Cell and Gene Therapy (CGT) Access Model State Request for Applications (RFA)

Center for Medicare and Medicaid Innovation
July 29, 2024

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Agenda

1. Welcome and Introductions
2. CGT Access Model Overview
3. Request for Applications (RFA) Overview
4. Requirements for State Participation
5. CMS Support
6. Model Timeline
7. Question & Answer Session
8. Closing & Resources

Welcome and Introductions

Today's Presenters

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CGT Access Model Overview

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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.

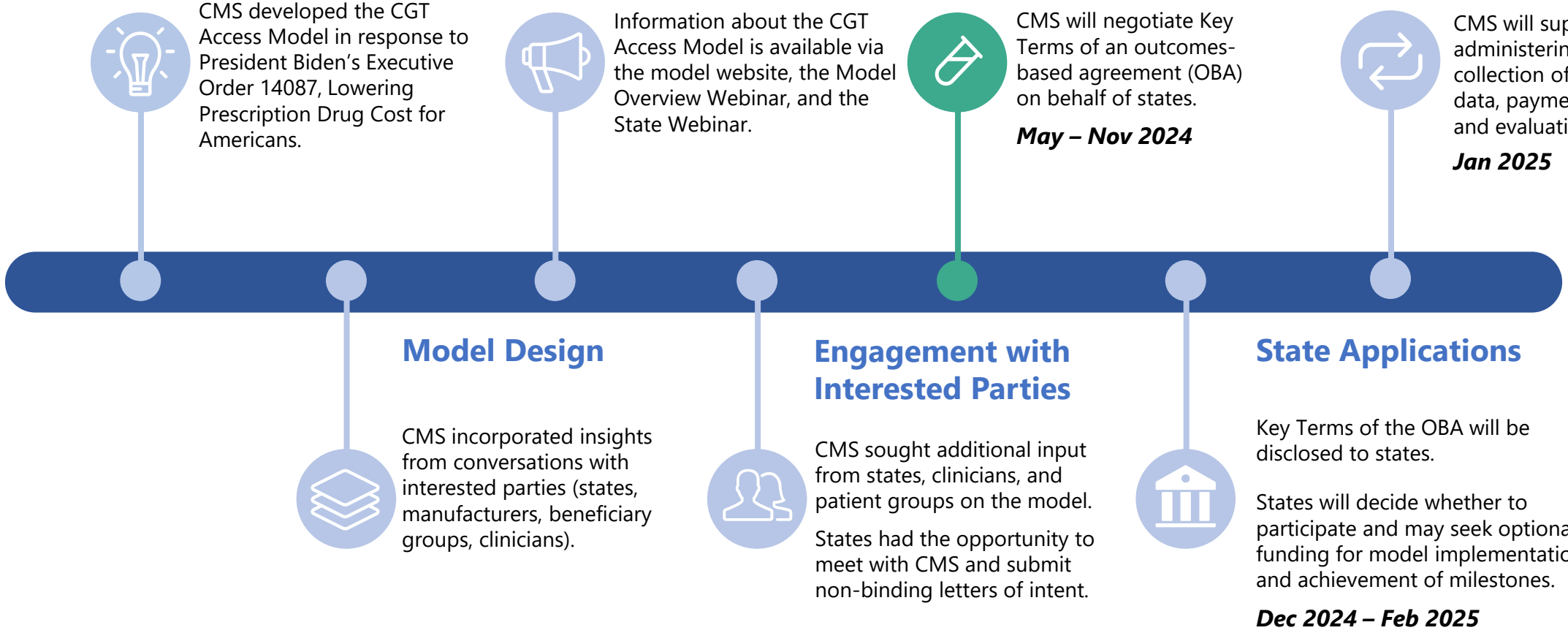
CMS directly negotiates Key Terms of OBAs with manufacturers

States decide whether to enter into agreements with manufacturers regarding OBA Key Terms

CMS supports implementation, reconciliation, and evaluation

Where Are We Now?

CMS has released the State Request for Applications. The application portal will open in December 2024.



Executive Order

CMS developed the CGT Access Model in response to President Biden's Executive Order 14087, Lowering Prescription Drug Cost for Americans.

Model Design

CMS incorporated insights from conversations with interested parties (states, manufacturers, beneficiary groups, clinicians).

Model Announcement

Information about the CGT Access Model is available via the model website, the Model Overview Webinar, and the State Webinar.

