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High-Cost Drugs

Financial and Operational Impacts of High-Cost Cell and Gene Therapies (CGT)

August 8, 2024
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Mercer Agenda

1. Reimbursement and treatment cost complexities arising from recently approved high-cost Cell and Gene Therapies (CGT) that must be administered in an inpatient setting
2. Key considerations when estimating the potential fiscal impact of new and upcoming Cell and Gene Therapies
3. Risk mitigation options for all high-cost drugs in a managed care environment

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Learning Objectives

At the conclusion of this presentation, participants will be able to:

Identify payment complexities due to inpatient administration of cell and gene therapies

List risk mitigation options for high-cost drugs within managed care

Describe state-specific factors needed to estimate fiscal impact of high-cost cell and gene therapies

1

Cell and Gene Therapy: Inpatient Complexities

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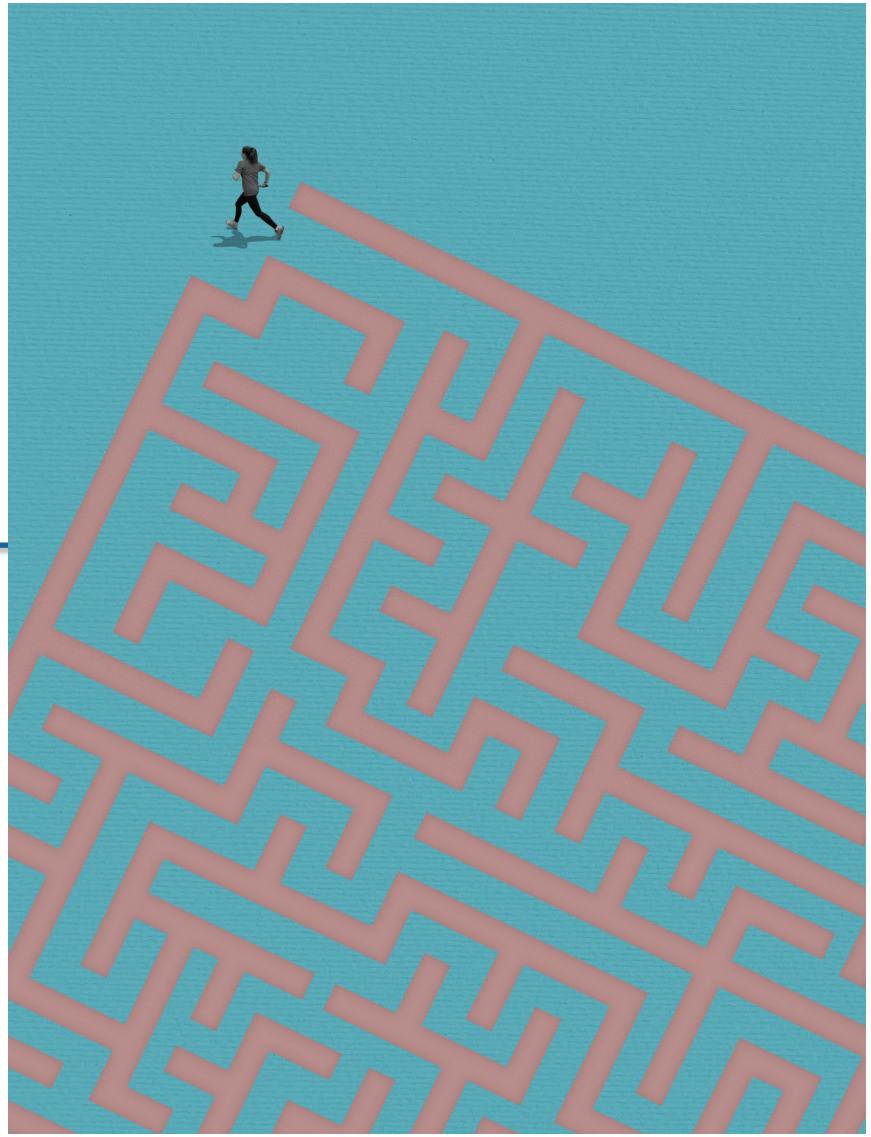
Inpatient Cell and Gene Therapy: Reimbursement Variables

Variations in Medicaid Payment Methodology

Enrolling and Credentialing Out-of-State Providers

Use of Single-case Agreements

Availability of Hospitals Authorized to Administer CGT



Inpatient Cell and Gene Therapy: Cost Variables

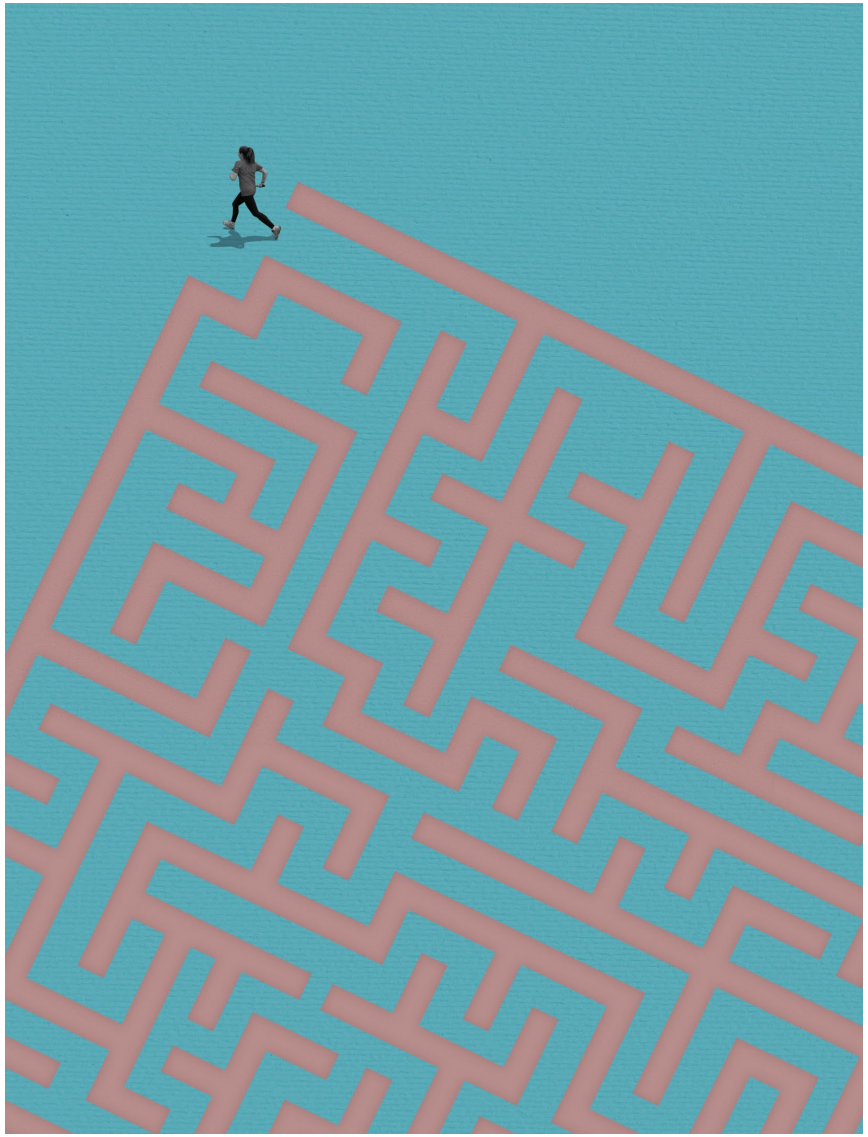
Drug cost differences among available treatment options

Potential for **extended** out-of-state **travel** to receive therapy

Ancillary costs associated with CGT administration

Fiscal impact based on state-specific prevalence variables

Federal rebate implications based on inpatient hospital reimbursement methodology in place



