



Chimeric Antigen Receptor T-Cell (CAR-T) Therapy Category III CPT Codes

Advisory Panel on Hospital Outpatient Payment Panel (HOP Panel)

August 26-27, 2024

Submitted by: The American Society of Transplantation and Cellular Therapy

Presentation Checklist

- Financial relationships – slide 3
- CPT/HCPCS codes and APCs involved – slide 4
- Description of the issue – slides 5-7
- Recommendation/rationale – slides 8-9
- Expected outcome – slide 10
- Potential consequences of not making the change – slide 11

Financial Relationships

Ellen Fraint, MD

Attending Physician, Pediatric Transplantation and Cellular Therapy, Nemours Children's Hospital

No financial relationships to report

Jugna Shah, MPH, CHRI

President, Nimit Consulting, Inc.

Paid consultant of the ASTCT

CPT/HCPCS Codes and APC Groups the Presentation Covers



This presentation involves the following CPT[®] codes and APCs:

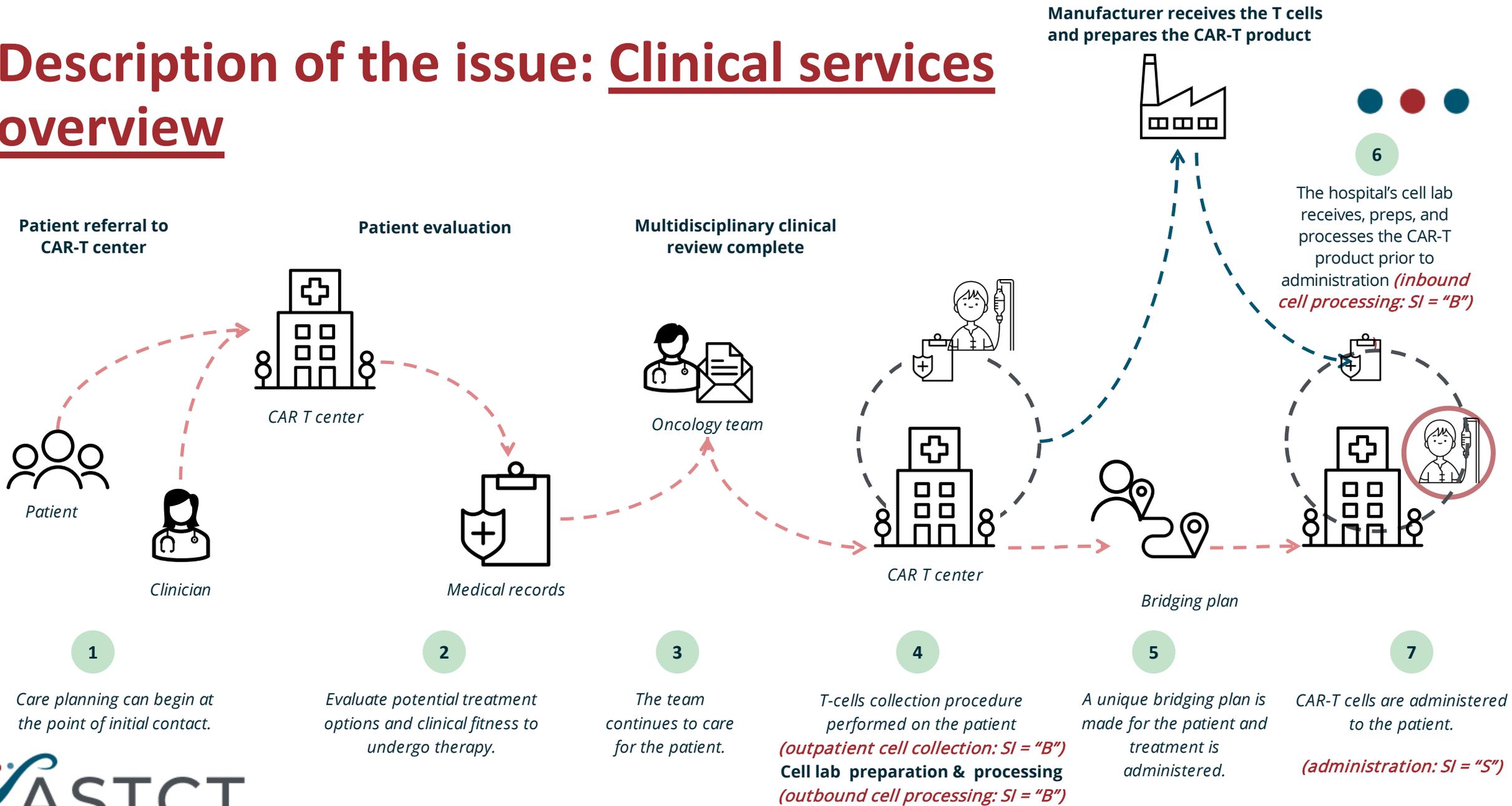
CY 2025 OPSS Proposed Rule					ASTCT's Request for CY 2025 OPSS Final Rule				
HCPCS Code	Short Descriptor	SI	APC	Payment Rate	HCPCS Code	Short Descriptor	SI	APC	Payment Rate
0537T	Bld drv t lymphcyt car-t cll	D		\$0.00	0537T	Bld drv t lymphcyt car-t cll	D		\$0.00
0538T	Bld drv t lymphcyt prep trns	D		\$0.00	0538T	Bld drv t lymphcyt prep trns	D		\$0.00
0539T	Receipt&prep car-t cll admn	D		\$0.00	0539T	Receipt&prep car-t cll admn	D		\$0.00
0540T	Car-t cll admn autologous	D		\$0.00	0540T	Car-t cll admn autologous	D		\$0.00
3X018	Car-t hrv bld-drv t lymphcyt	B		\$0.00	3X018	Car-t hrv bld-drv t lymphcyt	S	5242	\$1,644.59
3X019	Car-t prep t lymphcyt f/trns	B		\$0.00	3X019	Car-t prep t lymphcyt f/trns	S	5241	\$431.37
3X020	Car-t receipt&prepj admn	B		\$0.00	3X020	Car-t receipt&prepj admn	S	5241	\$431.37
3X021	Car-t admn autologous	S	5694	\$327.68	3X021	Car-t admn autologous	S	5694	\$327.68

