Cell & Gene Therapy (CGT) Access Model Overview Webinar

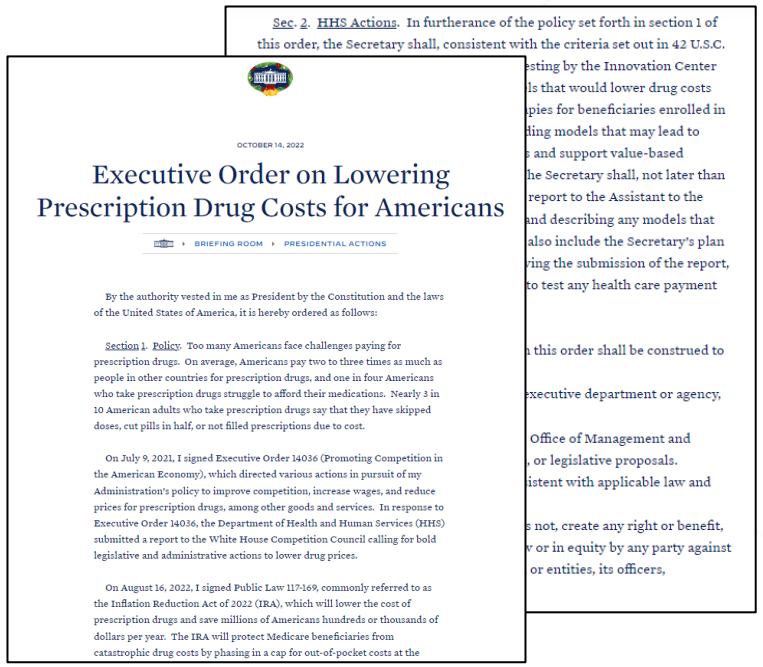
Center for Medicare and Medicaid Innovation
October 24, 2024

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Model Background

The CGT Access Model aims to reduce healthcare costs by facilitating outcomes-based agreements between manufacturers and states.

The Cell and Gene Therapy (CGT) Access Model was developed in response to **President Biden's Executive Order 14087, Lowering Prescription Drug Costs for Americans** and intends to drive down prescription drug costs, building on the Inflation Reduction Act.



OCTOBER 14, 2022

Executive Order on Lowering Prescription Drug Costs for Americans

BRIEFING ROOM › PRESIDENTIAL ACTIONS

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Policy. Too many Americans face challenges paying for prescription drugs. On average, Americans pay two to three times as much as people in other countries for prescription drugs, and one in four Americans who take prescription drugs struggle to afford their medications. Nearly 3 in 10 American adults who take prescription drugs say that they have skipped doses, cut pills in half, or not filled prescriptions due to cost.

On July 9, 2021, I signed Executive Order 14036 (Promoting Competition in the American Economy), which directed various actions in pursuit of my Administration's policy to improve competition, increase wages, and reduce prices for prescription drugs, among other goods and services. In response to Executive Order 14036, the Department of Health and Human Services (HHS) submitted a report to the White House Competition Council calling for bold legislative and administrative actions to lower drug prices.

On August 16, 2022, I signed Public Law 117-169, commonly referred to as the Inflation Reduction Act of 2022 (IRA), which will lower the cost of prescription drugs and save millions of Americans hundreds or thousands of dollars per year. The IRA will protect Medicare beneficiaries from catastrophic drug costs by phasing in a cap for out-of-pocket costs at the

Sec. 2. HHS Actions. In furtherance of the policy set forth in section 1 of this order, the Secretary shall, consistent with the criteria set out in 42 U.S.C. esting by the Innovation Center ls that would lower drug costs pies for beneficiaries enrolled in ding models that may lead to s and support value-based he Secretary shall, not later than report to the Assistant to the nd describing any models that also include the Secretary's plan ring the submission of the report, to test any health care payment

this order shall be construed to

executive department or agency,

Office of Management and , or legislative proposals. istent with applicable law and

s not, create any right or benefit, or in equity by any party against or entities, its officers,

The model is a framework wherein **CMS negotiates with manufacturers on behalf of states** for outcomes-based agreements, or OBAs, for CGTs that cover beneficiaries for whom Medicaid is the primary payer.

MODEL GOALS

- Improve Beneficiary Access to Transformative CGT Therapies
- Reduce Long-Term Health Care Utilization and Expenditures
- Improve Health Outcomes

Overview of Cell & Gene Therapies

CGTs are a rapidly growing class of one-time treatments, many of which are developed to treat rare and severe diseases.

Cell therapy aims to treat diseases by altering sets of cells in the body or by using cells to carry a therapy through the body.

Gene therapy aims to treat diseases by replacing, inactivating, or introducing genes into cells.

