

Cell and Gene Therapy (CGT) Access Model Overview for States

Center for Medicare and Medicaid Innovation
February 8, 2024

Housekeeping & Logistics

This event is being recorded. It is recommended that you listen via your computer speakers. Additional options for audio listening:

Dial-In: +1 929 436 2866

ID/Passcode: 946 7779 4039/ 099210

Closed captioning is available on the bottom of the screen.

Please submit comments in response to the event via the Q&A box on the bottom of your screen.

Please complete a short survey, which will be available at the end of the event.

Agenda

- 1** | Welcome and Introductions
- 2** | Model Overview
- 3** | Why States Should Join
- 4** | Potential Outcomes-Based Agreement Structure
- 5** | Ensuring Equitable Access to Sickle Cell Disease Gene Therapy Care
- 6** | State Participation
- 7** | Model Timeline
- 8** | Question & Answer Session
- 9** | Closing & Resources

Welcome and Introductions

Today's Presenters



Laurie McWright
*Deputy Director, Seamless
Care Models Group*



Melissa Majerol
*CGT Access Model Co-Lead,
Division of Drug Innovation,
Seamless Care Models Group*



Corinne Alberts
*CGT Access Model Co-Lead,
Division of Drug Innovation,
Seamless Care Models Group*



Caroline Horrow
*CGT Access Model Team Member,
Division of Drug Innovation,
Seamless Care Models Group*



Cathy Traugott
*Senior Policy Advisor, Division of
Pharmacy, Center for Medicaid and
CHIP Services*



Alexis Gibson
*Acting Division Director, Division
of Managed Care Policy, Center
for Medicaid and CHIP Services*



Jason Petroski
*Director
Division of Drug Innovation
Seamless Care Models Group*

Today's Objectives

This webinar will address the following questions:



MODEL FEATURES

- How will the CGT Access Model work?
- What might the CGT Access Model's negotiated deal look like?



STATE PARTICIPATION & SUPPORT

- Why should states join the CGT Access Model?
- How else does the CGT Access Model help states ensure access to gene therapy?
- What would states have to do to participate in the CGT Access Model?
- How can states join the CGT Access Model?

Model Overview

Model Framework

The CGT Access Model aims to bring states together to negotiate collectively with manufacturers, supported by CMS.

The Cell and Gene Therapy (CGT) Access Model is a framework wherein CMS negotiates with manufacturers on behalf of states for outcomes-based agreements (OBAs) for CGTs that cover Medicaid enrollees.



State Eligibility

Which states are eligible to participate in the CGT Access Model?



Who Can Apply

All states and territories that participate in the Medicaid Drug Rebate Program (MDRP) are encouraged to apply for the model.



Letter of Intent

States are encouraged to provide input on the model by meeting with the model team and submitting non-binding letters of intent (LOIs).



Model Start

States can apply to the model beginning in December 2024. The model will begin in 2025 with a “rolling start” – states can choose to begin participation from January 1, 2025, to January 1, 2026.

Model Populations

The CGT Access Model will focus on Medicaid beneficiaries with sickle cell disease (SCD) in participating states.



Primary Population

Beneficiaries for whom Medicaid is the primary payer and Medicaid expansion Children's Health Insurance Program (CHIP) beneficiaries ("Title XIX beneficiaries") in fee-for-service and Medicaid managed care.*

**The Model includes an option for manufacturers and states to include separate Title XXI CHIP beneficiaries through separate agreements.*

Eligible Beneficiaries

Beneficiaries in the model population with sickle cell disease (SCD) who receive a gene therapy made by a participating manufacturer.

