

## **CAR T-cell Coding, Coverage, and Reimbursement (2025): (Frequently Asked Questions)**

(answers (in blue) are for general guidance only)\*

- 1) What CPT codes should be used to correctly bill for professional services for specific leukapheresis procedures: a) WBC depletion; b) Hematopoietic Stem Cell Collection (Autologous); c) Hematopoietic Stem Cell Collection (Allogeneic); d) CAR T-cell collection?

Answer: It is very important to use the correct CPT codes when billing for each of these leukapheresis procedures; failure to utilize the correct CPT codes could be construed as fraudulent billing:

- WBC depletion: CPT 36511
- Hematopoietic Stem Cell Collection (Autologous): CPT 38206
- Hematopoietic Stem Cell Collection (Allogeneic): CPT 38205
- CAR T-Cell Collection (Autologous): CPT 38225

- 2) If one is performing WBC collection for CAR T-cell research, is that paid per collection?

Answer: Yes. In general, WBC collections for CAR T-cell research initiatives and clinical trials specifically are paid by the research group funders; remuneration normally includes payment for the technical procedure and the fee for professional services.

- 3) If an <sup>1</sup>academic (or other) medical center: a) evaluates and approves a cancer patient (based on appropriate criteria) for an FDA-approved CAR T-cell therapy, and the patient's main insurance is Medicare, and b) the autologous CAR-T cell product is successfully created and infused safely into the designated patient without significant adverse effects, would CMS pay the <sup>1</sup>academic (or other) medical center a designated lump-sum (under the appropriate HCPCS and APC codes), for technical and professional services, from which the <sup>1</sup>medical center pays the manufacturer a negotiated sum (for the specific CAR T-cell therapy), and also pays the entities which provided: a) WBC collection (CPT 38225), b) preparation of WBC for transportation/storage/cryopreservation (CPT 38226), c) receipt of CAR T-cell product and preparation for intravenous administration (CPT 38227), and d) CAR T-cell administration (CPT 38228)?

Answer: Yes. The <sup>1</sup>medical center authorized to provide the specific CAR T-cell treatment may perform any or all of the <sup>2</sup>technical services (defined by CPT 38225-38228) in-house. In which case, the hospital's finance function would pay for the WBC collection via an internal transfer of funds to the department(s) which provide(s) the WBC collection and/or other technical services.

- 4) Is CMS currently paying MD/Advanced Practice Provider (APP) fees for <sup>3</sup>professional services for WBC collection for CAR T-cell development? [See answer to Question #5].

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- 5) Given the new HCPCS/CPT codes for CAR-T cell (38225, 38226, 38227, and 38228) with associated total Non-Facility and Facility RVUs, is there information in the CMS website which provides guidance regarding the following: a physician (or APP) should (or should not) directly bill (and expect reimbursement from) CMS for <sup>3</sup>professional services associated with CPT codes 38225, 38226, 38227, or 38228?

**Answer:** recommend this webpage: <https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notice/cms-1807-f>; and click on: [CY 2025 PFS Final Rule Addenda \(Updated 12/26/2024\)](#) in the “Downloads” section. Review the excel file titled “Addendum B Relative Value Units and Related Information CY 2025 CMS 1807-F”.

Use the “Find” function to search for 38225, and review this table:

Addendum B – Relative Value Units and Related Information Used in CY 2025 Final Rule										
CPT <sup>1</sup> / HCPCS	Mod	Status	Not Used for Medicare Payment	DESCRIPTION	Work RVUs <sup>2</sup>	Non- Facility PE RVUs <sup>2</sup>	Facility PE RVUs <sup>2</sup>	Mal- Practice RVUs <sup>2</sup>	Total Non- Facility RVUs <sup>2</sup>	Total Facility RVUs <sup>2</sup>
38225		B	+	Car-t hrv bld-drv t lymphcyt	1.94	NA	0.76	0.20	NA	2.90
38226		B	+	Car-t prep t lymphcyt f/trns	0.79	NA	0.31	0.07	NA	1.17
38227		B	+	Car-t receipt&prepj admn	0.80	NA	0.31	0.07	NA	1.18
38228		A		Car-t admn autologous	3.00	5.46	2.07	0.20	8.66	5.27

A physician (or APP) can bill Medicare for CPT 38225, 38226, and 38227 <sup>3</sup>professional services provided to a traditional fee-for-service Medicare patient, just as he/she would fill out a claim for any other insurer. But CMS will not pay for any of those 3 professional services, because they’re bundled (status “B”) into the applicable CAR T-cell therapy APC (see the first table on page 28 of the 2025 ASFA Reimbursement Guide for the CAR T-cell inpatient stay (MS-DRG 018)). CMS defines this process by including a “+” in the column indicating that these CPT codes are “not used for Medicare payment.” Other insurers, in particular commercial insurers, may cover and pay separately for the <sup>3</sup>professional services associated with CPT 38225, 38226, and 38227. When in doubt, it is recommended that the physician, or APP, submit the claim.

Conversely for CPT 38228 (according to Addendum B, RVU used in CY 2025 Final Rule), Medicare has set up the mechanism to cover (and pay) for physician (or APP) <sup>3</sup>professional services associated with administration of the CAR T-cells in either the physician office/clinic or hospital treatment settings. The RVUs are actually higher when the CAR T-cells are administered in the non-facility (physician office/clinic) setting (8.66 RVUs) than the hospital inpatient or outpatient setting (5.27 RVUs). [Also see answer to question #6].

