



PARTNERSHIP FORUM

No.1 = 2022

High-Investment Medications

APRIL 26-27, 2022 | RENAISSANCE ARLINGTON CAPITAL VIEW HOTEL



Moderator Welcome



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AMCP Partnership Forums

Collaboration for Optimization



AMCP Partnership Forums bring key decision makers in managed care, integrated care, the pharmaceutical industry, and others together to discuss and collaborate on tactics and strategies to drive efficiencies and outcomes in integrated care and managed care.

Partnership Forums

- Provide a voice for stakeholders
- Find common ground and gain consensus
- Identify actionable results
- Amplify to raise visibility



Goals of this Partnership Forum

- Identify stakeholder challenges associated with high-investment medications
- Explore opportunities and financial tools to address those challenges
- Discuss potential policy solutions to improve the predictability, affordability, and accessibility of high-investment treatments



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Agenda

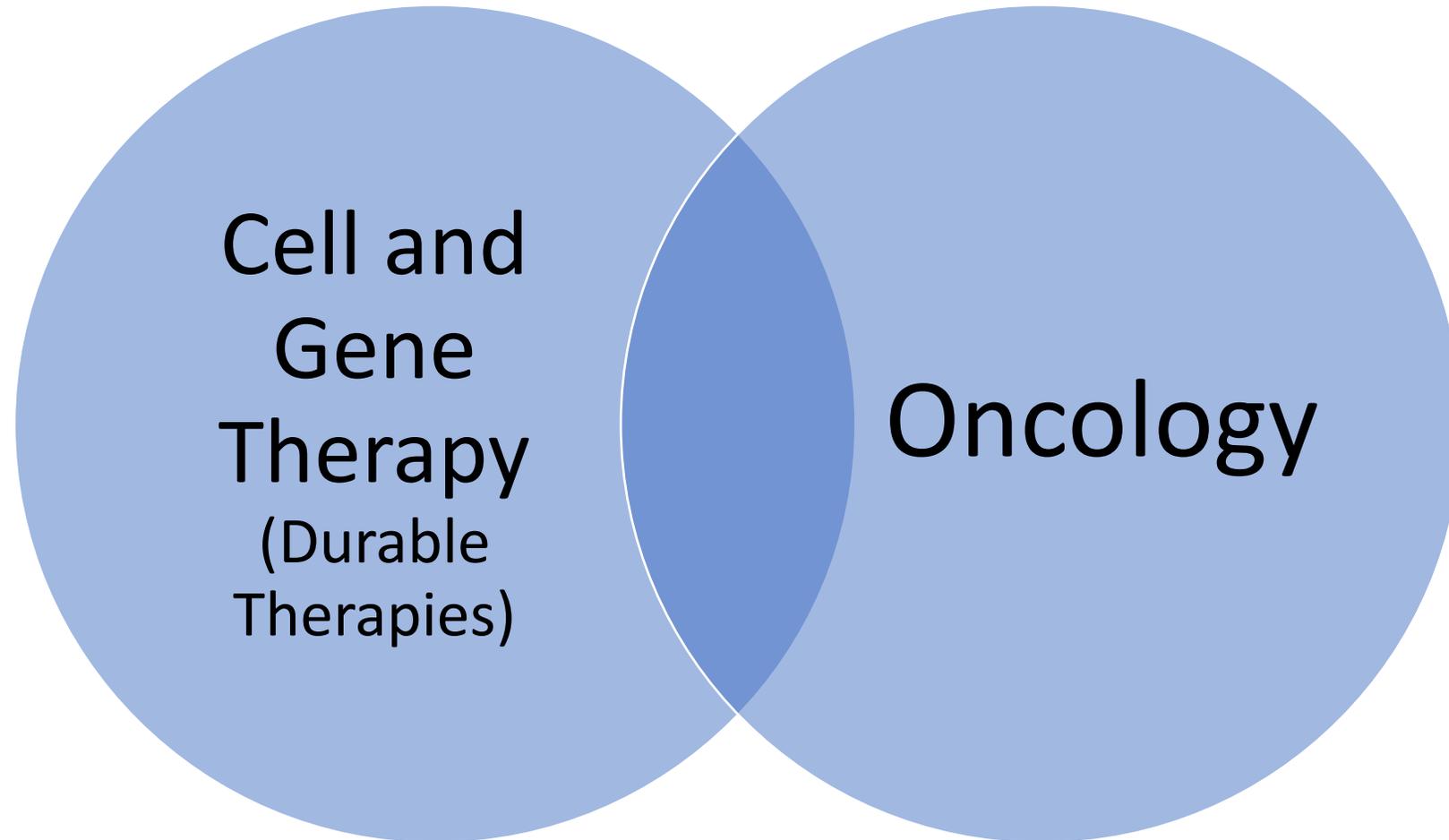
- Key Background
- Forum findings
 - Stakeholder Challenges
 - Existing and Emerging Financial Tools
 - Q&A
- What's next?