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Cell and Gene Therapy: Planning for the Unknown

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Current Landscape of High-Cost Drugs

- The FDA has approved 37 Cell and Gene Therapies as of April 2024
- A robust pipeline of new therapies will contribute to accelerated growth
- Currently eligible populations will continue to increase with expanded indications on the horizon
- Interaction with managed care necessitates discussion on how costs should be built into capitation rates

Select List of Approved Gene and Cell Therapy Products

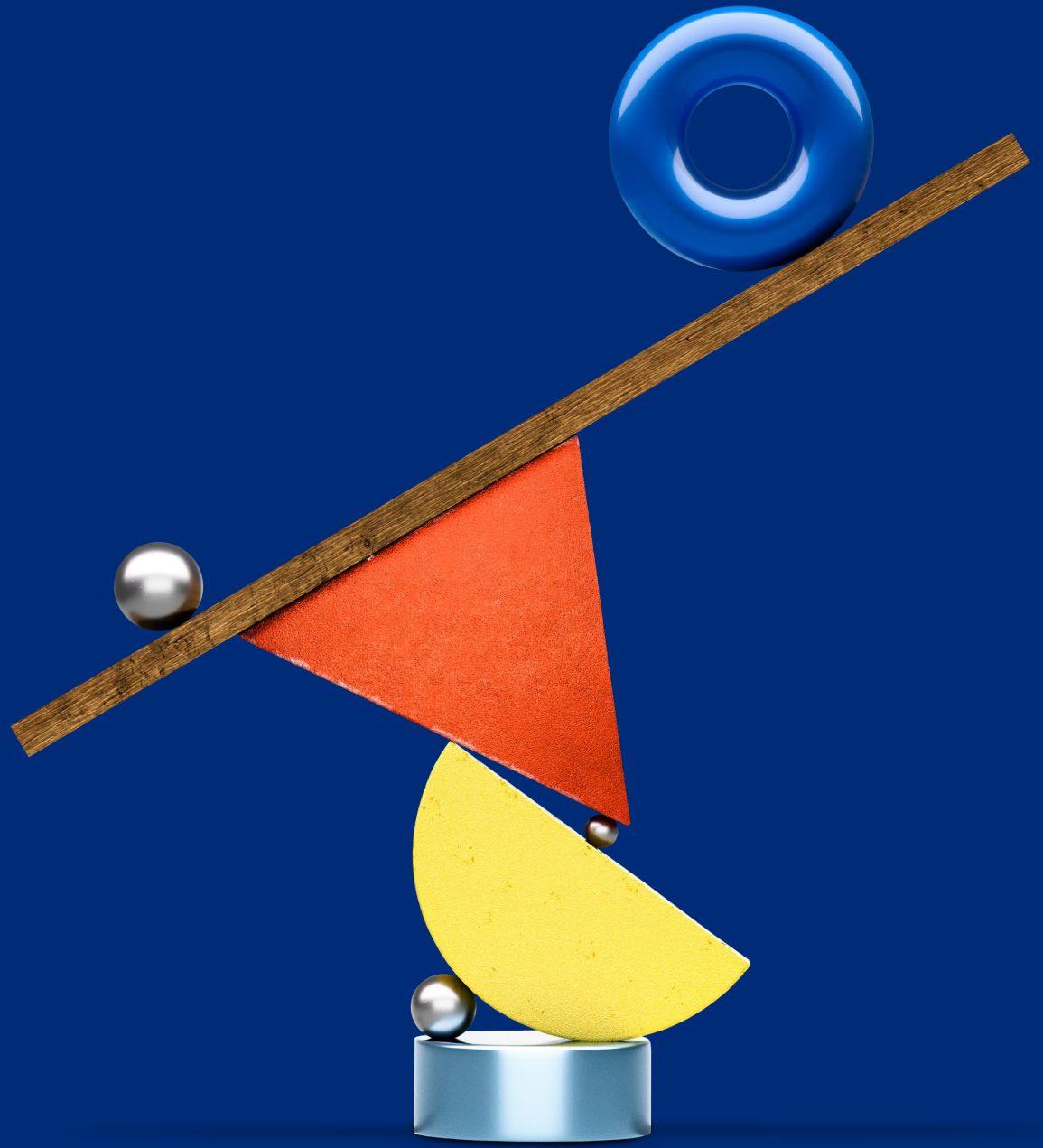
Drug	Condition	Approval Date	Total US Prevalence; Potentially Eligible Subset	Restrictions	One-Time Drug Cost
Zolgensma®	Spinal Muscular Atrophy (SMA)	May 2019	1 in 10,000 births	Age less than 2	$2.125 million
Zynteglo®	Transfusion-Dependent β-Thalassemia (TDT)	August 2022	1,000 prevalence	Ages 4 and older	$3.1 million
Hemgenix® and Beqvez™	Hemophilia B	November 2022 and April 2024	6,070 prevalence; 1,440 eligible	Ages 18 and older; no inhibitors	$3.5 million
Elevidys	Duchenne Muscular Dystrophy (DMD)	June 2023	10,000 to 15,000 prevalence; 8,200+ eligible	Ages 4 and older	$3.2 million
Roctavian®	Hemophilia A	June 2023	30,000 prevalence; 2,400 eligible	Ages 18 and older; no inhibitors	$2.9 million
Lyfgenia™ and Casgevy™	Sickle Cell Disease (SCD)	December 2023	100,000 prevalence; 20,000 eligible	Ages 12 and older with severe SCD	$3.1 million and $2.2 million

Fiscal Impact of Cell and Gene Therapies

- Member level data to support prevalence and eligible population estimates
- Member level drug utilization to support potential uptake estimates
- Provider relationships to understand member preferences and prescribing patterns
- Assessment of current policies that may limit access or otherwise affect current or future uptake rates
- Ability to engage in value-based purchasing (VBP) supplemental rebate agreements with manufacturers
- Ability to collect federal rebates for inpatient-administered CGTs
- Estimation of drug-specific cost offsets and/or ancillary costs

3

Risk Mitigation



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High Level Overview of Risk Mitigation Considerations

Managed Care Philosophy

Is there a risk of uneven distribution across MCOs?

What is the prevalence of the condition being treated?

How important is care management to this drug or condition?

How administratively complex is the risk mitigation?

How predictable is the utilization of the drug?

Is there a concern about overutilization?

Will the State pay a premium for the plan to manage the risk?

