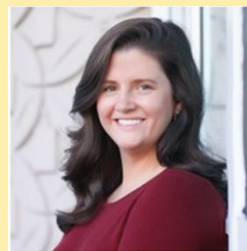


Welcome



Bri Palowitch, PharmD, BCGP
Manager, Pharmacy Affairs
Academy of Managed Care Pharmacy

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Agenda

- 1 AMCP Partnership Forums
- 2 Designing Benefits and Payment Models for Innovative High-Investment Medications
- 3 Forum Findings and Recommendations
- 4 Q&A
- 5 Closing

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AMCP Partnership Forums Collaboration for Optimization

The live, hands-on 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...

- **Proactive, collaborative approach** to solving important issues and challenges
- **Provide a voice** to all stakeholders
- **Gain consensus** on tactics to address a key challenge or opportunity, as well as how to **remove barriers** to improve patient care and optimize expenses
- Represent opportunities for payers, manufacturers, and other stakeholders to **work together on common goals and interests**
- **Have high visibility** among industry stakeholders and policy-makers
- Bring individuals and organizations with different priorities together to **find common ground and actionable results**



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Past Forum Results

- **The Pharmaceutical Information Exchange Act (PIE Act)**
- **“Patient Reported Outcomes - The Missing Link to Defining Value”** developed much needed definitions and parameters on using this important metric to determine value in care
- **Value-Based Contracting Forum** - Resulted in a consensus definition that will help advance this important model
- **AMCP’s Biologics and Biosimilars Collective Intelligence Consortium (BBCIC)** - Is the only organization actively engaged in post-marketing surveillance of biologics and their corresponding biosimilars.





LEADING CHANGE

On health care issues that are important to you

Live and hands-on, AMCP Partnership Forums, bring together key decision-makers in managed care, integrated care, the pharmaceutical industry, and others to drive efficiencies and outcomes in managed care.



2018 Partnership Forums



- ❖ Managing Total Cost of Care Through Medical and Pharmacy Integration
- ❖ Building the Foundation for Patient Reported Outcomes: Infrastructure and Methodologies
- ❖ Integrated Delivery Networks' Role in Value-Based Agreements for Pharmacy and Medical Benefits



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FORUM

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Susan Trieu, PharmD
Director, Enterprise Specialty
Clinical Solutions
MedImpact Healthcare Systems,
Inc.



Jane Barlow, MD, MPH, MBA
Chief Clinical Officer
Real Endpoints



Stephen George, PharmD, MS
Senior Consultant
Milliman

Why Focus on High-Investment Medications?

- They offer breakthrough treatments that can greatly improve outcomes for patients with serious health conditions
- Many are associated with significant costs that create barriers to patient access and affordability
- These treatments have higher short-term costs but are anticipated to deliver substantial benefits

Forum Goals

1. Gain insights on how managed care views high-investment medications for chronic versus curative diseases.
2. Develop new solutions for benefit designs and overall value assessment for high investment medications.
3. Identify non-traditional contracting methods and reimbursement models.
4. Identify any legal or regulatory barriers

Forum Participants

25+ participants from health plans, integrated delivery systems, pharmacy benefit managers, employers, data and analytics experts, biopharmaceutical companies and government agencies

AbbVie
Accredo
Alnylam Pharmaceuticals
Amgen
Analysis Group, Inc
Applied Policy
AstraZeneca
Cambia Health Solutions
Celgene
Employers Health Coalition
Express Scripts
Fairview Pharmacy Services
Food and Drug Administration
Gilead Sciences
Global Healthy Living Foundation
Harvard Pilgrim Health Plan

InterContinental Hotels Group
Johns Hopkins University School of Medicine
Kaiser Permanente Washington
MassHealth / University of Massachusetts Medical School
Medicaid Health Plans of America (MHPA)
MedImpact Healthcare Systems, Inc
Milliman
National Pharmaceutical Council
National Comprehensive Cancer Network (NCCN)
Pharmaceutical Research and Manufacturers of America (PhRMA)
Santa Clara Family Health Plan
Takeda Pharmaceuticals, USA
UnitedHealth Group
University of Colorado Anschutz Medical Campus
Xcenda