Engagement with Interested Parties

CMS sought additional input from states, clinicians, and patient groups on the model.

States had the opportunity to meet with CMS and submit non-binding letters of intent.

Manufacturer Negotiation

CMS will negotiate Key Terms of an outcomes-based agreement (OBA) on behalf of states.

May – Nov 2024

State Applications

Key Terms of the OBA will be disclosed to states.

States will decide whether to participate and may seek optional funding for model implementation and achievement of milestones.

Dec 2024 – Feb 2025

Model Launch

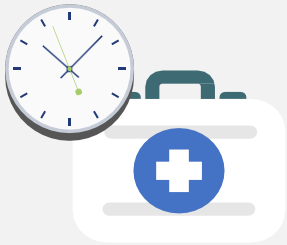
CMS will support states in administering OBAs through collection of clinical and claims data, payment reconciliation, and evaluation of data.

Jan 2025

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

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

4. Optional funding

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

Potential Negotiated OBA Key Terms

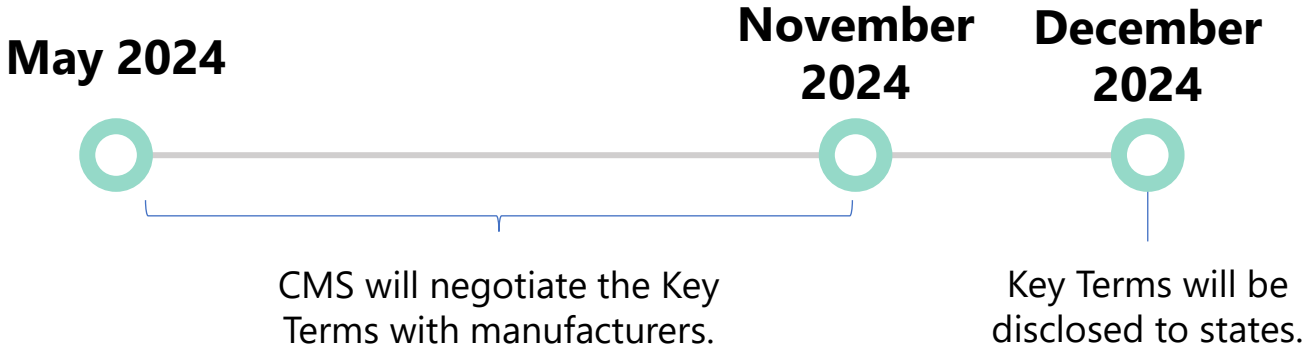
CMS will negotiate Key Terms of OBAs with manufacturers on behalf of states.

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:



CMS intends to represent states' interests in negotiations.

CMS has been engaging with states over the last few months to understand their priorities and is open to continued meetings.

Optional State Funding

In Summer 2024, CMS will release a Notice of Funding Opportunity (NOFO) for CGT Access Model participants, as well as a NOFO Factsheet summarizing key details.

States may choose to apply for model funding via the NOFO to support implementation activities and activities that help increase equitable access to SCD gene therapy.

