



Navigating Market Access with Magnolia

From Evidence to Access:
Understanding Payer Decisions and
Evolving Engagement Strategies

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a medical knowledge group company

Navigating Market Access with Magnolia

Today's Moderators and Speakers



Amanda Forys
Managing Partner,
Magnolia Market Access



Becky Roman
Vice President,
Value & Access Solutions



Maren Fustgaard
Vice President,
Value & Access Solutions

Agenda

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How Payers Make Access Decisions

2

What Influences Payer Decisions

3

Evolving Payer Engagement

4

Questions

What We'll Cover Today

1

How Payers Make Access Decisions

What goes into payer coverage and access decisions

We'll cover

- Where payer decisions fit in the product journey
- How plans make coverage decisions
- Differences by sector, benefit, and product type, including devices

2

What Influences Payer Decisions

The evidence, stakeholder perspectives, and other inputs that influence those decisions

We'll cover

- Internal priorities and external pressures
- How unmet need shifts cost vs. efficacy
- How pharma shares information vs. what payers need
- Key evidence areas, whether vs. how to cover, and what makes information influential

3

Evolving Payer Engagement

How manufacturers can rethink payer engagement to deliver relevant information to the right decision-makers

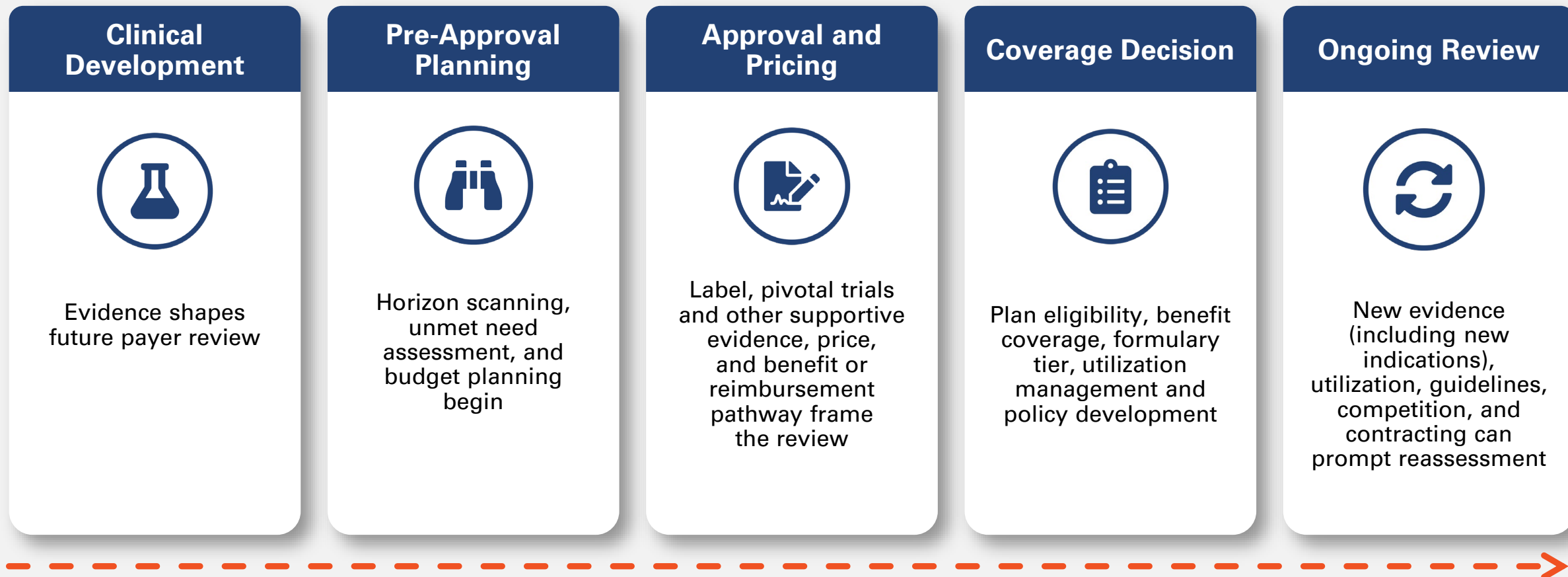
We'll cover

- How payers prefer to engage
- When to engage around evidence milestones
- Who payers listen to
- Next steps for manufacturers

Payer Coverage and Access Decisions

A combination of clinical evidence, affordability, and operational considerations

Where Payer Decisions Fit in the Product Journey



Access Results From a Series of Connected Decisions

Clinical Review



- P&T or technology assessment committee
- Assess evidence quality, benefits, risks, and uncertainty
- Identify appropriate patients and place in therapy (coverage policy)
- Compare the product with relevant alternatives