Jan 1, 2025



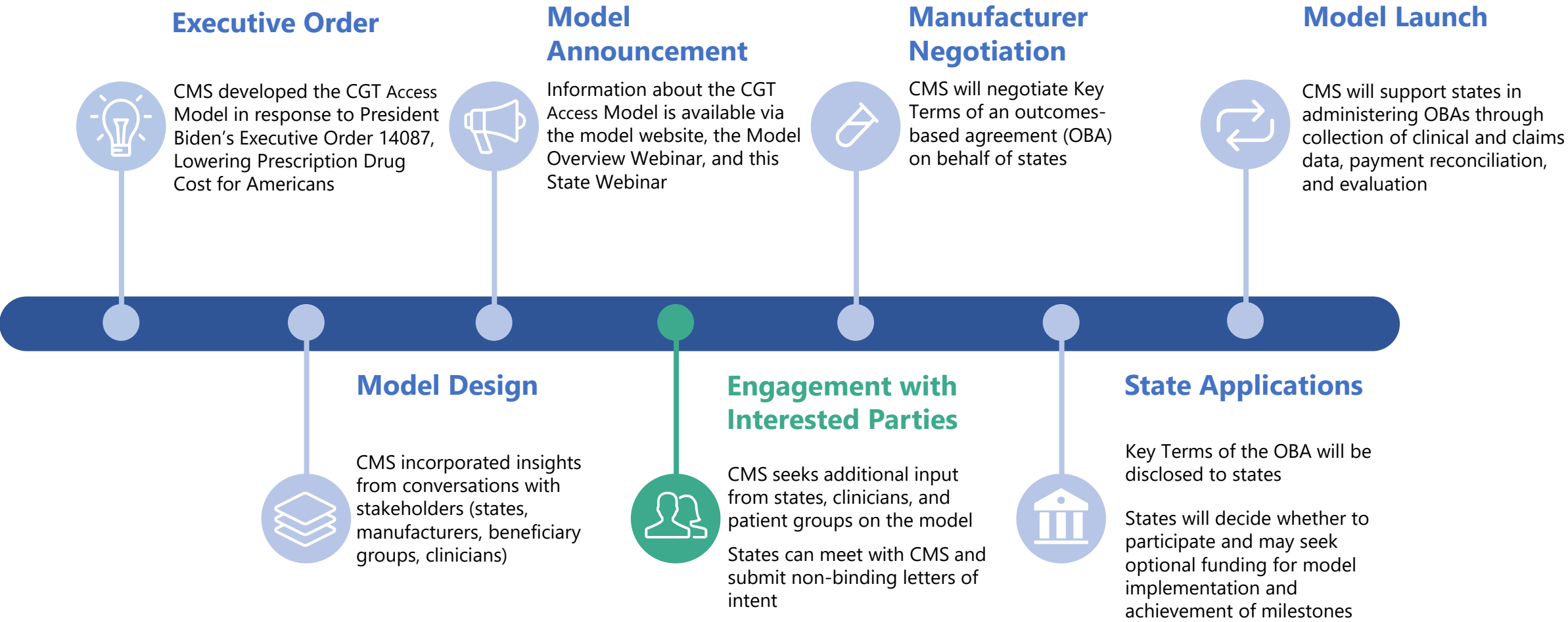
During the "rolling start" period (2025), states may choose to begin with only their fee-for-service members and bring their managed care lives into the agreement as late as January 1, 2026.

Jan 1, 2026



Where Are We Now?

CMS is currently engaging interested stakeholders to gather additional insights.



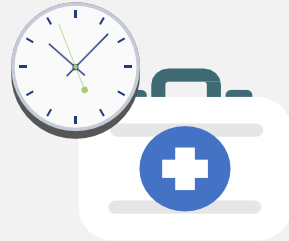
Why States Should Join

Challenges with Gene Therapy

The CGT Access Model aims to help states in the following ways:



High cost of expensive gene therapies



Clinical uncertainty for newly approved gene therapies



Burden of negotiating and implementing OBAs for gene therapies



Population with high health care utilization that has been historically underserved

CMS will be positioned to negotiate greater discounts through pooled, multi-state bargaining

OBAs provide the possibility of additional rebates in cases where treatment with gene therapies does not produce expected results

CMS will support states in implementing, monitoring, reconciling, and evaluating the financial and clinical outcomes outlined in OBAs

Greater access promotes health equity and may drive long-term reductions in health expenditures

CMS Support for States

States can negotiate supplemental rebates on their own, but through the CGT Access Model, CMS can offer:

1. OBA negotiation

- Burden of negotiating with manufacturers
- Greater leverage through pooled, multi-state bargaining, a standardized access policy across states, and manufacturer payment for certain fertility preservation services



4. Optional funding

- Support implementation of model requirements
- Support activities that promote equitable access to care and multi-disciplinary, comprehensive care

2. Favorable pricing and OBA structures

- Greater negotiation leverage may lead to discounted pricing
- Broader OBAs that incorporate multiple types of rebates
- Ability to incorporate multiple types of outcomes through claims data and partnerships with patient registries

3. Support in OBA implementation

- Technical assistance for model implementation
- Monitoring, reconciling, and evaluating the financial and clinical outcomes outlined in OBAs

Potential Outcomes-Based Agreement (OBA) Structure

Potential Negotiated OBA Key Terms

CMS will negotiate Key Terms of OBAs with manufacturers on behalf of states.