Though CGTs hold great potential, they often cost millions of dollars.

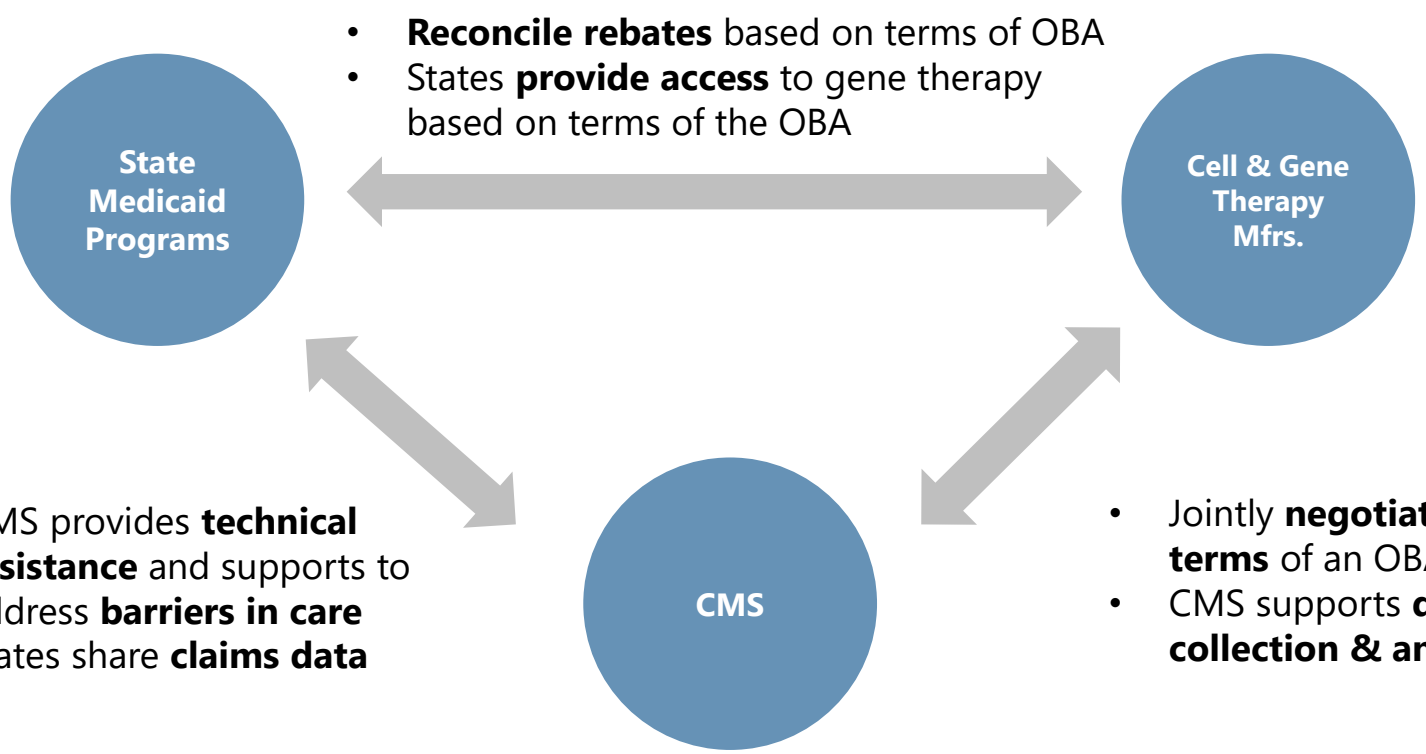
To help states and beneficiaries gain access to these treatments, CMS will:

Negotiate with manufacturers on behalf of states for outcomes-based agreements which tie payment to specific outcomes.

Negotiate for discounted prices and develop a broader strategy to address barriers to equitable care.

Model Overview

The **Cell and Gene Therapy Access Model** is a framework where CMS negotiates with manufacturers on behalf of states for outcomes-based agreements for cell & gene therapies that cover non-dually eligible Medicaid enrollees.

