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 U.S. Food and Drug Administration (FDA)-approved CGT medications are currently included in the CGT Access Model:››

- CASGEVY® by Vertex Pharmaceuticals
- LYFGENIA™ by bluebird bio, inc.

Note: Under the CMS CGT Access Model, there are specific outcome benchmarks that have been determined by CMS and the CGT sickle cell disease medication manufacturers that must be reached for the 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. Additionally, DHCS has certain, quarterly data reporting requirements under the CGT Access Model.

Eligibility

‹‹Full-scope Medi-Cal members that are also enrolled in the California Children's Services (CCS) program or the Genetically Handicapped Persons Program (GHPP) may also participate in the CGT Access Model, which includes Medi-Cal members in both Medi-Cal fee-for-service and Medi-Cal managed care delivery systems.

- For more information on the CCS program, including eligibility requirements and how to become a CCS provider, see the DHCS California Children's Services web page.
- For more information on GHPP, including eligibility requirements and how to become a GHPP provider, see the DHCS Genetically Handicapped Persons Program web page.

Note: Individuals who are not Medi-Cal eligible and who are enrolled in CCS state-only or GHPP state-only may not participate in the CGT Access Model and therefore this policy does not address those populations.››

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 Sickle Cell Disease Medications

Medi-Cal members who meet all of the clinical criteria and label indications from the 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 in accordance with Medi-Cal policy requirements. The most current version of the FDA-approved medications treating sickle cell disease include:

- CASGEVY
- LYFGENIA

Per the CGT Access Model requirements, coverage criteria for each CGT sickle cell disease are as follows:

CASGEVY	LYFGENIA
• 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 sickle cell disease expertise. • ‹‹Administered at specialized treatment centers known as Authorized Treatment Centers (ATCs).›› • ‹‹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, or currently receiving chronic transfusion therapy for recurrent VOCs.	• 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. • ‹‹Administered at specialized treatment centers known as Qualified Treatment Centers (QTCs).›› • 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.

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. In accordance with Medi-Cal policy, providers must obtain an approved *Treatment Authorization Request* (TAR) or Service Authorization Request (SAR) before administering the sickle cell disease CGT medication.‹‹The TAR/SAR approval is limited to once in a member's lifetime.››

Obtaining CGT medications under the CGT Access Model

‹‹The process for obtaining CGT medications (either CASGEVY or LYFGENIA) under the CGT Access Model will vary depending on a Medi-Cal member's full-scope eligibility, as follows:››

Medi-Cal Fee-for-Service

- ‹‹Medi-Cal fee-for-service members should contact their treating health care provider to determine eligibility and learn more about CGT medications from enrolled Medi-Cal fee-for-service providers who bill DHCS directly for services.
  - Medi-Cal fee-for-service providers can assist eligible Medi-Cal fee-for-service 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, continuity of care and assisting their eligible Medi-Cal managed care members with accessing one of the two CGT sickle cell disease medications.
  - Medi-Cal MCPs must ensure that Medi-Cal managed care members continue to have access to their same CGT sickle cell disease providers until at least one year after receiving one of the two CGT sickle cell disease medications.››

Note: 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 on the Medi-Cal Managed Care Health Plan Directory web page of 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 sickle cell disease
  - CASGEVY, or
  - LYFGENIA
- Fertility preservation services
  - ‹‹As part of the reimbursement for the CGT sickle cell disease medications, CGT medication 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 Medi-Cal member's full-scope 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 medication, fertility preservation and qualifying lodging, meals, and travel expenses associated with fertility preservation, as noted above).
- Medi-Cal managed care: Medi-Cal MCPs must cover all other medical and non-medical CGT-related services, including transportation services (outside of the cost of the medication, fertility preservation and qualifying lodging, meals, and travel expenses associated with fertility preservation as noted above).››

‹‹Authorization

As noted previously and in accordance with Medi-Cal policy, CGT medications for sickle cell disease require an approved TAR/SAR for coverage and reimbursement. Depending on the Medi-Cal member's full-scope eligibility, TARs/SARs should be submitted to DHCS, as follows:

Full-Scope Medi-Cal Members Not in the CCS Program or GHPP

For Medi-Cal members in both fee-for-service and managed care who are not in the CCS program or GHPP, providers should submit their TARs (or electronic TARs) in accordance with all current Medi-Cal policy requirements. TARs will be reviewed and adjudicated by DHCS clinical staff. For more information on TAR requirements, refer to the following Medi-Cal provider manual sections:

- *TAR Overview* in the appropriate Part 1 manual
- *TAR Completion* in this manual

Full-Scope Medi-Cal Members in the CCS Program or GHPP

CGT medications for sickle cell disease are carved out of managed care, including all Medi-Cal MCP and Whole Child Model (WCM) MCP contracts. Providers must submit a TAR/SAR for CGT medications for sickle cell disease, along with supporting documents, using the Provider Electronic Data Interchange (PEDI) web portal and notify DHCS as follows.