Business Determination



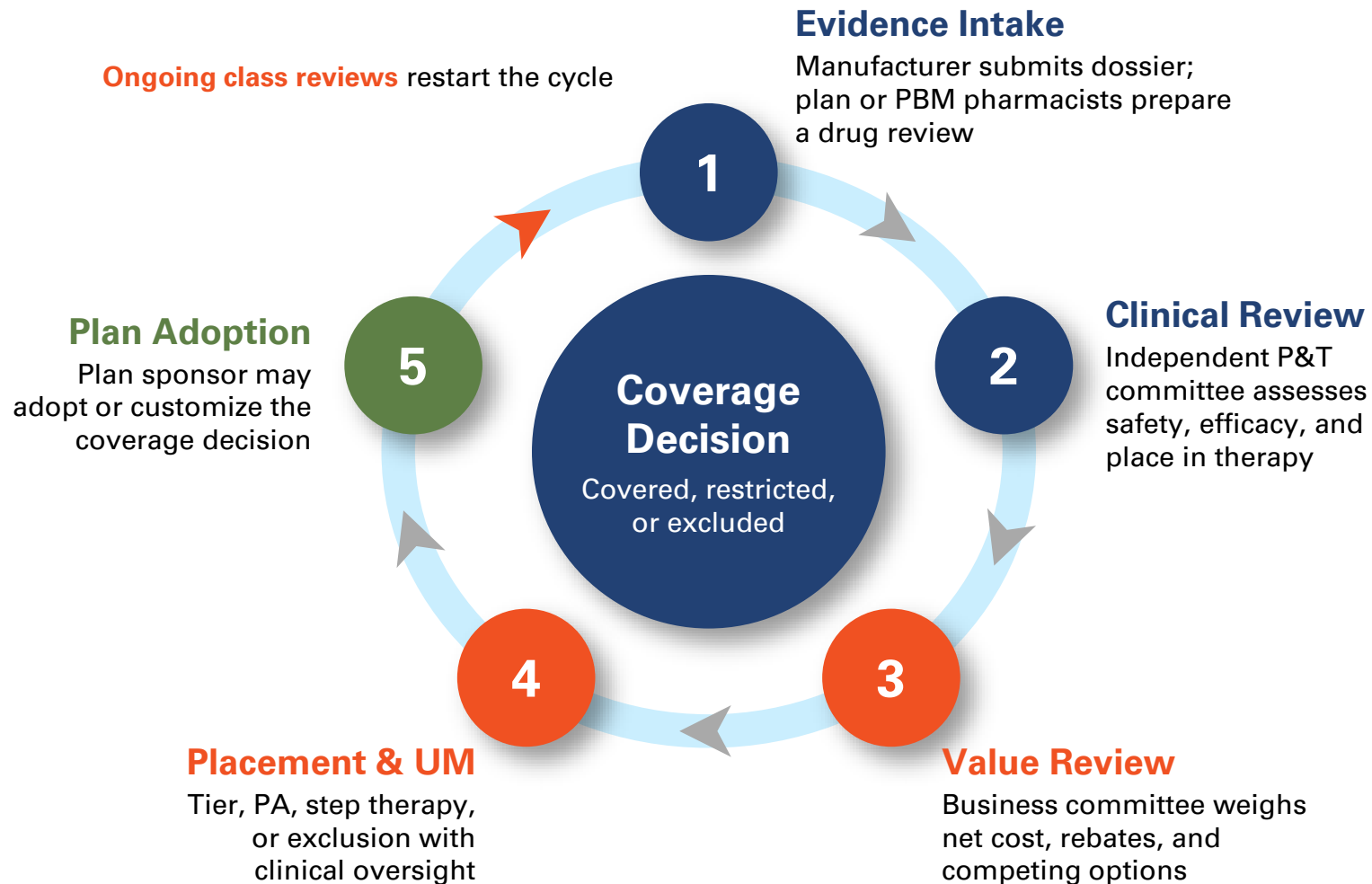
- Define benefit placement and coverage status
- Set formulary tier or medical policy position
- Establish prior authorization, step therapy, or other management

Implementation



- Coding and reimbursement requirements
- Site-of-care and provider requirements
- Claims and operational rules
- Contracting terms

How Plans Make Coverage Decisions



Who Owns Each Step

- **Clinical:** independent clinicians and/or payer employed clinicians
- **Business:** PBM or health plan staff
- **Sponsor:** plan or employer choice

What to Plan Around

Variable, but ~90-180 days from launch to a coverage decision

Ongoing class reviews can move products after launch

Clinical first: economics are weighed only after clinical review

P&T, pharmacy and therapeutics; PA, prior authorization; PBM, pharmacy benefit manager; UM, utilization management. Sources: AMCP Format for Formulary Submissions; AMCP, JMCP 2024 formulary primer; CVS Caremark Formulary Development and Management (2026); FTC PBM Interim Staff Report (2024); House Committee on Oversight PBM report (2024). Committee names and timing vary by plan and PBM.

How Coverage Decisions Differ by Line of Business

	Commercial	Medicare	Medicaid
Who Decides	<ul style="list-style-type: none"> Health plans and PBMs; employers pick the formulary P&T for clinical review, business committees for placement 	<ul style="list-style-type: none"> Part D: plan sponsors and PBMs, with CMS formulary review Part B: national and local coverage policy 	<ul style="list-style-type: none"> State agency with a P&T or DUR board; MCOs follow state rules
Coverage Rules	<ul style="list-style-type: none"> Few federal mandates EHB plans: at least one drug per USP class or equal to benchmark plan 	<ul style="list-style-type: none"> Part D: two drugs per class; all or most in six protected classes Part B: no formulary; paid at ASP+6% 	<ul style="list-style-type: none"> Must cover nearly all drugs from rebate-program manufacturers
Key Levers	<ul style="list-style-type: none"> Rebates, tiers, exclusions, PA, and step therapy 	<ul style="list-style-type: none"> Part D rebates, tiers, and UM IRA price negotiation and out-of-pocket cap 	<ul style="list-style-type: none"> Preferred drug lists, PA, quantity limits State supplemental rebates, often multistate pools
What It Means	Win plan by plan on net price and differentiation	Part D access is negotiated; Part B access hinges on coverage policy and provider economics	Coverage is near-guaranteed; preferred status is earned through supplemental rebates

ASP, average sales price; DUR, drug utilization review; EHB, essential health benefits; IRA, Inflation Reduction Act; MCO, managed care organization; PA, prior authorization; UM, utilization management; USP, US Pharmacopeia. Sources: 45 CFR 156.122; GAO-23-105270; MedPAC Part B Payment Basics (2024); CMS Part B Drugs and Biologicals; MACPAC Prescription Drugs; HHS Medicaid drug pricing summary.

How Payer Decisions Differ by Product Type

	Rare Disease	Small Molecule	Specialty Pharmacy
	50% of FDA drug approvals in 2025 had orphan drug designation	89% of prescriptions are generics, yet only 12% of drug spend	~50% of drug spend comes from 1 to 2% of claims
Process	<ul style="list-style-type: none"> Often individual drug reviews Criteria confirm diagnosis and severity; reauthorization tied to outcomes 	<ul style="list-style-type: none"> Therapy class-based review approach Tiering, step through generics, national exclusion lists 	<ul style="list-style-type: none"> Split across medical and pharmacy benefits PA standard; specialty pharmacy network and site-of-care rules
Influences	<ul style="list-style-type: none"> Specialists, centers of excellence, guidelines Budget impact: costlier, more prevalent drugs restricted more 	<ul style="list-style-type: none"> Net cost and rebates vs. interchangeable options Generic availability sets the bar 	<ul style="list-style-type: none"> Budget impact and crowded-class competition PBM-affiliated pharmacies and private labels steer use
Engagement	<ul style="list-style-type: none"> Educate early on disease and unmet need Offer outcomes-based agreements backed by RWE and registries 	<ul style="list-style-type: none"> PBM contracting drives tier position Prove differentiation vs. generic standard of care 	<ul style="list-style-type: none"> Engage medical and pharmacy decision makers Align specialty pharmacy, hub, and value-based contracting

