

CAR-T Cell Collection and Processing Procedural Services

Advisory Panel on Hospital Outpatient Payment

August 2024

Financial Relationship

- The National Association of Healthcare Revenue Integrity, NAHRI, is a membership and certification organization representing Revenue Integrity professionals working in healthcare settings
- Presenters are volunteer members of the NAHRI Advisory Board, and have no financial relationship to report related to this presentation
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Action Requested

- CMS should assign Status Indicator “S” to CAR-T CPT® codes 3X018, 3X019, and 3X020
- CMS should assign to most clinically appropriate APCs

Description of the Issue

- CPT® Category III codes 0537T, 0538T, and 0539T are assigned SI “B”
- Existing codes are replaced with new CPT® Category I codes 3X018, 3X019, and 3X020 effective January 1, 2025
 - 3X018 Chimeric antigen receptor T-cell therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day
 - 3X019 Chimeric antigen receptor T-cell therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)
 - 3X020 Chimeric antigen receptor T-cell therapy; receipt and preparation of CAR-T cells for administration
- CMS maintains SI “B” in 2025 via NPRM Addendum B
- These clinical services occur months to weeks in advance of potential CAR-T cell infusion, and are distinct services separate from the manufacturing of the CAR-T cell product and should be allowed to be reported and paid separately at the time they occur
- The work to collect and prepare the cells comes at a cost to the hospital and are not captured in current ratesetting or through the payment of the product when CAR-T is administered in the outpatient setting

Description of the Issue

- SE19009 (<https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/se19009.pdf>) provides charging and billing scenarios which are financially and operationally burdensome and untenable for hospitals
- CMS offers three non-manualized scenarios for submitting charges for these services that may be summarized as follows
 - *Option 1: Report CPT codes and charges on outpatient claims and accept a rejection per OCE edit 111.*
 - Best practice: but not always used, since the rejection from CMS raises questions
 - *Option 2: Build charges for cell collection and cell processing services into the CAR-T Q-code drug/product charge and report only a single charge*
 - Problem: hospital service charges buried in the drug/biological charge; information not used in rate-setting
 - Problem: does not address instances where product is ultimately not administered
 - *Option 3: Report outpatient cell collection and cell processing charges on inpatient claim (whether separately or as part of drug/product charge*
 - Problem: outpatient charges occurring > 3 days prior to the inpatient stay are reported on an inpatient claim and these charges are used in the outlier payment calculation and future rate-setting; counting these charges as covered and payable on inpatient claims but not outpatient claims seems to be inconsistent
- These instructions are inconsistent with both OPPS and IPPS claims reporting and processing principles, require providers to “hold charges” over time, and usually require human intervention prepare the claim(s) for submission

Recommendation and Rationale for Change

- Recommendation
 - CMS should assign status indicator "S" to CPT codes 3X018, 3X019, and 3X020
 - CMS should assign to most clinically appropriate APCs
- Rationale
 - Under OPPS, hospitals report the services performed at each outpatient encounter and bill these on individual outpatient claims with the date that the service was provided and with most specific CPT/HCPCS code available.
 - Cell collection and cell processing are outpatient hospitals services that should be allowed to be reported as they occur using standard claims reporting practices consistent with 100-04 Medicare Claims Processing Manual principles
 - Hospitals incur a cost for the services they provide to patients and should receive payment for these services separately from any drug product payment as that may or may not occur
 - By streamlining the reporting of these services, providers will be able to report the clinical services rendered to patients in real-time on outpatient claims, without facing a rejection
 - CMS will eliminate much confusion and reporting inconsistency caused by current billing scenarios

Potential Consequences of Not Making Change



- Hospital providers will continue to receive no payment for the clinical/procedural services associated with cell collection and outbound/inbound cell processing, which occur well in advance of CAR-T administration
- Hospital providers will continue to be subjected to administrative burden, confusion, and unusual practices which inhibit use of usual claims submission processes
- Lack of separate payment for services ordered by clinicians and provided by hospital staff places unreasonable financial pressure on hospitals and is not in line with how CMS pays for other clinical services and could lead to reduced access to care

Summary

- NAHRI respectfully requests the HOP Panel recommend to CMS that it assign status indicator “S” to CPT codes 3X018, 3X019, and 3X020 and assign resource homogeneous APCs to these services.