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 data quality standards.
- Each state participant must submit documentation and reports to CMS on Model implementation and performance.

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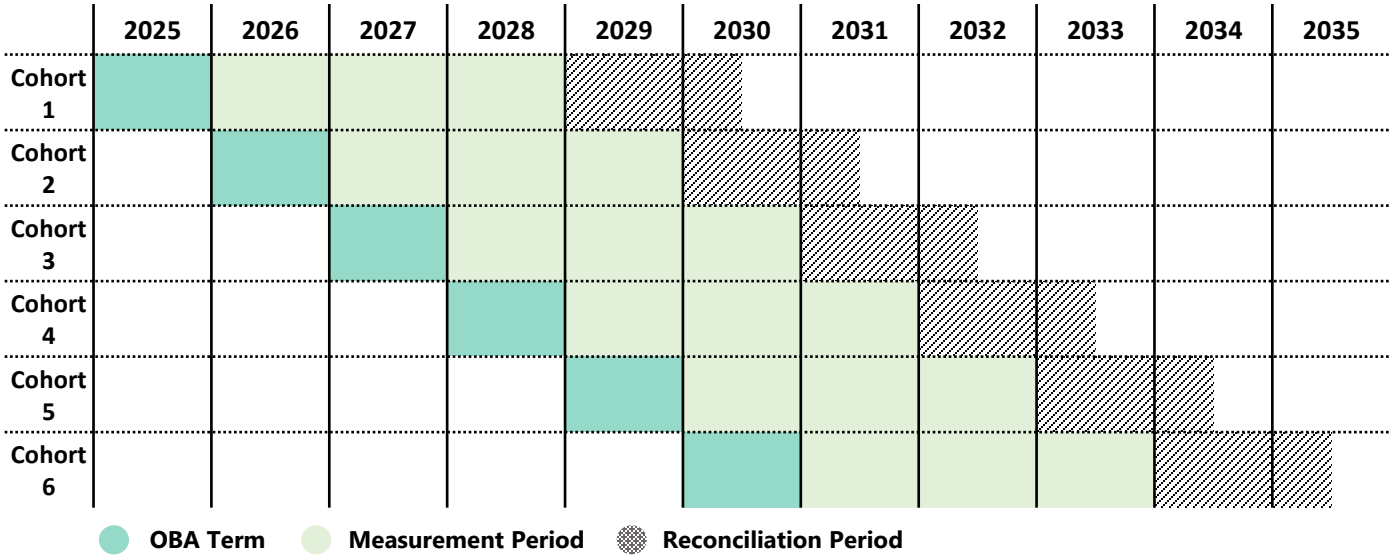
APPLICATION PROCESS AND TIMELINE

The Model will 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.

EXAMPLE PERFORMANCE PERIOD

The duration of the OBA Term, Measurement Period, and Reconciliation Period will be determined in CMS-manufacturer negotiations. In the example below, administration of gene therapy would occur during PYs 1-6, and beneficiaries who receive a Model Drug in each PY would represent a different cohort. For each cohort, measurement of outcomes would begin the year following administration of gene therapy, and final reconciliation of rebates would follow the measurement period.



PERFORMANCE PERIOD START DATE

States can begin performance on a date of their choosing from January 1, 2025 to January 1, 2026. States may choose to begin performance in the Model with only their fee-for-service members and bring their managed care lives into the Model as late as January 1, 2026.

TIMELINE

Important dates begin in Summer 2024:

June 2024
State RFA released

Dec 2024
Key Terms disclosed to states

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

States may submit applications to participate in the 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.

In order to participate in the Model, 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.

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CMS SUPPORT

CMS will perform certain activities to support the Model.

CMS Responsibilities

- 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

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

LEARNING SYSTEM

State participants will have the opportunity to participate in a learning system designed to support their success in achieving the aims of the Model. The goals of the learning system are to:

- Facilitate connections between states for exchange of ideas, knowledge, tools, and resources
- Disseminate emergent learnings about what has worked for states to improve access to gene therapies and improve outcomes for individuals living with SCD
- Offer various mechanisms for sharing feedback to CMS about lessons learned from implementing the Model

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 will execute a separate Cooperative Agreement with CMS governing optional Model funding.

Model Contact Information and Resources

Sign Up for the CGT Access Model Listserv
CGT Access Model Overview Factsheet
CGT Access Model Website

State RFA
State RFA Frequently Asked Questions

Email: CGTModel@cms.hhs.gov