Key Background



High-Investment Medications Encompass Many New Drugs



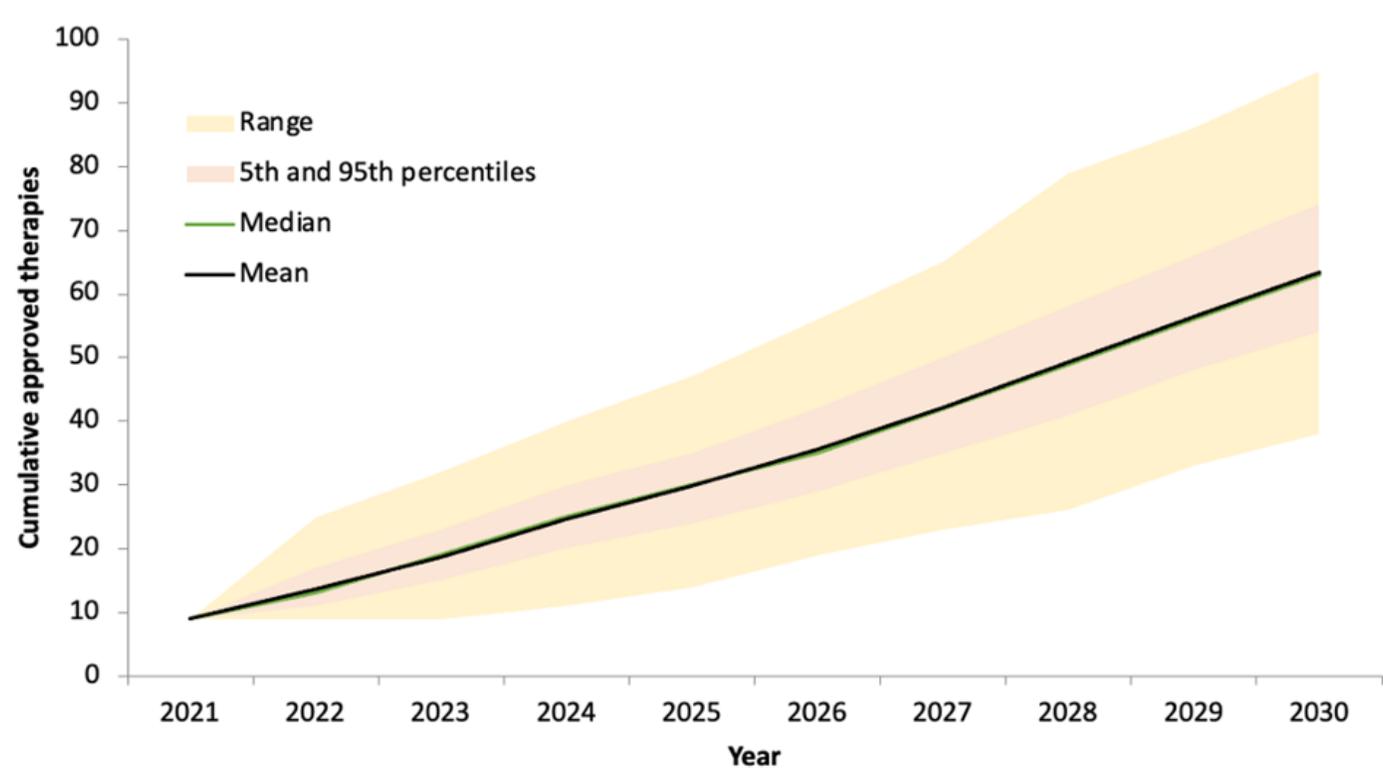


Gene and Cell Therapies

- Hemophilia A & B
- Duchenne muscular dystrophy
- Sickle cell disease
- Beta thalassemia
- Choroideremia
- Mucopolysaccharidosis type IIIA
- Leber's hereditary optic neuropathy
- Severe combined immunodeficiency
- Wiskott Aldrich syndrome
- Von Gierke disease
- Wilson's disease
- Retinitis pigmentosa
- Metachromatic leukodystrophy
- Urea cycle disorders
- Bladder cancer
- Angina pectoris
- Osteoarthritis
- Macular degeneration
- Diabetic foot ulcers
- Aromatic l-amino acid decarboxylase deficiency
- Ichthyosis
- GM1 gangliosidosis
- GM2 gangliosidosis (Tay-Sachs & Sandhoff disease)
- Achromatopsia
- Congenital adrenal hyperplasia
- Huntington's disease
- Canavan disease
- Primary immunodeficiency
- Fanconi anemia
- Mucopolysaccharidosis I
- Mucopolysaccharidosis II
- Fabry disease
- Gaucher disease
- Cystinosis
- Phenylketonuria
- Pompe disease
- Parkinson's disease
- Melanoma
- HIV-1 infection
- Overactive bladder
- Spinal muscular atrophy
- B-Cell lymphoma
- Mantle cell lymphoma
- Non-small cell lung cancer