P&T, pharmacy and therapeutics; PA, prior authorization; PBM, pharmacy benefit manager; RWE, real-world evidence. Sources: US FDA New Drug Therapy Approvals 2025; AMCP Rare Disease Partnership Forum 2020; Cencora, AMCP 2025 rare disease VBC research; Drug Channels, Big Three PBM 2026 formulary exclusions; AAM 2026 Generic & Biosimilar Savings Report; Becker's Payer Issues (via Forbes); Tichy et al. *Am J Health-Syst Pharm.* 2026;83:728-744.

Decision Pathways Vary by Benefit Type

Each pathway involves different decision-makers, evidence requirements, and implementation processes

Pharmacy-Benefit Drugs

PBM and plan P&T committee review; formulary coverage vs. exclusion; tier; utilization management edits

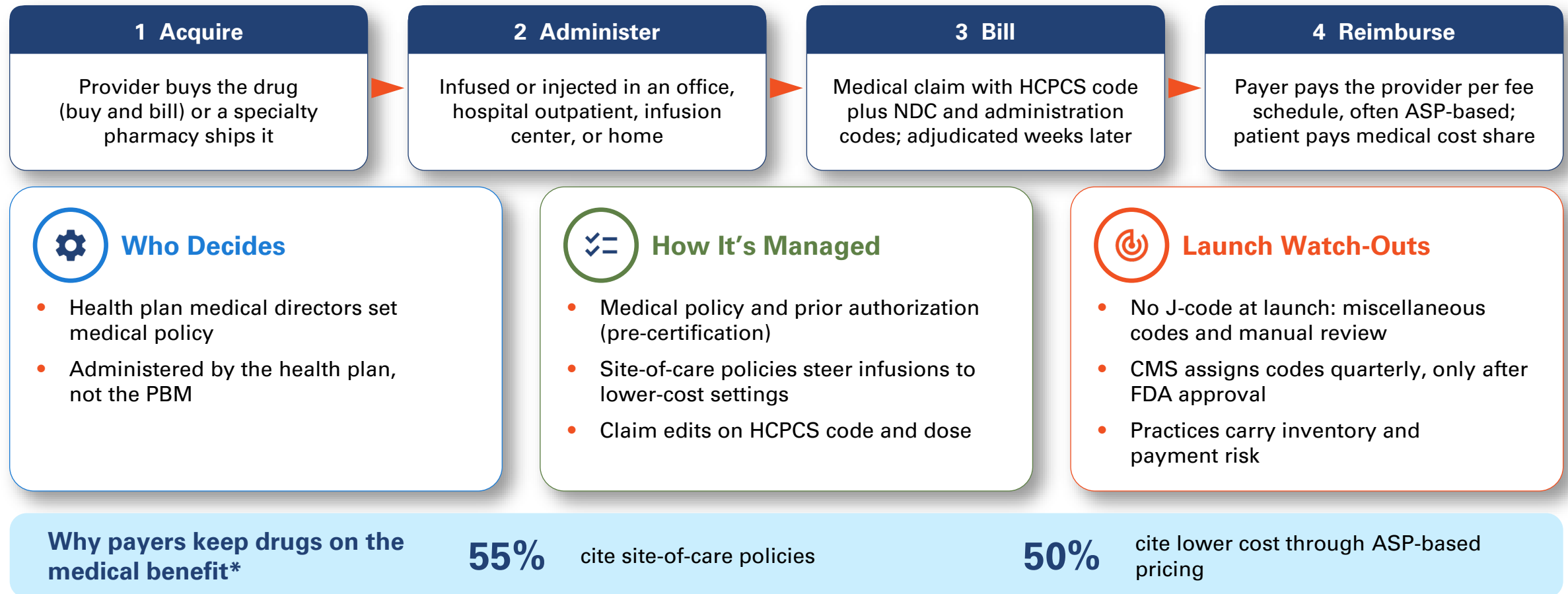
Medical-Benefit Drugs

Medical policy and clinical review; claims coding, site of care management, and drug sourcing restrictions shape access

Medical Devices

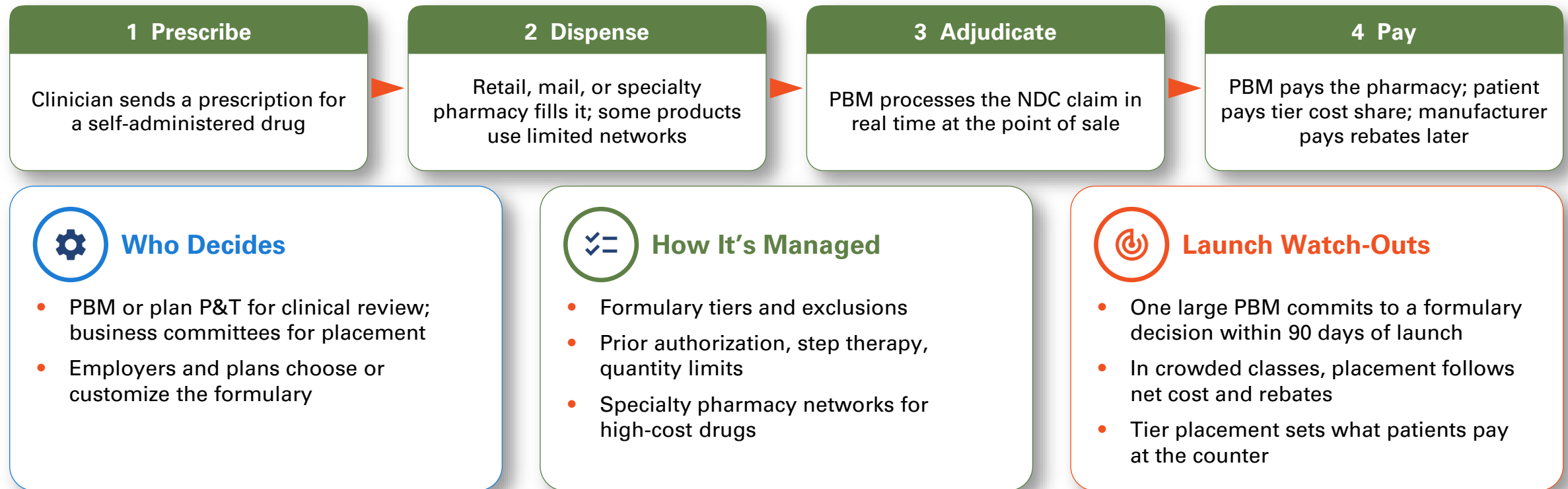
Technology assessment and medical policy review; coverage often hinges on coding, procedure payment, and provider adoption

