AUGUST 2024

Spotlight: CMS Must Value CAR-T Services in Both the Hospital and Physician Office Settings

Four new Current Procedural Terminology (CPT®) codes for CAR-T cell collection, cell processing (outbound and inbound), and administration (3X018-3X021) were approved by the American Medical Association (AMA) in May 2023 and will go into effect January 1, 2025.[1]

The Centers for Medicare and Medicaid Services (CMS)' annual release of the Medicare Physician Fee Schedule (MPFS) proposed and final rules is the policy vehicle by which these and other codes are assigned payment values. **For CMS to correctly value and pay for the new CAR-T CPT® codes, providers need to submit comments before September 9th on the CY 2025 MPFS proposed rule**.[2] Specifically, CMS needs to hear that it should finalize payment values for all of the new codes and, relatedly, that the existing HCPCS Level II CAR-T Product Q-code descriptions *must* be changed to remove the clinical services described by the new CAR-T Category I CPT® codes.

CMS should implement the AMA's recommendations on new code values

The AMA has a multispecialty committee called the Relative Value Scale Update Committee (RUC).[3] This expert panel makes recommendations to CMS on the resources required to provide medical services.

In making recommendations, the RUC considers physicians' work effort (the time and intensity associated with a service) and practice expense (PE). This includes clinical staff time, medical supplies, medical equipment, and professional liability insurance associated with performing a service.

The RUC regularly reviews medical services and submits recommendations to CMS for consideration. CMS makes all final decisions about what the payments should be for each service under the Medicare program, via an annual rule-making process.

The finalized values impact payments to physicians providing services in hospitals (facility setting) and free-standing physician offices (non-facility [NF] setting).

As part of its September 2023 meeting, the RUC reviewed the physician work and PE for the four new CAR-T codes and forwarded recommendations to CMS for consideration.

Stakeholders should respond to CMS' request for comments and tell the agency ***to finalize the physician work RVUs proposed by the RUC*** for all four CAR-T CPT® codes (3X018-3X021) ***as well as the proposed PE RVU for CAR-T administration*** (3X021).

CMS did not establish NF PE RVUs for the cell collection and processing codes (3X018-3X020). ***Stakeholders should also consider providing their recommendations to CMS on the appropriate valuation for the NF PE RVUs for these three services.***

Because CMS seeks input on PE RVUs for cell collection and cell processing, Nimitt believes it shows that CMS understands these are clinical services separate and distinct from the drug/biological product; but, CMS needs more information in order to value the services correctly for payment purposes in the non-facility setting.

CMS should assign NF PE RVUs to cell collection and lab processing services in order to provide appropriate reimbursement in the physician office setting

As stakeholders already know, these services are furnished by specially trained clinical staff and involve equipment, supplies, and staffing costs. Physicians may perform these services directly, as "incident to" services, or refer patients to another physician or hospital that will perform the services.

Stakeholders need to respond to CMS' request for input on what NF PE RVUs would be appropriate for CAR-T cell collection and cell processing services.

CMS has the regulatory authority to assign interim NF PE RVUs for CY 2025. This will enable CMS to reimburse for these services when provided in the non-facility setting. Nimitt believes that CMS expects this to occur, given its release of *Transmittal 11774,* providing detailed billing guidance.[4]

Level II product HCPCS codes should not include clinical services described by Level I HCPCS codes (i.e., CPT® codes)

Under the Health Insurance Portability and Accountability Act (HIPAA) rules that govern medical code sets, the HCPCS Level II code set 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]".[5]

Now that HCPCS Level I (CPT) codes exist for these distinct CAR-T clinical services,[6] the HCPCS Working Group should revise existing HCPCS Level II CAR-T product Q-code descriptions by removing reference to cell collection and cell processing. This will enable CMS to align with its own core principle under HIPAA.

Thankfully, the HCPCS Working Group appears to have recognized the importance of this core principle, as evidenced by its April 2024 release of two new HCPCS Level II product codes for Hematopoietic Stem Cell (HSC) gene therapy products.[7]

Neither of the gene therapy product code descriptions mention cell collection or cell processing services, despite the fact that these same distinct clinical services are as necessary for developing the gene therapy products as they are for developing CAR-T products.[8]

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!

Take Action With CMS Now!

- Comments are due **September 9**; but submit sooner so staff have more time to review
- Submit via this website
- 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 and ask them to include the changes that we have described in their comment letters

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

[2] Centers for Medicare & Medicaid Services (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. Download the PDF here (pg. 139 display copy).

[3] American Medical Association (AMA), *An Introduction to the RUC,* Chicago (IL): AMA, no date. Download the PDF here.

[4] CMS, *Medicare Claims Processing Transmittal 11774, NCD 110.24: Chimeric Antigen Receptor (CAR) T-cell Therapy*, Baltimore (MD): December 30, 2022. Download the PDF here.

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

[6] AMA, "Tab # 10," *CPT® Editorial Summary of Panel Actions*. Download the PDF here.

[7] 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.

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