CMS Cell and Gene Therapy Access Model

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Overview

The Department of Health Care Services (DHCS) applied for participation in the federal Centers for Medicare and Medicaid Services (CMS) Cell and Gene Therapy (CGT) Access Model on March 11, 2025. DHCS received formal approval from CMS and was accepted into the CGT Access Model for Medi-Cal as of March 25, 2025. In alignment with CMS requirements, the initial focus of the CGT Access Model will be for CGTs specifically indicated for the treatment of sickle cell disease. The following CGT medications are included in the CGT Access Model:

- CASGEVY by Vertex Pharmaceuticals, effective September 1, 2025, subject to final approval by CMS.
- LYFGENIA by bluebird bio, Inc., effective July 1, 2025, as approved by CMS.

Note: There are specific outcome benchmarks that have been determined by the CMS and the CGT sickle cell disease medication manufacturers that must be reached for the CGT sickle cell disease therapy to be considered a success. DHCS, CMS and the CGT sickle cell disease medication manufacturers will work together to determine that these benchmark outcomes have been reached and report back to CMS as required under the CGT Access Model. Additionally, DHCS has certain, quarterly data reporting requirements under the CGT Access Model.

Eligibility

CGT Access Model

To be eligible for the CGT Access Model, Medi-Cal members must meet all of the following criteria:

- Have a documented medical diagnosis of sickle cell disease
- Be actively enrolled in full-scope Medi-Cal at the time the CGT medication is received
- Have Medi-Cal as their primary health insurance payer
- Receive one of the two CGT medications from a participating manufacturer and
- Meet all published Medi-Cal policy and all CGT Access Model requirements.

For more information on the CGT Access Model, refer to the Cell and Gene Therapy (CGT) Access Model web page of the CMS website. Providers can find additional information on the Cell and Gene Therapy Access Model web page of the DHCS website.

CGT SCD Medications

Medi-Cal members who meet all of the clinical criteria and label indications from the federal Food and Drug Administration (FDA) may be eligible to receive one of the two CGT sickle cell disease medications under the CGT Access Model if determined to be medically necessary by their provider. The most current version of the FDA-approved drugs treating SCD are the following:

- CASGEVY
- LYFGENIA

Providers are responsible for determining which CGT sickle cell disease medication is most appropriate for the Medi-Cal member they are treating based upon clinical criteria and FDA label indications as well as other individual circumstances. Per the CGT Access Model requirements, coverage criteria for each CGT sickle cell disease is as follows:

CASGEVY – Effective September 1, 2025 (Subject to final CMS approval)	**LYFGENIA – Effective July 1, 2025**
• Confirmatory genetic testing. • Based on provider's professional judgment, prior use of or intolerance to hydroxyurea at any point in the past. • Age 12 or older at the expected time of administration. • Clinically stable and fit for transplantation. • Prescribed by or in consultation with a board-certified hematologist with SCD expertise. • Based on provider attestation, experienced recurrent Vaso-Occlusive Crises (VOCs), which is defined as more than or equal to two (2) documented VOCs per year in the previous 24 months.	• Confirmatory genetic testing. • Based on provider's professional judgement, failure or intolerance to hydroxyurea at any point in the past. • Age 12 or older at the expected time of administration. • Clinically stable and fit for transplantation. • Prescribed by or in consultation with a board-certified hematologist with sickle cell disease expertise. • Treatment center has a sickle cell enter. • Based on provider attestation, either: – Currently receiving chronic transfusion therapy for recurrent Vaso-Occlusive Events (VOEs), or – Experienced four (4) or more VOEs in previously 24 months as determined by the provider.

Obtaining CGT medications under the CGT Access Model

As noted above, under the CGT Access Model, the policy for CASGEVY will be effective on September 1, 2025, subject to final CMS approval, and the policy for LYFGENIA will be effective on July 1, 2025, as approved by CMS. The process for obtaining CGT medications under the CGT Access Model will vary depending on a Medi-Cal member's eligibility, as follows.

Medi-Cal Fee-for-Service

- Medi-Cal fee-for-service members obtain CGT medications directly from enrolled Medi-Cal fee-for-service providers who bill DHCS directly for services. Medi-Cal fee-for-service members should consult their treating health care provider to determine eligibility and learn more about CGT sickle cell disease medications.
  - Medi-Cal fee-for-service providers can assist members with accessing one of the two CGT sickle cell disease medications.

