

NEW DIGS

# FoCUS

Financing and Reimbursement  
of Cures in the US

## Self-Insured Employers Workshop: New Commercial Solutions

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MIT CENTER FOR BIOMEDICAL INNOVATION



# New Commercial Solutions



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# Here's what we will cover today



- Overview of the project
- Key Findings
- Implications for Self-Insured Employers

# The Project

- Identify existing and emerging products to address the financial challenges of gene and cell therapy in the marketplace
- Conduct RFI survey to gather and assemble relevant information
- Publish results as a white paper

## How We Gathered the Relevant Information

- Electronic Survey using Qualtrics®
- 45 questions in these major categories
  - Responding organization information
  - Product history and description
    - Therapies included
    - Targeted customers
    - Eligibility requirements
  - Financing challenges addressed by product
  - Impacts to patients and ability to address patient mobility
  - Data tracking: financial and clinical
  - Quality Assurance
  - Physician or provider requirements

100% of those surveyed provided a response



# The 4 Buckets Defined

- **Reinsurance/Stop Loss/Risk Carve Out**
  - additional insurance to cover costs ONLY related to the covered therapy
- **Contract Negotiation and Data Management**
  - Act as third parties to negotiate contracts for cell and gene therapies
- **Provider Contract Negotiations/ including COE**
  - Solutions designed to help payer negotiate with providers (ex: health systems, doctors) and includes access to Centers of Excellence for the treated condition
- **Financial & Warranty Services**
  - Solutions that offer payment financial payment plans or those that arrange can provide protection to payers for suboptimal therapy performance



# The 4 Buckets

Assume Payer Financial Risk	Reinsurance/Stop Loss/Risk Carve Out	Contract negotiation and Data Management Services	Provider Contract Negotiations, including COE	Financial Services and Warranty Services	Assume/Manage Manufacturer Financial Risk
	<b>Evernorth</b> <i>Embarc Benefit Protection Program</i>	<b>Audaire Health</b> <i>Gene &amp; Cell Therapy Outcomes Management service</i>	<b>BCBS Association</b> <i>Blue Distinction Center for Cellular Immunotherapy</i>	<b>August Care</b> <i>Outcomes Based Financial Solutions</i>	
	<b>BCS Financial</b> <i>BCS Financial-Stop Loss GT</i>	<b>Real Endpoints</b> <i>RE Marketplace</i>	<b>Emerging Therapy Solutions</b> <i>ETS Programs of Excellence</i> <i>ETS Analytics</i> <i>ETS Buyer's Group</i>	<b>OutcomeRx</b> <i>Specialty Therapy Warranty</i>	
	<b>OutcomeRx</b> <i>PACCT</i>			<b>CVS Health</b> <i>Gene Therapy Payment Plan</i>	
	<b>CVS Health</b> <i>Gene Therapy Stop Loss</i>				
	<b>MedImpact</b> <i>MedShield</i>				
	<b>Optum Rx</b> <i>Gene Therapy Risk Protection</i>				
	<b>PayRx</b> <i>PayRx, Inc. Benefit Protection</i>				



# Reinsurance- Stop Loss- Risk Carve Out

- Targeted customers included mainly self-insured employers, commercial health plans, Medicare, Medicaid
  - MedShield and PACCT do not include employers as targeted customers
- Recent entrants into the market, none before 2020
- For the most part, approved gene and cell therapies are covered
- Outside of requirements should a patient leave the payer/plan, there is little impact to providers and patients
- No performance guarantees or rebates involved in these products

## Developer/Payer Contract Negotiation and Data Tracking

- These products add manufacturers as potential customers
- Recent entrants into the market (2020 and 2021)
- For the most part, approved gene and cell therapies are covered
- Possible performance guarantee and retention of savings as a fee for one product
- Will allow customer audit rights

# Provider Contract Negotiation and COE

- This group added stop loss reinsurers to the previously stated customers
- Products have been on the market longer than the others with launch dates in 2018 and 2019
- There are two products in this category, one is specific to CAR-T therapy and other covers approved gene and cell therapies
- Education for existing and future therapies provided to both patients and providers

# Financial and Warranty Services

- Targeted customers are very different for the products in this category
  - CVS Health's *Gene Therapy Payment Plan* and August Care's *Outcomes-based Financial Solutions* are available to self insured employers
- Cover approved gene and cell therapy
- For the warranty product, manufacturers may amend rebate strategy based on coverage
- Except for the simple payment plan product, these products have therapy dependent performance guarantees