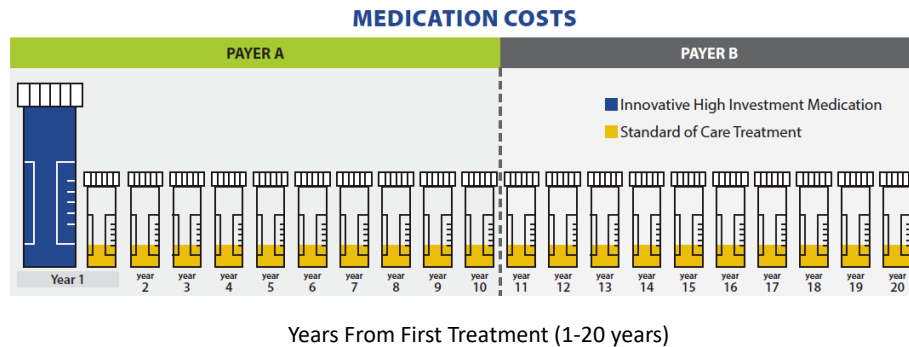


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Some Challenges and Considerations for High Investment Medications



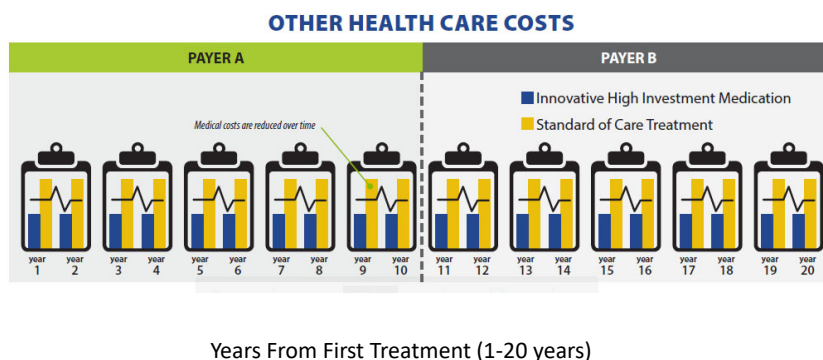
Comparison of Costs over Time for Innovative and Traditional Therapy








Large one-time treatment cost replaces continuous treatment under current standard of care



Comparison of Costs over Time for Innovative and Traditional Therapy



Models for Five Hypothetical Therapies for Different Conditions

	HEPATITIS C	BETA-THALASSEMIA	ALZHEIMER'S DISEASE	CVD: FH	CVD: PRIOR CVD
PATIENT POPULATION	ADULTS 	PEDIATRIC 	SENIORS 	ADULTS 	ADULTS 
DISEASE-RELATED BURDEN	Cirrhosis, liver cancer, liver transplants	Chronic iron overload management (chelation, transfusion), CVD	Elder Care Costs	MI Stroke	MI Stroke
TIMING OF DISEASE-RELATED BURDEN	Many years after viral exposure	Ongoing, from childhood	Increases with advanced age and disability	Early adulthood on	Mid-life through advanced age
NEW THERAPY TYPE	One-time drug therapy Curative	One-time gene therapy Curative	Chronic/Ongoing Disease-modifying	Chronic/Ongoing Disease-modifying	Chronic/Ongoing Disease-modifying
INITIAL PAYER	Commercial Insurance or Medicaid	Commercial Insurance or Medicaid	Medicare	Commercial Insurance or Medicaid	Commercial Insurance or Medicaid

Challenges for Innovative Benefit Designs

- Needs of various stakeholders
- Fragmented payer landscape
- Market constraints
- Evolving standards of care
- Strategies for aligning innovative payment models with benefit lifecycles
- Budget cycle timelines
- Legal and regulatory barriers
- Need for long-term, real world data for assessing outcomes

