JULY 2024

Spotlight: Tell CMS to Provide Separate Payment for Outpatient CAR-T Services!

The Centers for Medicaid & Medicare Services (CMS) should provide separate payment to hospitals for the CAR-T cell collection and cell processing clinical services they provide to patients.

New codes approved by the American Medical Association (AMA) for these services go into effect on January 1, 2025[1]—so, now is the time for stakeholders to submit comments to CMS on the CY 2025 Outpatient Prospective Payment System (OPPS) proposed rule.[2] Tell the agency that these codes *must* be paid for separately and that existing HCPCS Level II CAR-T Product Q-code descriptions *must* be changed.

Cell collection and cell processing are distinct clinical services that warrant separate payment

For CAR-T patients, cell collection and cell processing ("leukapheresis and dose preparation") are specific clinical services ordered by treating clinicians and furnished by specially trained clinical staff. Collecting and processing cells involves personnel, equipment, and supply costs that are borne by each furnishing hospital and should be reimbursed by CMS.

Cell collection and lab processing services occur before the manufacturer receives the patient's cells, and dose preparation occurs after the manufacturer returns the CAR-T product to the hospital for administration (i.e., these services are on behalf of the patient and not part of the manufacturing process).

CMS recognizes that cell collection (CPT® code 3X018) and cell processing (CPT® codes 3X019 and 3X020) are distinct clinical services that are eligible for payment separate from the CAR-T product. This is evidenced by the agency's request for comment in the CY 2025 Medicare Physician Fee Schedule (MPFS) proposed rule on what the *practice expense component* for these services should be in the office (i.e., non-facility setting).[3]

If these services were not viewed as distinct clinical services that represent an expense to the entity performing the service, there would be no reason for CMS to seek input on what practice expense values to assign.

Given this, stakeholders should ask CMS to treat these services in an equivalent manner under OPPS. CMS could do so by assigning payable status indicators and APCs (see Table 1) to these services.

Comment deadline is September 9th!

Submit your comments to CMS as soon as possible.

Cell collection and cell processing are separate from product costs or payments

It is obvious that hospitals incur costs when they collect cells from patients and when their laboratories process cells for the CAR-T therapy. By not separately paying hospitals for cell collection and cell processing services, CMS, unlike other payers, seems to suggest that hospitals receive payment from some other source, such as the manufacturer. Yet, hospitals anecdotally report that this is not the case.

If CMS assumes that its product payment should cover hospital clinical service cost for collection and processing, it is not accounting for the reality that, in an estimated 10-15% of cases, patients' cells are collected and processed but the patient cannot receive the final CAR-T product. This happens for a variety of reasons, such as when the patient has a change of clinical status or if there are any manufacturing defects.

Table 1

		CMS' Proposal for CY 2025			What CMS Should Finalize for CY 2025		
HCPCS Code	Short Descriptor	SI	APC	Payment Rate	SI	APC	Payment Rate
3X018	Car-t hrv bld-drv t lymphcyt	B		$0.00	S	5242	$1,644.59
3X019	Car-t prep t lymphcyt f/trns	B		$0.00	S	5241	$431.37
3X020	Car-t receipt&prepj admn	B		$0.00	S	5241	$431.37
3X021	Car-t admn autologous	S	5694	$327.68	S	5694	$327.68

Additionally, sometimes one hospital performs cell collection and outbound lab processing, while another performs inbound lab processing and administers the CAR-T product. In both situations, the hospital that provided cell collection and outbound lab processing receives no payment, despite having expended resources. CMS must provide separate payment for these services at the time they are rendered, and to the entity that does the work and incurs the costs.

Level II product HCPCS codes should not include clinical services described by Level I HCPCS codes

Under the part of the Health Information Portability and Accountability Act (HIPAA) that governs medical code sets, HCPCS Level II is described as "…a standardized coding system that is used primarily to identify drugs, biologicals and non-drug and non-biological items, supplies, and services **not included in the CPT® code set jurisdiction** [emphasis added]".[4]

Now that HCPCS Level I (CPT®) codes exist for distinct CAR-T clinical services,[5] the HCPCS Working Group will be in conflict with its own statement about what HCPCS Level II codes are used to identify if it continues to include cell collection and cell processing in CAR-T product descriptions.

The HCPCS Working Group recognized the importance of this in April 2024, when it released HCPCS Level II product codes for Hematopoietic Stem Cell (HSC) gene therapy products.[6] Neither of the gene therapy product code descriptions mention cell collection or cell processing services, despite the fact that these clinical services are as necessary for developing gene therapy products as they are for CAR-T products.[7] Moreover, the FDA approved CAR-T and HSC gene therapy products as biologics so there is no basis for CMS to treat the product code descriptions or the services associated with each therapy differently.

CMS must make consistent coding decisions that follow its own rules across all therapies. CMS should update all 6 HCPCS Level II CAR-T Q-codes as follows (example product description shown):

CAR-T product X, up to 200 million autologous anti cd19 car positive viable t cells~~, including leukapheresis and dose preparation procedures, per therapeutic dose~~

Stakeholders must weigh in now to get CMS to act!

Stakeholders need to ask CMS to change the Level II HCPCS CAR-T code desecriptions so that they no longer reference clinical services and ensure appropriate payment is provided to hospitals for the clinical services they provide to patients (Table 1). The fix is easy and within scope as CMS finalizes OPPS and HCPCS codes for CY 2025.

Stakeholders must work together to tell CMS to make these needed changes; together, we can ensure that proper coding and reimbursement is in place for implementation on January 1, 2025.

Take Action With CMS Now!

- Comments due **September 9**; submit sooner so staff have more time to review
- Submit via the comment link
- Comment as an individual if you cannot submit on behalf of an organization
- Ask other stakeholders to submit comments
- Contact your professional society or advocacy organization (e.g., AHA, HFMA, ASTCT, ASH) and ask them to include the changes described in Table 1 and the example HCPCS product box in their comment letters

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[1] Centers for Medicare & Medicaid Services (CMS), "Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems…" *Federal Register*, July 22, 2024. Download the PDF here.

[2] American Medical Association (AMA), "Tab#10," in *CPT® Editorial Summary of Panel Actions May 2023*, June 1, 2023, pg 2. Download the PDF here.

[3] CMS, "Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies…," *Federal Register*, July 31, 2024, pg. 139 (display copy). Download the PDF here.

[4] CMS, *Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures*, Baltimore (MD): CMS, December 2022, pg. 1. Download the PDF here.

[5] AMA, "Tab#10," *CPT® Editorial Summary of Panel Actions*.

[6] CMS, "ZYNTEGLO™-HCP231229C71X3" and "LYFGENIA™-HCP231229CVUDD," in *Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Recommendations: First Quarter, 2024 HCPCS Coding Cycle,* Baltimore (MD): CMS, no date, pp. 11-12.

[7] J3394 (Lyfgenia): "Injection, lovotibeglogene autotemcel, per treatment;" J3393 (Zynteglo): "Injection, betibeglogene autotemcel, per treatment."