Avalanche of Indication Approvals Expected

- 54-74 projected US cumulative product-indication approvals by end of 2030





Most Expensive Drugs in the US

Elivaldogene autotemcel	\$3,000,000	Tebentafusp-tebn	\$975,520
Betibeglogene autotemcel	\$2,700,000	Metreleptin	\$929,951
Onasemnogene abeparvove	\$2,125,000	Voretigene neparvovec-rzyl	\$850,000
Lonafarnib	\$1,073,760	Pralatrexate	\$842,585
Naxitamab-gqgk	\$1,011,882	Cerliponase alfa	\$755,898



Significant Affordability and Access Concerns Anticipated

- **Medicaid/Children's Health Insurance Program Budget Impact Expected ~\$1-4B**
 - Ultra-orphan pediatric conditions
 - Genetic disorders
- **Medicare Anticipated Budget Impact \$9-16B**
 - Oncology Medications
 - Musculoskeletal
 - Ophthalmological (wet AMD)

Key Challenges

Predictability

- Treatment benefits
- Costs

Accessibility

- Patient Utilization
- Equity considerations/
Centers of Excellence

Affordability

- High up-front costs
- Sustainability

Audience Polling: Which of the following is of greatest concern to your organization?

1. Predictability (Treatment benefits)
2. Predictability (Costs)
3. Affordability (High-up front costs)
4. Affordability (Timing of treatment benefits vs. costs)
5. Accessibility (Patient Access)

Stakeholder Prioritize Predictability, Affordability, and Accessibility in Different Ways



Stakeholders Prioritize Challenges Differently

		Predictability	Affordability	Accessibility
	Patients	High	Medium	Medium
	Employers and Unions	Medium	Medium	High
	Health Systems	High	High	Medium
	Medicaid	Medium	Medium	High
	Medicare	Medium	High	High
	Regional commercial plans	Medium	Medium	High
	National commercial plans	Low	High	Low
	Pharmacy benefit managers	High	Low	High

Legend: Low Medium High Priority

**No Single Financial Tool
Will Meet All Stakeholder
Needs**





Multiple Tools Were Considered

Risk management approaches	Stop-loss/ Reinsurance	Orphan Reinsurer Benefit Manager	Risk-carve out
Performance-based	Outcomes-based Contracts	Warranty	Annuity-based Contract with/without outcomes
Contract negotiations	Contract Negotiation	Provider Contract Negotiation (e.g., Centers of Excellence)	Subscription

No One Model Meets All Purposes; Details Matter



Potential To Impact

Predictability

Affordability

Accessibility

	Predictability	Affordability	Accessibility
Stop-loss	High Potential to Impact	High Potential to Impact	Low Potential to Impact
Orphan reinsurer	High Potential to Impact	Low Potential to Impact	High Potential to Impact
Risk-carve out	High Potential to Impact	Low Potential to Impact	High Potential to Impact
Outcomes-based contracts	Medium Potential to Impact	Low Potential to Impact	Low Potential to Impact
Annuity with outcomes annuity	Low Potential to Impact	Low Potential to Impact	Low Potential to Impact
Annuity	Medium Potential to Impact	Medium Potential to Impact	Low Potential to Impact
Warranty	Medium Potential to Impact	High Potential to Impact	Medium Potential to Impact
Subscription	High Potential to Impact	Low Potential to Impact	High Potential to Impact
Contract negotiation	Medium Potential to Impact	Low Potential to Impact	High Potential to Impact
Provider contract negotiation	Low Potential to Impact	High Potential to Impact	High Potential to Impact

Participant Rating: Low Potential to Impact , Medium Potential to Impact, High Potential to Impact

*Terms/Details Matter

No One Model Meets All Purposes; Details Matter



	Strengths	Challenges
Stop-loss	<ul style="list-style-type: none"> • Known, • Works with random high-costs events (care accidents) 	<ul style="list-style-type: none"> • Recurring events not covered • Diminishes other value-contracting
Orphan reinsurer	<ul style="list-style-type: none"> • Pools risk • Ability to learn about Product value • Reduced administrative Burden 	<ul style="list-style-type: none"> • Adds cost to system • Lose ability to learn
Risk-carve out	<ul style="list-style-type: none"> • Requires carving out full condition • Reduced plan/employer burden • Improved cost predictability 	<ul style="list-style-type: none"> • Potential network challenges • Lose ability to learn
Outcomes-based contracts	<ul style="list-style-type: none"> • Shared risk between manufacturer • Ability to collect real-world evidence 	<ul style="list-style-type: none"> • Administrative burden • Agreement on and ability to collect outcomes • Ability to achieve outcomes may be dependent on care • Patient portability challenges

No One Model Meets All Purposes; Details Matter Cont.



