Maryland
DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Meena Seshamani, M.D., Ph.D., Secretary

MARYLAND MEDICAL ASSISTANCE PROGRAM
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General Provider Transmittal No. 112
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TO: Managed Care Organizations
Hospitals
All Providers

FROM: Monchel Pridget, Acting Director
Office of Medical Benefits Management

RE: Cell and Gene Therapy Access Model for Sickle Cell Disease, Effective January 1, 2026

NOTE: **Please ensure that appropriate staff members in your organization are informed of the contents of this transmittal.**

This transmittal outlines the requirements of the Cell and Gene Therapy Access Model (CGT Model) for Medicaid participants with sickle cell disease. This model was developed by the Centers for Medicare and Medicaid Innovation. The benefit will begin on January 1, 2026.

The CGT Model focuses on improving access to cell and gene therapy treatments for individuals living with sickle cell disease. The CGT Model supports outcomes-based agreements between states and manufacturers to provide treatments to qualified individuals.

The two medications available in this Model are CASGEVY™, manufactured by Vertex Pharmaceuticals, Inc., and LYFGENIA™, manufactured by Genetix Biotherapeutics, Inc. (formerly bluebird bio, Inc.). Only an authorized treatment center (ATC) can administer the medications. Maryland Medicaid covers both medications under the HealthChoice and Medicaid Fee-for-Service (FFS) programs. Currently, two ATCs in the Maryland region provide cell and gene therapies under the Model: Children's National Medical Center (CNMC) and University of Maryland Medical Center (UMMC). CNMC offers both LYFGENIA and CASGEVY. UMMC offers LYFGENIA.

The care journey for participants in the CGT Model involves:

(1) Preparation for the process, including ongoing disease management;
(2) Collection of the patient's stem cells, through a process known as apheresis;

(3) Creation of the gene therapy using the patient's stem cells;
(4) Infusion of the gene therapy and recovery; and
(5) Ongoing monitoring of the patient's condition after infusion.

The care journey, through the conclusion of the therapy infusion, lasts approximately 12 months. After infusion, the patient will have an initial six-week follow-up, then monthly visits for the first year. After the first year, the patient will shift to annual follow-up visits.

Individuals who are eligible for and authorized to receive CASGEVY or LYFGENIA may receive assistance from the ATCs for transportation and lodging for themselves and their parents or guardians, if applicable, during the care journey. ATCs may also assist eligible CGT Model participants with childcare arrangements.

Fertility preservation is an optional benefit under the CGT Model. Medicaid FFS and HealthChoice MCOs are not responsible for reimbursement of fertility preservation services a CGT Model participant utilizes. Instead, ATCs and fertility preservation providers must bill the gene therapy manufacturers directly by invoice if a participant chooses to receive the service.

Clinical Criteria

Coverage limits these therapies to Medicaid participants with sickle cell disease who meet the Maryland Medicaid clinical criteria. Both MCOs and Medicaid FFS participants must follow the same clinical criteria under the Model. Step therapy is not permitted as a requirement before accessing the covered therapies. HealthChoice MCOs may not impose clinical criteria that are more expansive or restrictive than those required by Maryland Medicaid. The clinical criteria for LYFGENIA can be found here. The clinical criteria for CASGEVY can be found here.

Codes and Billing

Model Drug	HCPCS Code	Description	Cost
CASGEVY*	J3392	Injection, exagamglogene autotemcel	Payable by Invoice
LYFGENIA	J3394	Injection, lovotibeglogene autotemcel	Payable by Invoice

*While Casgevy is also FDA approved for the treatment of Transfusion-dependent β-thalassemia (TDT), treatment of TDT is not part of the CGT Model.

These HCPCS codes are paid "by invoice," meaning providers must submit an invoice along with their claim for reimbursement. For more billing information, refer to the UB04 provider manual. These therapies may not be billed on a CMS1500 claim form. Under the parameters of the model, both MCOs and Medicaid FFS will reimburse the ATCs at no less than the actual

acquisition cost for the cell and gene therapies. Medicaid FFS billing instructions can be found here. As a condition of the CGT Model, no ATC may use a 340B discount on CASGEVY or LYFGENIA. Currently, Maryland Medicaid does not allow any specialty pharmacies to submit claims for the CGT Model medications.

Model Participation for HealthChoice Participants

HealthChoice MCOs are responsible for overseeing a participant's care journey, including, but not limited to, care coordination and assisting members in accessing a CGT sickle cell disease medication.

MCOs will coordinate with the local health department of the enrollee to provide timely nonemergency medical transportation services and related travel for enrollees and their caregivers, as applicable. If the enrollee is unable to receive nonemergency medical transportation, the MCO may either cover these costs optionally as a value-added service or coordinate with the ATCs for wraparound resources and support. MCOs will also work with the ATCs to coordinate enrollees' access to housing and childcare support.

Receiving CASGEVY or LYFGENIA requires preauthorization from the HealthChoice MCO under the Model clinical criteria. Authorizations for the CGT Model drugs are valid for a period of at least 12 months from the decision date. If the HealthChoice MCO denies preauthorization, participants may appeal the denial through existing MCO appeal and state fair hearing processes. The Maryland Department of Health (MDH) has the discretion to review preauthorization denials issued by HealthChoice MCOs for appropriateness and alignment with Model clinical criteria.

If an ATC is out-of-network for an MCO, the CGT Model requires the MCO and the ATC to enter into a single case agreement for the participant's treatment. If a participant switches MCOs or moves into Medicaid FFS, the receiving MCO or Medicaid FFS must honor the CGT Model authorization approved under the participant's previous plan, including establishing single case agreements to continue the treatment.

Model Participation for FFS Participants

For individuals in Medicaid FFS, providers will request preauthorization for CASGEVY or LYFGENIA through the preauthorization submission process found here. MDH will review the request and issue a determination letter.

In addition to seeking preauthorization for the CGT Model drugs, ATCs must obtain authorization from the Utilization Control Agent for any inpatient stays, including the infusion stay. All review requirements, concurrent, continued stay, and retrospective review procedures apply in accordance with COMAR 10.09.92.06.

To ensure reimbursement at the actual acquisition cost, MDH will release specific billing guidance for ATCs. ATCs must bill the medications on a UB04 claim. As Maryland Medicaid

reimburses at the line item level, the medications may be billed on the same claim as the inpatient stay when they are administered.

The Maryland Medicaid CGT Model for Sickle Cell Disease website can be found here. More information can be found at CMS Information on CGT Access Model or at Maya's Care Journey.

For questions regarding this transmittal, please contact mdh.cgtmodel@maryland.gov.