# The Challenges Defined

- **Risk**
  - **Actuarial/financial risk:** product addresses the uncertainty in the number of patients likely to be treated with a high-cost cell or gene therapy and the resulting financial risk associated with the cell or gene therapy.
  - **Performance risk:** product addresses the uncertainty over effectiveness and durability of the cell or gene therapy, which may not be well-established at approval.
  - **Payment timing risk:** product addresses the high upfront cost of treatment relative to benefit realization.
- **Cost**
  - **Product cost:** product covers the cost of cell or gene therapy alone.
  - **Ancillary cost:** product covers additional costs of treatment with cell or gene therapy.
- **Administration**
  - **Data tracking:** product addresses need to track outcomes for patients receiving cell or gene therapy, solely or as related to a performance-based agreement.
  - **Contract administration:** product assists with contracting between stakeholders, including initiation, management, and/or adjudication of contract.
- **Patients and providers**
  - **COE access:** product assists stakeholder with access to COE for administration of cell or gene therapy.
  - **Patient access:** product addresses the barriers to patient access to cell and gene therapies.
  - **Patient care:** product is focused on delivering optimal patient care throughout treatment with cell or gene therapy.

# Challenges Addressed by Each Product

Company product	RISK			COST		ADMINISTRATION		PATIENT/PROVIDER		
	Actuarial/ financial	Performance	Payment timing	Product	Ancillary	Data tracking	Contracts	COE access	Patient access	Patient care
<b>Payer reinsurance/stop-loss/carve-out</b>										
BCS Financial <i>Stop-Loss Gene Therapy</i>	•		•	•	•					
CVS Health <i>Gene Therapy Stop-Loss</i>	•			•	•				•	
Evernorth <i>Embarc Benefit Protection Program</i>	•	•	•	•	•	•	•	•	•	•
MedImpact Healthcare Systems <i>MedShield</i>	•			•					•	
OptumRx <i>Optum Gene Therapy Risk Protection</i>	•	•	•	•		•	•		•	•
OutcomeRx <i>Patient Access to Costly and Curative Therapies</i>	•		•	•		•			•	
PayRx <i>PayRx Benefit Protection</i>	•	•	•	•	•	•				
<b>Contract negotiation &amp; data management services for payers and pharma companies</b>										
Audaire Health <i>Gene &amp; Cell Therapy Outcomes Management Service</i>		•	•	•		•	•			
Real Endpoints RE Marketplace	•	•		•		•	•		•	
<b>Provider contract negotiation</b>										
BlueCross Blue Shield Association <i>Blue Distinction Center for Cellular Immunotherapy</i>		•	•	•	•	•	•	•	•	•
Emerging Therapy Solutions <i>ETS Programs of Excellence, ETS Analytics &amp; ETS Buyer's Group</i>	•		•	•	•	•	•	•		
<b>Financial and pharma company warranty services</b>										
August Care <i>Outcomes-based Financial Solutions</i>	•	•	•	•		•	•	•	•	•
CVS Health <i>Gene Therapy Payment Plan</i>			•	•					•	
OutcomeRx <i>Specialty Therapy Warranty</i>		•				•	•		•	

Company product	Approved cell therapies	Approved gene therapies	Pipeline <sup>a</sup>	Other therapies <sup>b</sup>
<b>Audaire Health</b> <i>Gene &amp; Cell Therapy Outcomes Management Service</i>	●	●	●	●
<b>August Care</b> <i>Outcomes-based Financial Solutions</i>	●	●		
<b>BCS Financial</b> <i>Stop-loss Gene Therapy</i>		●	●	●
<b>BlueCross Blue Shield Association</b> <i>Blue Distinction Center for Cellular Immunotherapy</i>	●			
<b>OutcomeRx</b> <i>Patient Access to Costly and Curative Therapies</i>		●		
<b>OutcomeRx</b> <i>Specialty Therapy Warranty</i>	●	●		
<b>CVS Health</b> <i>Gene Therapy Stop Loss</i>		●	●	
<b>CVS Health</b> <i>Gene Therapy Payment Plan</i>		● <sup>c</sup>	●	
<b>Emerging Therapy Solutions</b> <i>ETS Programs of Excellence, ETS Analytics &amp; ETS Buyer's Group</i>	●	●		
<b>MedImpact Healthcare Systems</b> <i>MedShield</i>		●	●	
<b>PayRx</b> <i>PayRx Benefit Protection</i>				●
<b>Real Endpoints</b> <i>RE Marketplace</i>	●	●	●	●
<b>OptumRx</b> <i>Optum Gene Therapy Risk Protection</i>		●	●	●

<sup>a</sup>Pipeline products include those that are in late-stage trials and/or undergoing FDA review, but are not yet approved.