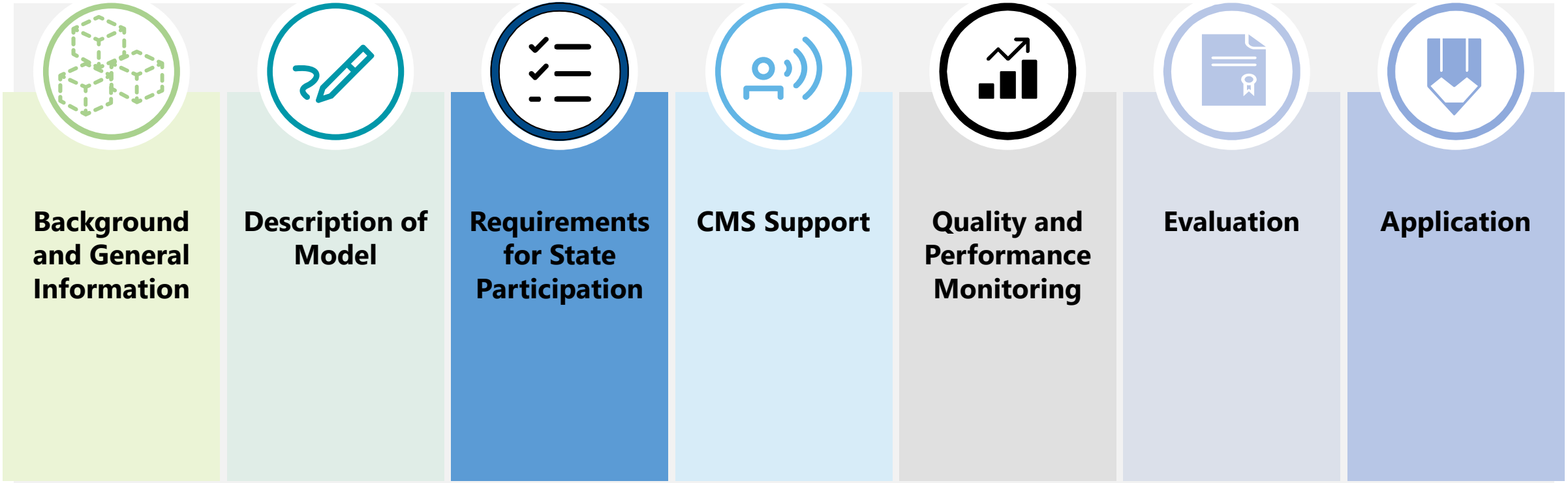
Applications for the NOFO will be due on February 28, 2025, through a separate submission process.

State participants that are awarded funding under the NOFO will receive a Cooperative Agreement award from CMS.

Request for Applications (RFA) Overview

State RFA Contents

The CGT Access Model State RFA includes the 7 sections outlined below.



An application template may be found in the State RFA in Appendix A.

State Eligibility (RFA Section 2.2)

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

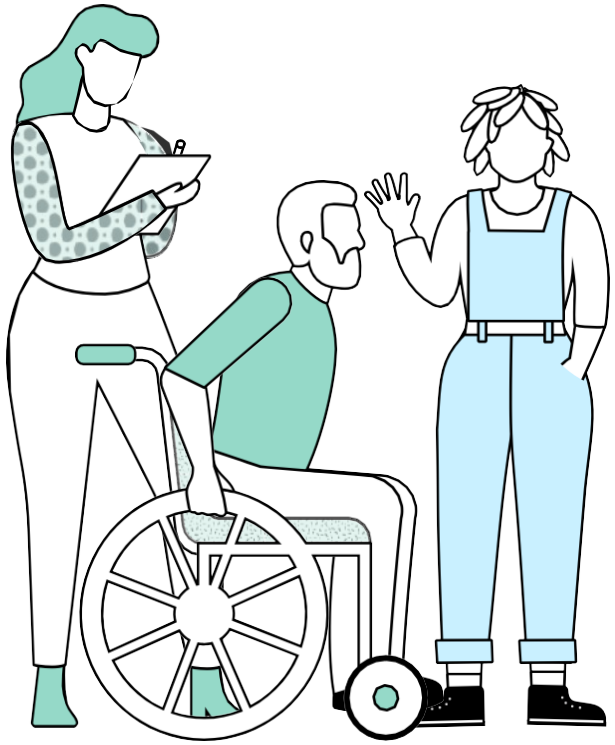
States may respond to the CGT Access Model State RFA even if they did not submit a preliminary non-binding Letter of Intent in response to the model announcement.

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 (RFA Section 2.3)

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 SCD who receive a gene therapy made by a participating manufacturer.

Jan 1, 2025

Jan 1, 2026

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.

Performance Period (RFA Section 2.4)

State applicants should keep the important dates below in mind.

Performance Period Start Date

States can begin performance on a date of their choosing from January 1, 2025, to January 1, 2026.