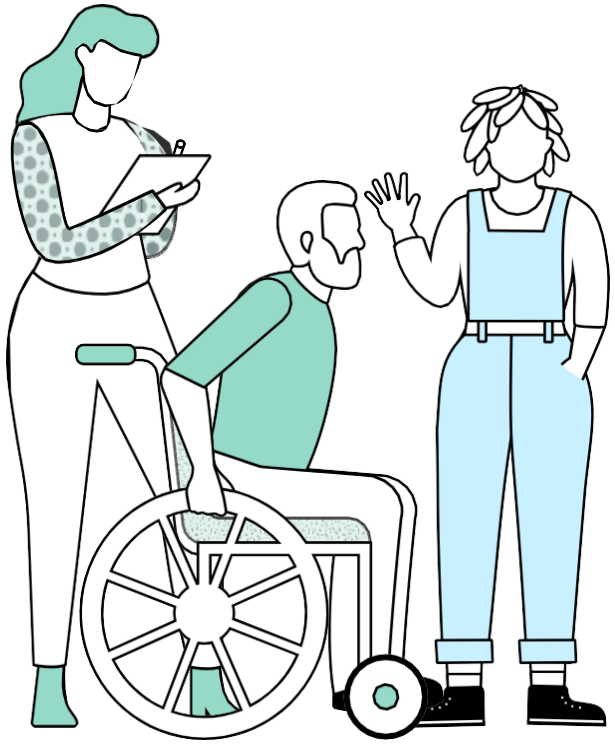


BENEFICIARY IMPACT

- Increased access to transformative therapies for SCD
- Reduced burden of SCD for beneficiaries
- Improved quality of life, including the ability to achieve major life goals related to education, work, and family life
- Easier navigation of care due to streamlined authorization process

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.

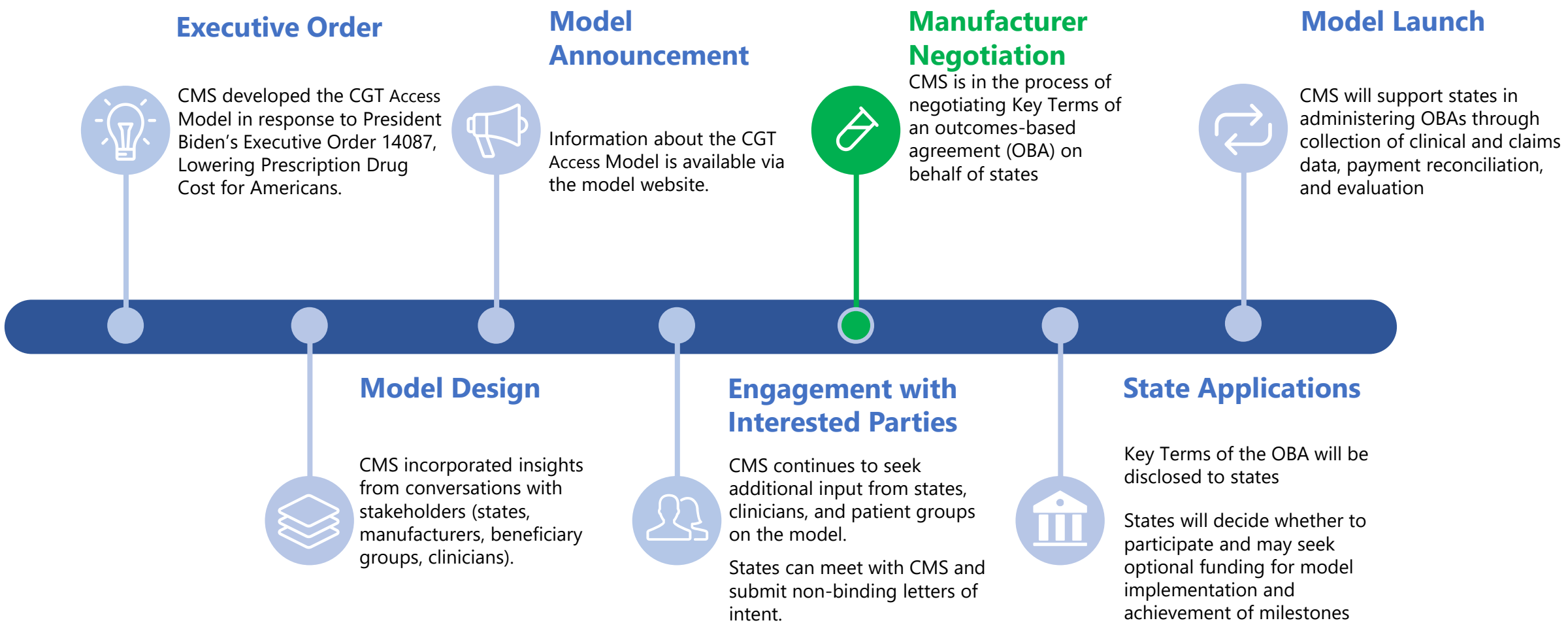
Jan 1, 2025

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.

