Guidance for Centers for Medicare and Medicaid Services (CMS) Cell and Gene Therapy (CGT) Access Model

Overview:

Effective January 1, 2026, The New York State (NYS) Department of Health began participation in the federal Centers for Medicare and Medicaid Services (CMS) Cell and Gene Therapy (CGT) Access model. The model is voluntary for State Medicaid programs and manufacturers and will test whether a CMS-led approach to developing outcomes-based agreements (OBAs) for cell and gene therapies increases Medicaid beneficiaries' access to innovative treatment, improve health outcomes, and reduces health care costs to State Medicaid programs. 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).

Scope of Coverage:

Medicaid Managed Care plans will be responsible for the following:

- Coverage of any pre-treatment, inpatient care, and follow-up care after administration of Casgevy or Lyfgenia for up to one year post treatment.
- Coverage of MMC representatives (primary and secondary) for case management.

Continuity of Care/Transitional Care:

MMC plan enrollees receiving Casgevy or Lyfgenia after 1/1/2026 are permitted to keep their sickle cell disease gene therapy providers for at least one year after receiving the gene therapy.

Responsibilities of MMC Plans:

- The gene therapy is administered at an in-network qualified treatment center or have a single case agreement.
- Providers who submit a claim must be a member of the CMS-designated patient registry (i.e., the Center for International Blood & Marrow Transplant Research - CIBMTR) and participate in a CMS-specified study. A list of participating centers is available on the CIBMTR website.
- Continuity of care for beneficiaries that may transition between fee-for-service and managed care, or among Managed Care Plans.
- Beneficiaries continue to have access to their Sickle Cell Disease gene therapy providers for at least one year after receiving gene therapy.

- Providers have access to a primary and secondary Managed Care Plan representative.
- A Managed Care Plan representative is aware of the coverage policy guidance in the October 2025 Medicaid Update.

Billing and Payment

- It is expected that MMC plans will establish a process for reimbursement to providers when the member has transitioned from the MMC plan under which treatment was originally covered (up to 1-year post treatment)
- No additional payment will be made to the MMC plan by NYS Department of Health.

Network Requirements

- If the participating center within the CIBMTR is no longer a NY Medicaid provider, the MMC plan will enter into a single case agreement with the provider and/or allow the member to have access to the necessary care on an out-of-network basis.