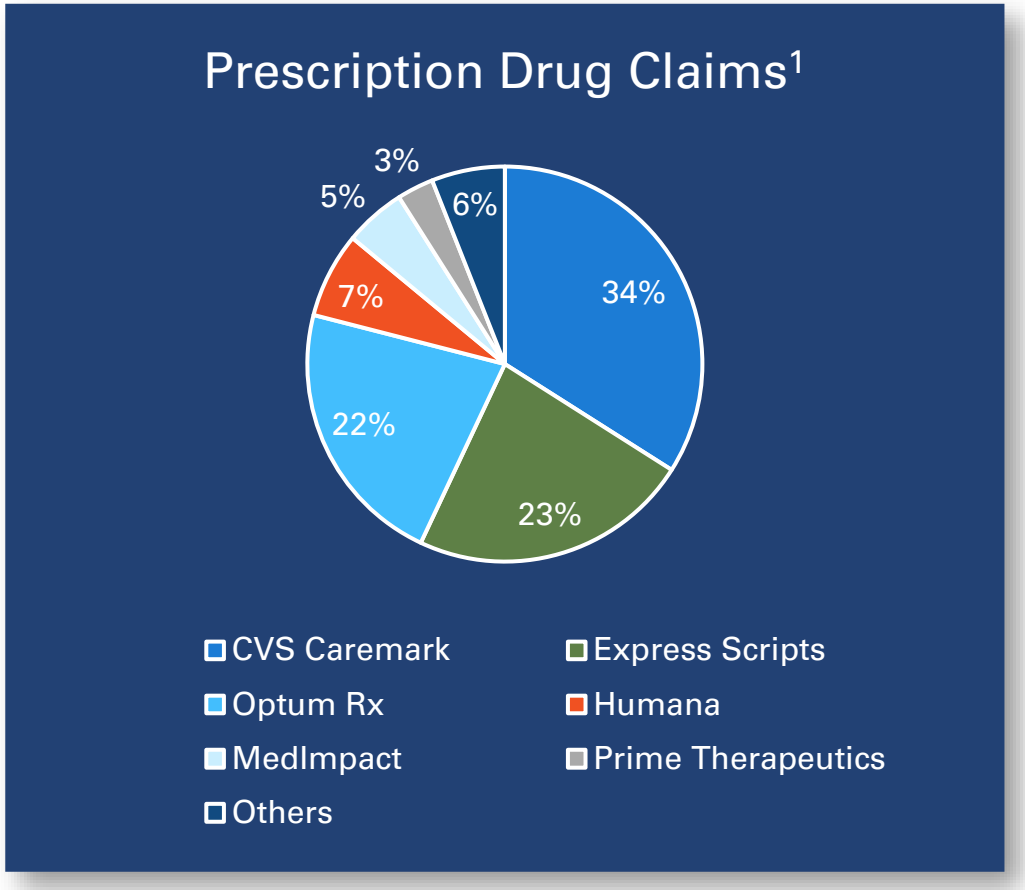
Horizontal Consolidation[1]

79% of Prescription Claims are Managed by Three PBMs





1. Graphic and Data from U.S. Federal Trade Commission Interim Report on PBMs. July 2024

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Vertical Integration[1]

Consolidation of the Pharmaceutical Supply Chain

1. Graphic from Drug Channels Institute (DCI)

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Consolidation and Integration

Impact on Pharmaceutical Manufacturers

Challenges

Increased negotiation pressure

Broader exclusions and utilization management controls

Positives

Increased focus on total cost of care

More connected systems

Enhanced data capabilities

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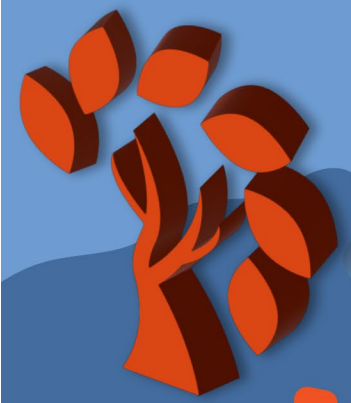
Challenge:
Payer Concerns