	Strengths	Challenges
Annuity	<ul style="list-style-type: none"> • Improved predictability • Addresses high up-front costs • Works when have good disease understanding 	<ul style="list-style-type: none"> • Not relevant for Medicaid • Patient portability challenges
Warranty	<ul style="list-style-type: none"> • Manages Medicaid Best Price challenges • Potential for patient out-of-pocket relief 	<ul style="list-style-type: none"> • Requires third-party • Would need a treatments with large enough population • Ability to achieve outcomes may be dependent on care
Subscription	<ul style="list-style-type: none"> • Predictable • Potential for a portfolio of products 	<ul style="list-style-type: none"> • No impact on outcomes • Need sufficient understanding of condition
Contract negotiation and data management	<ul style="list-style-type: none"> • Reduced staff time for analysis 	<ul style="list-style-type: none"> • Requires finding the right third-party • Reduced analytic learning
Provider contract negotiation	<ul style="list-style-type: none"> • Provider differentiation • Potential for improved care for rare conditions through 	<ul style="list-style-type: none"> • Breadth of centers of excellence or networks

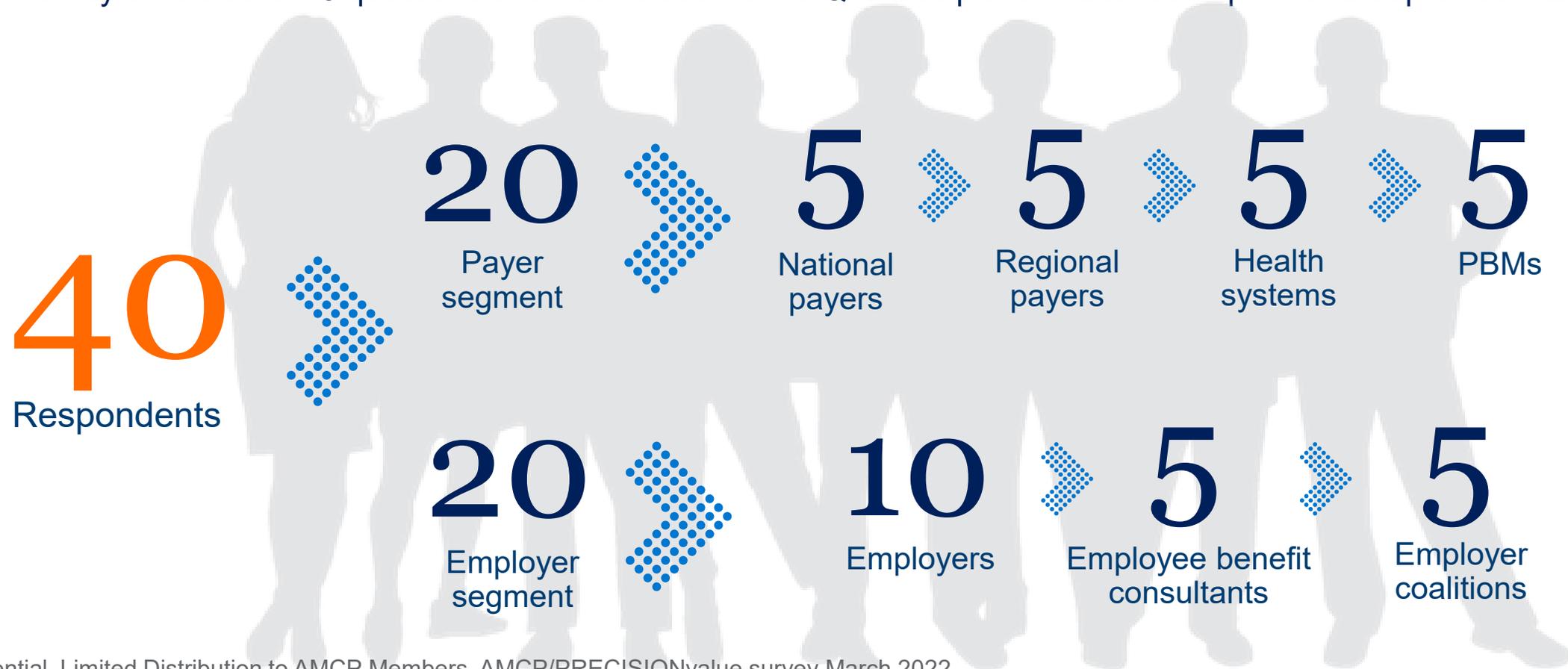
Uptake of New and Innovative Payment Models is Modest But Growing