Key Terms may include...

Rebate structure

Standardized access policy

Manufacturer payment for fertility preservation

CMS support in OBA implementation

States will be responsible for their share of the gene therapy cost, but at a discounted price tied to specific outcomes, as negotiated by CMS.

Negotiation Timeline:

May 2024

November
2024

December
2024



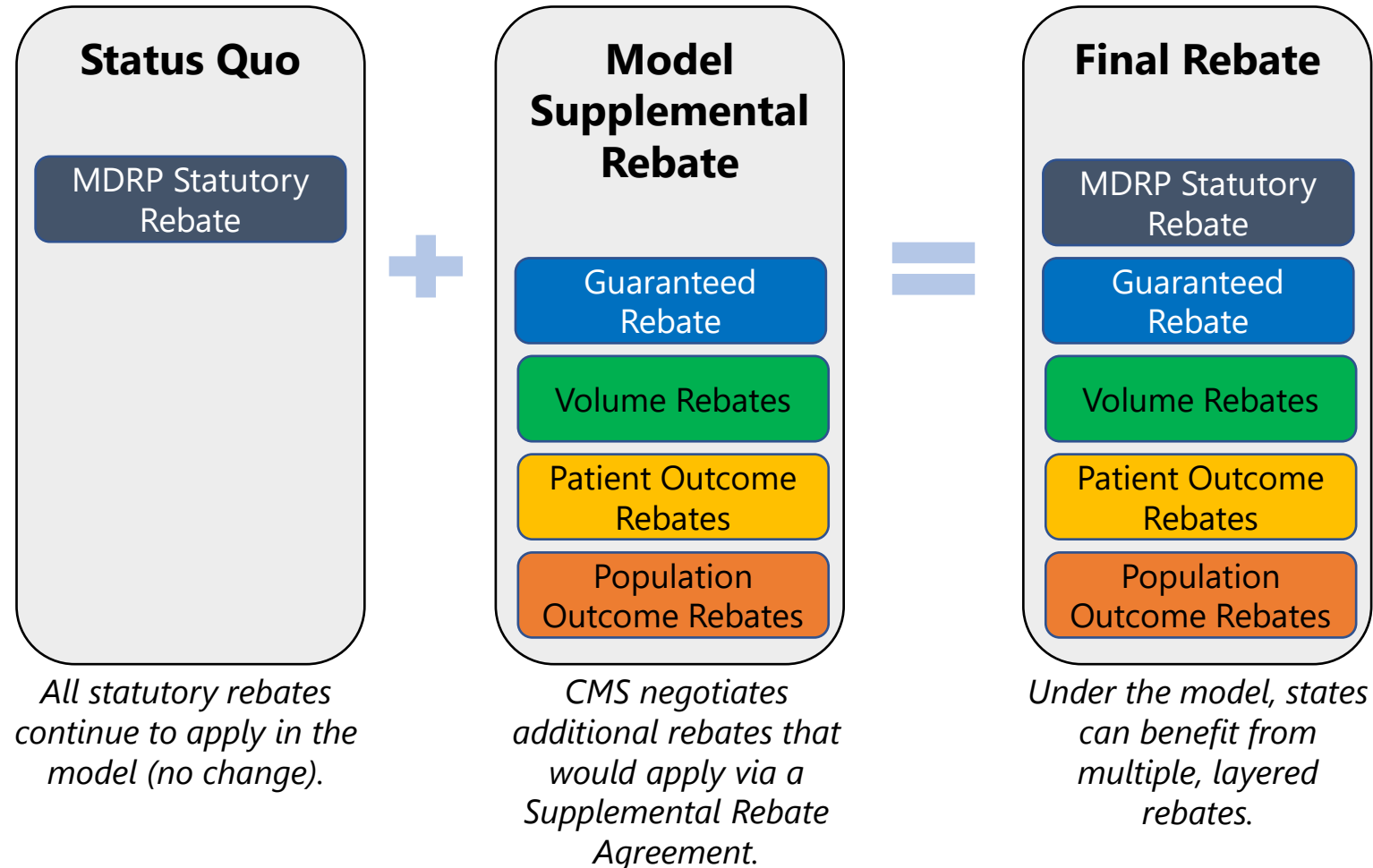
CMS will negotiate the Key Terms with manufacturers.