The focus of today's presentation is the non-payable status of CPT[®] codes 3X018, 3X019, and 3X020, which represent clinical services that are necessary to deliver CAR-T therapy to patients. The ASTCT is asking **the HOP Panel once again* recommend to CMS** that the agency assign status indicator "S" to CAR-T cell collection and cell processing services, in recognition of the fact that these are clinical services completely separate from the manufacturing process of the drug/biologic.



* HOP Panel recommendations document for the Category III CPT that became effective January 1, 2019: <https://www.cms.gov/regulations-and-guidance/guidance/facaapc-panel-archives/august-20-2018-agenda-recommendations-presentations-and-virtual-attendance-instructions>

Description of the issue: Clinical services overview



Description of the issue: Lack of separate payment problematic for hospitals



Since the implementation of Category III CPT[®] codes in 2019 for distinct CAR-T clinical services, CMS has not recognized separate payment for (1) leukapheresis/cell collection; (2) cell processing; and (3) dose preparation procedures. When asked about this, CMS has stated the following:

- CY 2019 OPPS final rule: *“The procedures described by CPT[®] codes 0537T, 0538T, and 0539T describe various steps required to collect and prepare the genetically modified T cells, and Medicare does not **generally** [emphasis added] pay separately for each step used to manufacture a drug or biological.”*
- CY 2020 OPPS final rule: *“... we note that CAR T-cell therapy is a unique therapy approved as a biologic, with unique preparation procedures, and it cannot be directly compared to other therapies or existing CPT[®] codes. We note that the current HCPCS coding for the currently approved CAR T-cell therapy drugs, HCPCS codes Q2041 and Q2042, include leukapheresis and dose preparation procedures as these services are including in the manufacturing of these biologicals. Therefore, payment for these services is incorporated into the drug Q-codes.”*

Description of the issue: Lack of separate payment and operational burden is problematic for hospitals



- Hospitals face significant operational burden due to CMS' status indicator "B" assignment, which results in a rejection of CPT[®] codes for clinical CAR-T services and does not allow claims to process normally
- CMS' reference in the CY 2020 OPPS final rule to the descriptions of HCPCS *Q2041 and Q2042* including the words "*leukapheresis and dose preparation procedures*" does not mean that hospitals are paid for these services
 - In 2019, ASTCT along with many other stakeholders requested CMS' HCPCS Working Group to remove references to the clinical services of "*leukapheresis and dose preparation procedures*" from the HCPCS Level II code descriptors*
 - Charges reported on outpatient claims for CAR-T Q-codes are not used for rate-setting since CMS uses the Average Sales Price (ASP) methodology to set payment rates for drugs and biologicals and those data come from manufacturers
- CMS has not explained what makes CAR-T unique such that it is being treated differently from other therapies
 - However, with the HCPCS Working Group's recent decision** to release two gene therapy product codes***—which, like CAR-T require leukapheresis and dose preparation procedures (without those words included in the product code descriptors)—we believe that recognition now exists that it is inappropriate to include clinical services in HCPCS Level II code descriptions when HCPCS Level I codes (e.g., CPT[®]) already exist

* https://www.astct.org/Portals/0/Docs/Advocacy_Statements/April_2019_HCPCS_CAR-T_Q_Code_Statement_1_.pdf

** CMS, "ZYNTEGLO™-HCP231229C71X3" and "LYFGENIA™-HCP231229CVUDD," in HCPCS Application Summaries and Coding Recommendations: First Quarter, 2024 HCPCS Coding Cycle, Baltimore (MD): CMS, pp. 11-12.