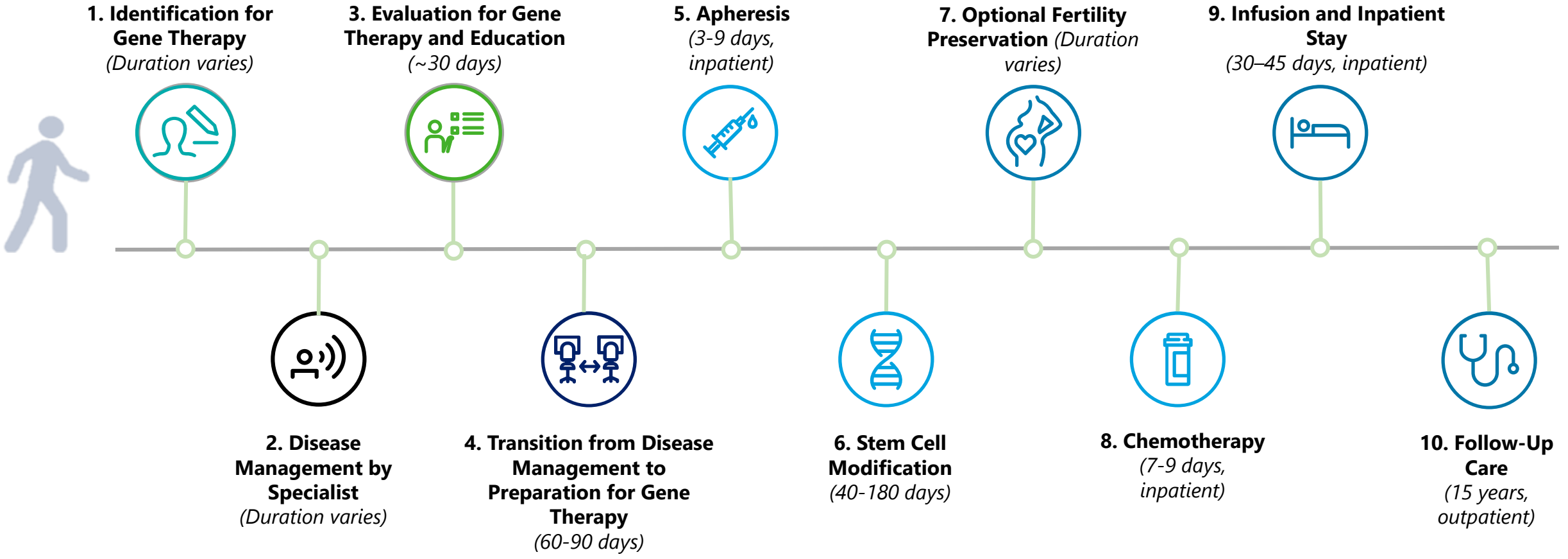
Where Are We Now?

CMS is currently in the manufacturer negotiation phase of model development.



Patient Care Journey for SCD Gene Therapy

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



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

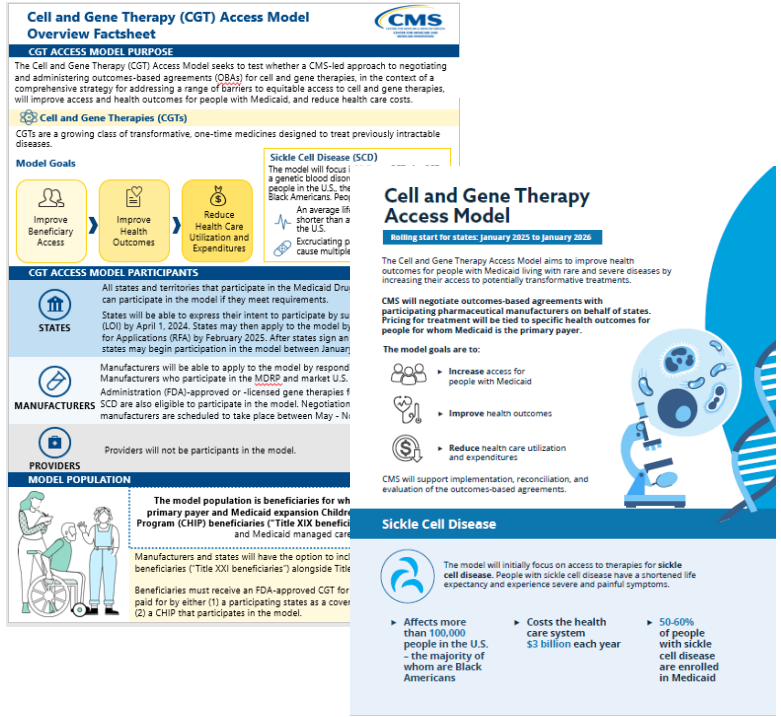
Treatment Centers

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

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.

Helpdesk
If you have questions for the model team, please reach out to us via email at to CGTModel@cms.hhs.gov.

Question and Answer Session