Marketplace Factors

- Payer challenges assessing risk over time and integrating new financing models with existing benefits
- Application of new models to different types of benefits, including medical benefits, pharmacy benefits, and high-deductible plans
- The impact of rebates on pricing structures must be considered when implementing new payment and coverage models
 - Innovative contract models are distinct from rebates
 - Cost savings to payers associated with rebates must be considered when designing new models

Patient Selection

- Identifying appropriate patients is essential to ensure resources are used wisely
- Selection criteria should be designed with input from clinicians and relevant therapeutic guidelines
 - Real-world evidence, FDA labeling, and compendia could also be used to refine criteria
- To minimize coverage denials, providers should understand which patients are appropriate candidates and what information is required for submission
 - Reasons for denials should be clear and someone with clinical expertise should be available to explain them to providers

Patient Engagement

- Particular important for chronic or complicated regimens to encourage adherence and persistence for high-investment treatments and any ancillary services
- Patients need clarity, transparency, and predictability of costs and coverage
 - Accurate, comprehensive cost information is crucial, and ideally should occur at the point of service or time of decision-making.
- Patient health literacy gaps must be addressed to support patient understanding of clinical goals and financial obligations
- Care coordination and coaching can assist patients with understanding plan designs and cost barriers



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Defining Value for High-Investment Medications

- Value assessments should be comprehensive
 - Consider factors including survival, quality of life, effectiveness, safety, the patient's perspective, and comprehensive medical and prescription costs
- Ideally, the value of the standard of care has already been identified so that comparisons can be made
- Innovative contract models, such as coverage with evidence generation, could capture real world evidence of value
 - Developing the infrastructure to capture and assess real world data may require additional investment



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Addressing Legal and Regulatory Barriers



LAWS AND REGULATIONS THAT MAY IMPACT PAYMENT MODELS

- Anti-discrimination laws
- Anti-trust laws
- Anti-Kickback Statute
- Average Sales Price reporting
- False Claims Act
- Health Insurance Portability and Accountability Act
- Laws and regulations regarding off-label promotion
- Medicaid Best Price
- Stark Law (prohibits self-referral)
- State laws and regulations, such as required reserves for plans and benefit mandates

Payer Perspective & Potential Payment Models

National Survey of Payer Perspectives

- 21 national and regional managed care organizations
 - Representing 123 million commercial, Medicare Advantage, and Managed Medicaid covered lives
- Financial risks and impacts of high-investment medications are important concerns for payers
- Interested in alternative payment models, given the right circumstances
- Payers expect to use both traditional and alternative payment models to address high-investment medications

Ciarametaro M, Long G, Johnson M, et al. *Health Affairs Blog*. June 28, 2018.



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Payer Survey Key Findings Regarding Gene Therapy

PAYER SURVEY KEY FINDINGS REGARDING GENE THERAPY

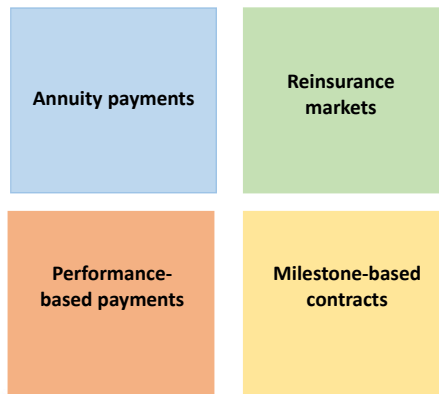
- KEY FINDING 1:** Financial risk and impact of gene therapies is an important concern for payers
- KEY FINDING 2:** Payers would consider alternative payment models to manage plan risk under the right set of circumstances
- KEY FINDING 3:** Payers expect to use a combination of new and existing approaches to manage the financial risk of gene therapy
- KEY FINDING 4:** Given uncertainty about magnitude and duration of clinical effects, payers likely will require performance guarantees with alternative payment approaches
- KEY FINDING 5:** Greatest patient access challenges may be encountered at smaller employer plans and managed Medicaid plans
- KEY FINDING 6:** Payers' preferred approaches may not be entirely effective in addressing their concerns
- KEY FINDING 7:** Many payers were uncomfortable with "patient portability" proposals