Advantages and Disadvantages

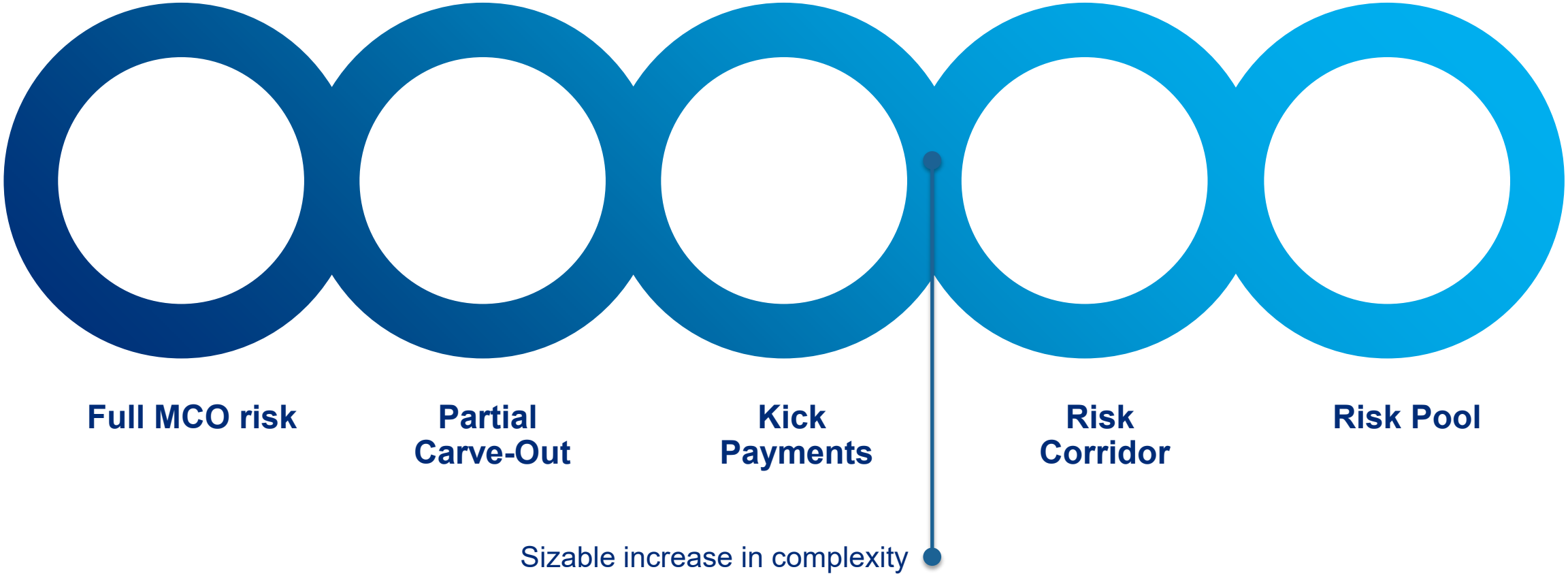
High-Cost Drug Risk Mitigation Options

	MCO Full Risk	Limited Carve-Outs	Risk Corridors	Kick Payments	Risk Pools	State Administered Reinsurance
Budget Predictability	+	–	–	–	+	+/–[1]
Incentive for MCOs to Manage Utilization	+	–	+	–	+	+
Incentive for MCOs to Manage Unit Cost	+	–	+	+	+	+
Directs Funds to MCOs with Highest Utilization	–	–	+	+	+	+
Maintains Integrated Managed Care Model	+	–	+	+	+	+
Requires Maintenance of a High-cost Drug List	–	+	+	+	+	–
VBP Operational Simplicity	–	+	–	–	–	–

[1] *Dependent on the design of the reinsurance. Capped reinsurance is more predictable than open ended reinsurance arrangements funded by the State.*

Administrative Complexity Continuum

Least Complex to Most Complex



Budget Predictability Continuum

Least Risk to the State to Most Risk to the State

Full MCO Risk Or Risk Pool

Risk Corridor

State Administered Reinsurance

Kick Payments

Carve Outs

Questions

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Guidehouse

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High-Cost Drugs

August 8, 2024

Agenda

01

Diabetes and Weight Loss Drugs

There is heavy focus on the GLP-1 drugs for weight loss and other possible indications. This presentation is an update and discussion of possible impact and future of this class of medicine.

02

CMS Sickle Cell Value-Based Payment (VBP) Model

CMS is launching a voluntary, value-based payment model for State Medicaid programs with CMS negotiating the deal terms through November 2024.

Diabetes and Weight Loss Drugs

GLP-1 Current State

Approval for Diabetes

Approval for Weight Loss

Approved for Cardiovascular Risk Reduction

Excluded from Medicare

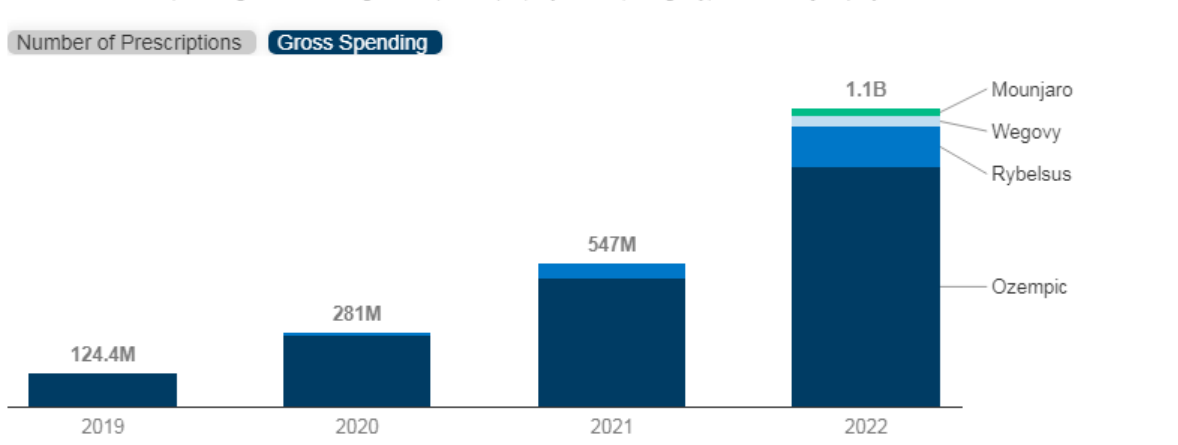
Medicaid GLP-1 Utilization

U.S. Medicaid Utilization from KFF vs Single State Findings

Figure 1

Medicaid Utilization and Gross Spending on New Drugs Used for Weight Loss has Increased Rapidly in Recent Years

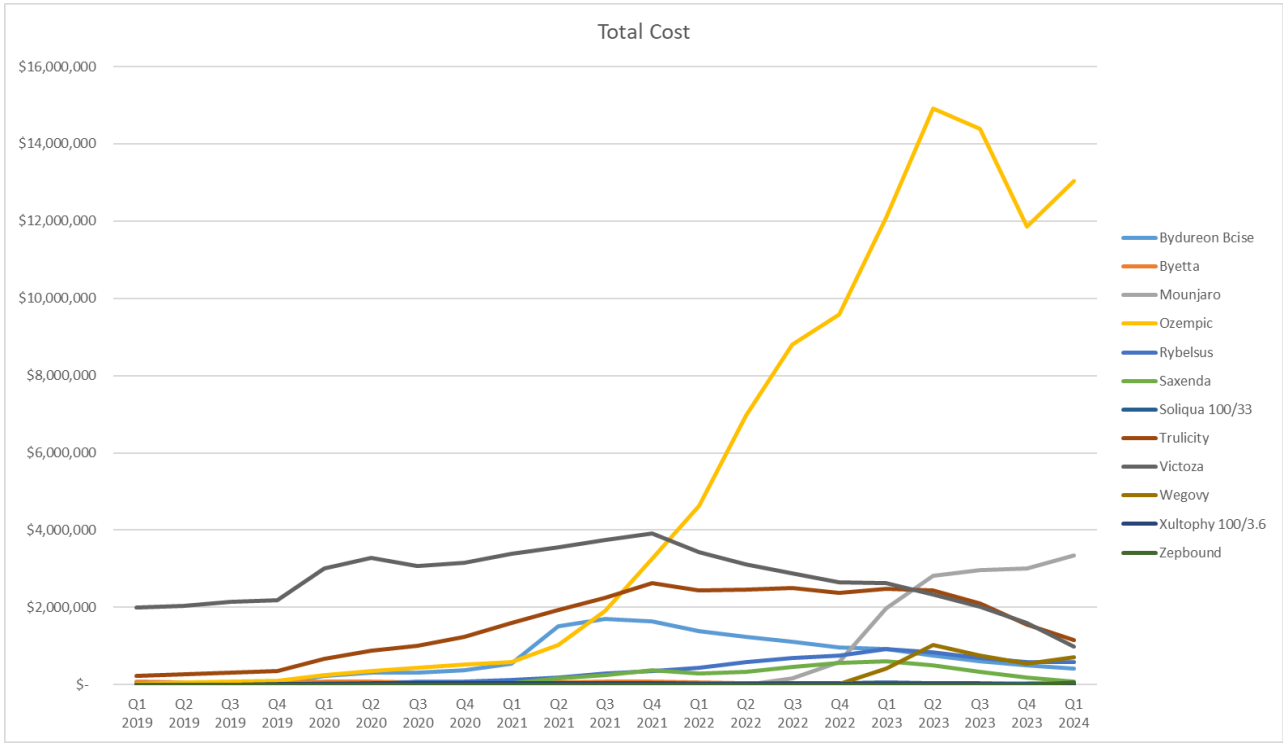
Medicaid Gross Spending on GLP-1 Agonists (Ozempic, Rybelsus, Wegovy, and Mounjaro) by Year