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Payer Concerns

Affordability

Clinical Value and Unknowns

Equitable Access to Care

Adverse Selection

Increasing Regulation

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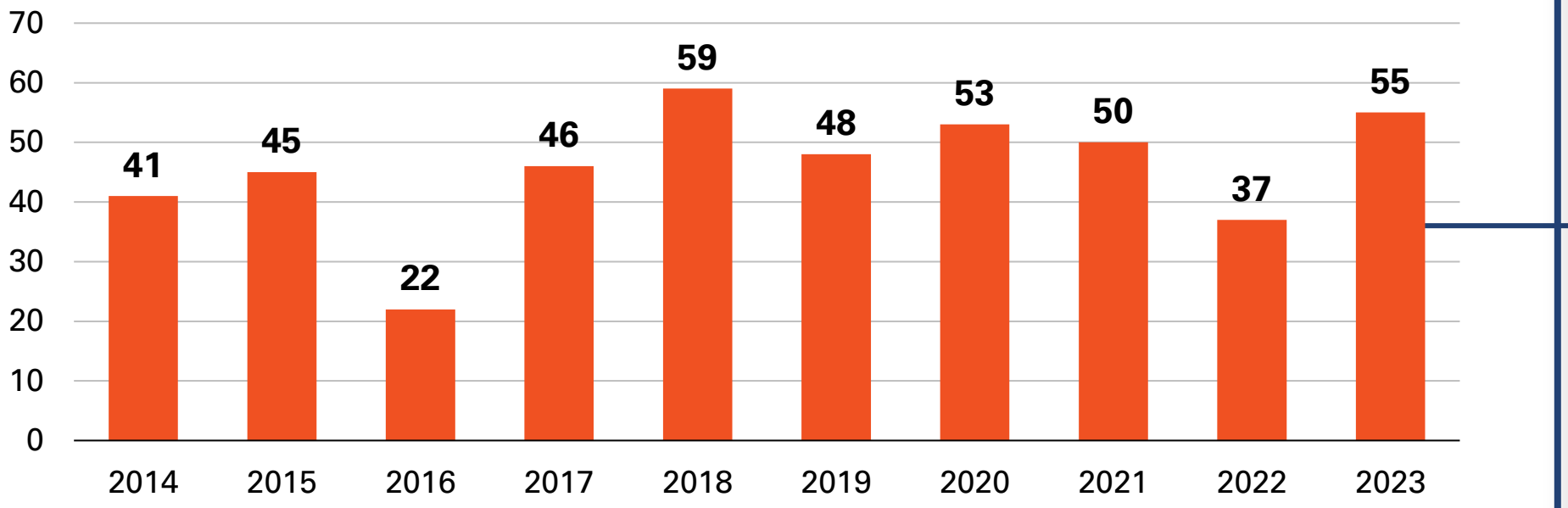
Affordability



- 51% orphan designated
- 36% first-in-class

- **High-cost Drug Pipeline:** 92% of employers concerned or very concerned[2]
- **Pharmacy Cost Trend:** 91% of employers concerned or very concerned[2]

1. Center for Drug Evaluation and Research (CDER). New Drug Therapy Approvals 2023. January 2024.
2. Business Group on Health. 2024 Large Employer Health Care Strategy Survey. August 22, 2023.