<sup>b</sup>Other therapies include non-cell or gene therapies that are high cost.

<sup>c</sup>Select gene therapies dispensed through CVS Specialty.

Evernorth responded as 'Confidential'



# Available Today for Self-Insured Employers

Reinsurance/Stop Loss/Risk Carve Out	Contract negotiation and Data Management Services	Provider Contract Negotiations, including COE	Financial Services and Warranty Services
<b>Evernorth</b> <i>Embarc Benefit Protection Program</i>	<b>Audaire Health</b> <i>Gene &amp; Cell Therapy Outcomes Management service</i>	<b>BCBS Association</b> <i>Blue Distinction Center for Cellular Immunotherapy</i>	<b>August Care</b> <i>Outcomes Based Financial Solutions</i>
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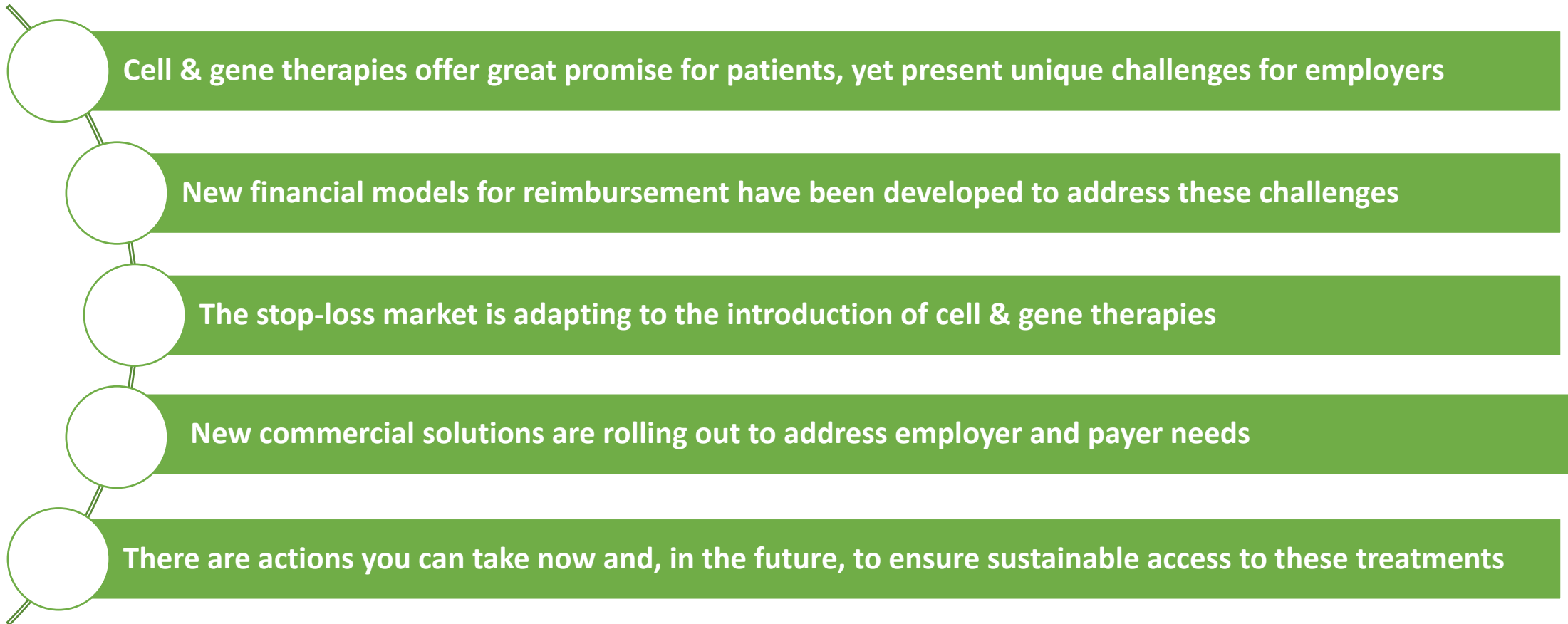
# Implications for Self-Insured Employers