Managed Care Start Date

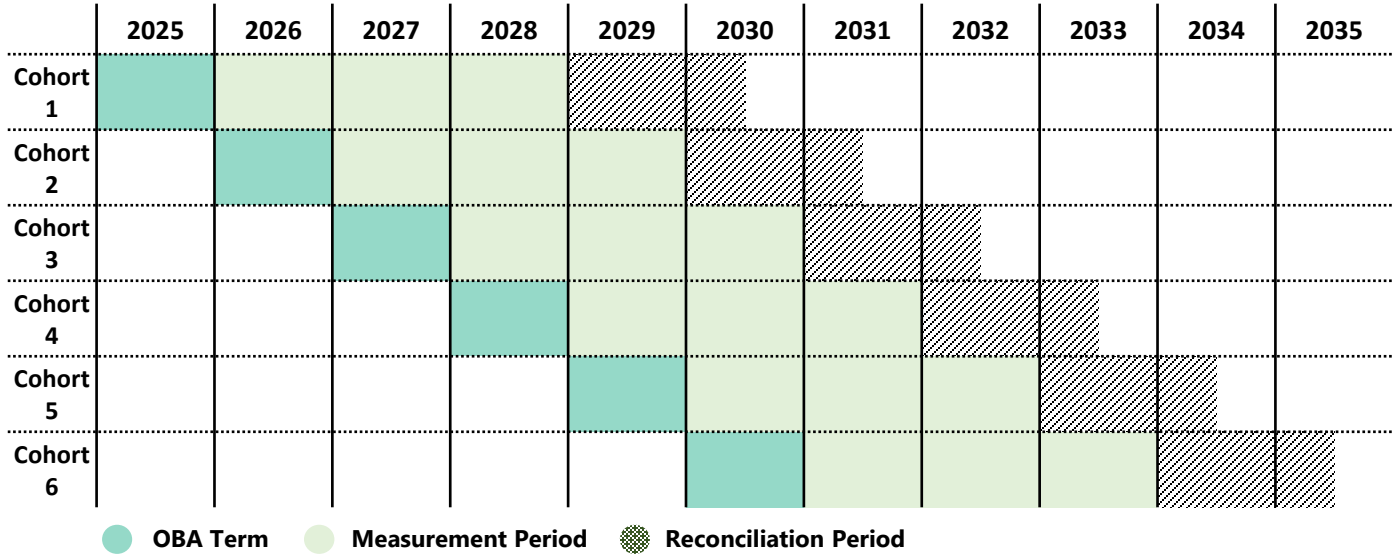
States may choose to begin performance in the Model with only their fee-for-service beneficiary population and bring their managed care beneficiary population into the model as late as January 1, 2026.

Separate CHIP Start Date

If CMS and a manufacturer have also negotiated separate CHIP Key Terms, states may choose to bring their separate CHIP beneficiaries into the model as late as January 1, 2026.

EXAMPLE PERFORMANCE PERIOD

The model is expected to consist of eleven Performance Years (PYs). Some state obligations will apply for the entire duration of the model, and others will only apply during certain periods.



Requirements for State Participation: Agreements with Manufacturers

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Value-Based Purchasing (VBP) Supplemental Rebate Agreement (SRA) for Medicaid Beneficiaries (RFA Section 3.2.1)

State participants must execute a VBP SRA with a participating manufacturer.

Participating states must select at least one Model Drug from a participating manufacturer as their **"State-Selected Model Drug(s)"** and adopt the Key Terms associated with that therapy.

If there are multiple participating manufacturers, states may change their selected drug during the performance period.

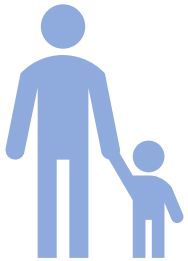
The VBP SRA must reflect the **Key Terms** as negotiated by CMS with the manufacturer, except as necessary to comport with state laws and regulations and as approved by CMS.

State participants must **renew and/or revise their VBP SRAs** as appropriate to ensure that State-Selected Model Drug(s) are governed by the Key Terms for the duration of the OBA Term.

Once its Model VBP SRA takes effect, a state participant may **not have any additional SRAs** for the State-Selected Model Drug(s) applicable to Medicaid beneficiaries during the OBA Term.

Optional VBP Agreement for Separate CHIP Beneficiaries (RFA Section 3.2.2)

State participants may choose to execute a VBP agreement for separate CHIP beneficiaries.



If CMS and a manufacturer have also negotiated **separate CHIP Key Terms** that apply to separate CHIP beneficiaries, states may choose to execute a **VBP agreement** with a participating manufacturer that reflects those separate CHIP Key Terms.

Requirements for State Participation: Operational Requirements

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Summary of Operational Requirements for State Participation

States participating in the CGT Access Model must meet the following operational requirements during the model.

Have the authority to implement the model, including CMS approval of a State Plan Amendment (SPA).

Establish a standardized Model Drug access policy consistent with CMS-manufacturer negotiated Key Terms.