Key Terms will be disclosed to states.

*CMS intends to represent states' interests in negotiations.
States may express their priorities to CMS through a non-binding letter of intent (LOI) and by meeting with the model team.*

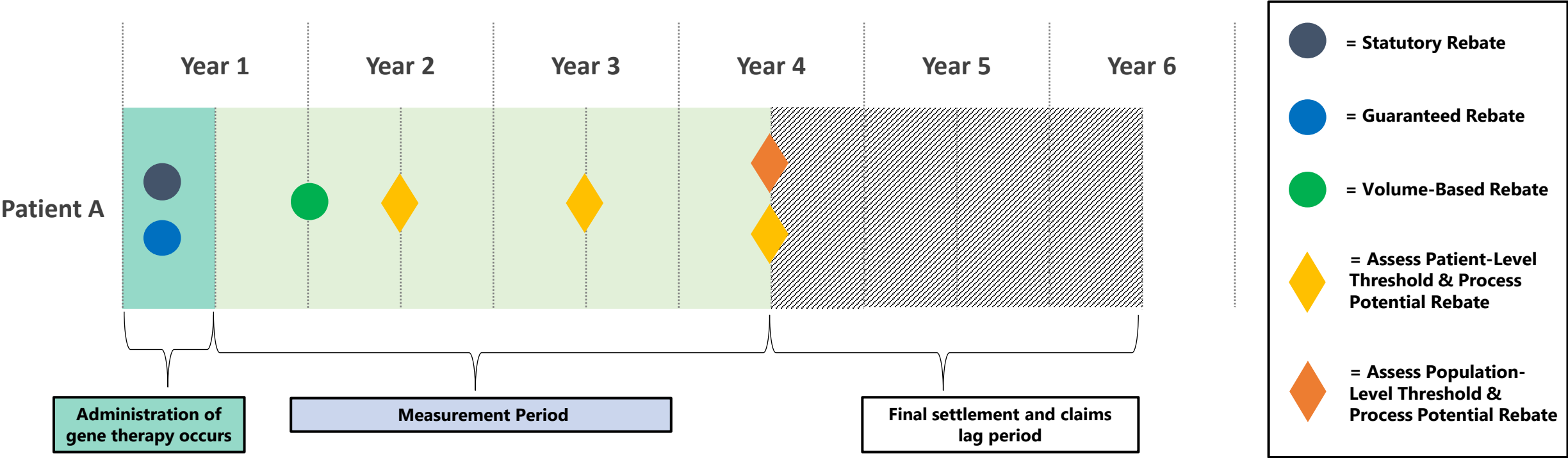
Potential Rebate Structure

Pricing may reflect both the statutory rebate and the CMS-negotiated rebates, including volume-based and outcome-based rebates.