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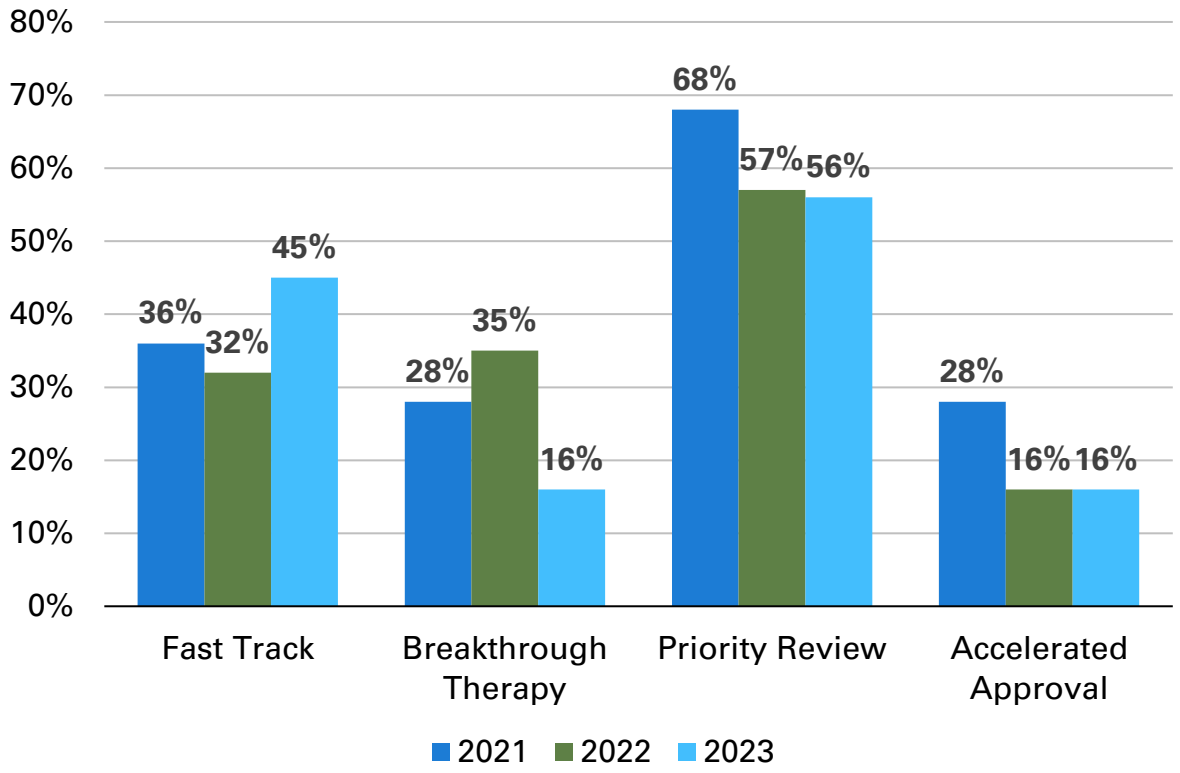
Clinical Value and Unknowns

FDA expedited development and review pathways[1-3]



Clinical Unknowns

- Applicability to general population
- Therapy sequencing
- Combination therapy
- Durability
- Success measurements
- Comparative data

1. CDER. New Drug Therapy Approvals 2023. January 2024.
2. CDER. New Drug Therapy Approvals 2022. January 2023.
3. CDER. New Drug Therapy Approvals 2021. January 2022.

Equitable Access to Care

Provider and pharmacy accessibility

High out-of-pocket costs leading to

- **Prescription abandonment:** ~20%[1,2]
- **Nonadherence:**
  - 50% of prescriptions taken incorrectly[1]
  - 21% have taken an over-the-counter drug instead of prescription[2]
  - 12% have skipped doses or cut pills in half[2]

Multiple conditions and multiple medications

1. CDC. *MMWR* .2017; 66(45).
2. Lopes, L et al. *KFF*. March 1, 2024.

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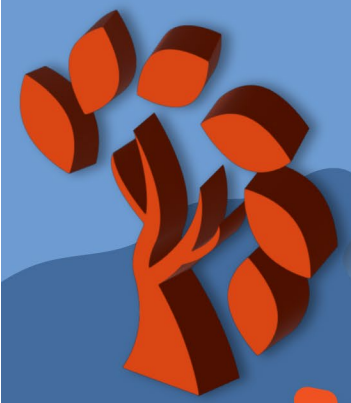
Adverse Selection

- Balance comprehensive formulary with overly generous plans
- Increased utilization management requirements

Increasing Regulation

- Benefit design
- Drug coverage requirements
- Formulary and utilization management
- Pricing/reimbursement