Medi-Cal Managed Care

- Medi-Cal managed care members should contact their treating health care provider or reach out to their Medi-Cal Managed Care Plan (MCP) to determine eligibility and learn more about CGT sickle cell disease medications. Medi-Cal MCPs are responsible for care coordination and assisting their members with accessing one of the two CGT sickle cell disease medications.
  - For more information on Medi-Cal MCP care coordination and other requirements, review the applicable All Plan Letter on the DHCS Managed Care All Plan Letters - 1998 to Current web page.
  - Each Medi-Cal MCP includes a point of contact, which can be found in the Medi-Cal Managed Care Health Plan Directory on the DHCS website.

CGT Access Model Covered Services

Under the CGT Access Model, the following costs are covered:

- One of the two CGT medications for SCD
  - CASGEVY (effective September 1, 2025, subject to final CMS approval), or
  - LYFGENIA (effective July 1, 2025, as approved by CMS)
- Fertility preservation services
  - As part of the reimbursement for the CGT sickle cell disease medications, drug manufacturers cover the following:
    - ❖ Up to three rounds of reproductive material collection and preservation and up to fifteen years of storage for eligible members.
    - ❖ Qualifying lodging, meals and travel expenses may also be covered, if necessary to receive fertility preservation services.

Services Not Included Within the CGT Access Model

The following services are not covered under the CGT Access Model but must be provided and covered depending on the member's eligibility and enrollment in either the Medi-Cal fee-for-service or managed care delivery system:

- Medi-Cal fee-for-service: Fee-for-service providers must deliver and bill DHCS directly for all other medical and non-medical CGT-related services, including transportation services (outside of the cost of the drug, fertility preservation and qualifying lodging, meals, and travel expenses associated with fertility preservation, as noted above).
- Medi-Cal managed care: The member's Medi-Cal MCP must cover all other medical and non-medical CGT-related services, including transportation services (outside of the cost of the drug, fertility preservation and qualifying lodging, meals, and travel expenses associated with fertility preservation as noted above).

Billing

Under the CGT Access Model, HCPCS codes J3392 and J3394 are carved out of the managed care delivery system for the treatment of sickle cell disease only and consistent with the effective dates listed above in this policy, which means that Medi-Cal MCPs are not directly billed and not responsible for payment. Under the CGT Access Model, HCPCS codes J3392 and J3394 are separately payable services that are also not reimbursed under the DRG payment methodology. Medi-Cal providers must ensure the following:

- Claims for sickle cell disease CGT medications are billed directly to DHCS.
- The sickle cell disease CGT is billed separately using the appropriate HCPCS code.
- The CGT is not included in the inpatient DRG claim or bundled hospital reimbursement.
- All related services (for example, consultations, evaluations, infusion procedures, etc.) are billed under standard Medi-Cal billing protocols (fee-for-service or managed care, as applicable).
- Providers must obtain an approved *Treatment Authorization Request* (TAR) or Service Authorization Request (SAR) before administering the CGT, in accordance with Medi-Cal policy; and
- All claims for CGT drugs are submitted on medical claims using the *CMS-1500* (or the equivalent electronic forms: 837 professional claim and 837 institutional claim).

For more information about how to complete the paper *CMS-1500* form or electronic 837 claim form, refer to the following sections in the appropriate Part 2 manual:

- *CMS-1500 Completion*
- *CMS-1500 Tips for Billing*
- *CMS-1500 Submission and Timeliness Instructions*
- *CMS-1500 Special Billing Instructions*
- *Electronic Data Interchange (EDI) 837 Claims Overview.*

For billing requirements for HCPCS codes J3392 and J3394 for other drug indications, refer to the *Cell and Gene Therapy Overview* section of the provider manual.

Federal 340B Program

The 340B program does do not apply to CGT medications under the CGT Access Model because drugs administered in inpatient settings do not qualify for 340B discounts because they are directly reimbursed, even if they are considered “covered outpatient drugs” for the purposes of Medicaid Drug Rebate Program. Accordingly, providers may not claim 340B discounts on CGT Access Model CGT medications.

Legend

Symbols used in the document above are explained in the following table.

Symbol	Description
‹‹	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
››	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.