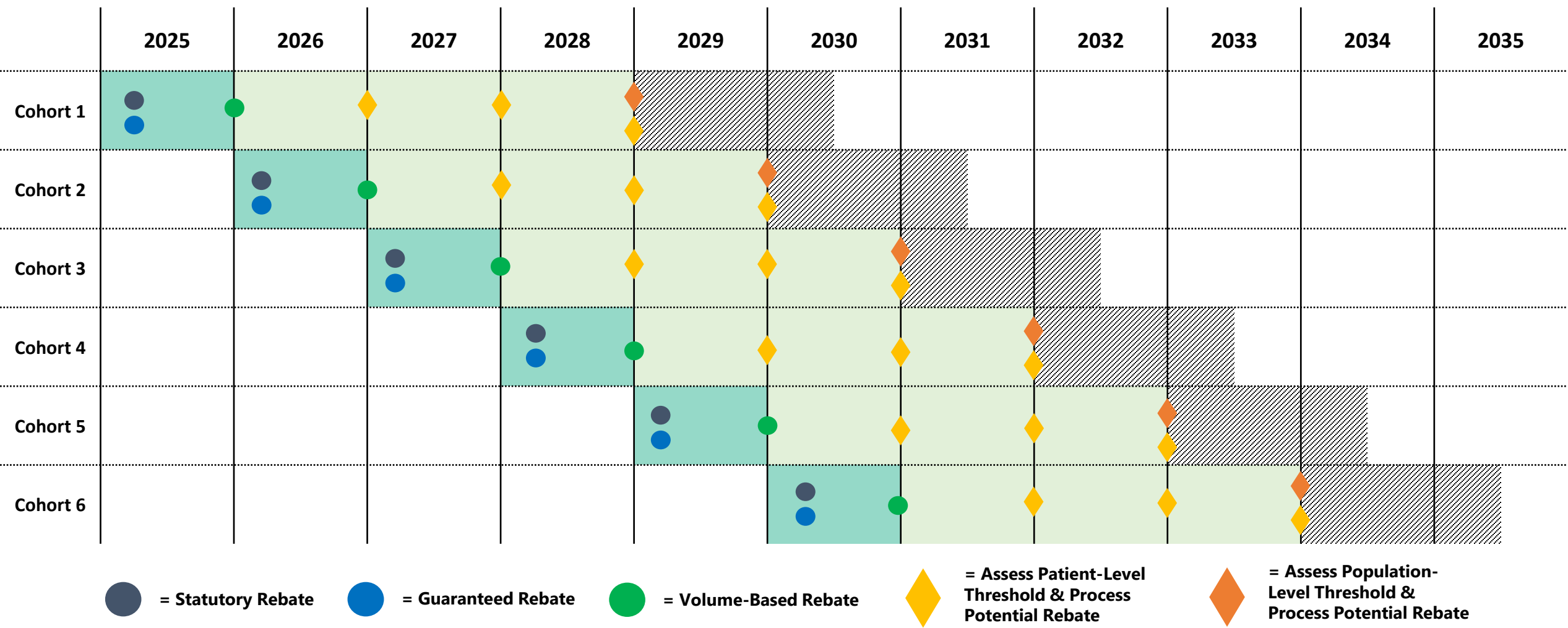
Potential Rebate Structure

Rebates may be paid over time, based on the rebate type.



Potential Rebate Timeline

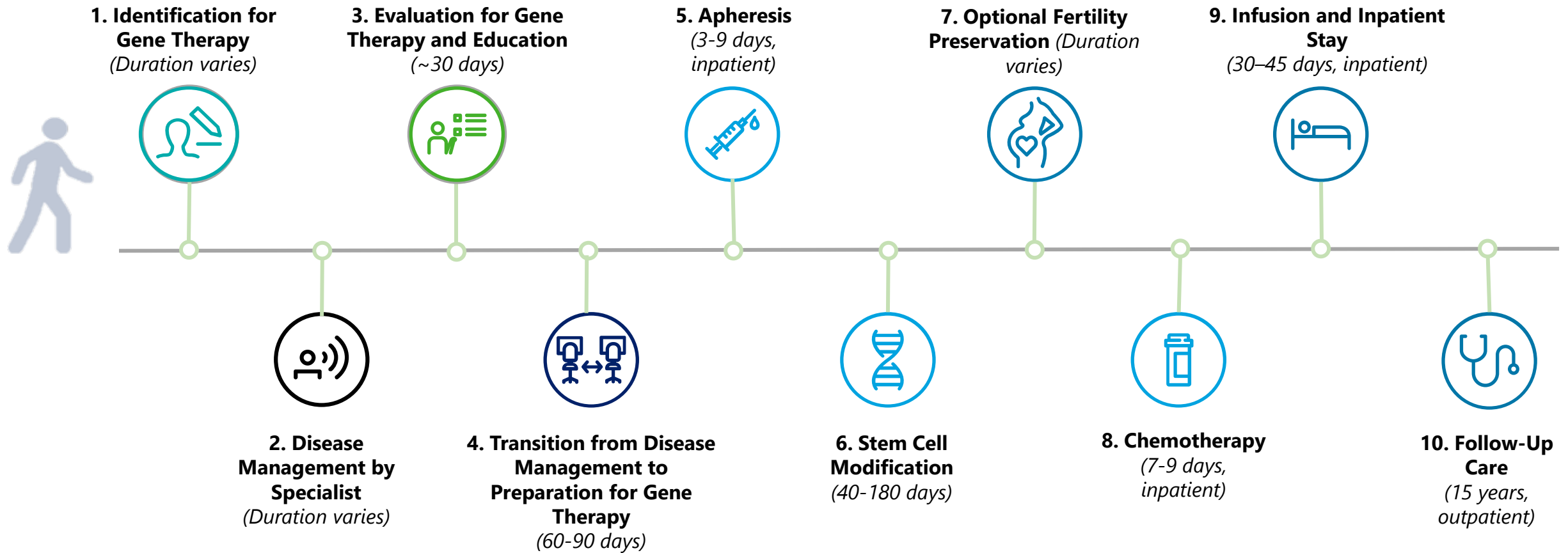
Multiple cohorts may be tracked over the model lifetime.