Methodology and respondent demographics



- PRECISIONvalue recruited 40 respondents from a proprietary network of market access decision-makers
- Respondents had responsibility or influence for decisions related to the financing of high-investment medications. The survey consisted of 15 questions and was fielded via the Qualtrics platform between April 1 and September 12, 2022

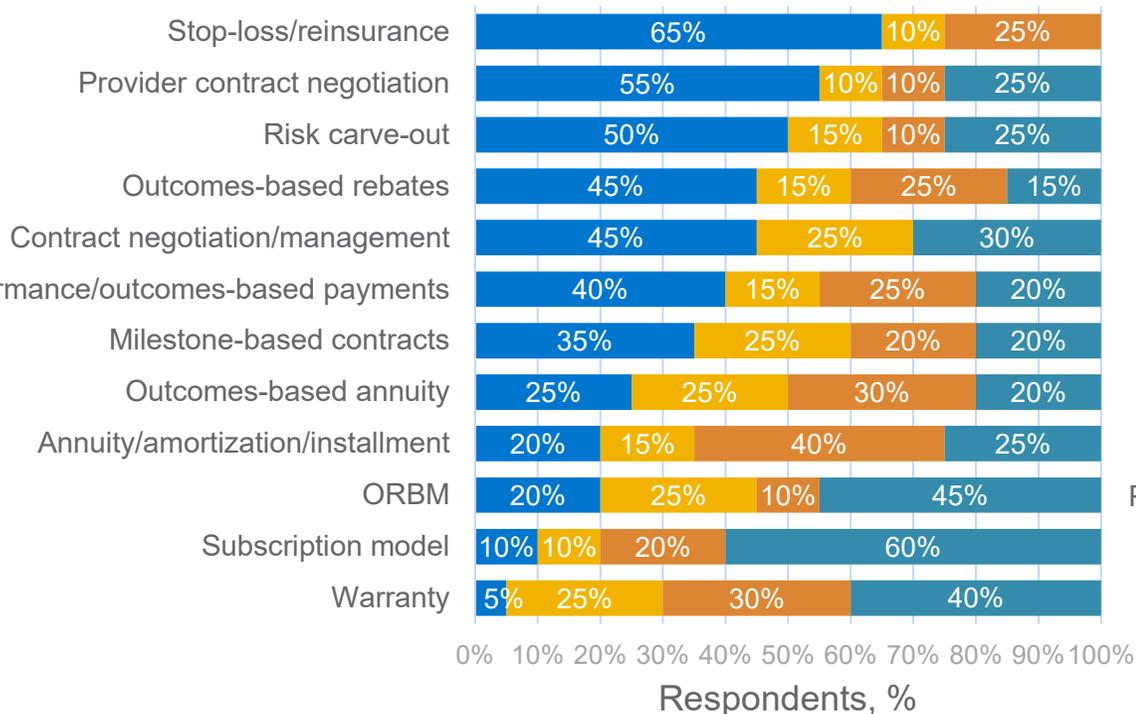


Stop-loss Insurance is the Favored Model for High-investment Medications among both Payers and Employers