Carve Model Drugs out of an inpatient payment bundle, if necessary, and make payment for the Model Drugs such that rebates under the MDRP apply.

Require providers to follow model-specific requirements related to registry participation and claims submission.

Not claim any costs paid for by a manufacturer (e.g., for certain fertility preservation services) as state expenses.

Ensure that applicable Medicaid managed care plan policies align with model requirements.

Legal Authority Requirements (RFA Section 3.1.1)

State participants must have, or obtain, the necessary authority to implement the CGT Access Model.

State participants must have an approved **State Plan Amendment (SPA)** allowing them to enter value-based purchasing (VBP) supplemental rebate agreements (SRAs).

Depending on state Medicaid program design, states may also need other **program waivers or state-level legislative changes**. States should consider any impact on existing section 1115 demonstrations.

States that need a SPA or Medicaid section 1115 demonstration authority to participate in the model should **meet with the Center for Medicaid & CHIP Services (CMCS)** as early as possible.

Standardized Access Policy (RFA Section 3.1.2)

State participants must establish a standardized Model Drug access policy consistent with the CMS-manufacturer negotiated Key Terms.

For each Model Drug, a standardized access policy will be described in the Key Terms and include:

Prior authorization

Utilization management

Provider qualifications

Patient eligibility criteria

- By the Performance Period Start Date, state participants must **establish an access policy** for the State-Selected Model Drug(s) that is consistent with the standardized access policy.
- States may create additional criteria within their access policy, as long as they are no more restrictive than the standardized access policy.
- State criteria and policies must be uniform across all beneficiaries enrolled in fee-for-service and Medicaid managed care plans within the state.

Model Drug Carveout (RFA Section 3.1.3)

State participants must carve Model Drugs out of an inpatient payment bundle, if necessary, and make payment for the Model Drugs such that rebates under the MDRP apply.

State participants must make payments to providers (e.g., hospitals, treatment centers, or specialty pharmacies) for State-Selected Model Drug(s) in the form **of direct reimbursement** in accordance with Section 1927 of the Social Security Act.

These reimbursements should **not be less than the actual acquisition cost**.

If a State typically pays for inpatient drugs administered as part of a bundled payment (e.g., Diagnosis-Related Groups (DRGs) or Ambulatory Payment Classifications (APCs)), it must **carve the State-Selected Model Drug out of the inpatient payment bundle**.*

*For more information, states can reach out to their pharmacy contact at the Center for Medicaid and CHIP Services.

Provider Reimbursement Requirements (RFA Section 3.1.4)

State participants must require providers to follow Model-specific requirements related to registry participation and claims submission.

A provider who submits a claim for administration of a State-Selected Model Drug **must be a member of the CMS-designated patient registry** for the model and **seek patient consent for a CMS-specified study.**

A provider who submits a claim for a State-Selected Model Drug must **adhere to the state's billing instructions**. CMS will provide states with billing instruction guidance.

State participants must require providers administering State-Selected Model Drug(s) to follow Model-specific requirements for registry participation and claims submission and must condition payment on ongoing adherence to these Model requirements.

Permissible State Expenses (RFA Section 3.1.5)

State participants must not claim any costs paid by a manufacturer as state expenses.

FERTILITY PRESERVATION

As part of the model, CMS will require participating manufacturers to provide payment for a defined scope of fertility preservation services for individuals who receive a Model Drug.

For more information, see the Manufacturer RFA published on March 7, 2024.

STATE REQUIREMENTS

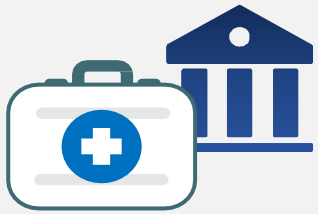
State participants must **not claim any costs for services paid for by a manufacturer as state expenses** for purposes of federal financial participation (FFP).

State participants will **certify** that the non-federal share for services provided under the CGT Access Model is obtained from **permissible state and/or local funds** that are not funds provided by the manufacturer to providers.

Managed Care Alignment (RFA Section 3.1.6)

State participants must ensure that applicable Medicaid managed care plan policies align with model requirements.

By the specified Managed Care Start Date, states must ensure that applicable Medicaid managed care plan policies are consistent with model requirements, such that the **Key Terms apply equally to fee-for-service (FFS) and managed care members.**



State participants must ensure **continuity of care** for model beneficiaries that switch between FFS and managed care coverage or among Medicaid managed care plans within the State.