Ensuring Equitable Access to Sickle Cell Disease (SCD) Gene Therapy Care






Care Journey

The recommended care journey for SCD gene therapy is long, rigorous, and complex.



Funding to Address Gaps and Barriers

The CGT Access Model will provide optional state funding through a Cooperative Agreement. Funding will be available to help states implement the Model, as well as to support states that engage in activities that would increase equitable access to gene therapy and promote multi-disciplinary, comprehensive care for beneficiaries with SCD receiving gene therapy.

	Topic	Challenges	State Options to Address
	Patient Knowledge	<ul style="list-style-type: none"> • Patient awareness of gene therapy • Patient knowledge of & access to non-emergency medical transportation (NEMT) 	<ul style="list-style-type: none"> • Partnering with CBOs and non-profits • Directly expanding or increasing reimbursement rates for these benefits -- including through the existing optional SCD benefit. <p><i>More details will be released in a Notice of Funding Opportunity by Summer 2024.</i></p>
	SCD Care	<ul style="list-style-type: none"> • Access to SCD specialist • Access to out-of-state providers 	
	Other Specialty Care	<ul style="list-style-type: none"> • Access to behavioral health providers • Access to other specialty care services and providers 	
	Social Needs	<ul style="list-style-type: none"> • Health-related social needs (HRSNs), including childcare 	
	Care Coordination	<ul style="list-style-type: none"> • Care coordination / Patient navigation • Navigating changes in insurance coverage 	

Manufacturer Support to Address Barriers



Fertility Preservation

CMS will require manufacturers to pay for a defined scope of fertility preservation services.

- Manufacturers pay for collection, cryopreservation, and storage of reproductive materials in clinical trials
- Meets conditions of CMS-sponsored model safe harbor 42 CFR 1001.952(ii)
- May yield learning to inform state Medicaid agencies' future decision-making regarding coverage for fertility preservation services in connection with CGT



Treatment Centers

CMS intends to negotiate an access policy with manufacturers that ensures treatment centers offer appropriate, multi-disciplinary care.

- Behavioral Health Services (mental health, SUD treatment, pain management)
- Case Management

State Participation

Key Requirements for States

States participating in the CGT Access Model must meet the following requirements:*



Execute value-based purchasing supplemental rebate agreements (VBP SRAs) with manufacturers that reflect the Key Terms negotiated by CMS

Pursue state plan amendments (SPAs) where appropriate

Establish a standardized access policy for included gene therapies

Carve included gene therapies out of any inpatient payment bundle

Require providers to follow requirements for data reporting and claims submissions

Ensure beneficiaries have access to care with in-state or out-of-state qualified gene therapy provider(s)

Ensure necessary transportation and related travel expenses to beneficiaries (NEMT)

Meet minimum T-MSIS data requirements

* As applicable, these requirements apply with respect to a state's beneficiaries enrolled in fee-for-service and Medicaid managed care. As discussed earlier, a state may choose to begin in 2025 with only their fee-for-service members and bring their managed care lives into the agreement as late as January 1, 2026.

More details will be released in the State Request for Applications by Summer 2024.