Medical Benefit: How Coverage Works



ASP, average sales price; HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code; P&T, pharmacy and therapeutics. *Payers covering HCP-administered orphan drugs (JMCP 2023 survey of payers, providers, and employers). Sources: UK College of Pharmacy CAPP, Medical vs Pharmacy Benefits (2026); Mass General Brigham Health Plan; CMS HCPCS Level II Drug and Biological Coding Manual; MedPAC Part B Payment Basics.

Pharmacy Benefit: How Coverage Works



Why payers move drugs to the pharmacy benefit*

71%

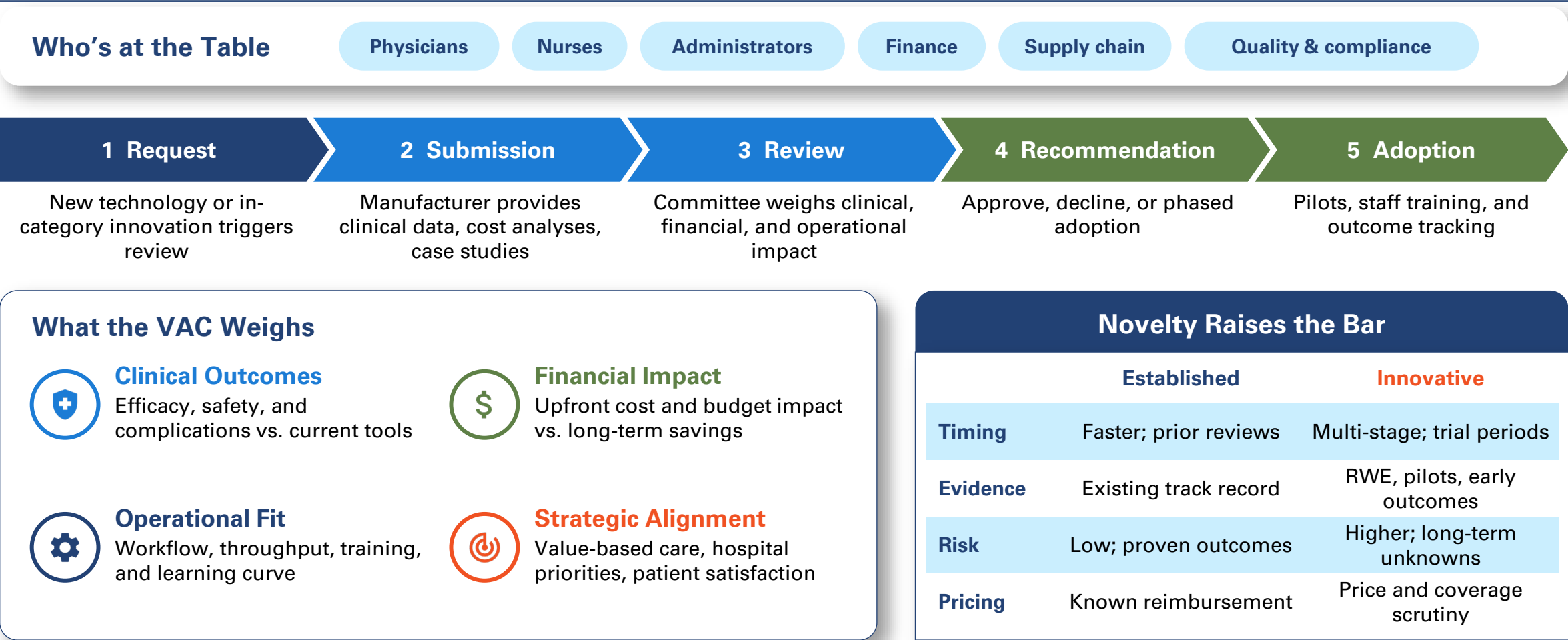
cite better ability to manage the product

62%

cite access to rebates

NDC, National Drug Code; P&T, pharmacy and therapeutics; PBM, pharmacy benefit manager. *Payers covering HCP-administered orphan drugs (JMCP 2023 survey of payers, providers, and employers). Sources: UK College of Pharmacy CAPP, Medical vs Pharmacy Benefits (2026); CVS Caremark Formulary Development and Management (2026); GAO-23-105270; AMCP formulary primer (JMCP 2024).

