Cell and Gene Therapy Access Model

Rolling start for states: January 2025 to January 2026

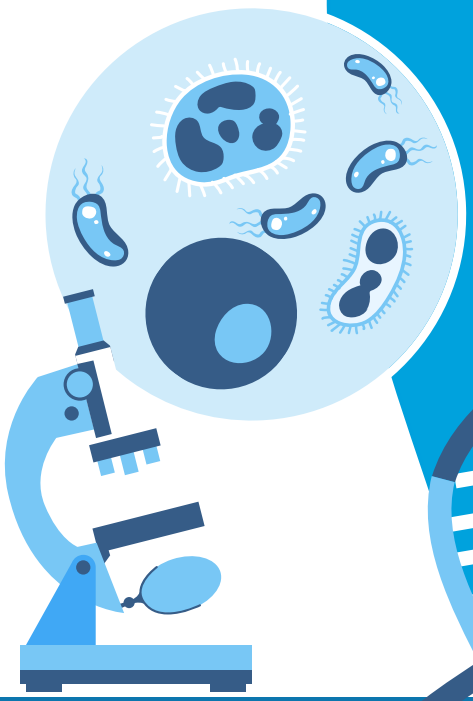
The Cell and Gene Therapy Access Model aims to improve health outcomes for people with Medicaid living with rare and severe diseases by increasing their access to potentially transformative treatments.

CMS will negotiate outcomes-based agreements with participating pharmaceutical manufacturers on behalf of states. Pricing for treatment will be tied to specific health outcomes for people for whom Medicaid is the primary payer.

The model goals are to:

- **Increase** access for people with Medicaid
- **Improve** health outcomes
- **Reduce** health care utilization and expenditures

CMS will support implementation, reconciliation, and evaluation of the outcomes-based agreements.



Sickle Cell Disease

The model will initially focus on access to therapies for **sickle cell disease.** People with sickle cell disease have a shortened life expectancy and experience severe and painful symptoms.

- **Affects more than 100,000 people in the U.S. – the majority of whom are Black Americans**
- **Costs the health care system $3 billion each year**
- **50-60% of people with sickle cell disease are enrolled in Medicaid**