Solution:
Strong Payer Value Proposition



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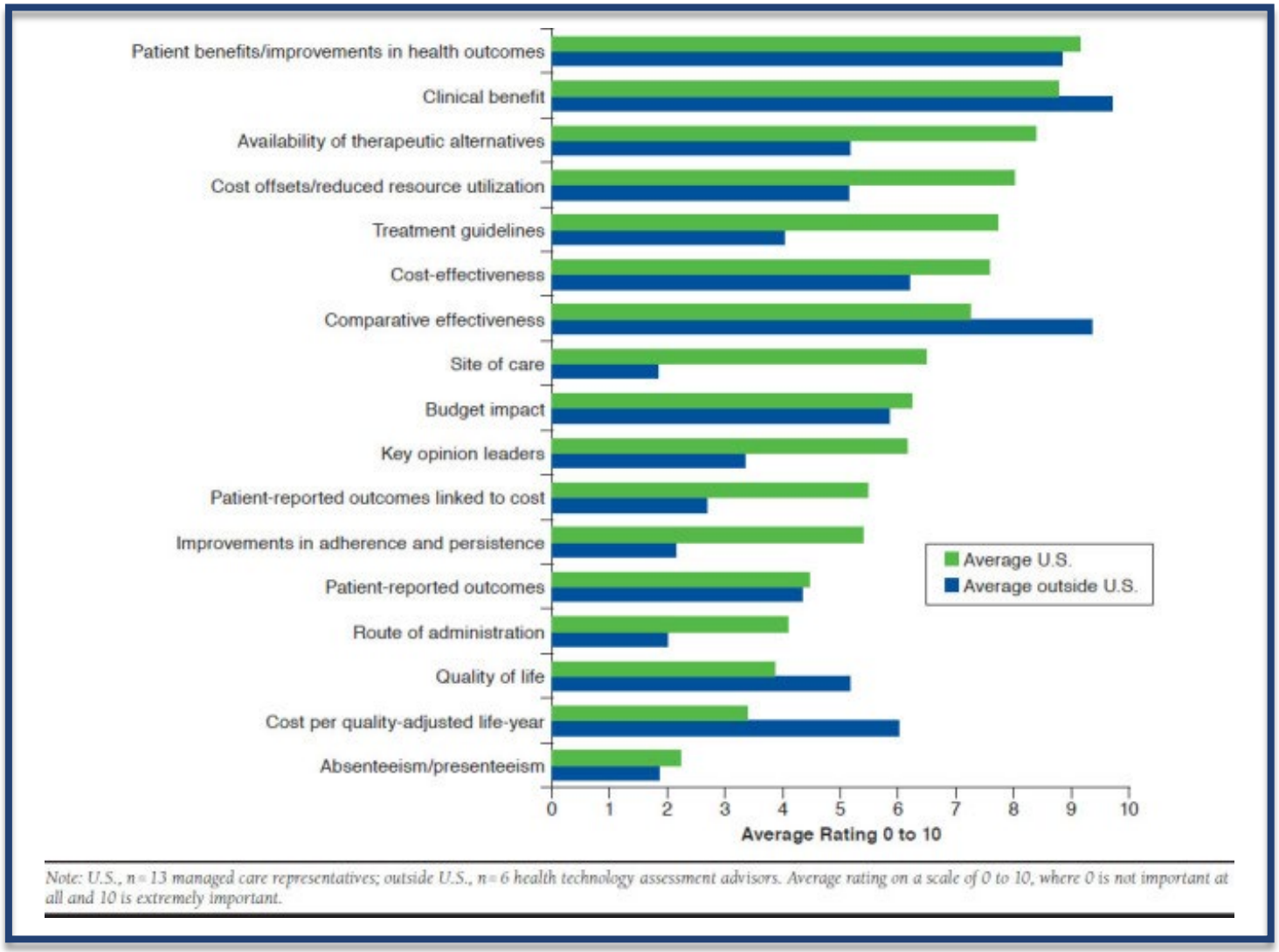
Payer Factors and Processes Driving Value Assessments[1]



Clinical and patient benefits or improvements in health outcomes were rated high by all payers

