

MODEL OVERVIEW

The Cell and Gene Therapy (CGT) Access Model is a first-of-its-kind voluntary partnership between the Centers for Medicare & Medicaid Services (CMS), state Medicaid agencies, and drug manufacturers. Rather than requiring each state to negotiate key terms individually with manufacturers, CMS negotiates centralized agreements on behalf of participating states—reducing burden and giving states access to stronger terms than most could secure on their own. States then choose whether to adopt these agreements in their Medicaid programs.

The model aims to improve access to high-cost cell and gene therapies for Medicaid beneficiaries with rare and severe diseases. CMS selected sickle cell disease (SCD) as the first condition to focus on due to the emergence of two newly approved gene therapies with curative potential. CMS-negotiated rebates help make these therapies more financially sustainable for states while ensuring Medicaid beneficiaries can access potentially life-changing treatments.

PARTICIPANTS

Manufacturers

2 of 2 Manufacturers signed on schedule

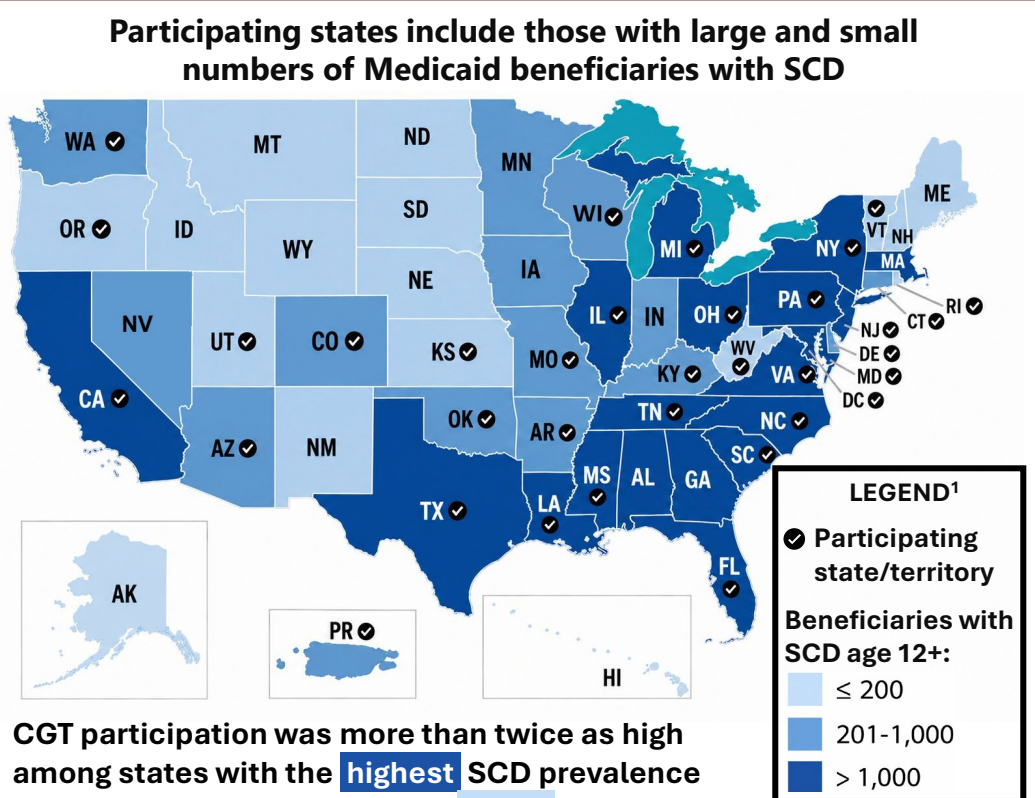
Key terms in the participation agreements that CMS discussed with both manufacturers included: outcomes-based rebates, volume-based rebates, fertility preservation services, an access policy, and coverage criteria.

State Medicaid Agencies

34 State or Territory Medicaid agencies joined

- Participants include states with and without prior value-based contract experience.
- States with the **highest** SCD Medicaid populations were more likely to participate.
- Non-participating states cited small SCD populations, state-specific legal or statutory barriers, or a preference to negotiate independently with manufacturers.

84%
of Medicaid
beneficiaries with
SCD are included
the model.



¹This map shows the participating states denoted by a check mark. The color gradient represents the number of Medicaid beneficiaries with SCD age 12+ per state.

FINDINGS



Advantages of CMS-led agreement development:

- ✓ Leverage in discussions with drug manufacturers by pooling beneficiaries across states.
- ✓ CMS adds capacity and resources for discussions with manufacturers that some states lack.
- ✓ Shared administrative burden of collecting data and managing potential dispute resolution for outcome rebates.



In interviews, states and manufacturers described

- Positive aspects of the agreement process:

- + CMS represents the combined Medicaid SCD population giving CMS **leverage** no single state could bring alone.
- + Stakeholders broadly support **adding** other high-cost drug categories to **the CMS-led model** and cited this as a reason for participation.
- + States that **lacked resources or negotiation experience** benefited most from the CMS-led model.
- + The model provided reimbursement **assurances to qualified treatment centers**, which helped facilitate access.
- + Only CMS could offer a **fertility preservation safe harbor**.
- + **Centralized rebate determinations** benefit states and manufacturers by reducing burden.
- + States valued CMS as a **neutral third-party intermediary** for potential failed-outcome disputes between states and manufacturers.

- Considerations for Model Participation

- Manufacturers sought **early certainty** about state participation; states preferred to review final terms before committing.
- States had to quickly **assess** key terms, **navigate** complex agreements, **amend** Managed Care Organization contracts, and **submit** participation documents to CMS.

KEY TAKEAWAYS

1

CMS-led discussions with both manufacturers of high-cost CGTs for SCD were **effective** in securing acceptable terms for state Medicaid agencies.

2

The model demonstrated that CMS-led discussions can be a reasonably **efficient** alternative to state-by-state discussions.

3

Strong participation from manufacturers and states indicates support for CMS-led drug pricing discussions.