- There are products available today
  - They don't address ALL the challenges, but new offerings are emerging to address them
  - You may have direct access already with your current plan administrator or PBM
- Majority of those surveyed consider self-insured employers a target customer
- Some products provide coverage for other high-cost drugs in addition to gene and cell therapy

# Implications for Self-Insured Employers

- Your decision to consider these products may depend on:
  - Your company size
  - Your company culture
  - Employee turnover
  - Ability to contract directly with manufactures or health systems
  - Current stop loss (or maybe no stop loss currently)
  - Fiscal risk tolerance
- <https://payingforcures.mit.edu/toolkit/> : can help you in your evaluation
- The evolving landscape will require attentive management over the next few years and where your consultants and brokers (or other advisors) can add significant value

# Key takeaways from today



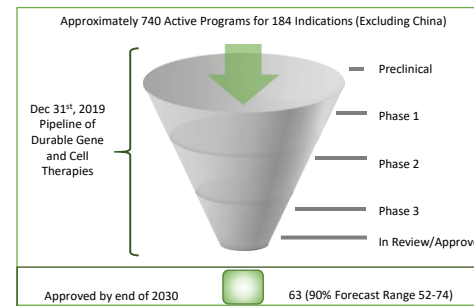
Go to <https://payingforcures.mit.edu>

Research Briefs and  
Peer-Reviewed Publications

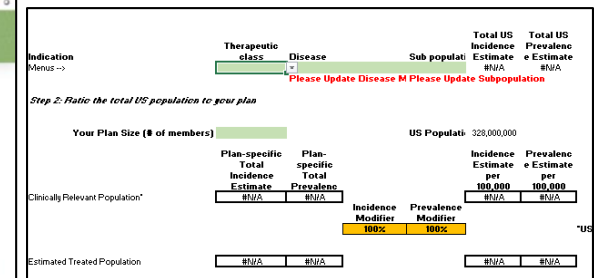
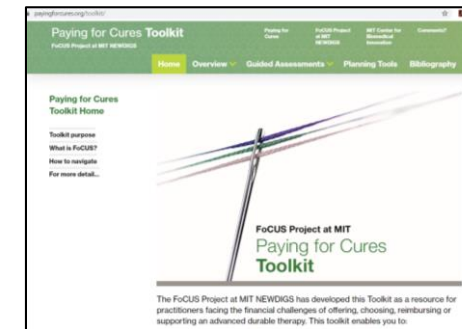


Unique Gene and Cell Therapy  
Pipeline Impact Modeling

50-75 Therapies Approved for the US Market by 2030



On-line Toolkit to Educate and Support  
Practitioners Developing Financing Solutions



Public Speaking Engagements

- FoCUS Financing and Reimbursement of Cures in the US
- ### Speaking Engagements
- Jan 29 MassBio Policy Breakfast (M. Trusheim; Boston)
  - Feb 6-7 Blue Cross Blue Shield Association / Aspen Institute (M. Trusheim; DC)
  - Feb 7 Medicaid Innovation Summit (D. Rollman; Orlando)
  - Feb 13 TBD - Milken Institute FasterCures Workshop (M. Trusheim; DC)
  - Feb 21 American Society for Transplantation and Cellular Therapy (ASTCT)/CIBMTR TCT Meeting (Trusheim; Orlando)
  - Mar 23-25 MedImpact 2020 (J. Barlow; Dan Mytelka - Carlsbad, CA)
  - Mar 30-Apr 2 Hanson-Wade 4th Annual Gene Therapy for Rare Disorders (M. Trusheim; Boston)
  - April 7-9 Alliance for Healthcare Research and Quality? (AHRQ) (M. Trusheim; LA)
  - April 15-16 Eye for Pharma Philadelphia 2020 (M. Trusheim; Philadelphia)
  - April 21 National Cooperative Rx Annual Meeting (J. Barlow; Madison, WI)
  - May 1 Terrapin World Orphan Drug Congress (M. Trusheim; DC/MD)
  - TBD Mellon Financial "Double Take" Podcast (D. Mytelka)

Educational Events



Design Labs