Quality of life and route of administration were lower rated factors

No formal definitions of value or formal assessment processes to determine value

General processes: P&T Committee, Value Committee, Contracting Team

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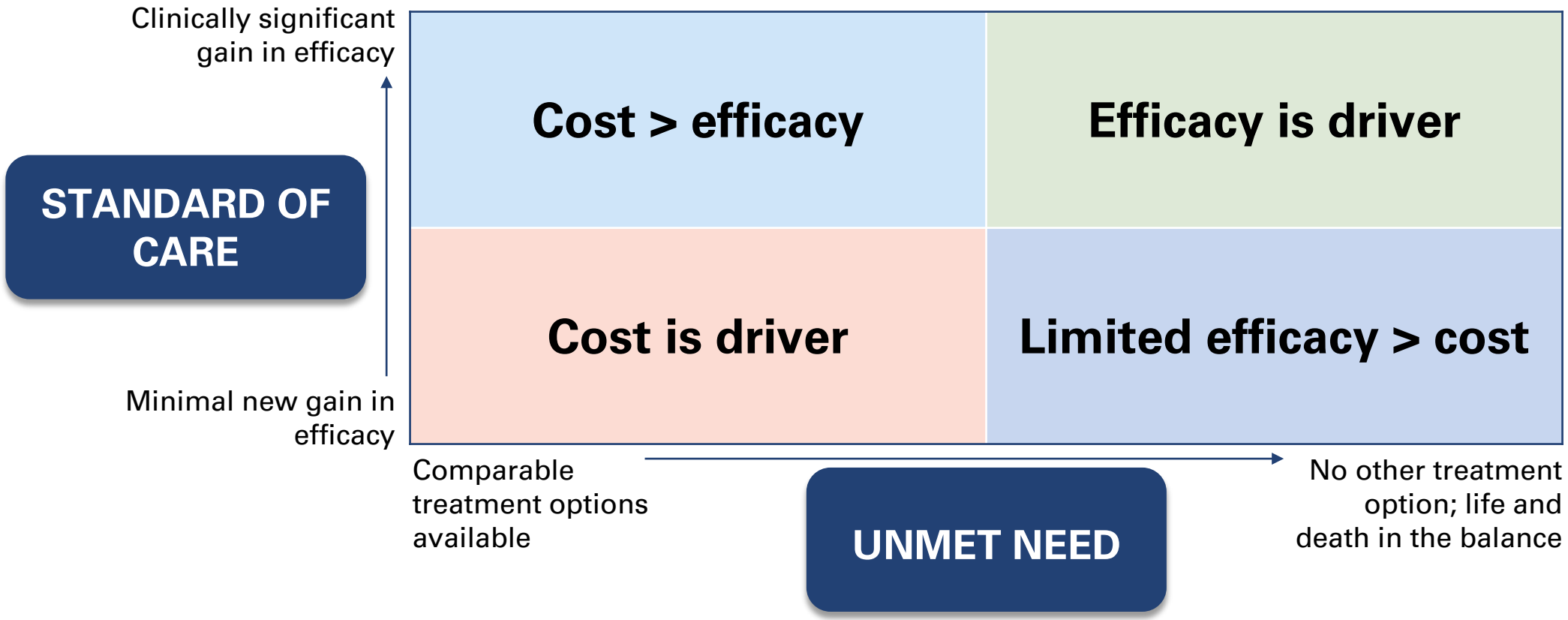
1. Brogan, AP et al. *J Manag Care Spec Pharm*. 2019; 25(12).

Payer Value Messages

Efficacy and Cost Evaluation Driven by Unmet Needs and Standard of Care



Adapted from: Studin, I. PharmExec.com. October 29, 2020.