*** J3394 (Lyfgenia): "Injection, lovoitibeglogene autotemcel, per treatment" and J3393 (Zynteglo): "Injection, betibeglogene autotemcel, per treatment"

Recommendation



ASTCT requests the HOP Panel, once again*, recommend to CMS that it assign status indicator “S” and the APCs that are shown in the table below to the new Category I CAR-T CPT[®] codes for January 1, 2025

HCPCS Code	Short Descriptor	ASTCT's Request for CY 2025 Final Rule		
		SI	APC	Payment Rate
3X018	Car-t hrv bld-drv t lymphcyt	S	5242	\$1,644.59
3X019	Car-t prep t lymphcyt f/trns	S	5241	\$431.37
3X020	Car-t receipt&prepj admn	S	5241	\$431.37
3X021	Car-t admn autologous	S	5694	\$327.68

* HOP Panel recommendations document for the Category III CPT that became effective January 1, 2019: <https://www.cms.gov/regulations-and-guidanceguidancefacaapc-panel-archives/august-20-2018-agenda-recommendations-presentations-and-virtual-attendance-instructions>

Rationale for Recommendation



- Clinical services represented by HCPCS Level I (CPT) codes should not be embedded in HCPCS Level II codes*
- Implementation of AMA's Category I CPT codes for leukapheresis and dose preparation procedures on January 1, 2025** is an opportunity to assign status indicator "S" while simultaneously changing CAR-T product Q-code descriptions
- Release of revenue codes 0871-0873 by the National Uniform Billing Committee (NUBC) for CAR-T clinical services and a separate revenue code, 0891, for drugs/cell therapy product*** indicates that clinical services are separate from products
- CY 2024 implementation of a revenue code to cost center mapping where CAR-T clinical service revenue codes (0871-0873) map to clinical cost centers (e.g., clinic, hematology, IV therapy) rather than the drugs charged to patient cost center
- Release of HCPCS Level II codes for two gene therapies in April 2024 by the HCPCS Working Group that do not include any reference to leukapheresis and dose preparation procedures**** despite the therapy requiring those clinical services
- Consistent coding and payment decisions across all cell and gene therapies
- Hospitals will be paid for the distinct clinical services they provide to patients, as described by AMA CPT® codes
- Elimination of hospital operational burden, since CMS would no longer reject AMA CPT® codes for CAR-T services
- Better visibility of cost information on claims submitted by hospitals, which can be used for future rate-setting

* <https://www.cms.gov/medicare/coding/medhcpcsgeninfo/downloads/2018-11-30-hcpcs-level2-coding-procedure.pdf> (page 1)

** <https://www.ama-assn.org/system/files/cpt-summary-panel-actions-may-2023.pdf>

*** <https://www.nubc.org/system/files/media/file/2020/02/Cell-Gene%20Therapy%20Code%20Changes.pdf>

**** <https://www.federalregister.gov/documents/2023/11/22/2023-24293/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment> (page 81550-81551)

***** CMS, "ZYNTEGLO™-HCP231229C71X3" and "LYFGENIA™-HCP231229CVUDD," in HCPCS Application Summaries and Coding Recommendations: First Quarter, 2024 HCPCS Coding Cycle, Baltimore (MD): CMS, pp. 11-12.

Expected outcome



- **Reduced financial burden** if CMS provides separate payment to hospitals for the cell collection and cell processing costs, they incur, that they are not currently reimbursed for
- **Reduced operational burden** because CMS will be able to retire the guidance provided in Special Edition (SE) article 19009; this will enable hospitals to simply follow standard claims submission practices for reporting covered outpatient hospital services in a manner that is consistent with all other Part B outpatient hospital services
- **Expanded patient access without an increase in financial burden** as more products, for different indications, and for earlier lines of therapy, are approved
- **Availability of better claims data** for CMS' tracking and future rate-setting purposes

Potential consequences of not making the change



- Even if CMS believes that its ASP-based CAR-T product payment is sufficient to cover the clinical services hospitals provide to patients, there will be zero payment in about 10-15% of cases, when patients do not receive *any* product due to disease progression, death, or manufacturing failures
- Growing volume will amplify current hospital concerns and could lead to patient access issues:
 - In addition to the currently approved CAR-T products, more are coming that will involve similar cell collection
 - Earlier lines of therapy with current CAR-T products mean increased volume
 - Expansion to more hospitals by manufacturers also means an increase in expected total volume
- Increased provider confusion and questions around why CMS makes separate payment for some cell collection and cell processing services for other therapies that clinicians provide (such as stem cell transplants and gene therapies) but not for CAR-T
- Lack of transparency around hospital charges due to CMS providing three reporting options for CAR-T clinical services in Special Edition Article (SE 19009) and providers reporting inconsistent claims
- Mismatch between revenue code reporting and cost reporting practices for CAR-T cell therapy