DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Cell and Gene Therapy (CGT) Access Model: Billing Information Guide

This guide is intended to aid Model-Participating States for the CGT Access Model in creating provider billing instructions for gene therapy for sickle cell disease and certain related services.

There are four requirements for the billing instructions for State-Selected Model Drugs that are promulgated by Model-participating states and their managed care plans:

1. Billing instructions must support a reimbursement policy that meets the requirements of "direct reimbursement," such that the statutory Medicaid Drug Rebate Program (MDRP) requirements and model supplemental rebate provisions apply.
2. Billing instructions must support a billing and reimbursement policy that meets the requirements of each manufacturer's negotiated Key Terms to qualify for guaranteed and outcomes-based rebates.
3. Billing instructions must facilitate reimbursement at no less than "actual acquisition cost".
4. Billing instructions must make clear that providers may not claim 340B discounts on Model drugs.

This guide walks through each of these requirements and provides additional resources to states in developing their billing instructions for providers.

{I} Billing Instructions Must Facilitate "Direct Reimbursement"

Participating States must ensure that payments to providers (e.g., hospitals, treatment centers, or specialty pharmacies) for State-Selected Model Drug(s) for Model Beneficiaries are made in the form of direct reimbursement as described in 42 C.F.R. § 447.502. Direct reimbursement for a drug may include both:

- Reimbursement for a drug alone, or
- Reimbursement for a drug plus the service, in a single inclusive payment if:
  - The drug, charge for the drug, and number of units of the drug are separately identified on the claim; and
  - The inclusive payment includes an amount directly attributable to the drug; and
  - The amount paid that is attributable to the drug is based on a reimbursement methodology that is included in the applicable section of the State plan.

The model team will be working closely with the CMCS Division of Pharmacy in supporting states in meeting this requirement. The CMCS Division of Pharmacy will be willing to provide technical assistance to any state that reaches out.

(2) Billing Instructions Must Facilitate Billing and Reimbursement That Qualifies for Supplemental Rebates With Respect to the Relevant Manufacturer(s)

Participating States that choose Casgevy® (Vertex Pharmaceuticals, Incorporated) as a State-Selected Model Drug must ensure that Casgevy®, as administered to Model beneficiaries, is reimbursed separately from associated ancillary services, including but not limited to gene therapy administration, pre- and post-treatment regimens, and hospitalization (i.e., separately from a DRG or other bundled payment). A single inclusive payment may qualify as "separate reimbursement" for the purposes of the Vertex's requirement, depending on the particulars of how it is set up, and we encourage states who opt for the single inclusive payment route to work closely with CMS and Vertex.

Participating States that choose Lyfgenia™ (bluebird bio, Inc.) as a State-Selected Model Drug may carve out Lyfgenia™ as either separate claims or as part of inclusive payments if the drug costs are itemized on the provider's bill. Itemization must include the identification of the number of units dispensed, and confirmation the drug is paid according to the State's approved plan methodology for the State-Selected Model Drug(s). Providers must submit on the claim the number of units of the drug administered, the appropriate National Drug Code (NDC) identifier and corresponding HCPCS code(s) for the State-Selected Model Drug(s) as listed in the Key Terms.

(3) Billing Instructions Must Allow States to Reimburse At No Less Than Actual Acquisition Cost

Participating States must ensure that payments to providers for State-Selected Model Drug(s) for Model Beneficiaries are made according to the applicable reimbursement methodology in the State plan, which does not result in the provider being reimbursed less than the provider's Actual Acquisition Cost as defined in 42 C.F.R. § 447.502.

According to 42 C.F.R. 447.502, "Actual acquisition cost (AAC) means the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers." The State's methodology for calculating AAC must be specified in the State plan, in accordance with 42 C.F.R. 447.518. Each participating State may determine which documentation (e.g., invoice), if any, a provider must submit to verify AAC.

(4) Billing Instructions Should Make Clear that Hospitals May Not Claim 3408 Discounts on Model Drugs

Under the model, administration of gene therapy for sickle cell disease will be for individuals who are inpatient. The 340B program does not apply to drugs used for individuals who are inpatient. The Model Team has consulted with our colleagues at HRSA, who have made clear that drugs administered in inpatient settings **do not qualify for 3408 discounts** even if, because they are directly reimbursed, they are considered "covered outpatient drugs" for the purposes of MDRP. Participating states may choose to direct covered entities that the State-Selected Model Drug(s) should not be acquired through the 340B program for Model Beneficiaries.

Resources:

States may choose to consult the following resources as they develop billing instructions:

- Vertex's "Coding and Billing Guide" for CASGEVY®
- Bluebird Bio's "Billing and Coding Guide" for Lyfgenia™

States may reach out to the model team at CGTModel@cms.hhs.gov for questions or technical assistance.