

# Navigating Market Access with Magnolia

## Integrating HEOR and Payer Considerations in Clinical Trial Design to Improve Access

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a medical knowledge group company

# Navigating Market Access with Magnolia

## Today's Moderators



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# Panel Topics

How the FDA & US payers evaluate clinical evidence

Translate HEOR into US-relevant evidence needs

Designing trials with patient access in mind

Common design pitfalls & best practices



# Our Shared Goal: Access Is at the Center of Everything We Do



**One Goal:** Many different stakeholders sharing one goal

**Different Roles:** Different, and necessary roles to reach shared goal

**Complicated Journey:** Journey can be complicated; many decisions along the way

**Data-backed Decisions:** Reliance on data to ensure the right decision is made for each patient



How do we find the right data, synthesize it, and translate it in a way that will support critical decision making?

# Stakeholders

## Iterative Process Across Drug Development and Commercialization Lifecycles

**Core Trial Leaders**

**Value and Access Contributors**

**Commercial and Strategic Input**

**Role**

Own protocol strategy and execution feasibility

Ensure evidence supports reimbursement and uptake

Ensure evidence supports patient access and reimbursement

**Groups**

Clinical Development  
Biostatistics  
Clinical Operations  
Regulatory Affairs

HEOR  
Market Access/Payer Strategy  
Medical Affairs

Commercial/Brand Strategy  
Pricing & Contracting  
Patient Advocacy  
Portfolio/Corporate Strategy



**Trial design should be cross-functional to ensure decisions made early in development support long-term commercial success.**

# FDA Approval Does Not Mean Payer Coverage

## FDA approval = Regulatory standard

- FDA evaluates safety, efficacy, benefit-risk profile, manufacturing quality
- Answers question: “Does this drug work and is it safe enough to market?”
- Drug can be approved based on surrogate endpoints, single-arm trials, small populations, accelerated approval pathway
- Does not consider cost, cost-effectiveness, affordability for healthcare system, comparative value vs. alternatives
- Regulatory decision

## US Payer Coverage = Reimbursement & value decision

- Payers evaluate clinical benefit vs SOC, strength of evidence, magnitude of improvement, costs vs alternatives, budget impact, utilization management feasibility
- Ask/answer: “Is this product worth covering at this price?”
- Financial and policy decision considering cost

 **Considering payer coverage in clinical study design supports access to therapy**

# Which US Stakeholder Most Influences Access for Your Products Today?



**A** Commercial health plans

**B** PBMs

**C** IDNs

**D** Medicare/ Medicaid

**E** Varies significantly by product

# How US Payers Evaluate Clinical Evidence

## What Matters Most

- Incremental benefit vs. SOC (clinically meaningful, not just statistically significant)
- Real-world relevance (representative populations, durability, safety)
- Plan-level budget impact (eligible population × net price × short-term costs)

## Evidence Expectations Vary by Benefit Design

- Pharmacy benefit: Tiering, step therapy, cost per script
- Medical benefit: Total episode cost, site of care, administration burden
- Buy-and-bill vs. specialty pharmacy: Different reimbursement and UM lever

## Expanding Role of Utilization Management

- Step therapy anchored to lowest net-cost option
- PA criteria aligned to trial inclusion/exclusion
- Increasing use of indication-based management
- Growing reliance on real-world evidence post-launch