Ciarametaro M, Long G, Johnson M, et al. *Health Affairs Blog*. June 28, 2018. 26

Selected Payment Strategies

- Forum participants selected four payment strategies for detailed discussion:



Annuity Payments

- Annuities allow payers to make installment payments over an extended period
 - Viable financing model for short-term high-investment curative or durable therapies
 - Patient annuity payments considered financially impractical for most patients
 - Not inherently tied to outcomes, but could potentially be linked
- Annuity payments do not address the price of treatment unless they are combined with other contracting strategies
 - Might be most suited to treatments where a large initial treatment population is expected
- A relatively short re-payment time frame (e.g., 3 to 4 years) may be preferred to manage risks associated with patients who switch plans or die during the course of the annuity

Reinsurance Markets

- Reinsurance markets pool risk—payers are insured by a third party to protect against high-cost claims
- Generally most useful for smaller payers and self-insured employers who have a need to share risks
 - Larger plans are more able to predict the size of their risk pool and factor costs into plan premiums
- Reinsurance markets are a short-term solution to address financial risk for smaller entities
- Long-term, reinsurance premiums are likely to rise as more high-investment medications enter the market



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Performance-based Payments

- Most appropriate for treatments with clinical uncertainty
- Payments are based on the achievement of pre-determined outcomes
 - Outcomes must be clinically appropriate, relevant, and measurable
 - Patient population must be clearly defined
- When used for chronic therapies, contracts should include appropriate care coordination and interventions over time
- An infrastructure for capturing and analyzing real-world evidence regarding performance is needed
- Several legal and regulatory barriers (e.g., Medicaid Best Price)



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Milestone-based Contracts

- Similar to performance-based contracts
 - Similar issues regarding regulation, needs for well-defined and measurable milestones, and the need for access to real-world data
- Key difference is that payment is based on achievement of specific events such as initial therapy administration and therapeutic response, rather than being based on outcomes over time

Strategies for Moving Forward

- While consensus was not reached by all Forum participants, broadly, implementation of innovative payment models requires that stakeholders
 - Address legal and regulatory challenges
 - Implement strategies that improve transparency
 - Support access to real-world evidence
 - Strengthen industry partnerships

AMCP Roles and Opportunities

- Convener of key resources and stakeholders to advance strategies for better managing high-investment medications
- Clearinghouse to collect and disseminate the designs and results of alternative payment model experiments
- Facilitator for stakeholder collaborations
- Conduit for communication and education about factors including legal and regulatory issues and benefit design
- AMCP Foundation could support pilots for innovative contracting strategies
- AMCP's dossier system could be leveraged to create a centralized source of PIE and to facilitate value assessments for high-investment medications
- Partnerships with other organizations to maintain a sustainable and innovative healthcare system



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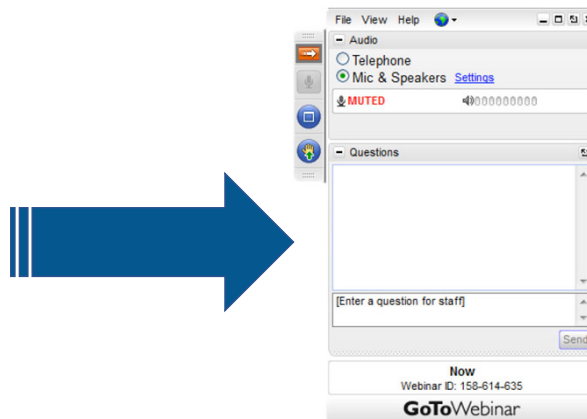
Key Points

- High-investment medications must be economically justified within sustainable pricing models to maintain the long-term viability of the insurance market
- A new paradigm that addresses concerns about how to pay for these medicines is needed to ensure patients have access to these innovations
- Several innovative models have been proposed, each with their own benefits, challenges, and potential roles in the payment landscape
- Aspects of various models could potentially be combined with each other as well as other models that were not specifically addressed at the forum



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Reminder: How to Ask Questions During the Webinar



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