Acute Hospitals – Billing Instructions for Cell and Gene Therapy for Sickle Cell Disease Carve-Out Drugs

INTRODUCTION

To ensure proper payment, Hospitals **shall** follow **special billing instructions, which are set forth below**. Failure to follow these special billing instructions could result in an overpayment that will be subject to recoupment, and could subject the provider to sanctions for improper billing. Qualifying hospitals shall be a member of the Center for International Blood and Marrow Transplant Research (CIBMTR) and participate in the study related to the Cell and Gene Therapy (CGT) Access Model.

**These billing instructions may be updated from time to time.*

I. IDENTIFICATION OF CARVE-OUT DRUGS

The CGT designated Adjudicated Payment per Discharge (**APAD) Carve-Out Drugs provided in an inpatient acute hospital setting** that are subject to these billing instructions are identified as:

1. Casgevy

2. Lyfgenia

II. OTHER REQUIREMENTS AND CONDITIONS OF PAYMENT

Other requirements and conditions of payment apply to Hospitals for APAD Carve-Out Drugs that are not included here. For example, special requirements apply regarding (1) prior authorization, (2) preadmission screening (as applicable), and (3) reporting of efficacy and member progress as a result of being treated with the drug in question. Some of these requirements for APAD Carve-Out Drugs may differ substantially from the requirements for other drugs. IMPORTANT: To ensure compliance with these billing instructions, the Hospital's billing department or agents that submit claims to Louisiana Medicaid managed care organizations (MCOs) shall coordinate, as appropriate, with Hospital personnel or agents that handle the Hospital's payment arrangements with the drug manufacturer (or other party) for these APAD Carve-Out Drugs, and with the clinical staff that handles the Hospital's prior authorization requests to the MCO, for these drugs.

III. BILLING INSTRUCTIONS FOR APAD CARVE-OUT DRUGS (acute inpatient hospitals)

The following **billing instructions** apply to inpatient claims **for APAD Carve-Out Drugs** submitted by ***Acute Inpatient Hospitals*** **(Provider Type 60),** referred to as "**Hospitals**".

1. Special Requirements for Transmitting Claims for APAD Carve-Out Drugs:

a. Costs, charges, and any other claims-based data corresponding to the APAD Carve-Out Drug **shall be *excluded from any facility/institutional claim*** (Claim Type 01) that the Hospital submits for the member's stay.

b. The Hospital shall instead claim separate payment for APAD Carve-Out Drugs **on an outpatient hospital claim (claim type 03).**

c. Along with the member's name, date(s) of service, and other usual information, the separate outpatient claim for the APAD Carve-Out Drug **shall also** include:

(i) The appropriate **National Drug Code (NDC)** identifier with hospital revenue code 0892 and ***HCPCS* code(s)** for the drug;

1. Lyfgenia:
    a. HCPCS: J3394 Injection, lovotibeglogene autotemcel, per treatment
    b. NDC: 73554-1111-01
        i. Enter the HCPCS Level II code, J3394 Injection, lovotibeglogene autotemcel, per treatment, along with the applicable modifier. In lieu of a gene therapy-specific code for the infusion, the 96413 CPT4 code may be required.
2. Casgevy:
    a. HCPCS: J3392 Injection, exagamglogene autotemcel, per treatment
    b. NDC: 51167-0290-09 **and**

(ii) The **number of units** of the drug administered to the member that is covered by the claim.

d. The Hospital shall also include the following as **separate attachments** to the claim for the APAD Carve-Out Drug, which the MCO shall deem incorporated into and part of the claim:
    (i) A **statement of the Hospital's actual acquisition cost** of the drug (**as defined in #2, below**) used to treat the member, appropriately verified; and
    (ii) A **copy of the invoice(s)** for the APAD Carve-Out Drug from the drug manufacturer, supplier, distributor, or other similar party or agent; and
    (iii) If applicable, **any other documentation that is necessary** for the Hospital **to evidence** that the amount listed on the attachment(s) to the direct data entry (DDE) claim (referenced in #1.d.(i), above) is the Hospital's **actual acquisition cost** of the APAD Carve-Out Drug **(as defined in #2, below**). **NOTE**: The MCO may require additional documentation upon receipt of the claim, if necessary to evidence this.
e. **See also important instructions in #3, below**, regarding the timing of submitting the claim if the Hospital is party to, or a direct beneficiary of, a "**Performance-Based Guarantee"**.
f. The Hospital shall not utilize 340B stock or use 340B pricing discounts for the APAD Carve-Out Drugs.