NOTE: GLP-1 = glucagon-like peptide-1. Gross spending is Medicaid spending before rebates. State Medicaid coverage of drugs approved for weight-loss (Wegovy in this analysis) is limited, but Ozempic, Rybelsus, and Mounjaro are approved to treat type 2 diabetes and covered by Medicaid in all states for that label indication.

SOURCE: KFF analysis of 2019-2022 State Drug Utilization Data, accessed August 2023. • PNG

KFF



GLP-1 Future Studies

- Heart Disease/ Cardiovascular Health
- Sleep Apnea
- Chronic Kidney Disease
- Alzheimer's Disease
- Parkinson's Disease
- Multiple Sclerosis
- Non-Alcoholic Fatty Liver Disease
- Addiction/ Substance Abuse
- Attention Deficit Disorder (ADD)
- Polycystic Ovary Syndrome (PCOS)
- Reducing Risk of Colorectal Cancer
- Possible Reduction In Other Cancers


GLP-1 Drugs Show Promise in Alcohol, Opioid Use Disorders

Published: Aug 03, 2023 | By Heather McKenzie

HEALTH

Fatty liver disease was alleviated by Lilly's 'triple-G' obesity drug in small study

By Elaine Chen June 26, 2023


Novo Nordisk's Ozempic cuts mortality risk in kidney disease

May 24, 2024 7:06 AM ET | Novo Nordisk A/S (NVO) Stock | LLY, BAX, DVA... | By: Dulan Lokuwithana, SA News Editor | 6 Comments


Eli Lilly's weight loss drug Zepbound found to reduce sleep apnea, company says

If the drug's approval is expanded to treat obstructive sleep apnea, insurers may be more likely to cover the pricy medication.


WEIGHT | NEWS

Could Blockbuster Weight Loss Drugs Also Be Used to Treat Heart Disease, Alzheimer's, and Cancer?

Researchers around the globe are betting that GLP-1 medications like Ozempic, Mounjaro, and Wegovy may help treat a variety of medical conditions.

By Becky Upham Fact Checked Published on January 5, 2024


'Ozempic babies' are surprising women taking weight loss drugs. Doctors think they know why.

Katie Camero
USA TODAY

Published 11:49 a.m. ET March 21, 2024 | Updated 7:46 a.m. ET April 17, 2024


HEALTH AND SCIENCE

Wegovy could prevent up to 1.5 million heart attacks, strokes over 10 years, study says

PUBLISHED WED, AUG 16 2023•4:38 PM EDT

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MEDICALNEWSTODAY

Can weight loss drugs actually help lower depression and anxiety risk?

New Potential Weight Loss Phase 3 Molecules

Company	Molecule/Product	Target	Administration Route
Boehringer Ingelheim	survodutide	GIP/GLP Glucagon receptor agonist	Subcutaneous (SC)
Eli Lilly	orforglipron	GIP/GLP Glucagon receptor agonist	Oral
Eli Lilly	mazdutide	GIP/GLP Glucagon receptor agonist	SC
Eli Lilly	retatrutide	GIP/GLP Glucagon receptor agonist	SC
Eurofarma Laboratorios	Sibutramine + Topiramate XR	Other	Oral
Novo Nordisk	Cagrilintide + semaglutide	Other	SC
Sciwind	ecnoglutide	GIP/GLP Glucagon receptor agonist	SC
Takeda	cetilistat	Gastric and pancreatic lipase inhibitor	Oral

Source: IQVIA, Fierce Biotech: A look at the R&D landscape in obesity, led by GLP-1s (fiercebiotech.com)

As new products enter the market, will prices of existing products abate?

Status of Data Protection and Global Patent Expiry for GLP-1 Receptor Agonist

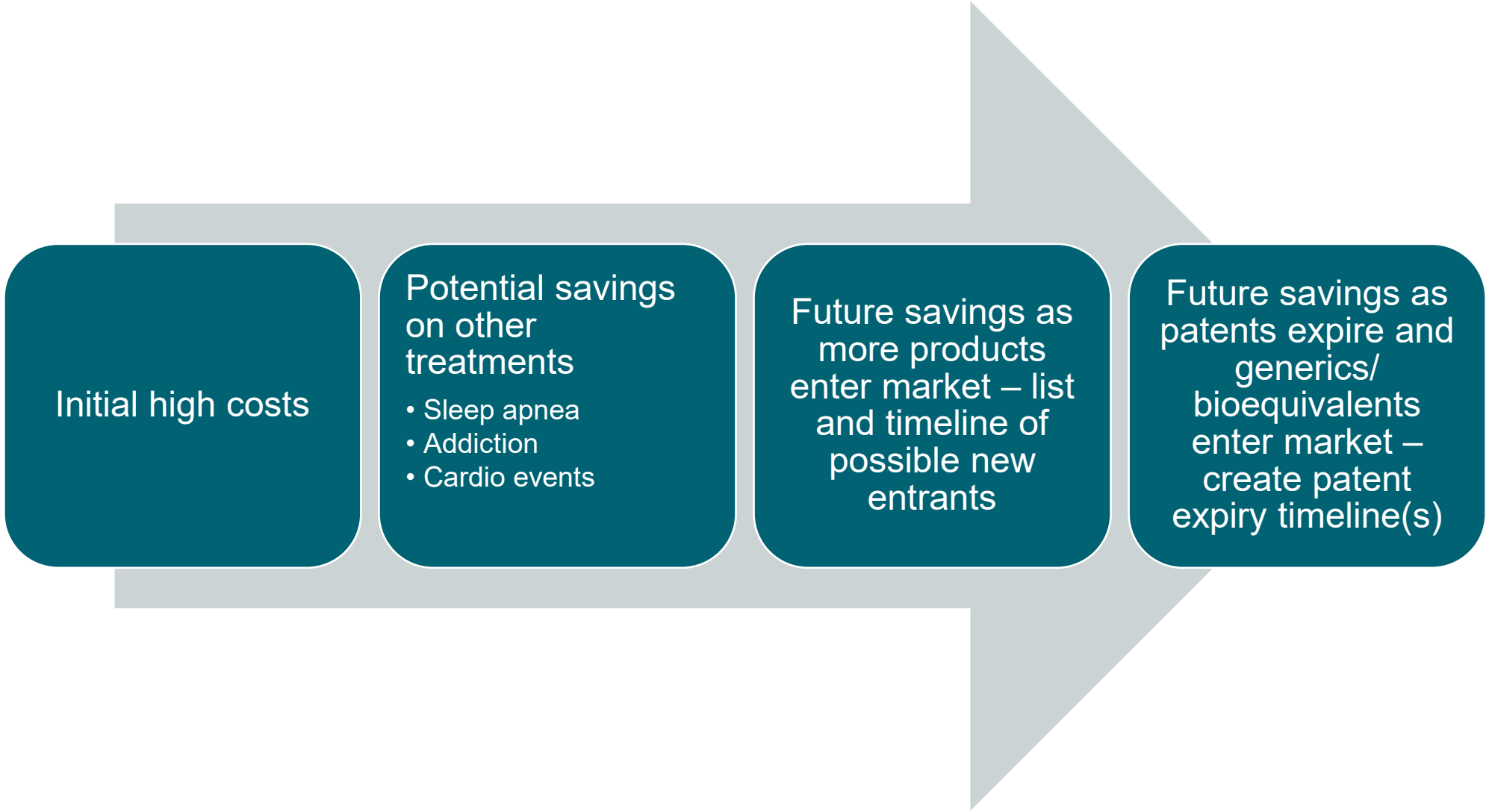
Generic name	Brand name	Data protection expiry date	Pediatric extension	Data protection ended	Global Patent end date (US is later)	Patent expired
				(yes/no)	(for longest filed)	(yes/no)
Semaglutide	Ozempic	4-Jan-26	NA	No	20-Mar-26	No
	Rybelsus	4-Jan-26	NA	No	20-Mar-26	No
	Wegovy	4-Jan-26	NA	No	20-Mar-26	No
Liraglutide	Victoza	21-May-18	NA	Yes	18-Nov-24	No
	Saxenda	21-May-18	NA	Yes	18-Nov-24	No
Liraglutide–insulin degludec	Xultophy	21-May-18	NA	Yes	18-Nov-24	No
Dulaglutide	Trulicity	10-Nov-23	NA	No	25-Sep-39	No
Lixisenatide	Adlyxine	25-May-25	NA	No	26-Oct-32	No
Lixisenatide–insulin glargine	Soliqua	25-May-25	NA	No	26-Oct-32	No