States are **free to choose** how to manage their relationships with managed care plans, but must coordinate with plans to ensure beneficiaries receive relevant inpatient and outpatient services.

Requirements for State Participation: Beneficiary Access to Care

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Provider Network Adequacy (RFA Section 3.3.1)

States participating in the CGT Access Model must meet the following requirements for provider networks:

Attest that Model beneficiaries will have **access to gene therapy care** with at least one in-state or out-of-state SCD gene therapy provider.

Maintain a contract with at least one treatment center qualified to administer State-Selected Model Drug(s) and ensure enrollment in the state Medicaid program.

Publish the coverage criteria or utilization management policy for the State-Selected Model Drug(s) in a manner accessible by both enrolled and non-enrolled providers.

Submit to CMS a **template single case agreement (SCA)** for SCD gene therapy.

Identify a primary and secondary point of contact for providers regarding SCAs, prior authorization, and provider enrollment; make the contacts information available to all licensed SCD gene therapy providers; and respond to questions and requests in a timely manner.

Beneficiary Transportation (RFA Section 3.3.2)

States participating in the CGT Access Model must meet the following requirements for transportation support.

Cost of Meals

Cost of Lodging

Cost of a Transportation Attendant (when necessary)

Medicaid's **assurance of transportation** requires states to ensure that every beneficiary has access to transportation needed to receive covered services.* This includes necessary travel-related expenses like those above.

Attest that the state will ensure timely non-emergency medical transportation services and related travel expenses to model beneficiaries and applicable caregivers.

Describe how the state will communicate these services to beneficiaries and make them accessible in a timely manner.

*States should review the Medicaid Transportation Coverage Guide for more information on requirements and flexibilities regarding Medicaid's transportation assurance.

Requirements for State Participation: Data and Reporting

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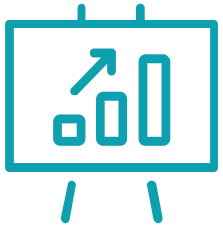
Data Submissions (RFA Section 3.4.1)

State participants must meet minimum data requirements and conduct data quality activities.

States will submit Medicaid claims data to CMS throughout the Model via the Transformed Medicaid Statistical Information System (T-MSIS), with potential other pathways if necessary.

Starting in PY2 (January 1, 2026), state participants must **meet (or have a plan in place to meet) the data quality expectations** specified in the T-MSIS Outcomes Based Assessment criteria:

- Critical priority issues
- High priority issues
- Expenditures



States must **conduct data quality activities** to comply with data quality targets and action plans. States can check and address potential data quality issues through the T-MSIS Operations Dashboard available on the CMS Enterprise Portal.

CMS will provide states with data quality technical assistance to monitor and address specific data quality issues. States must **cooperate with CMS to resolve data quality issues.**

Reporting (RFA Section 3.4.2)

State participants must submit reports to CMS on model implementation.

Each state must submit **documentation** to CMS to verify that the state has met the requirements for model participation. This may include:

- SPA for VBP SRAs approved by CMCS
- Published coverage policy or utilization management policy
- Provider billing instructions

State participants will also submit **quarterly reports** on model implementation and performance. These may include:

- Data on the amounts of supplemental rebates owed to and paid to the state by participating manufacturers under the OBA
- Information about gene therapy provider network and beneficiaries seeking SCD gene therapy
- Updates to state law or program policies that are relevant to the model

CMS Support

CMS Support (RFA Section 4)

CMS will perform certain activities to support the CGT Access Model.

Compiling, auditing, and analyzing data necessary to support the model*

Collecting data and assessing whether the outcome measure benchmarks are met

Determining the resulting financial obligations and sharing reports with states and manufacturers

Offering direct technical assistance to states to support implementation of model requirements

Providing states the opportunity to participate in a learning system designed to support their success in achieving the aims of the model

*Data may include utilization data, claims data, patient registry data, and patient-reported outcome measures (PROMs)

Model Timeline

Application Submission (RFA Section 7 & Appendix A)

States should keep in mind the following dates.

States may submit applications to participate in the CGT Access Model after the negotiated Key Terms have been communicated to states in December 2024. **The application portal will go live in December 2024 and will be open through February 28, 2025.**

States must submit applications at least 10 business days prior to their requested Performance Period Start Date. For example, if a state wishes to begin performance on January 1, 2025, its application must be submitted no later than December 16, 2024.

