



Medicaid Alert

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TO: Hospitals, Specialty Pharmacies - **For Action**
Health Maintenance Organizations - **For Information Only**

SUBJECT: **The Cell and Gene Therapy (CGT) Access Model and Related Billing Guidance for Sickle Cell Disease (SCD) Gene Therapy**

EFFECTIVE: Claims with service dates on or after January 1, 2026

PURPOSE: To advise manufacturer authorized treatment centers and specialty pharmacies on how to submit claims for services under the Cell and Gene Therapy (CGT) Access Model developed by the Centers for Medicare and Medicaid Services (CMS) in which New Jersey has chosen to participate.

BACKGROUND: The Cell and Gene Therapy (CGT) Access Model aims to improve the lives of people living with rare and severe diseases by increasing access to potentially transformative treatments. It is a multi-year, voluntary model for States and manufacturers to test whether a CMS-led approach to developing and administering Outcomes-Based Agreements (OBAs) for cell and gene therapies increases Medicaid beneficiaries' access to treatment, improves their health outcomes, and reduces health care costs and burden to state Medicaid programs.

The initial focus of the CGT Access Model is on access to gene therapy treatments for people living with Sickle Cell Disease (SCD).

ACTION: The CGT Access Model for SCD includes Casgevy (exagamglogene autotemcel), per treatment (J3392) and Lyfgenia (lovotibeglogene autotemcel), per treatment (J3394). All providers delivering these products to NJ FamilyCare members must adhere to the following requirements.

Claim Submission Requirements

- 1) The drug cost for SCD gene therapy must be excluded from any facility or institutional claim and not be submitted as part of a bundled payment, such as a Diagnosis-Related Group (DRG) or an Ambulatory Payment Classification (APC).

- 2) The provider must submit a separate professional claim on the CMS 1500 form for direct reimbursement of the drug's ingredient cost. The drug ingredient cost submitted in the "Charge" field on the CMS 1500 must equal the actual drug acquisition cost reported on the drug's purchase invoice.
- 3) **The drug purchase invoice reporting the provider's actual drug acquisition cost must be submitted as an attachment to the claim.**
- 4) SCD gene therapies must not be purchased at a 340B price or dispensed from a 340B inventory.
- 5) CGT Access Model claims must include the drug's assigned HCPCS procedure code, the drug's National Drug Code (NDC), the drug's Unit of Measure (UOM), and the number of drug units administered. Correct UOMs for NDCs are available on www.njmmis.com under "Physician Administered Drugs".
- 6) CGT Access Model claims shall adhere to standards and guidance outlined by the NJ FamilyCare Managed Care Contract or the Medicaid Newsletter Volume 19, Number 18 which is available on www.njmmis.com under "Newsletters & Alerts."
- 7) Drug cost may be billed as a POS (Point-of-Sale) or professional claim. Drugs paid by both POS claim and by submitting a professional claim are considered duplicative payments and will not be reimbursed.

Billing Codes for Drug Administration, Cell Collection and Conditioning

Providers should utilize appropriate billing codes for associated services. Manufacturer billing guides may be referenced for suggested applicable codes, including:

- Casgevy Billing and Coding Guide:
<https://www.casgevychp.com/sites/default/files/coding-and-billing-guide.pdf>
- Lyfgenia Billing and Coding Guide:
<https://www.lyfgenia.com/-/media/lyfgenia/launch%20com/files/billing-and-coding-guide.pdf>

Provider Requirements

Payments for SCD Gene Therapies to CGT Access Model beneficiaries are conditional on provider adherence to the following requirements:

- The provider must be a member of the Center for International Blood and Marrow Transplant Research (CIBMTR) patient registry; **and**
- The provider must participate in the CMS study related to SCD gene therapies.

If you have any questions regarding the CGT Access Model, please contact DMAHS CGT Access Model Team, at 609-808-3897. If you have any claim-related questions, please contact Gainwell Provider Services at 1-800-776-6334.

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