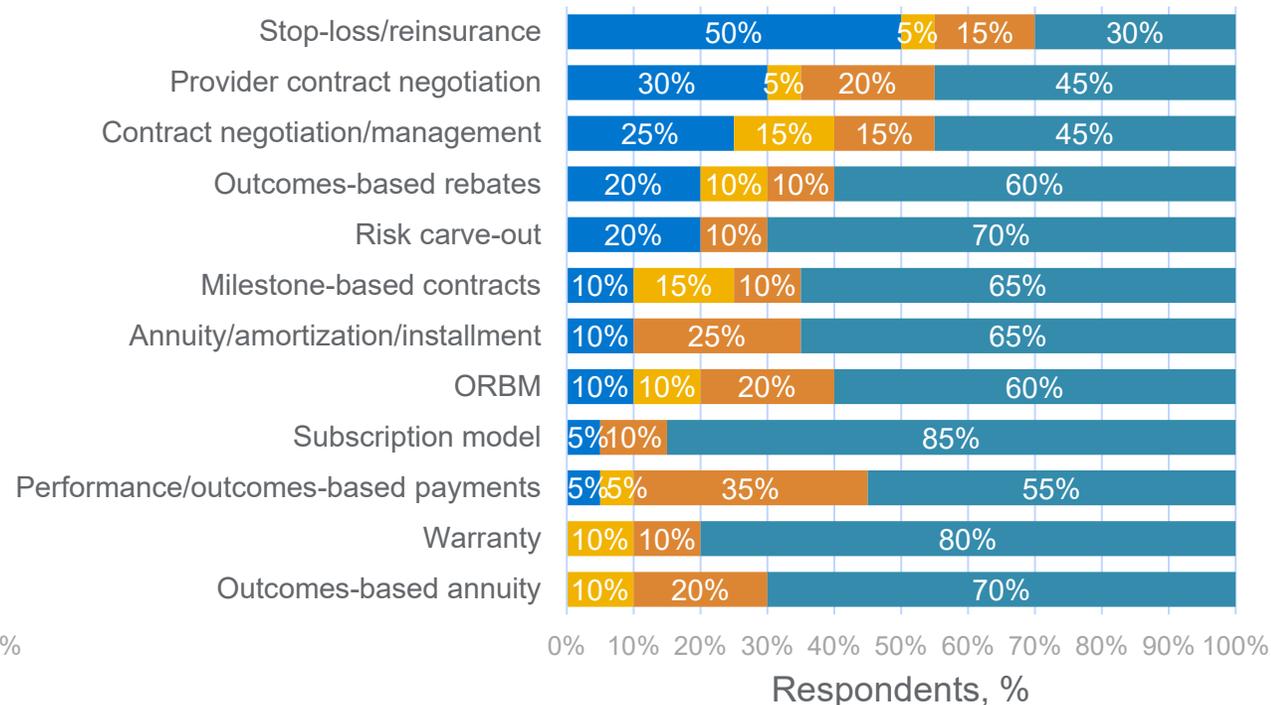


Payers have more likely to implement financial models, and to have plans in place to implement financial models in the future

Financial models for high-investment medications (payer)



Financial models for high-investment medications (employer)



- Currently use
- Plan to implement within 18 months
- Plan to implement beyond 18 months
- No plans to implement

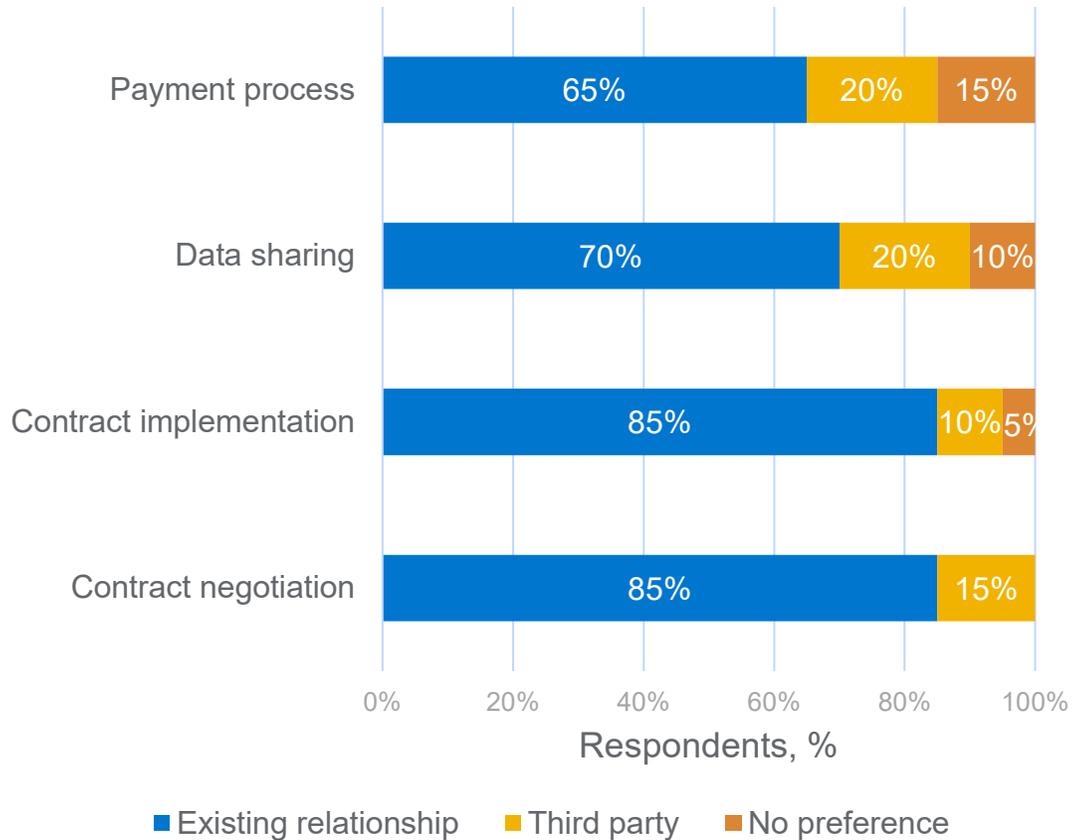
ORBM, Orphan Reinsurer and Benefit Manager n=20 payers; n=20 employers Sorted by "currently use"
 Q: Does your organization currently utilize or plan to utilize any of the following financial models to support plan affordability for high-investment medications?