June 2024
State RFA released

Dec 2024
Key Terms disclosed to states, application portal opens

Jan 1, 2025
Performance Year 1 begins

Feb 28, 2025
Applications due, CMS reviews on rolling basis

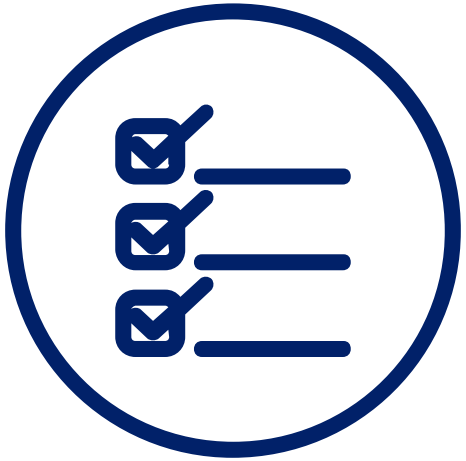
June 2025
State Agreements must be signed

Dec 31, 2025
Performance Year 1 ends

A link to the application portal will be available on the Model website.

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

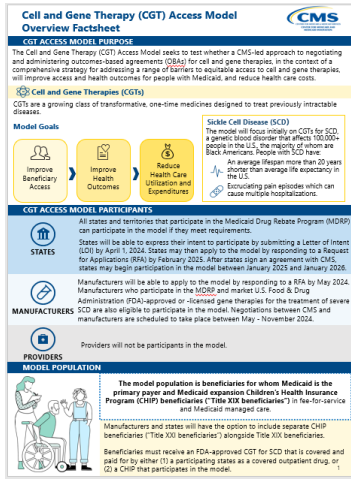
Open Q&A

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 states. To see the latest resources, visit the model's website at https://www.cms.gov/priorities/innovation/innovation-models/cgt.


Cell and Gene Therapy (CGT) Access Model
Overview Factsheet

CGT ACCESS MODEL PURPOSE

The Cell and Gene Therapy (CGT) Access Model seeks to test whether a CMS-led approach to negotiating and administering outcomes-based agreements (OBAs) for cell and gene therapies, in the context of a comprehensive strategy for addressing a range of barriers to equitable access to cell and gene therapies, will improve access and health outcomes for people with Medicaid, and reduce health care costs.

Cell and Gene Therapies (CGTs)

CGTs are a growing class of transformative, one-time medicines designed to treat previously intractable diseases.

Model Goals

Improve Beneficiary Access

Improve Health Outcomes

Reduce Health Care Utilization and Expenditures

Sickle Cell Disease (SCD)

The model will focus initially on CGTs for SCD, a genetic blood disorder that affects 100,000+ people in the U.S., the majority of whom are Black Americans. People with SCD have:

An average lifespan more than 20 years shorter than average life expectancy in the U.S.

Excruciating pain episodes which can cause multiple hospitalizations.

CGT ACCESS MODEL PARTICIPANTS

STATES

All states and territories that participate in the Medicaid Drug Rebate Program (MDRP) can participate in the model if they meet requirements.

States will be able to express their intent to participate by submitting a Letter of Intent (LOI) by April 1, 2024. States may then apply to the model by responding to a Request for Applications (RFA) by February 2025. After states sign an agreement with CMS, states may begin participation in the model between January 2025 and January 2026.

MANUFACTURERS

Manufacturers will be able to apply to the model by responding to a RFA by May 2024. Manufacturers who participate in the MDRP and market U.S. Food & Drug Administration (FDA)-approved or -licensed gene therapies for the treatment of severe SCD are also eligible to participate in the model. Negotiations between CMS and manufacturers are scheduled to take place between May - November 2024.