How the VAC Makes Decisions

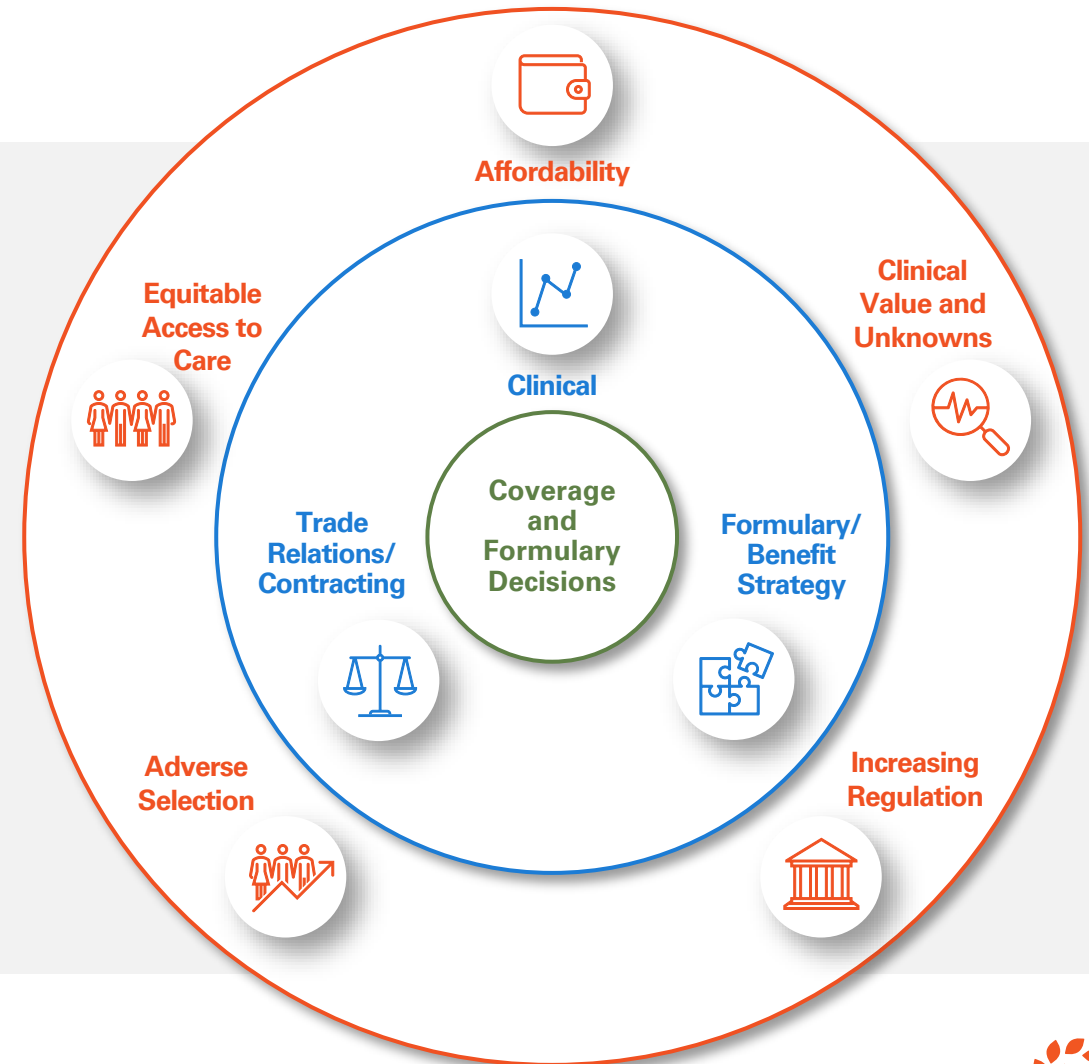


Factors Influencing Payer Decisions

Clinical evidence informs whether coverage is granted;
other considerations shape the terms of access

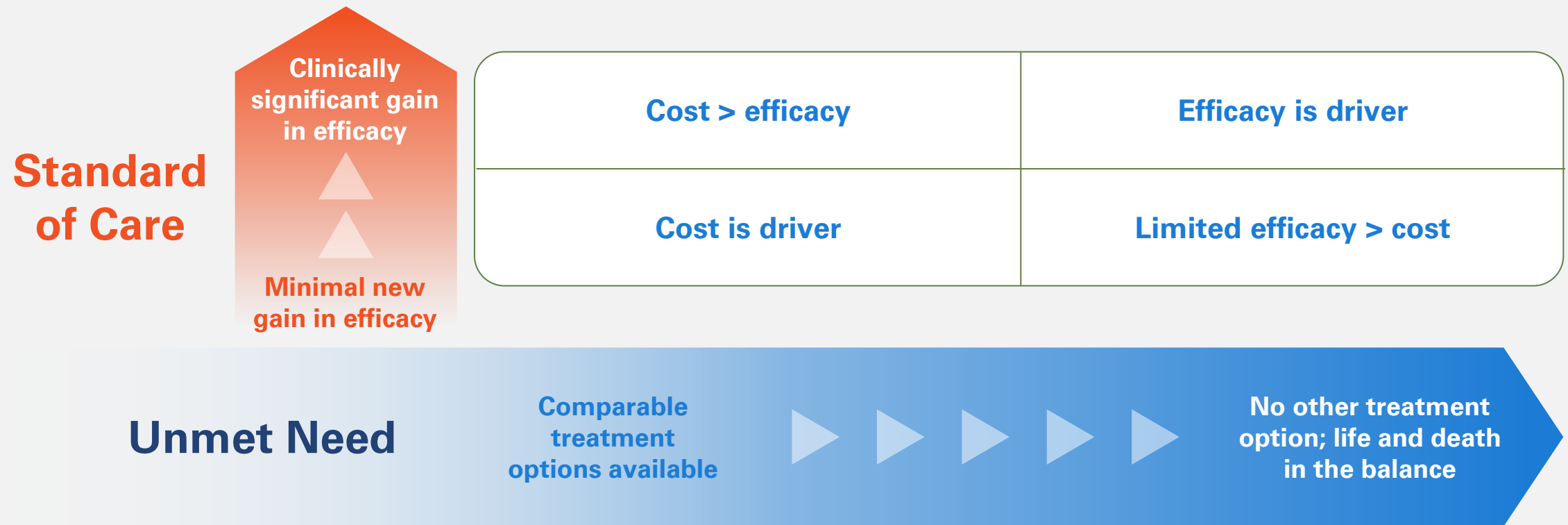
Internal Priorities and External Pressures Behind Payer Decisions

Every coverage decision weighs clinical value against the realities of running a health plan, from budget pressure and regulation to who the plan's members are



How Unmet Need Shifts the Cost vs. Efficacy Balance

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



How Pharma Shares vs. What Payers Want

	Pharma Tends To Lead With		Payers Want
Evidence	Pivotal trial endpoints built for FDA approval	▶	Comparative and real-world outcomes
Source	Manufacturer-generated materials	▶	Independent, peer-reviewed sources
Format	Long dossiers and rep-led detailing	▶	Concise, interactive, self-serve digital content
Timing	Near or after launch	▶	Pre-approval, ideally 3–12 months before PDUFA
Value Story	Clinical benefit to justify price	▶	Differentiation, budget impact, cost offsets

What Payers Value Most

83%

use published guidelines to evaluate products

4.1/5

credibility of peer-reviewed trials, the highest of any source

86%

want more real-world evidence in the AMCP dossier

40%

rank effective differentiation as the top partner trait

AMCP, Academy of Managed Care Pharmacy; PDUFA, Prescription Drug User Fee Act. Sources: Sermo U.S. Payer Sentiment Report, Nov 2022 (n=30 pharmacy/medical directors); Cencora/Xcenda AMCP Nexus 2023 poster (n=25 healthcare decision makers).