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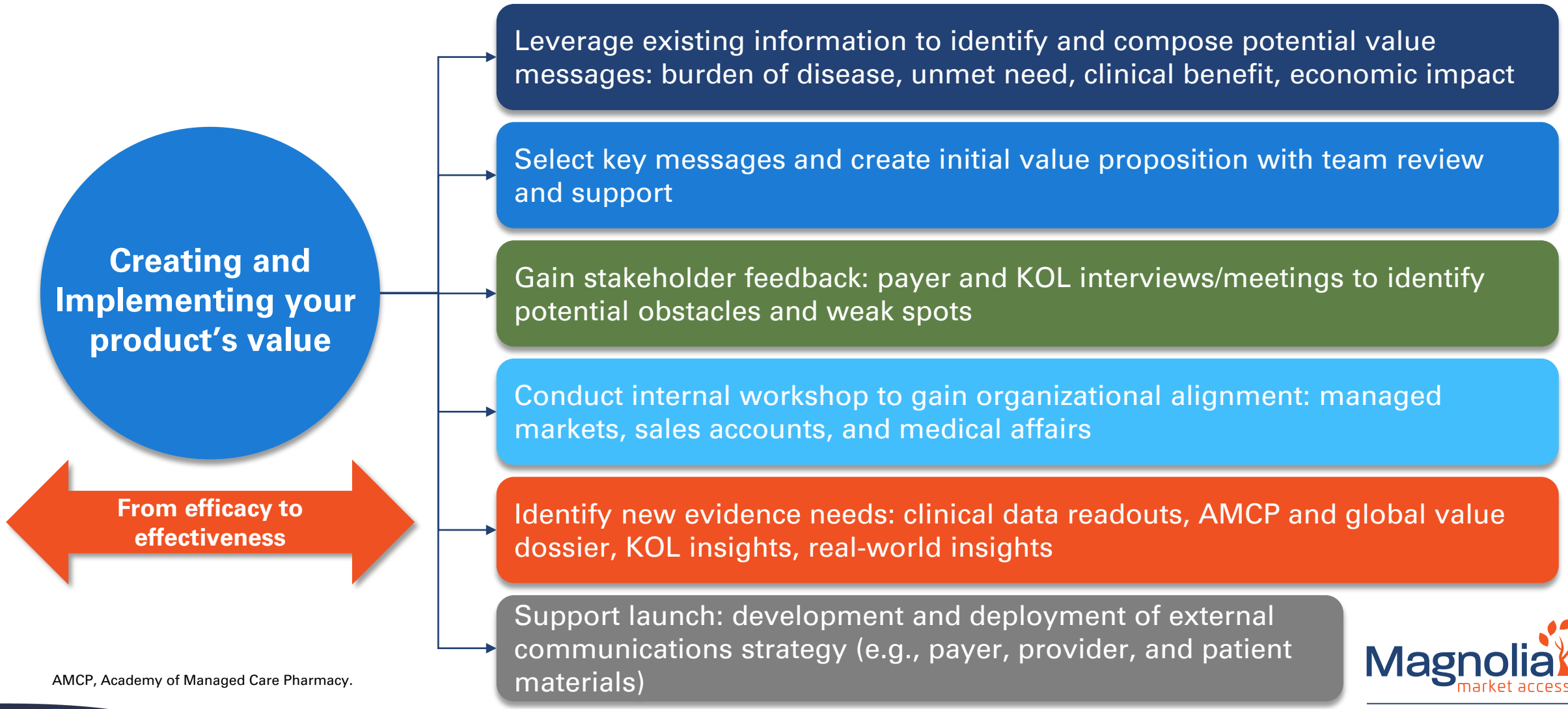
Developing a Strong Value Proposition:

Use Evidence and Input to Differentiate Your Product's Value



AMCP, Academy of Managed Care Pharmacy.

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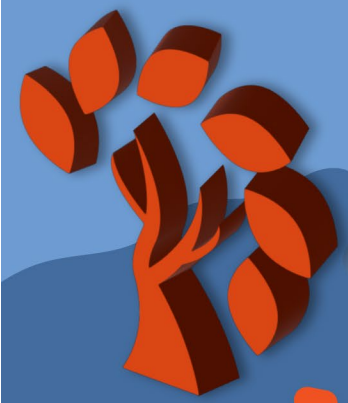
Solution:
Anticipate and Address Payer Objections



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General Strategies for Payer Objection Handling

Be Prepared

- Develop a list of common questions
- Determine and practice responding
- Know the payer and their role
- Gather competitive intelligence

Practice Active Listening

- Clarify the question if needed
- Understand the underlying question or concern

EVOLVE: Strategize and develop data-driven responses to objections

Respond Honestly and Directly

- Be succinct in answering questions
- Provide facts, not opinions
- Know what data is not available and what is under investigation

Be Collaborative

- Ask the payer questions – perceived clinical value, place in therapy
- Discuss additional data or information needs
- Explore solutions to expand access

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Case Study 1 – Crowded Class

Product Description: A new formulation allowing self-administration is launching

Standards of Care

- Previous formulation required HCP administration
- Other therapeutic options for the condition are self-administered but are not always effective and have higher adverse reactions

Unmet Needs

- Numerous treatment options
- Other self-administered options already available

Clinical Data

- Equal efficacy and safety with HCP-administered formulation
- Increased quality of life and treatment satisfaction

Economic Information

- New formulation: $50K/year
- Previous formulation: $50K/year
- Other options: $35-45K/year