PROVIDERS

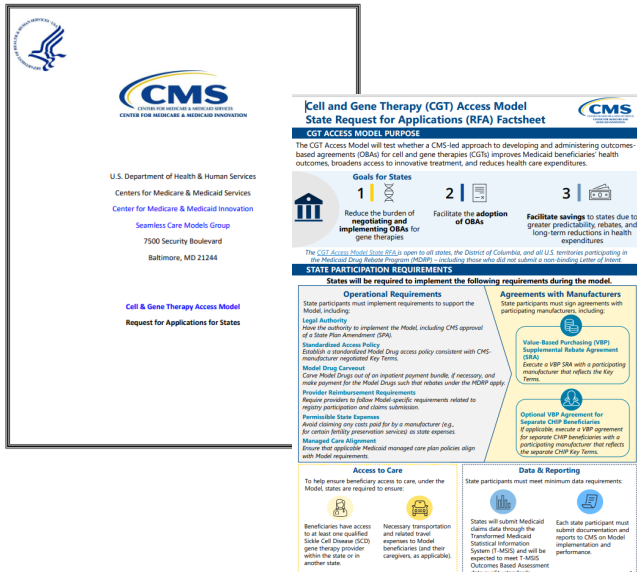
Providers will not be participants in the model.

MODEL POPULATION

The model population is 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.

Manufacturers and states will have the option to include separate CHIP beneficiaries ("Title XXI beneficiaries") alongside Title XIX beneficiaries.

Beneficiaries must receive an FDA-approved CGT for SCD that is covered and paid for by either (1) a participating states as a covered outpatient drug, or (2) a CHIP that participates in the model.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Center for Medicare & Medicaid Innovation
Seamless Care Models Group
7500 Security Boulevard
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Cell & Gene Therapy Access Model
Request for Applications for States

Cell and Gene Therapy (CGT) Access Model
State Request for Applications (RFA) Factsheet

CGT ACCESS MODEL PURPOSE

The CGT Access Model will test whether a CMS-led approach to developing and administering outcomes-based agreements (OBAs) for cell and gene therapies (CGTs) improves Medicaid beneficiaries' health outcomes, broadens access to innovative treatment, and reduces health care expenditures.

Goals for States

1 Reduce the burden of negotiating and implementing OBAs for gene therapies

2 Facilitate the adoption of OBAs

3 Facilitate savings to states due to greater predictability, rebates, and long-term reductions in health expenditures

The CGT Access Model State RFA is open to all states, the District of Columbia, and all U.S. territories participating in the Medicaid Drug Rebate Program (MDRP) – including those who did not submit a non-binding Letter of Intent.

STATE PARTICIPATION REQUIREMENTS

States will be required to implement the following requirements during the model.

Operational Requirements

State participants must implement requirements to support the Model, including:

Legal Authority
Have the authority to implement the Model, including CMS approval of a State Plan Amendment (SPA).

Standardized Access Policy
Establish a standardized Model Drug access policy consistent with CMS-manufacturer negotiated Key Terms.

Model Drug Carveout
Carve Model Drugs out of an inpatient payment bundle, if necessary, and make payment for the Model Drugs such that rebates under the MDRP apply.

Provider Reimbursement Requirements
Require providers to follow Model-specific requirements related to registry participation and claims submission.

Permissible State Expenses
Avoid claiming any costs paid for by a manufacturer (e.g., for certain fertility preservation services) as state expenses.

Managed Care Alignment
Ensure that applicable Medicaid managed care plan policies align with Model requirements.

Agreements with Manufacturers

State participants must sign agreements with participating manufacturers, including:

Value-Based Purchasing (VBP) Supplemental Rebate Agreement (SRA)
Execute a VBP SRA with a participating manufacturer that reflects the Key Terms.

Optional VBP Agreement for Separate CHIP Beneficiaries
If applicable, execute a VBP agreement for separate CHIP beneficiaries with a participating manufacturer that reflects the separate CHIP Key Terms.

Access to Care

To help ensure beneficiary access to care, under the Model, states are required to ensure:

Beneficiaries have access to at least one qualified Sickle Cell Disease (SCD) gene therapy provider within the state or in another state.

Necessary transportation and related travel expenses to Model beneficiaries (and their caregivers, as applicable).

Data & Reporting

State participants must meet minimum data requirements:

States will submit Medicaid claims data through the Transformed Medicaid Statistical Information System (T-MSIS) and will be expected to meet T-MSIS Outcomes Based Assessment

Each state participant must submit documentation and reports to CMS on Model implementation and performance.

Model Overview Factsheet and Infographic

Read through the CGT Model Overview Factsheet and the CGT Model Infographic on the model website to learn more.

State RFA Resources

The State RFA is on the model webpage. Read through the CGT State RFA Factsheet, and the CGT State RFA Frequently Asked Questions on the model website to learn more.

CGT Model mailbox

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!

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