Confidential. Limited Distribution to AMCP Members. AMCP/PRECISIONvalue survey March 2022.

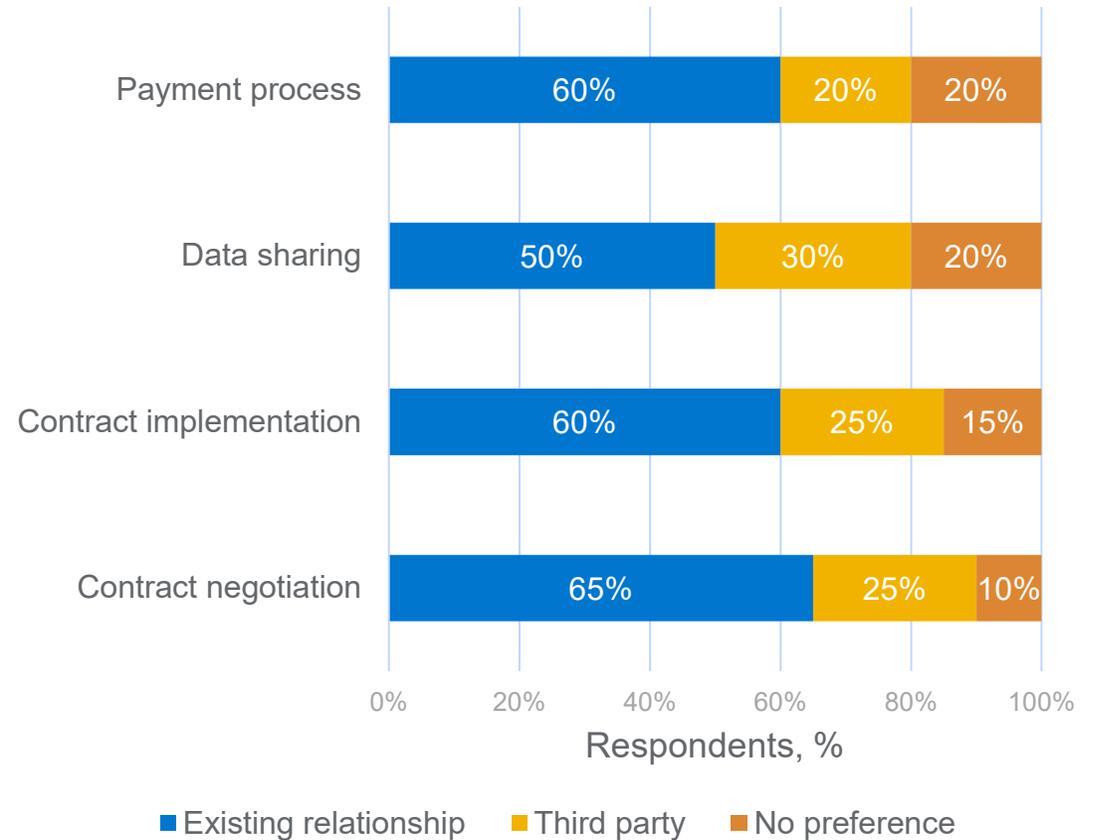
Both Payers and Employers Primarily Rely on Existing Partnerships to Execute Financial Models, but Employers are More Likely to Bring in a Third-party



Preferred partners for aspects of financial models (Payer)



Preferred partners for aspects of financial models (Employer)



n=20 payers; n=20 employers Q: As it relates to arrangements for financial models for high-investment medications, do you have a preference related to the entity you engage with for contract negotiation?



Multiple Policy Levers Were Considered

DATA, Enhancement, Streamlining and Exchange

Patient incentives for disease registries

Regulations to enable state pilots

High-investment medication reinsurance after catastrophic

National High-investment medication benefit

High-investment medication risk pools

Patient portability credits

Mandatory value-based contracts for drugs above a \$ threshold



Additional Takeaways

- Incremental changes needed now to prepare for the future impact
- Standardize terminology and education to provide awareness of new financial models and potential policy solutions
- Facilitate partnering and innovation across stakeholders

What's Next?



Next Steps



AMCP PARTNERSHIP FORUM 2022
High-Investment Medications

EXECUTIVE SUMMARY

As novel therapies to address important medical needs are approved, the high costs for these medications—especially cell and gene therapies—can raise sustainability and affordability concerns for employers, payers, and patients. High short-term investments present clinical and financial challenges that are magnified when the long-term health benefits are uncertain, patients switch employers or enroll in different health plans, or complex care coordination is needed. New payment policies and the application of 21st century financial and technical tools can mitigate risk and affordability concerns.