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- 6) Assuming the <sup>1</sup>academic (or other) medical center successfully infuses the CAR-T cell product into the designated patient, can the physician (or APP) bill (and expect to be paid by) CMS (using CPT 38228) for <sup>3</sup>professional services related to supervising the CAR T-cell product infusion?

Answer: Yes. Physicians, physician practice groups, or APPs directing apheresis treatment (and assuring its safety) can bill for CPT 38228 and should receive Medicare payment for professional services based on 8.66 RVUs (non-facility setting) or 5.27 RVUs (facility setting); see answer to Question #5.

However, note that (at the current time), CMS does not cover or reimburse separately for <sup>2</sup>technical services for any of the four CPT codes 38225-38228, as shown below from the CY 2025 hospital OPPS payment rate schedule (NC = not covered; B = bundled into the payment for the overall CAR T-cell service under the applicable Q code/APC or under MS-DRG 018; S = separately payable):

Addendum B-- OPPS Payment by HCPCS Code for CY 2025						
HCPCS Code	Short Descriptor	CI	SI	APC	Relative Weight	Payment Rate
38225	Car-t hrv bld-driv t lymphcyt	NC	B			
38226	Car-t prep t lymphcyt f/trns	NC	B			
38227	Car-t receipt&prepj admn	NC	B			
38228	Car-t admn autologous	NC	S	5694	3.7198	\$331.69

CMS has defined an APC (5694) and a payment rate (\$331.69) for the CAR T-cell administration service (CPT 38228), but <sup>2</sup>technical services related to CPT 38228 are currently not covered or paid under the CMS hospital OPPS.

- 7) If the WBC CAR-T cell product (anywhere along its development) is "out of spec", and cannot be used, or the patient expires while waiting for the development of the final CAR-T product, does CMS have the obligation to pay the <sup>1</sup>academic (or other) medical center any component of the designated lump sum? Is it correct that unless the appropriate CAR-T cell product is manufactured and successfully infused into the designated patient, this lump sum (covering all <sup>2</sup>technical and most <sup>3</sup>professional services of CPT 38225-38228 involved in the production and infusion of the specific CAR T-cell product) will not be paid by CMS?

Answer: Yes. The <sup>1</sup>academic (or other) medical center which went through the authorization process for the specific FDA-approved CAR T-cell product will not receive the designated lump sum reimbursement unless there is evidence the CAR T-cell product was administered to the patient. As CMS doesn't cover or pay individually for the T-cell harvesting procedure (or any of the other specific elements of the overall CAR T-cell treatment process, i.e., manufacturing, testing, cryopreservation, transportation, and administration), there is no mechanism for Medicare payment of the technical or professional services involved in the WBC harvesting procedure by itself.

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If the CAR T-cell product is “<sup>4</sup>out of spec” for any reason and cannot be used, the medical center may request a second (or third) WBC cell collection, and have the CAR T-cell manufacturing process repeated with the newly harvested T cells. If the CAR T-cell product remains “out of spec”, or the patient expires before receiving the final CAR T-cell product, CMS will not pay the designated lump sum (authorized for the successful completion of technical and professional services of CPT 38225-38228).

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**Footnotes:**

**<sup>1</sup>Academic (or other) medical center:** in this setting, this is defined as the medical center which completes the time-consuming, administrative task of medically qualifying the patient for an FDA-approved CAR T-cell therapy, and arranges for all of the steps involved in the creation and infusion of the single-dose therapy. Historically, this is the entity which receives the “lump-sum” payment from CMS (from which all <sup>2</sup>technical services (under CPT codes 38225-38228) and the following <sup>3</sup>professional services (under CPT codes 38225-38227, but not 38228) are paid).

**<sup>2</sup>Technical services:** all services involved in the harvesting, creation/manufacturing, testing, and infusion of CAR T-cell therapies are billed to CMS under CPT codes 38225, 38226, 38227, and 38228. All technical services are currently paid by CMS from the “lump-sum” bundled payment associated with the appropriate HCPCS “Q” and APC codes assigned to the specific CAR T-cell therapy.

**<sup>3</sup>Professional services:** all services provided by physicians (and APPs) in the supervision of the harvesting, creation, facilitation, testing, and infusion of CAR T-cell therapies are billed to CMS under CPT codes 38225, 38226, 38227, and 38228. All professional services related to CPT codes 38225, 38226, and 38227 are currently paid by CMS from the “lump-sum” bundled payment associated with the appropriate HCPCS “Q” and APC codes assigned to the specific CAR T-cell therapy. Professional services related to CPT code 38228 are billed and paid by CMS via application of Total Facility RVUs or Total Non-Facility RVUs (for 38228) based on the setting/location of the CAR T-cell infusion.

**<sup>4</sup>Out of spec:** manufacturing failure of the CAR T-cell product due to: 1) failure of cells to replicate in culture; 2) failure of cells to be successfully transfected and express the chimeric T-cell receptor; 3) bacterial contamination of (or presence of foreign material in) the cell cultures; or 4) inadequate viability of the cells after culture resulting in a less-than-adequate dose.

**Important – Please Note:**

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It is solely the responsibility of the provider to determine and submit appropriate codes, charges and other documentation in claims for services rendered.

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