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Evolved Objection Handling: Crowded Class

Potential Objections	Data-Driven Solutions
Any data comparing this product to other options?	Indirect treatment comparisons using clinical trial data and literature
Does self-administration and better side effect profile result in improved adherence/persistence?	• Literature review of another product with a similar profile • Follow forward with claims and EMR analyses
What is the success of this product in those who have failed other therapeutic options?	• Ideally consider during clinical trial design • Claims data analysis of current treatment patterns
What is the impact of this product on medical costs compared to other therapeutic options?	• Cost analysis of trial data (if healthcare resource utilization collected) • Cost-effectiveness model

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Case Study 2 – Additional Treatment Option

Product Description: Biologic product "NEW" received FDA approval to treat Condition Y. It is administered subcutaneously once weekly and has no special monitoring requirements

Standards of Care

- There are 2 other therapeutics on the market

Product	Dosing and Administration	Monitoring
Product One	Intravenous every 3 months	Potential for anaphylaxis; give in a monitored setting
Product Two	Subcutaneous every 2 weeks	Requires laboratory monitoring biweekly for first 2 months

- All 3 products have different mechanisms of action.

Unmet Needs

- Another mechanism of action with self-administration
- No special monitoring requirements

Clinical Data

- Product NEW was approved based on improvement in a standardized composite score specific to Condition Y compared to placebo at 12 months
- Same measure used for Products One and Two – both demonstrated improvement

Economic Data

Product NEW	**$350,000/year**
Product One	$300,000/year
Product Two	$275,000/year

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Evolved Objection Handling: Additional Treatment Option

Potential Objections	Data-Driven Solutions
Can these products be used in combination?	• Drug-drug and drug-disease interactions • If not included in trial design, follow forward
What is the right sequence of therapy?	Systematic literature review, clinical practice guideline evaluations, and treatment pathway development
What is the impact of this product on medical costs compared to other therapeutic options?	• Cost analysis of trial data (if healthcare resource utilization collected) • Account for all possible cost off-sets in BIM
Do you stop therapy if the patient has no improvement?	• Subgroup analyses of trial non-responders • Endpoint component analysis for benefit

BIM, budget impact model

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Case Study 3 – Novel Therapy

Product Description: : Intravenous infusion administered every 3 months for a rare genetic neuromuscular condition. Approved through the FDA's accelerated approval pathway.

Standards of Care

- No other FDA approved treatments
- Corticosteroids often used; immune globulin has limited efficacy

Unmet Needs

- Variable clinical presentation
  - **Type 1** – Rapid progression with debilitating symptoms (death within 5 years)
  - **Type 2** – Slower progression with mild symptoms (death within 20 years)
  - **Type 3** – Mild to no symptoms
- Estimated prevalence is 50,000 in US

Clinical Data

- Demonstrated improvement in inflammatory markers at 6 months in patients with Type 1
- FDA indication does not specify type

Economic Data

- $750-900K/year (depending on weight)

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Evolved Objection Handling: Novel Therapy

Potential Objections	Data-Driven Solutions
How does this endpoint equate to clinical outcomes?	Understand collaboration with FDA and providers to use surrogate endpoints
Is there any data in Type 2 patients?	• Prospective trial to evaluate • Other approaches – TBD, AI/ML solutions?
What is the prevalence of the different types? Is 50,000 an underestimate?	• Use of machine-learning to evaluate patient journey and identify those undiagnosed • Evaluate non-US data for extrapolation
What are the medical costs associated with this condition? How does this drug impact?	• Payer mix analysis and ability to adjust BIM for payer line of business • Claims analysis of associated costs • Primary market research on burden of illness

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Evolving Objection Handling

Consolidation and integration of the payer market provides challenges and opportunities

Understanding the payer's perspective and pressures lays a foundation for collaboration

Creating a strong value proposition focused on the burden of disease, unmet needs, clinical benefit, economic impact will guide payers in their assessments

Anticipating and strategizing data solutions for common objections may lead to increased market access

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Join us for our next
Navigating Market Access with Magnolia:

Real-World Data Curation 101: Understanding and Utilizing Unstructured Data

Thursday, August 22, 2024
12:00 PM to 1:00 PM Eastern

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Thank you!

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