CardinalCare
Virginia's Medicaid Program

DMAS Cell Gene Therapy Access Model Implementation Update

August 2026

DMAS

CGT Mandate

- 291.WWWW of the 2026 Appropriation Act

Virginia will begin participating in the federal Centers for Medicare and Medicaid Services (CMS) Cell and Gene Therapy (CGT) Access model. The initial focus of the model is on gene therapies for people living with sickle cell disease, inclusive of Casgevy™ (exagamglogene autotemcel) and Lyfgenia®* (lovotibeglogene autotemcel).

Anticipated Start Date: October 1, 2026

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Overview of Cell and Gene Therapy (CGT) Access Model

The Model tests whether a CMS-led approach to negotiating **outcomes-based agreements** (OBAs) for cell and gene therapies will **improve access** and **health outcomes** and reduce health costs for individuals with Medicaid.

Cell and Gene Therapies (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.
MANUFACTURERS	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.
PROVIDERS	Providers will not be participants in the model.

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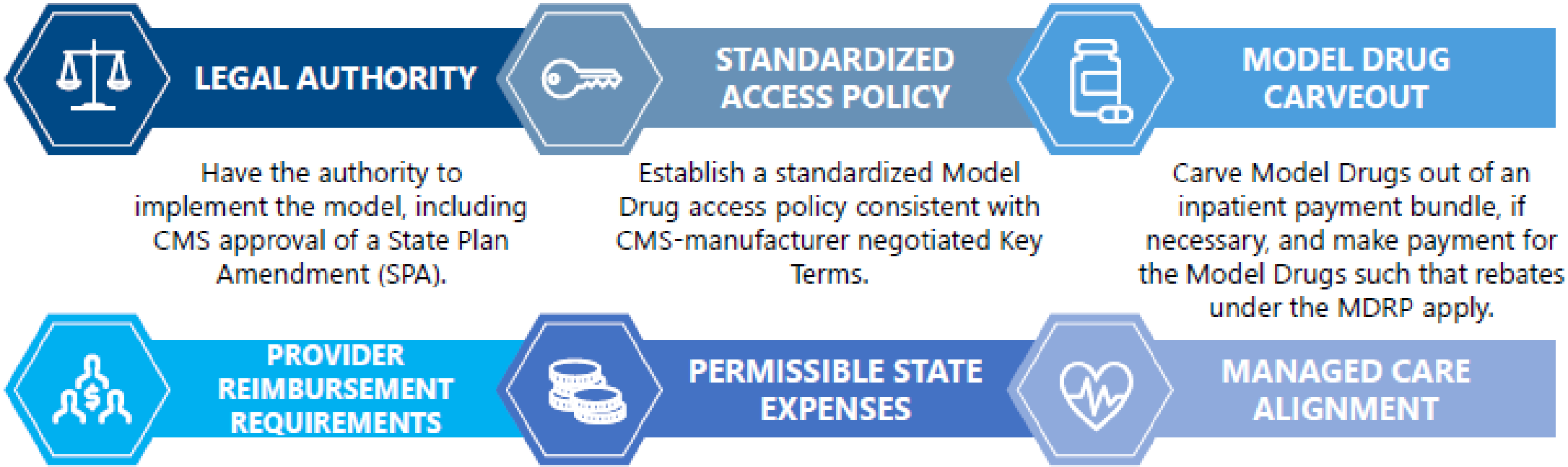
Operational Requirements for State Participation



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Finance - Model Drug Unbundling

Model Drugs must be unbundled from the inpatient payment bundle so that rebates under Medicaid Drug Rebate Program (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**.*

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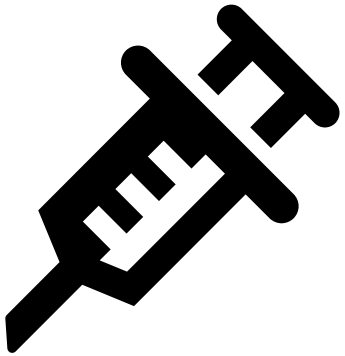
CGT – Coverage Requirements

- Pre-treatment
- Inpatient care
- Follow-up care after administration of Casgevy/Lyfgenia for up to one year post treatment
- Case Management
- Requires manufacturers to cover fertility preservation



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