GLP-1 = glucagon-like peptide-1

Source: NIH: https://www.ncbi.nlm.nih.gov/books/NBK602920/table/t03/

As global patents expire, TBD on how US pricing is impacted.

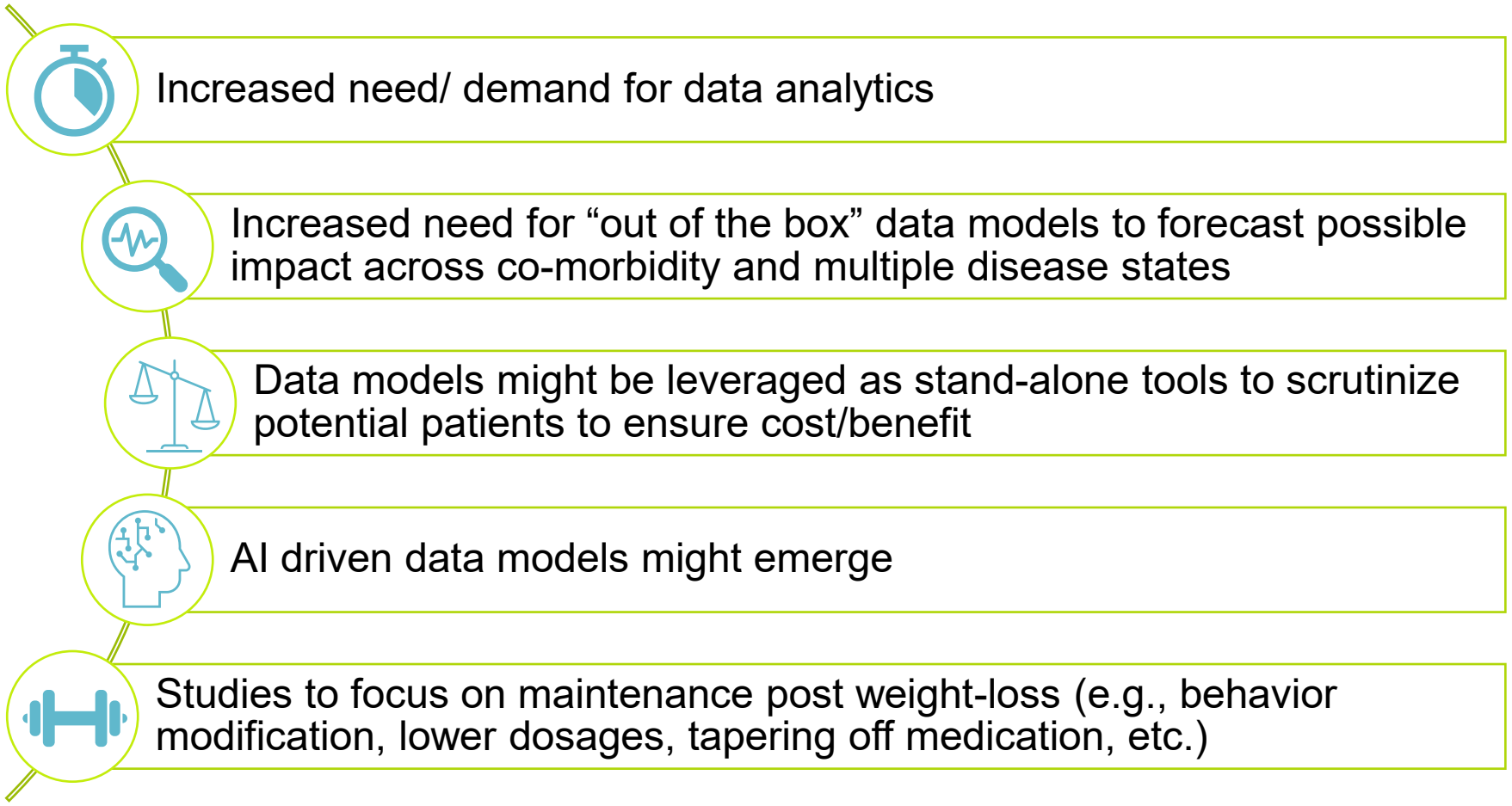
GLP-1 Financial Impact



GLP-1 Overall Impact to Payers

- Pressure to cover these drugs will continue to increase
- Pressure to find opportunities for potential savings on other covered products
- Possible prior authorization or combine with other services to try to measure/ increase savings/payback
- Increase interest in multi-state buying groups for Medicaid, etc.
- Once generics emerge on market, incredible price/ prescription swings to any new generics