To explore alternative payment models, financial tools, and policy initiatives to improve the predictability, affordability, and accessibility of high-investment treatments and ensure patients get the medications they need at a cost they can afford, AMCP held a multi-stakeholder Partnership Forum in Arlington, VA, April 26 and 27, 2022. Forum participants were asked to 1) identify stakeholder challenges associated with high-investment medications, 2) explore the challenges and opportunities related to financial tools to address predictability, affordability, and accessibility for high-investment medications, and 3) determine the challenges and opportunities of potential policy solutions to improve the predictability, affordability, and accessibility of high-investment treatments.

THEMES THAT EMERGED FROM THE PARTICIPANT DISCUSSION INCLUDED THAT:

- High-investment medications do not yet raise significant sustainability or affordability stakeholder concerns but are expected to in coming years. Among stakeholders, state Medicaid plans and employer groups are likely to have the most urgent need to address the predictability, affordability, and accessibility of these medications.

continued on next page

WATCH FOR FOLLOW-UP

This Partnership Forum was a valuable opportunity to evaluate the state of the evolving space of high-investment medications. AMCP's next steps will be to:

- Publish a proceedings document** describing the findings and recommendations from the Partnership Forum in an upcoming issue of AMCP's *Journal of Managed Care + Specialty Pharmacy (JMCP)* and disseminate it widely to decision makers around the country.
- Host a webinar** to report these findings and recommendations.
- Continue to engage stakeholders** on this topic by sharing these findings and recommendations.
- Create educational materials** providing background on the financial tools that may be utilized in the management of high-investment medications.
- Explore opportunities** for the private and public sector to permit, test, and encourage new financial tools and policy solutions to meet market needs.

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Operational complexity and alignment on metrics are key challenges to implementing outcomes-based and annuity contracts

Q. What are the greatest challenges you experienced in implementing each of the following financial tools?

Talking the TALK
In the World of Value-Based Care, Words Matter
A LEXICON FOR VALUE-BASED PURCHASING

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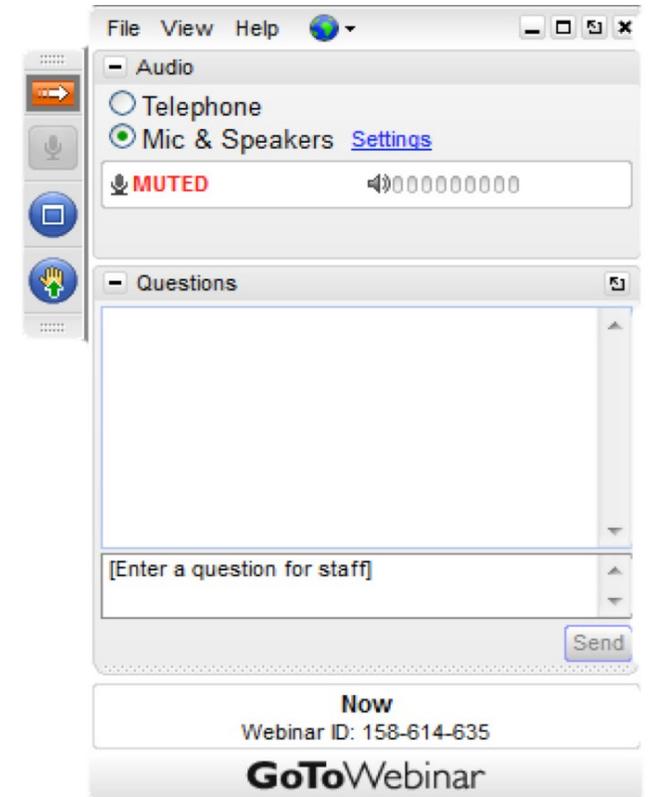
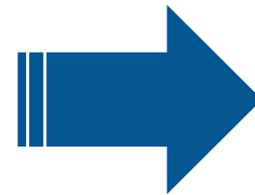
Real-world evidence enhances decision-making
J. Kim, S. H. Kim, S. H. Kim, et al.

JMCP's mission is to advance science, expertise, and evidence-based decision-making to improve patient health through access to high-quality, cost-effective medications and other therapies.

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Key forum takeaways

- High-investment medications will raise sustainability and affordability concerns
- Stakeholders prioritize needs differently
- Uptake of new and innovative payment models is modest but growing
- No one tool meets all needs
- Incremental changes needed now
- Enhance the collection, sharing and use of data
- Standardize terminology and education
- Partnership and innovation across stakeholders is needed





Mission

To improve patient health by ensuring access to high-quality, cost-effective medications and other therapies.