Medicaid Practitioner Administered Drugs Update: CMS Cell and Gene Therapy (CGT) Access Model for Casgevy™ (exagamglogene autotemcel) and Lyfgenia® (lovotibeglogene autotemcel)

The New York State (NYS) Department of Health has applied to participate 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).

With CMS approval to participate in the CGT Access Model, and an anticipated effective date of January 1, 2026, NYS Medicaid providers should be aware of the following the coverage guidelines:

- Casgevy™ and Lyfgenia® will be reimbursed by the NYS Medicaid fee-for-service (FFS) program for Medicaid Managed Care (MMC) enrollees and FFS members.
- For MMC enrollees, consideration of approval for treatment-related medical care will be determined by the individual managed care plan.
- The model also includes a fertility preservation provision provided by the manufacturers of Casgevy™ and Lyfgenia®.

Additional information is available on the CMS "CGT Access Model Frequently asked Questions" web page: https://www.cms.gov/cgt-access-model-frequently-asked-questions

Drug Claim Submission:

- Facilities and pharmacies enrolled with NYS Medicaid will be reimbursed for the **cost of Casgevy™ and Lyfgenia®**
- Pharmacy providers must have an **"0442"** category of service (COS) to submit the eMedNY 150003 form to NYS DOH. Please see the following for enrollment information: https://www.emedny.org/info/ProviderEnrollment/
- Providers will submit claims using the medical professional claim format with the New York State eMedNY 150003 paper claim form, located at: https://www.emedny.org/ProviderManuals/Pharmacy/PDFS/150003_Instructions_for_Drugs_Billed_Separately.pdf, that includes both of the following:

- the assigned Healthcare Common Procedure Coding System (HCPCS) code along with the National Drug Code (NDC) associated with the drug; and
- a copy of the drug invoice showing the actual acquisition cost of the drug, dated within six months prior to the date of service and/or should include the expiration date of the drug.

Providers may not use 340B inventory for the CGT Access Model drugs.

Additional information for billing: the eMedNY *New York State Medicaid General Professional Billing Guidelines*, located at: https://www.emedny.org/providermanuals/allproviders/General_Billing_Guidelines_Professional.pdf.

Drug Administration Claim Submission:

- **For FFS members**, **payment for drug administration** will be made through the outpatient Ambulatory Patient Groups (APG) payment when administered in a clinic setting or, if administered on an inpatient basis, following the All Patient Refined-Diagnosis Related Groups (APR-DRG).

- **For MMC enrollees**, **payment for drug administration** will be made through the MMC Plan. Providers should check with the **MMC Plan** regarding specific medical coverage criteria, and reimbursement. MMC Plan contact, and plan directory information is located on the NYS Department of Health "Medicaid Managed Care Plan Information web page: https://www.health.ny.gov/health_care/medicaid/redesign/mrt2/pharmacy_transition/mcp/index.htm

Questions and Additional Information:

- NYS Medicaid (FFS) billing and claim questions should be directed to the eMedNY Call Center at (800) 343-9000.
- NYS Medicaid FFS drug coverage and policy questions should be directed to the Office of Health Insurance Programs Division of Program Development and Management by telephone at (518) 486-3209 or by email at NYRx@health.ny.gov.