GLP-1 Opportunities for Payers

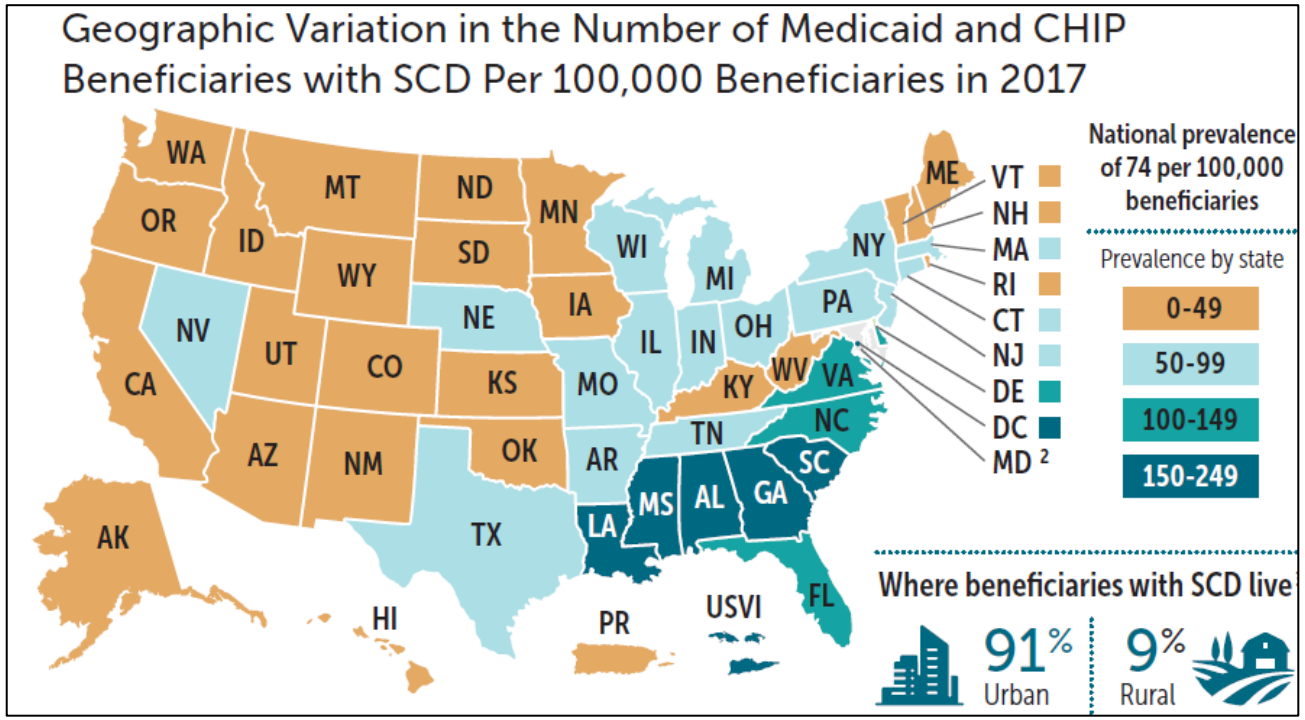


Sickle Cell Disease

Sickle Cell Disease (SCD) Fast Facts[1,2]

Medicaid has a high SCD prevalence, particularly concentrated in the South and in Black populations.

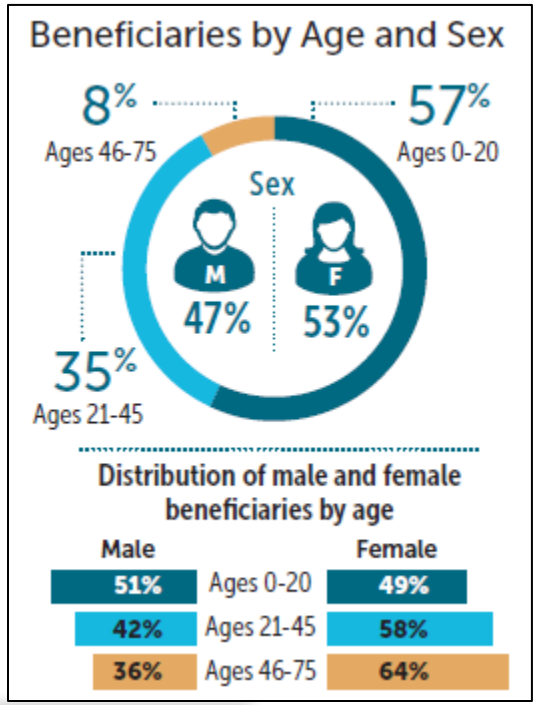
Prevalence is highly variable based on geography:



20,000: estimated Americans eligible for SCD gene therapy

42,000: estimated Medicaid SCD patients

100,000: estimated SCD patients in US



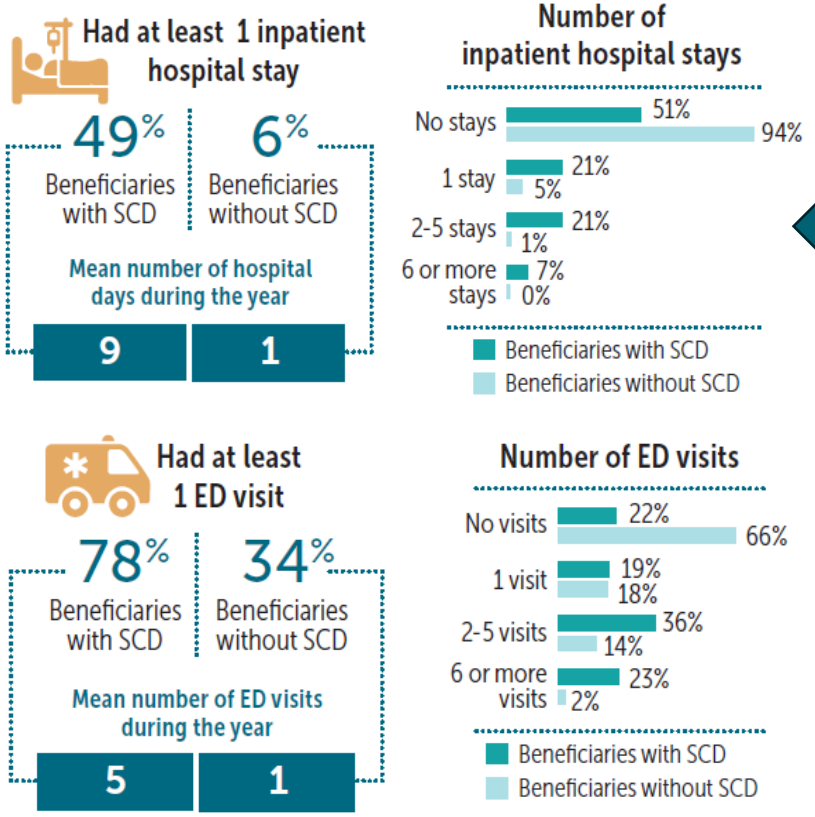
Sources:

1 https://www.medicaid.gov/medicaid/quality-of-care/downloads/sickle-cell-disease-infographic.pdf

2 https://www.nytimes.com/2024/05/06/health/sickle-cell-cure-first.html

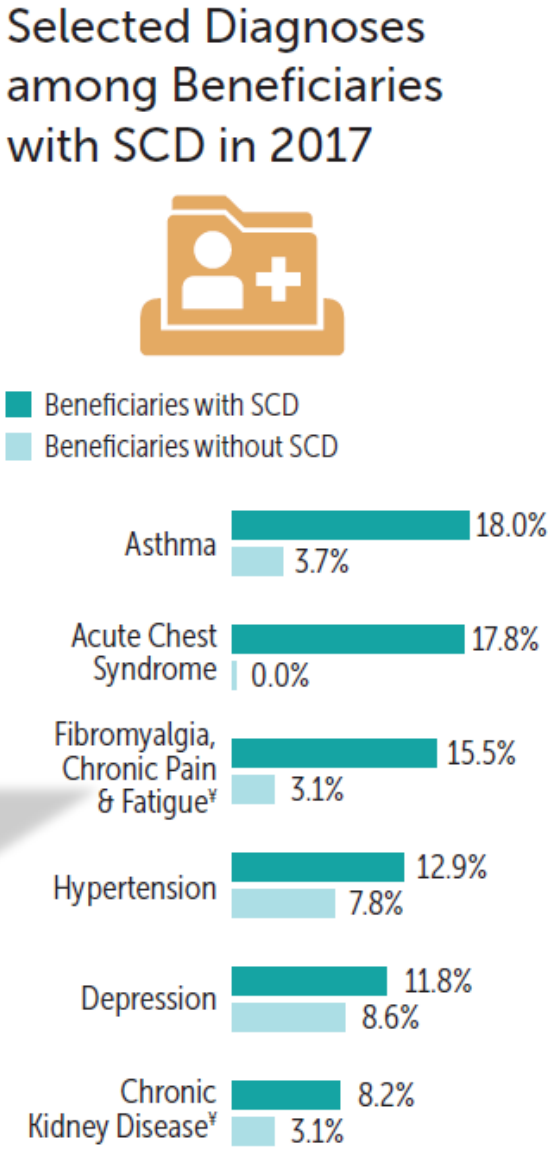
SCD Characteristics and Complications[1,2]