- For CCS members:
  - Submit via secure email CCSExpeditedReview@dhcs.ca.gov; or
  - Submit via secure facsimile (fax) via RightFax at (916) 440-5306.
- For GHPP members:
  - Submit via email FAXGHPP@dhcs.ca.gov; or
  - Submit via secure facsimile (fax) via RightFax at (916) 440-5318

Note: For Medi-Cal members who transition between Medi-Cal managed care and Medi-Cal fee-for-service, but for whom a prior authorization for one of the two CGT medications for sickle cell disease was previously submitted and approved by their former Medi-Cal MCP, DHCS will not require an additional TAR/SAR to be submitted for coverage under this section.››

Billing

‹‹The following HCPCS codes are used to bill for CASGEVY and LYFGENIA:

HCPCS Code	Description	Use
J3392	Injection, exagamglogene autotemcel, per treatment	CASGEVY
J3394	Injection, lovotibeglogene autotemcel, per treatment)	LYFGENIA:

When used for the treatment of sickle cell disease under the CGT Access Model, HCPCS codes J3392 and J3394 are covered as medical benefits only, which are billed on medical claims by enrolled Medi-Cal medical providers (for example, ATCs and QTCs). Currently, there is no billing pathway for pharmacy providers billing on pharmacy claims.

Reimbursement for HCPCS codes J3392 and J3394, under the CGT Access Model, is carved out of the managed care delivery system, which means that Medi-Cal MCPs, including WCM MCP contracts, are not directly billed and not responsible for payment. For Medi-Cal members residing in a WCM county and enrolled in a Medi-Cal MCP, providers must direct requests for these two CGT medications for sickle cell disease to DHCS. HCPCS codes J3392 and J3394 are separately payable services that are also not reimbursed under the DRG payment methodology.

For accurate reimbursement of a CGT medication, Medi-Cal providers must ensure the following:››

- In accordance with Medi-Cal policy, an approved TAR/SAR has been obtained before administering the CGT medication.
- ‹‹The CGT medication is submitted directly to DHCS.
- The claim for the CGT medication is billed separately (for example, on a separate claim) using the appropriate HCPCS code.
- The CGT medication is not included in the inpatient DRG claim or bundled hospital reimbursement.››
- All related clinical services (for example, consultations, evaluations, infusion procedures, etc.) are billed under standard Medi-Cal billing protocols (fee-for-service or managed care, as applicable).
- ‹‹The claim for the CGT medication is submitted on medical claims using the paper *UB-04* form or the equivalent electronic 837 institutional (837I) claim.››

‹‹For more information about how to complete the paper *UB-04* form or equivalent electronic 837I claim form, refer to the following sections in the appropriate Part 2 manual:

- *Electronic Data Interchange (EDI) 837 Claims Overview*
- *UB-04 Completion: Outpatient Services*
- *UB-04 Special Billing Instructions for Outpatient Services*
- *UB-04 Submission and Timeliness Instructions*

  UB-04 Tips for Billing: Outpatient Services

For billing requirements for HCPCS codes J3392 and J3394 outside of the CGT Access Model and for clinical indications other than sickle cell disease, refer to the *Cell and Gene Therapy Overview* section of the provider manual.

Special Billing Instructions

As mentioned previously, the *UB-04* claim form or the 837I claim form must be used to submit claims for HCPCS codes J3392 and J3394.

If the total cost and reimbursement amount requested exceeds $999,999.99, the total amount being claimed must be split among multiple claim lines, ensuring that the amount claimed on a single claim line does not exceed $999,999.99.

For example, if a provider is submitting a claim with a total cost of $2,400,00.00, the provider will submit three claim lines to represent the one service. The provider would enter one (1) in the *Service Units* field (Box 46) and $800,000.000 in the *Total Charges* field (Box 47) on claim lines one, two and three.

It is necessary to split the cost across three claim lines to avoid the appearance of requesting multiple sickle cell disease therapies and exceeding the maximum amount allowed per individual Medi-Cal member claim line on the *UB-04* claim.››

Medi-Cal Fee-for-Service Reimbursement

‹‹HCPCS codes J3392 and J3394 do not have established Medi-Cal fee-for-service rates on file. As a result, these codes are paid “by report,” which means that providers must submit an invoice along with their claim for reimbursement. For more information on “by report” billing, refer to the *UB-04 Special Billing Instructions for Outpatient Services* section of the provider manual.››

Non-applicability of Federal 340B Program

‹‹The 340B program does not apply to CGT medications included under the CGT Access Model because medications administered in inpatient settings do not qualify for 340B discounts. Eligibility for 340B is based on Medi-Cal member status, regardless of how the drug is billed (for example, on an outpatient claim form), even if the medication is considered a “covered outpatient drug” for the purposes of Medicaid Drug Rebate Program. In addition, CGT medications furnished under the CGT Access Model are subject to state-negotiated pricing and rebate arrangements. Accordingly, providers may not claim 340B discounts on CGT medications used under the CGT Access Model.››

Other Health Care (OHC) Coverage/Payer of Last Resort

State and federal statues provide for Medi-Cal to be the payer of last resort. Generally, providers must bill a Medi-Cal member’s OHC coverage before billing Medi-Cal when OHC coverage is known to exist. When other entitlements are discovered after billing Medi-Cal, providers are prohibited from billing the third party because Medi-Cal reimbursement (regardless of the percent of billed amount) constitutes reimbursement in full. For more information on OHC and related policy, refer to the following sections in the provider manual:

- *Other Health Coverage (OHC)*
- *Other Health Coverage (OHC) Guidelines for Billing*
- *Provider Regulations*
- *Provider Guidelines*

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.