Model Timeline

How to Join

Please keep in mind the important items and dates below:



Optional: Submit a non-binding LOI

- Letter of Intent (LOI) template is available now on the model website and has been emailed to states.
- Responses are important to help CMS represent state priorities in negotiation with manufacturers.
- **Was due April 1, 2024; extended to April 12, 2024.**



Required: Apply to join the model

- State Request for Applications will be released by Summer 2024.
- States can apply **December 2024 to February 2025**; CMS will review applications on a rolling basis.
- States may begin participation between January 2025 and January 2026.

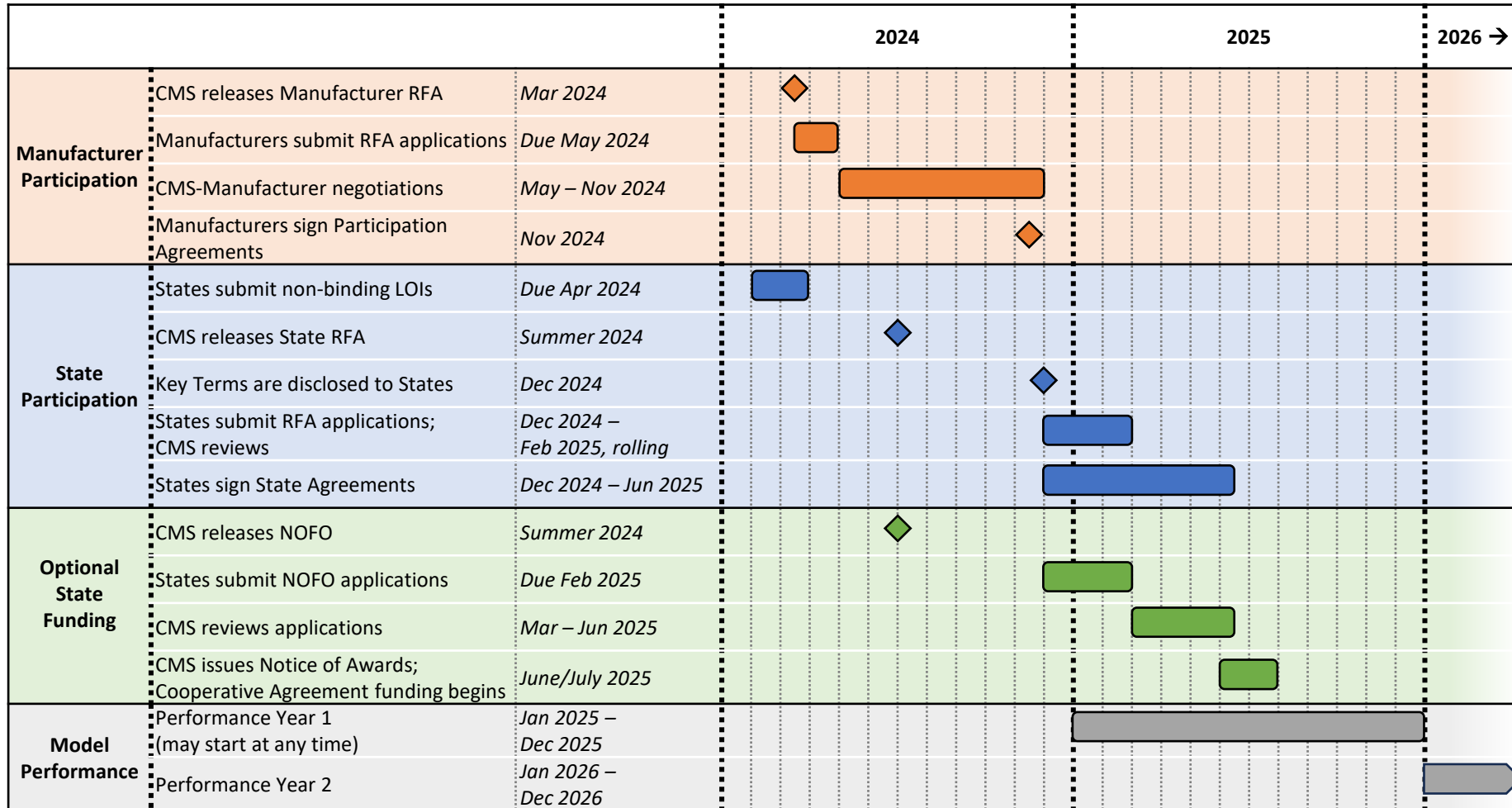


Optional: Apply for model funding

- Notice of Funding Opportunity (NOFO) will be released by Summer 2024.
- States can apply **December 2024 to February 2025**.
- CMS will issue Notice of Awards (and initial funding will be released) as early as June/July 2025.