2. Definition of "actual acquisition cost" for purposes of these instructions:

For purposes of these instructions, the Hospital's "**actual acquisition cost" of the APAD Carve-Out Drug** is defined as follows:

"The Hospital's invoice price for the drug, ***net of all*** on-or-off invoice reductions, discounts, rebates, charge backs and similar adjustments that the Hospital has or will receive from the drug manufacturer or other party for the drug that was administered to the Member while the member was admitted in the Hospital, including any efficacy-, outcome-, or performance-based guarantees (or similar arrangements), whether received pre- or post-payment."

3. Timing of Claims Submission for APAD Carve-Out Drug under Special Circumstances:

For purposes of these instructions, a **"Performance-Based Guarantee"** refers to any **efficacy-, outcome-, or performance-based guarantee (or similar arrangement)** from the drug manufacturer (or other party) to the Hospital that applies to the treatment of the member with the APAD Carve-Out Drug in question.

a. In the event the **Hospital is a party to or a direct beneficiary of a Performance-Based Guarantee from the drug manufacturer (or other party),** and the terms of the Performance-

Based Guarantee allow the Hospital to pay in full or in part for the APAD Carve-Out Drug ***only if*** certain conditions are met, the Hospital ***shall not*** submit a claim to the MCO for the APAD Carve-Out Drug ***until*** the Hospital actually makes the payment it will be required to make to the drug manufacturer or other party (and shall **not** submit ***any*** claim for the drug to the MCO in the event it is not ultimately required to pay for the drug).

b. If any other Performance-Based Guarantee (or similar arrangement, or other cost reduction) is triggered to the financial benefit of the Hospital ***after*** the Hospital submits a claim to the MCO for the APAD Carve-Out Drug, follow the instructions in #4, below.

4. Requirement to Notify the MCO and Adjust or Modify Claim for APAD Carve-Out Drug:

In the event that any **Performance-Based Guarantee, or any other financial benefit or cost reduction**, from the drug manufacturer (or other party) **is triggered** to the financial benefit of the Hospital for the APAD Carve-Out Drug ***after*** **the Hospital has submitted a claim** to the MCO for the drug ***(or*** the Hospital otherwise becomes aware that it previously submitted a claim to the MCO that incorrectly specified an amount that exceeded the Hospital's actual acquisition cost of the APAD Carve-Out Drug (as defined in #2, above)):

a. The Hospital shall i**mmediately notify the MCO** in writing **by e-mail** using the following address listed at: https://ldh.la.gov/medicaid/useful-managed-care-info and include "**Acute Hospital Carve-Out Drug Follow-Up"** in the subject line, specifying the drug in question; ***and*** the Hospital shall **adjust or modify the submitted claim in the manner specified by the MCO** to account for the financial benefit (or to correct the error, if applicable) to ensure that the full financial benefit has been passed back to the MCO (or the error, if applicable, is otherwise corrected). In particular, if such claim has processed to a paid status, the Hospital shall immediately adjust (or void) the claim to correctly reduce (or eliminate) payment, as applicable, consistent with the financial benefit (or in order to correct the error, if applicable).

5. Other General Billing Instructions:

With the exception of the instructions set forth above, all other applicable MCO billing instructions and conditions of payment continue to apply. The MCO may, on a case-by-case basis, provide additional or different instructions for submitting claims for APAD Carve-Out Drugs in certain circumstances (e.g., if the MCO deems it necessary or desirable to address new innovative payment structures from the drug manufacturer (or other party) that may be available for the APAD Carve-Out Drug, or to implement CMS guidance that may apply to the APAD Carve-Out Drug).

6. Claims Adjudication:

Claims for APAD Carve-Out Drugs submitted using the instructions set forth above will suspend for review and pricing by the MCO. Upon completion of the steps above, the MCO will release the claim to complete its adjudication.

7. Instructions for Reporting on the Cost Report:

Hospitals that receive payment for APAD Carve-Out Drugs shall separate the total cost and charges for these drugs to report on a separate non-reimbursable cost report cost center line from the "Drugs Charged to Patients" cost report line. No additional overhead costs shall be assigned to this separate

line. There will be no additional payment allowed through the cost report settlement process, supplemental payments (including state directed payments) or disproportionate share adjustment payments as the actual acquisition cost utilized for the claim is the final payment.