Lifetime medical costs associated with sickle cell disease average $1.7M.[3]



High Burden of SCD on Patients and Families

- CDC 2017 data study indicates high emergency department, inpatient, and outpatient usage
- Patients can experience extreme pain which is unable to be controlled even by opioids
- Life span can be 20 years less than average American



Sources:
1 https://www.medicaid.gov/medicaid/quality-of-care/downloads/sickle-cell-disease-infographic.pdf
2 https://www.nytimes.com/2024/05/06/health/sickle-cell-cure-first.html
3 Lifetime medical costs attributable to sickle cell disease among nonelderly individuals with commercial insurance | Blood Advances | American Society of Hematology (ashpublications.org)

SCD Impacts Beyond Healthcare[1]

SCD results in $1.5B in productivity and wage loss in the US annually, or $15k/year in lost wages per person.[1]

MISSED WORK

"Employed individuals **reported missing work an average of seven weeks per year** because of pain from sickle cell disease."

PAIN

"They reported **going to work while in pain an average of 100 days each year,** resulting in distraction and lost productivity."

OUTSIDE THE OFFICE

"75% reported impairment in their ability to complete everyday tasks, such as caring for children, running errands, doing housework, shopping for groceries and volunteering."

ADLs

"Respondents reported that pain from sickle cell **impaired their ability to complete activities of daily living on nearly three out of every 10 days** over the past year."

WAGE IMPORTANCE

"52% of respondents reported being the primary wage earner for their families.

Overall, 30% of patients reported having full- or part-time employment."

Sources:

1 The true cost of sickle cell disease: $1.5 billion in lost productivity per year - VCU News - Virginia Commonwealth University

Cell and Gene Therapy Treatment Background

Treatments are expensive and there are current capacity limitations on the number of patients who can be served.

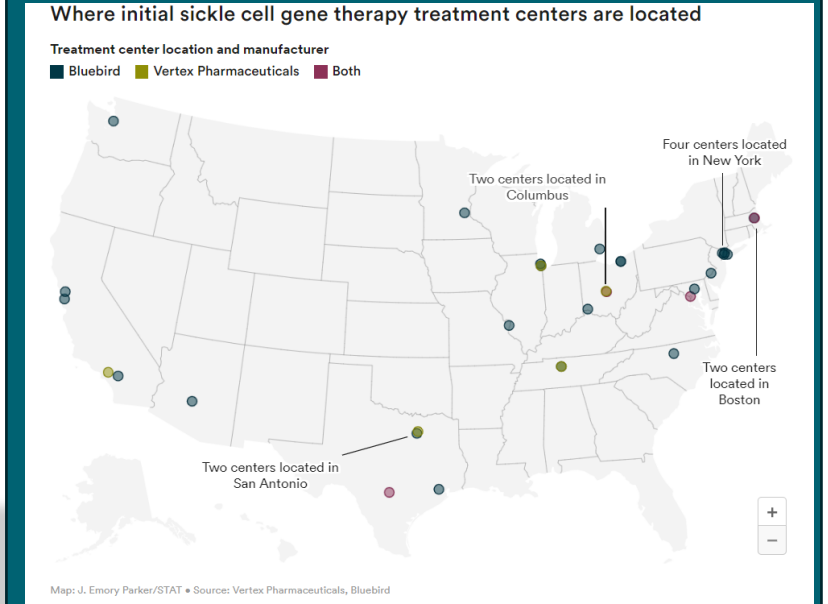
Costs

- **$1.7M: Avg lifetime medical costs** associated with sickle cell (pre-gene therapy treatments)[1]
- **$2.2M: Casgevy (Vertex) average cost per patient[2]**
- **$3.1M: Lyfgenia (Bluebird) avg cost per patient[2]**
- **Additional considerations:** weeks/months in hospital prior to delivery including chemo prior to stem cell implantation, fertility preservation coverage, travel expense coverage

Eligibility for Gene Therapy[2]

- "Clinical trials included 30-35 people with sickle cell, aged 12 to 35, who were, on average, experiencing **four severe pain episodes** per year and **just under three hospitalizations per year."**
- Bluebird estimates it can only treat **85-105 patients per year,** including sickle cell or beta thalassemia patients[3]
- One provider, Children's National, can accept only about 10 gene therapy patients a year.

Limited Treatment Center Locations[2]



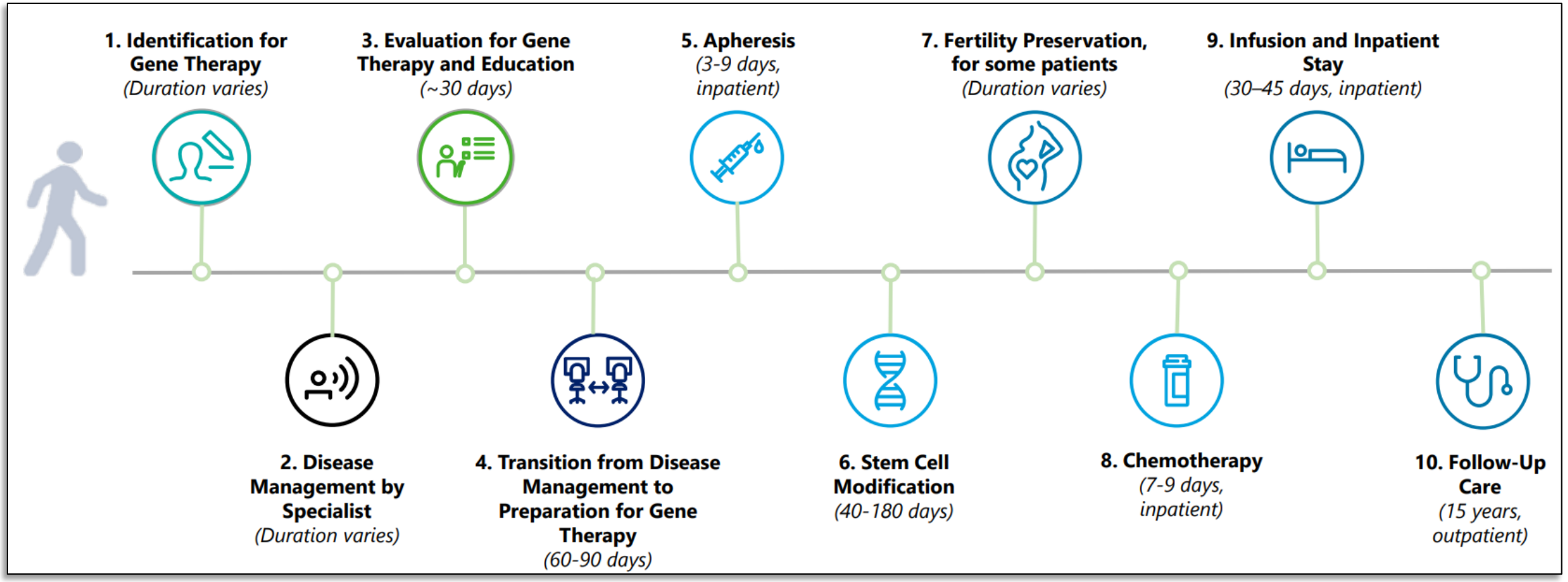
Sources:

1 Lifetime medical costs attributable to sickle cell disease among nonelderly individuals with commercial insurance | Blood Advances | American Society of Hematology (ashpublications.org)