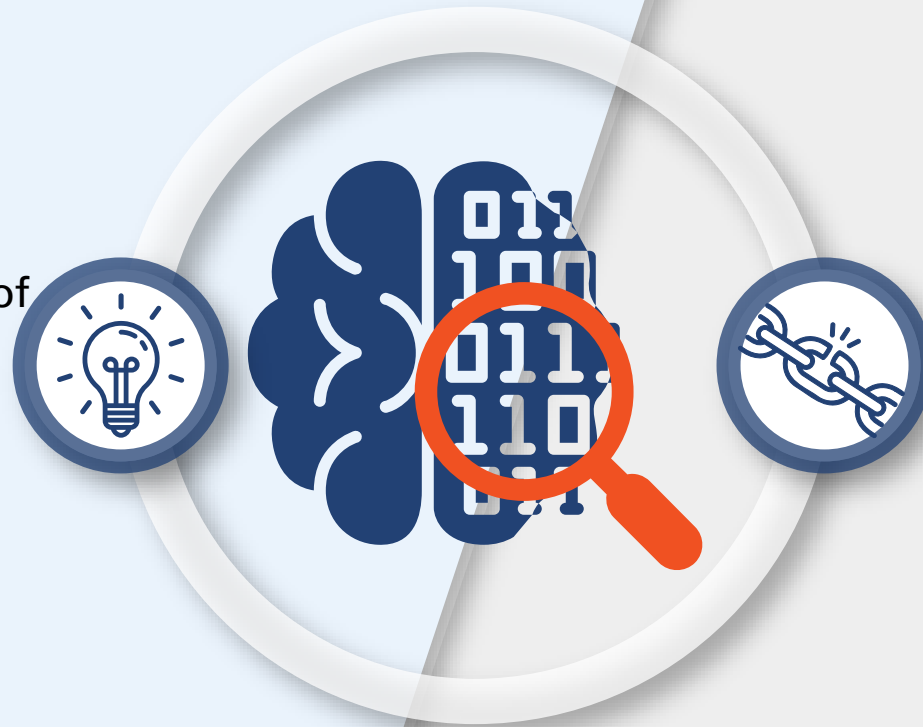
# Understanding Your Evidence from a Payer Lens

## Focus on Evidence That Translates to Real-world Value

### Strengths

#### What resonates with payers

- Robust clinical trial design
- Evidence-based medicine/ relevant endpoints that demonstrate an understanding of disease, its severity, and unmet needs
- Consistency across studies
- Head-to-head comparisons
- Health economic evidence
- Long-term safety & durability
- Post-marketing evidence reinforcing trial findings



### Weaknesses

#### What payers challenge

- Surrogate endpoints without validation
- Limited generalizability
- Small, single-arm, or open-label studies
- Short follow-up durations
- Conflicting or inconsistent evidence
- Economic evidence gaps
- Publication bias or lack of transparency

# How Evidence Expectations Differ Between Regulators & Payers

## Generating Evidence That Payers Need for Confident Coverage

### Endpoints & Outcomes

What's "enough" for FDA/EMA approval is not always enough for coverage and reimbursement

### Evidence Generation Strategy

Lack of alignment on which evidence is truly "decision-driving" for reimbursement

### Real-World Applicability

Limited generalizability of trial results makes payers cautious about broad coverage

### Economic Evidence

Trial endpoints do not always translate to value

### Communication & Engagement

Missed opportunities to collaborate early leads to misalignment and duplicated or wasted investment

### Value Definition

Different definitions of value create tension in pricing, access, and reimbursement discussions



# How Often Do US Payers Ask for Evidence Not Generated in Pivotal Trials?



**A** Almost always

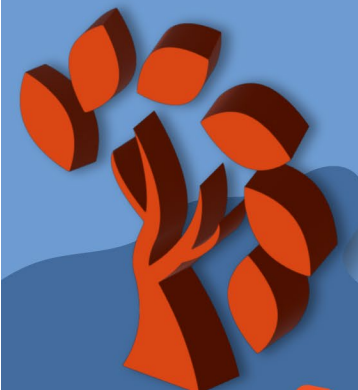
**B** Often

**C** Sometimes

**D** Rarely

**E** Not sure

# Designing Trials with Market Access in Mind



# The Value of Incorporating Patient Access Needs in Clinical Trial Design



**Stronger, more meaningful clinical evidence at launch**

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**Enhance real world relevance**

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**Reduce access barriers**

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**Strengthen value narrative**