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Six Areas of Evidence That Shape Payer Decisions

PARAMETER	KEY CONSIDERATIONS
 Clinical Efficacy	<ul style="list-style-type: none"> • Meaningful outcomes • Clinically significant results
 Safety and Tolerability	<ul style="list-style-type: none"> • Frequency, severity, and clinical significance of adverse events • Boxed warnings, warnings and precautions, and contraindications • REMS requirements and/or other specific clinical monitoring
 Comparative Differentiation	<ul style="list-style-type: none"> • Advantages or drawbacks compared with therapeutic alternatives • Availability of direct comparative evidence • Unmet needs addressed • Differences in safety that could impact clinical care
 Patient Population/ Appropriate Use	<ul style="list-style-type: none"> • Optimal patients to receive treatment and ease of identification • Placement in established treatment pathways
 Economic Impact	<ul style="list-style-type: none"> • Product net cost • Eligible population and budget impact • Offsets in medical costs/other drug therapies; impact to total cost of care
 Real-World and Patient Impact	<ul style="list-style-type: none"> • Impact on adherence, persistence, quality of life, or the patient experience • Real-world performance compared to clinical trials

REMS = Risk Evaluation and Mitigation Strategy.

Whether vs. How: Two Layers of Payer Review

Whether It Should Be Covered



- FDA approval; guidelines or compendia support
- Quality and maturity of the clinical evidence
- Comparative evidence vs. available alternatives
- Unmet need and place in therapy

How It Will Be Covered



- Patients most likely to benefit
- Treatment history and sequencing
- Budget impact and total cost of care
- Coding, reimbursement, and site of care
- Implementation burden
- Payer-manufacturer agreements (formulary placement and utilization management)

What Makes Information Influential to Payers



Credible

- Peer-reviewed, transparent methods
- Recognized guidelines and HTAs



Comparative

- Head-to-head or indirect comparisons
- Clear differentiation vs. standard of care



Relevant to Their Population

- Reflects the payer's own members
- RWE in comparable populations



Connected to a Decision

- Answers a specific coverage question
- Actionable for criteria, tier, or contract

From Information to Payer Action

Make evidence easier to find, assess, and use at the point of decision

Easier to Access

On-demand resources
available when reviews
actually happen

Easier to Evaluate

Interactive tools payers can
tailor to their own population

Easier to Apply

Content mapped to the
specific decision and
stakeholder role

Evolving Payer Engagement

The right information, to the right stakeholder, at the right decision point

One Value Story Will Not Meet Every Payer Need



Clinical

Comparative efficacy and safety, place in therapy, and appropriate patient population



Economic

Budget impact and total cost of care over a relevant time horizon



Contracting

Net cost, competitive position, and terms that support preferred access



Operational

Coding, site of care, utilization management criteria, and implementation requirements

Engagement That Evolves With the Product

Before Launch



- Build awareness of pipeline and budget impact
- Discuss unmet need and early evidence
- Map decision timing and stakeholders

At Launch



- Role-specific value materials
- Support formulary and policy reviews
- Clarify coding and implementation

After Launch



- Share new data and real-world evidence
- Respond to guideline and market shifts
- Learn from payer experience

How Payers Prefer to Engage With Industry

The Face-Time Gap

Share of industry interactions payers want in person

Today  23%

Ideal  38%

HCPs*  41%

+15 pts more in-person time wanted than payers get today

Yet ~62% of ideal interactions would still be virtual or non-personal



Digital Is the Default Workspace

- Over 3x the 0.7 hrs/day spent on non-digital resources
- All respondents now work hybrid or remote (vs. 56% mostly in-person before COVID-19)

2.3 hrs

per day on digital resources



Self-Serve Sources Come First

- Package inserts lead for formulary review prep
- Manufacturer websites and drug reference sources close behind (80% each)

90%

use package inserts to access product information



Match the Channel to the Message

- In person for new products, results, and indications
- Concise email for updates; scheduled video over phone