2 FDA approves world's first CRISPR-based medicine for sickle cell (statnews.com)

3 https://www.nytimes.com/2024/05/06/health/sickle-cell-cure-first.html

The patient's care journey is long and complex[1]



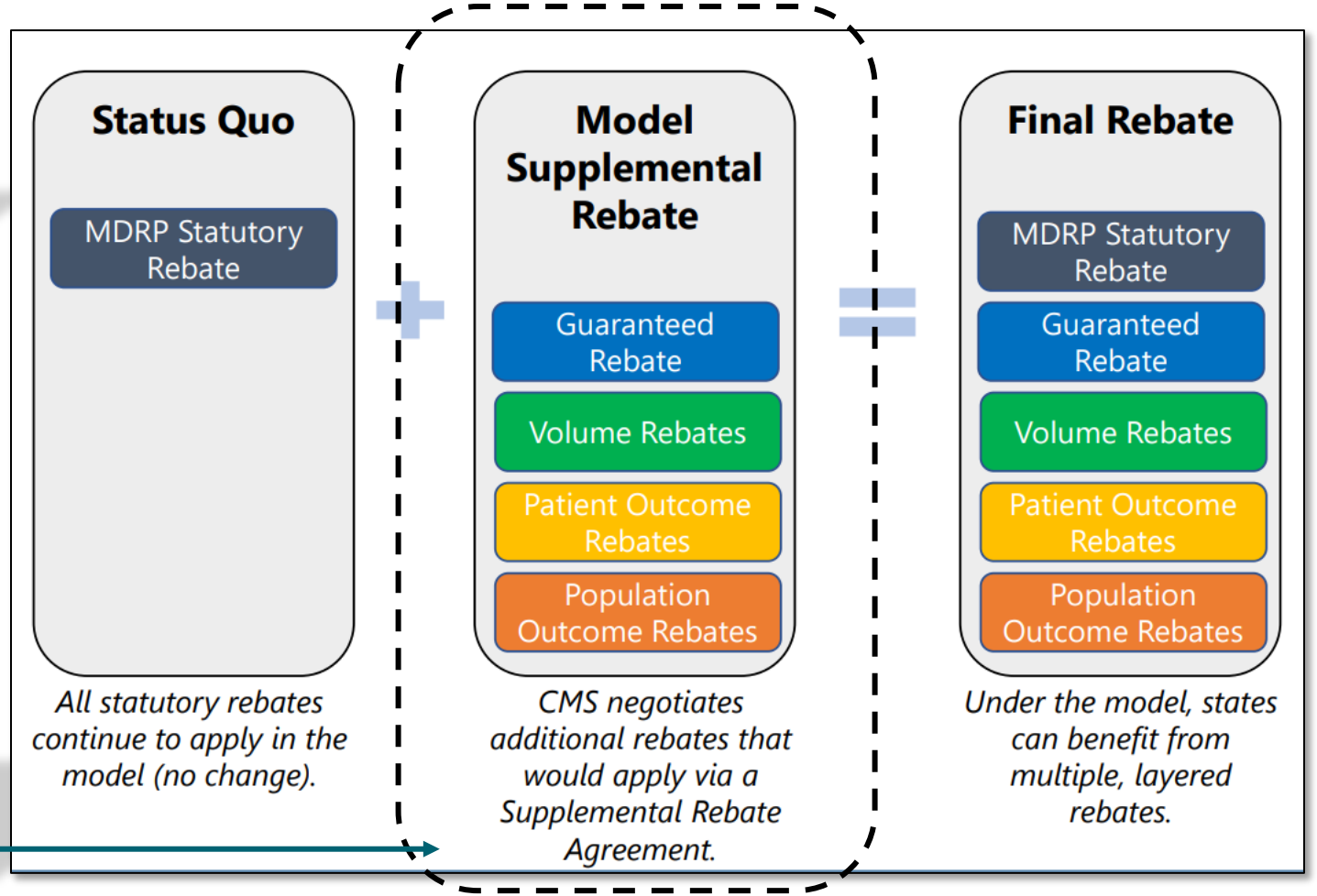
Sources:
1 Cell and Gene Therapy (CGT) Access Model Overview for States (cms.gov) (slide 21)

CMS Cell and Gene Therapy (CGT) Access Model

Outcomes-based model: An outcomes-based agreement (OBA) ties payment to the manufacturer to patients' health outcomes over a certain time period.

State Wins/Efficiencies:

- Less success on health outcomes → some manufacturer reimbursement
- Price concessions (e.g. volume-based rebates or guaranteed rebates).
- CMS-driven negotiations when Medicaid is the primary payer vs. state-by-state negotiation
- CMS establishing financial and clinical outcome measures, reconciling data, and evaluating results
- Pricing rebates based on outcomes

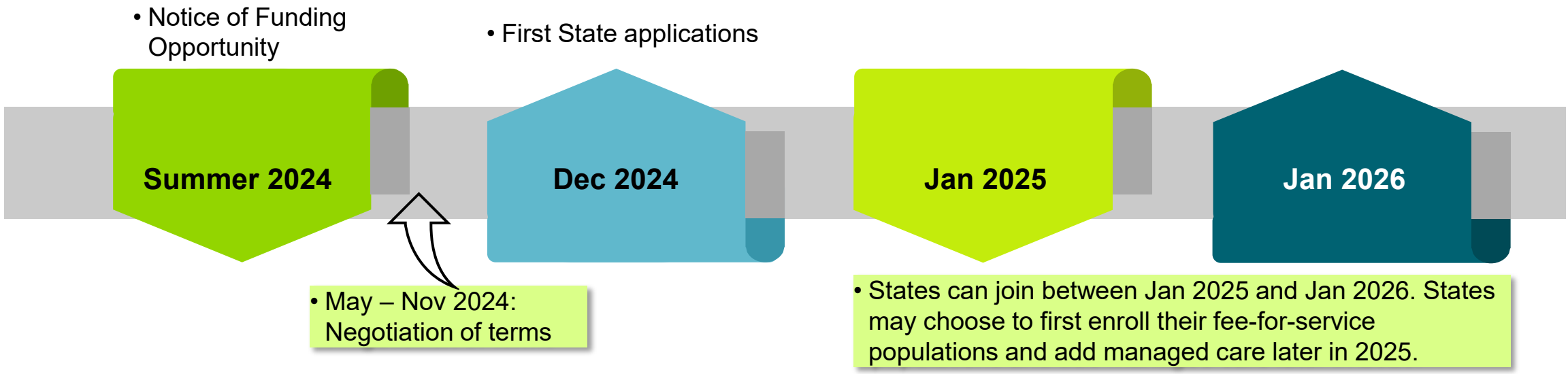


Sources: 1 Cell and Gene Therapy (CGT) Access Model Overview for States (cms.gov) (slide 25)

CMS Cell and Gene Therapy (CGT) Access Model

Much is happening in 2024-2025.

- All states and U.S. territories that participate in the Medicaid Drug Rebate Program (MDRP) are eligible to apply to participate in the model. Participation is voluntary.
- States encouraged to submit non-binding letters of intent.
- States have to meet minimum requirements to participate.



Sources:
1 CGT Access Model Frequently Asked Questions | CMS
2 Cell and Gene Therapy (CGT) Access Model Overview for States (cms.gov) (slide 25)

Other Considerations

States should consider a number of additional items in evaluating this model, particularly for states with managed care coverage.

- **Should a state consider carving these drugs out to fee-for-service to make the value-based payment easier to track and administer?**
- **If carved into managed care:**
  - Should the state consider implementing high-cost drug risk corridors, risk pools, or stop loss per patient if these mitigation techniques don't currently exist?
  - How might retroactive recoupments fit into overall program risk corridors?
- **Might a State use this as a test ground for pharmacy VBP?**

Questions?

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Thank You