# At What Stage are US Payer Evidence Needs Typically Considered?



**A** Phase I/early development

**B** Phase II

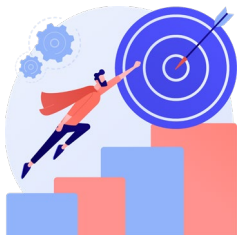


**C** Phase III

**D** After pivotal trials are complete

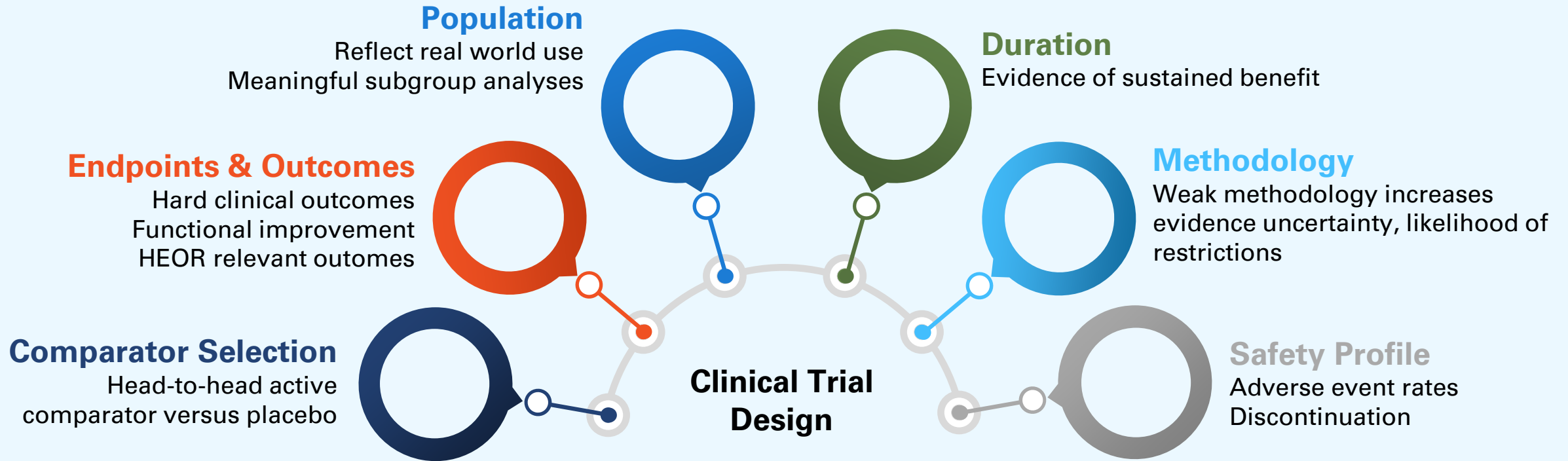
**E** Varies by program

# Consider Access Throughout Clinical Trial Phases

## Iterative Process Across Drug Development and Commercialization Lifecycles

	Early Development Preclinical – Phase I	Mid-Development Phase II – Early Phase III	Late Development Phase III – Pre-Launch
 <b>Goals</b>	Understand reimbursement landscape and payer unmet needs	Refine target product profile (TPP) and test payer expectations	Develop and refine value story and access strategy
 <b>Key Design Considerations</b>	Laying the foundation for value	Align trial design with reimbursement needs	Building the value dossier
 <b>Importance</b>	Align trial design with payer-relevant outcomes; initiate access planning	Guide comparator choice, endpoints, HEOR models	Anticipate formulary/access barriers (e.g., step edits, prior auth, tiering)

# Payer Trial Design Considerations



**Biggest payer risks in clinical trials come from: placebo-controlled trials, surrogate endpoints without validation, narrow/small populations with broad pricing assumptions**

# Market Access Considerations in Clinical Trial Population Selection



## Clinical Considerations

- Disease severity definition
- Inclusion/exclusion criteria
- Line of therapy positioning
- Biomarker or subtype selection
- Comorbidity restrictions
- Prioritize internal validity



## HEOR Considerations

- Will this population generate measurable:
  - Resource utilization differences
  - Cost offsets
  - Adherence/persistence insights
- Can subgroup analyses support economic modeling?
- Is follow-up duration sufficient to demonstrate economic impact?