Model Launch Timeline

Please keep in mind the important items and dates below.

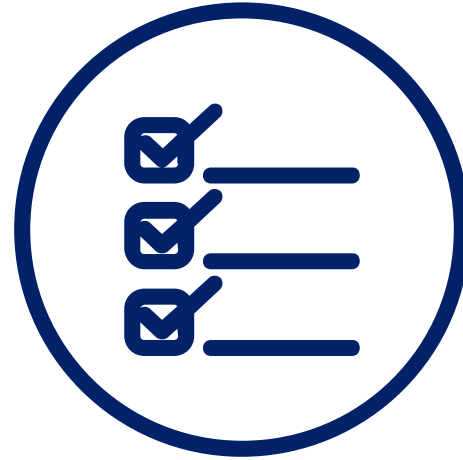


LEGEND

- Manufacturer activities
- State activities
- Funding timeline
- Model performance timeline

Question & Answer Session

Please Complete Our Survey



We appreciate your input!

Please click the link posted in the chat to take our survey.
We would love to learn how to make our events better.

Question & Answer



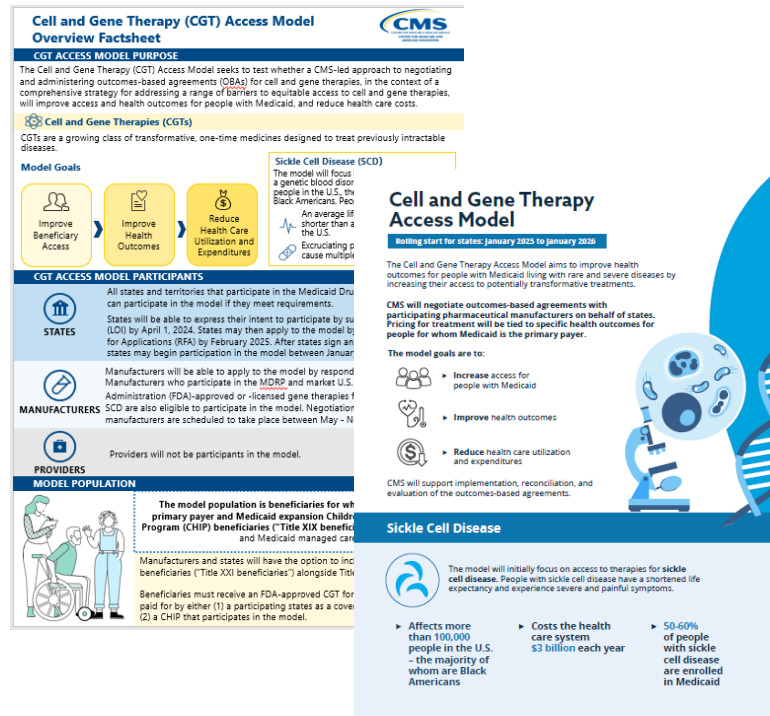
Open Q&A

Please **submit questions via the Q&A pod** to the right of your screen.
Specific questions about your organization can be submitted to
CGTModel@cms.hhs.gov.

Closing and Resources

Model Resources

The CGT Access Model team has a host of resources to support interested organizations. To see the latest resources, visit the model's website at <https://www.cms.gov/priorities/innovation/innovation-models/cgt>.



Model Factsheet and Infographic

Read through the [CGT Model Overview Factsheet](#) and the [CGT Model Infographic](#) on the model website to learn more.



State Letter of Intent (LOI)

[Non-binding LOI](#) was due April 1, 2024; extended to no later than 11:59pm EDT April 12, 2024



Helpdesk

If you have questions or would like to meet with the model team, please reach out to us via email at to CGTModel@cms.hhs.gov.

Thank You for Attending this Webinar



We appreciate your time and interest!

Please take the survey following this webinar so we can learn how to make our events better.

Do you have questions? Email your comments and feedback to CGTModel@cms.hhs.gov with subject line ***CGT Access Model State Announcement Webinar***

THANK YOU!