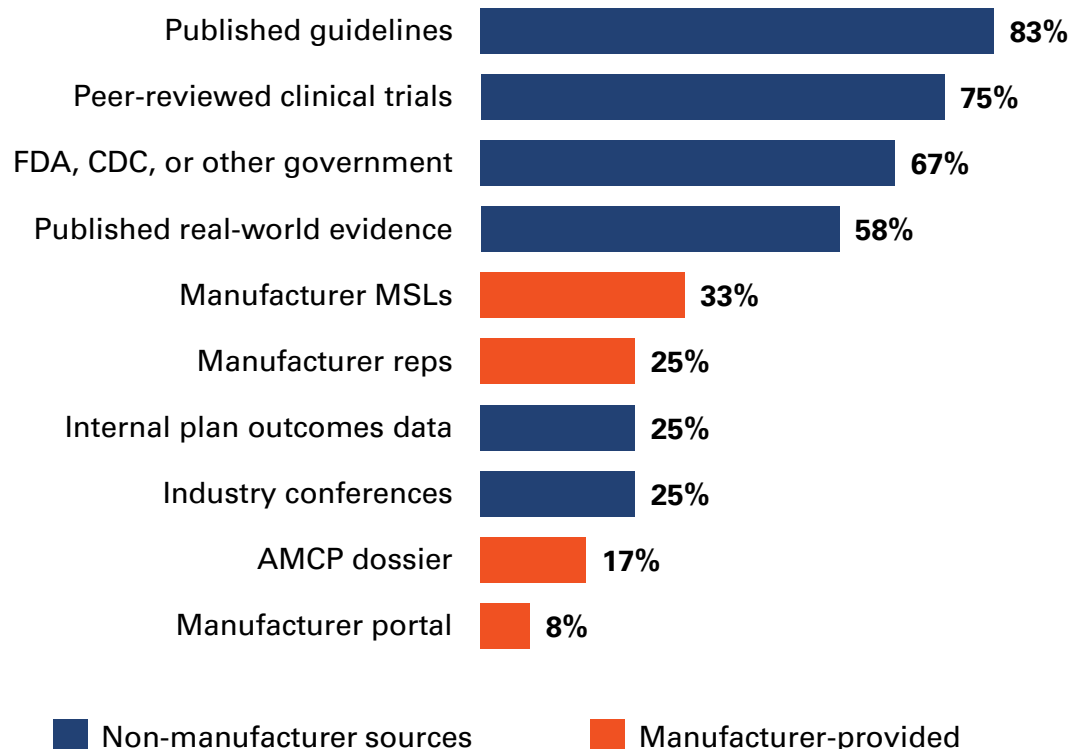
≤30 min

ideal in-person meeting length, per payers

HCDM, healthcare decision maker; HCP, healthcare professional. *IQVIA ChannelDynamics 2023: preferred share of 1:1 face-to-face interactions among >20,000 HCPs (US and EU5 aggregate); shown as a benchmark, not payer data. Sources: Sermo U.S. Payer Sentiment Report, Nov 2022 (n=30 pharmacy/medical directors); Cencora/Xcenda AMCP Nexus 2023 poster (n=25 HCDMs).

What Payers Want From Evidence Sharing

Where Payers Turn for Information



86%

want more RWE in the dossier

Modernize the Dossier

- Clinical evidence is the most-reviewed section (72%)
- Also want interactive design (67%) and shorter length (57%)

3–12

months before PDUFA: main review window (56%)

Engage Before Approval

- High cost, rare disease, and first-in-class prompt earlier review
- Another 24% review in the final 3 months

40%

rank differentiation as the #1 partner trait

Lead With Differentiation

- Top-ranked attribute of an ideal manufacturer partner
- Bring good data proactively—don't wait to be asked

AMCP, Academy of Managed Care Pharmacy; CDC, Centers for Disease Control and Prevention; MSL, medical science liaison; PDUFA, Prescription Drug User Fee Act; RWE, real-world evidence. Chart: % of payers selecting each source (select all). Sources: Sermo U.S. Payer Sentiment Report, Nov 2022 (n=30); Cencora/Xcenda AMCP Nexus 2023 poster (n=25 HCDMs).

When to Engage Payers: Aligning to Evidence Milestones

Longitudinal Payer Advisory Council: ongoing, before and after readouts

Rapid Post-Readout Activation

Targeted Payer Evidence Exchange

Before data readout

Priority data readout

After readout and launch

Longitudinal Payer Advisory Council

- Same payer decision-makers before and after key readouts
- Tests how evidence is read and what blocks adoption
- Refines engagement as evidence matures

Why it works: an ongoing relationship, not a one-time advisory board

Rapid Post-Readout Activation

- Ready-to-go package for each major data release
- Evidence summary, FAQs, live briefing, account prompts
- Follow-ups capture reactions and open questions

Why it works: moves from congress to payer while the data is new

Targeted Payer Evidence Exchange

- Small, invitation-only sessions after priority readouts
- Safety, eligible populations, comparative context, UM
- Findings shape the next round of engagement

Why it works: an independent payer moderator and HEOR experts, not a promotional format

Who Payers Listen To and How to Engage Them

Map who shapes decisions

Let peers lead the conversation

Solve shared problems together



Payer Influence Mapping

- Map priority accounts, influential medical and pharmacy leaders, and trusted evidence sources
- Include guideline and pathway contributors and conference faculty
- Flag accounts open to new forms of collaboration

Why it works: shows who to reach, where, and on which topics



Payer-to-Payer Perspective Program

- Current or former payer leaders discuss category decision challenges
- Panels, roundtables, podcasts, or recorded content
- Topics like safety differentiation, comparative evidence, and access vs. UM

Why it works: a credible forum that never asks participants to advocate for a product