## Payer Considerations

- Population align with the standard of care?
- Reflect patients actually covered by payers?
- Does the population support:
  - Favorable formulary tier placement
  - Avoidance of restrictive Prior Authorization?
  - Strong positioning in step therapy
- Are high-cost or high-utilization subgroups included?

**Patient population decisions drive downstream reimbursement risk.**  
Overly narrow trials may secure approval—but broader, payer-relevant populations drive coverage confidence and economic value demonstration.

# Which HEOR Outcomes Have Been Most Impactful in US Payer Discussions?



**A** Cost offsets / reductions in utilization

**B** Quality-of-life improvements

**C** Adherence or persistence data

**D** Productivity or caregiver burden

**E** None have materially influenced decisions

# Considerations When Selecting Clinical Trial Endpoints

## Think Beyond Regulatory Approval and Align with Payer Priorities

- ✓ **Clinical relevance:** outcomes are clinically meaningful and patient-centered (eg, survival, hospitalization rates, disease progression, functional status, quality of life)
- ✓ **Comparative value:** endpoints demonstrate how the therapy performs relative to the current standard of care, not just versus placebo
- ✓ **Health system impact:** endpoints connect to economic and utilization outcomes (eg, reduced ER visits, hospitalizations, long-term complications)
- ✓ **Generalizability:** endpoints reflect outcomes in real-world patient populations (not just narrowly defined trial groups) that are diverse
- ✓ **Duration and durability:** endpoints reflect both short-term efficacy and long-term safety and durability
- ✓ **Regulatory vs. payer needs:** endpoints are a balancing act (surrogate endpoints vs. real-world value)



# Evidence Planning Best Practices

## How to Design Trials That Support Coverage and Reimbursement

**Start Early – Before Phase II Protocol Finalization**

**1**

**Align Trial Objectives with the Value Narrative**

**2**

**Choose a Representative Patient Population**

**3**

**4**

**Use Real World Standard of Care Comparators (When Appropriate)**

**5**

**Meaningful, Hard Endpoints That Translate to Value**

**6**

**Align Cross-functionally to Reduce Downstream Risk**



# Case Study: FDA Approval for Aducanumab



## Regulatory Approval

- Aducanumab (Aduhelm) FDA approved for Alzheimer's Disease in 2021
- Key Trial Characteristics:
  - Key Endpoint: Reduction in beta amyloid plaques
  - Limited effect on cognitive improvement
  - Mixed Efficacy Results
  - Narrow Trial Population: Early Alzheimer's



## Payer Response

- **CMS National Coverage Determination (NCD)**
  - CMS limited coverage to patients enrolled in clinical trials (Coverage with Evidence Development)
  - Effectively restricted broad Medicare access
- **Commercial Payer Response**
  - Many plans delayed or restricted coverage
  - Extensive prior authorization requirements
  - Coverage aligned closely with CMS decision

# Case Study: How Trial Design Can Create Access Risk

## Surrogate Endpoints

- Payers questioned whether amyloid reduction translated meaningful clinical benefit
- Lack of hard outcomes

## Conflicting Trial Results

- Inconsistency across studies reduced payer confidence

## Economic Concerns

- High annual price, with large potential population
- Potential for massive budget impact

## Limited Evidence on Real World Impact

- Narrow trial population with limited long-term durability data
- Regular MRIs for safety monitoring added cost and operational complexity



# Key Takeaways

## Plan Evidence Generation with Payers in Mind and Engage with Payers Early and Iteratively



**Trial designs must balance regulatory and reimbursement relevance**

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**Early evidence planning reduces access risk**

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**Trial design decisions shape reimbursement outcomes**

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## Navigating Market Access with Magnolia

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# AI in Market Access: Real-life Applications of Identifying Influential Market Access Stakeholders

Thursday, March 26, 2026

12:00 - 1:00 PM Eastern

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