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CABINET FOR HEALTH AND FAMILY SERVICES

DEPARTMENT FOR MEDICAID SERVICES

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Cell and Gene Therapy (CGT) Access Model Billing

Overview:

Kentucky Department for Medicaid Services (DMS) has applied to participate in the Center for Medicare and Medicaid Services (CMS) Cell and Gene Therapy Access Model. The initial focus of the model is on gene therapies for people living with sickle cell disease, inclusive of Casgevy™ (exagamglogene autoemcel) and Lyfgenia® (lovotibeglogene autotemcel).

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

- Casgevy™ and Lyfgenia® will be reimbursed for the fee-for-service (FFS) program and for our Managed Care Organization (MCO) members.
- Members eligible for the gene therapy model must meet the requirements set forth by CMS see CGT Model webpage.
- 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.

Billing:

- For fee for service (FFS) members, the provider should have an agreed upon and signed single case agreement (SCA) with DMS, stating that DMS will reimburse at no less than actual acquisition (AAC) cost of the drug alone.
- The provider should submit a UB-04 paper claim form with only the CGT drug listed on the claim.
- The assigned Healthcare Common Procedure Coding System (HCPCS) code along with the National Drug Code (NDC) associated with the drug and number of units dispensed should be included on the claim.
- A copy of the drug invoice showing the actual acquisition cost (AAC) of the drug should be sent along with the paper claim.







• The paper claim and invoice should be mailed directly to DMS at the following address:

Rate Setting

Kentucky Department for Medicaid Services 275 East Main Street 6W-C Frankfort, KY 40601

- Supplemental charges to cover the administration of the drug shall be billed separate and reimbursed based on the appropriate Diagnosis-Related Group (DRG).
- Providers may not claim 340B discounts on the model drugs.
- For more information on Provider Hospital billing, please see the <u>Billing Instructions</u>.

Questions and Additional Information:

Kentucky DMS (FFS) billing and claim questions should be directed to the Division of Fiscal Management /Rate Setting Branch at (502) 564-8196.