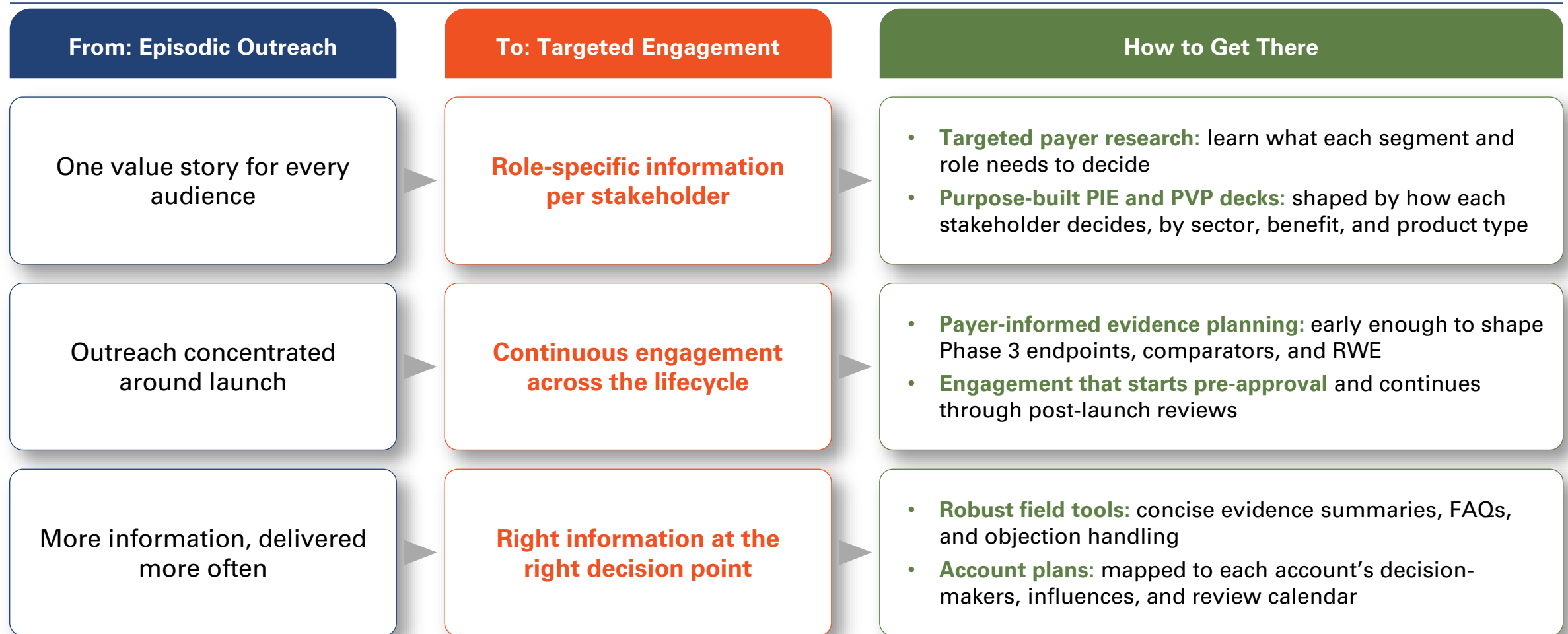


Payer Innovation Roundtables

- Working sessions on shared challenges: adverse events, persistence, population identification
- Surface partnership, data, and pilot opportunities
- Strengthen relationships with payer leaders over time

Why it works: builds relationships around problems payers already own

Key Takeaways: Putting It Into Action



PIE, pre-approval information exchange; PVP, payer value proposition; RWE, real-world evidence.

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Pets of Magnolia Market Access

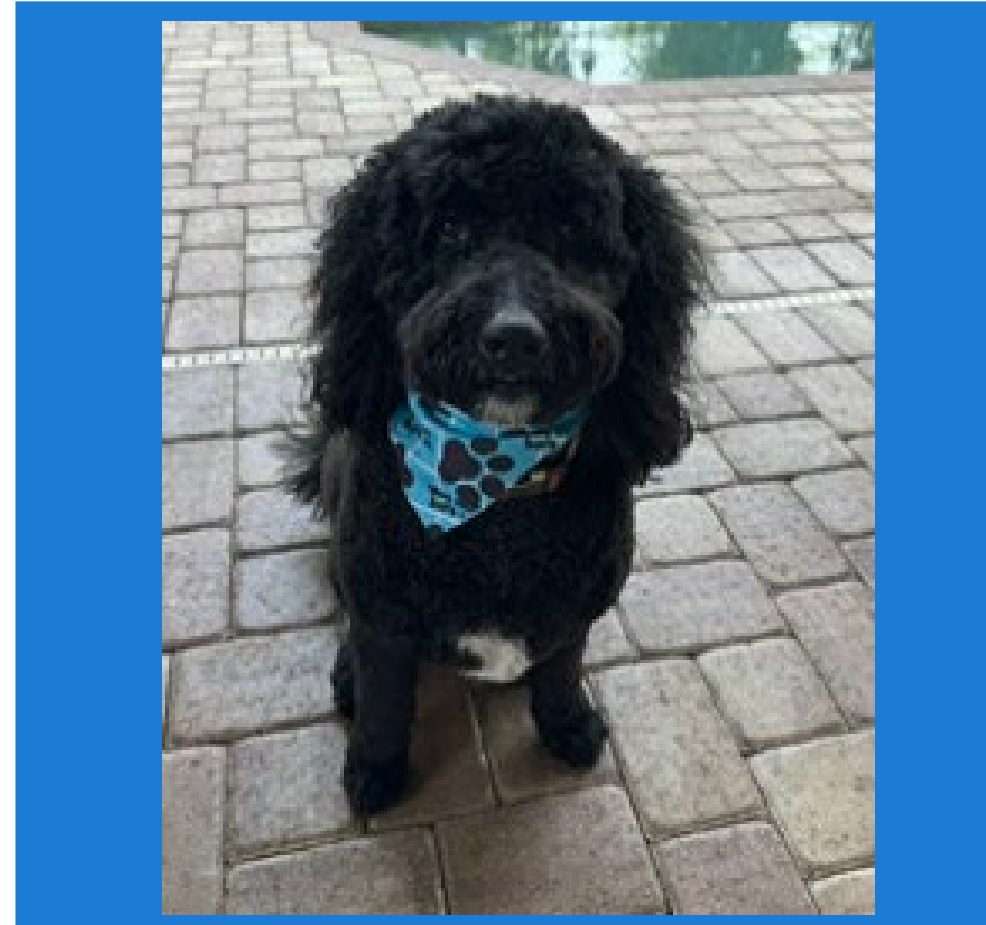
Calvin and Abuelita

- **Legal Guardian:** Maren Fustgaard
- **Age:** Calvin 14/Abuelita ??? (old enough to get away with anything)
- **Relationship Status:** Newlyweds
- **Disposition:** Calvin - Sweetest boy on earth/Abuelita - Grumpy old lady (and full of herself...she was the rescue Dog of the month on a recent MN Wild calendar)
- **Likes:**
 - Calvin – getting into the most toxic things imaginable
 - Abuelita – barking angrily (and toothlessly) at cats
- **Dislikes:**
 - Calvin – nail trims (aka torture sessions)
 - Abuelita – my 21-year-old daughter for absolutely no good reason (or perhaps because she's the owner of the cats??)



Maverick

- **Parent:** Becky Roman
- **Age:** 3 years
- **Title:** Chief Security Officer
- **Disposition:** Loyal guardian
- **Likes:**
 - Going for walks
 - Eating (especially his sister's food)
 - Counter surfing
 - Keeping a close watch for threats
- **Dislikes:**
 - Amazon
 - FedEx
 - UPS
 - Meetings that could have been an email



Maya (aka Goose)

- **Parent:** Becky Roman
- **Age:** 4 years
- **Title:** Chief Mischief Officer
- **Disposition:** Silly, playful, and happiest when she's muddy
- **Likes:**
 - Chewing bones
 - Napping in her favorite chair
 - Lounging belly-up
 - Rolling in grass or dirt
- **Dislikes:**
 - Sharing a water bowl with her brother
 - Baths
 - Dog food
 - Back-to-back meetings with no snack break



Questions

