

Autologous CAR-T Product Reporting Options <sup>1</sup>	Inpatient Claim - Facility Reporting						Outpatient Claim - Facility Reporting					
	Revenue Code <sup>2</sup>	Notes <sup>3</sup>	HCPCS Code <sup>4</sup>	HCPCS Product Code Description	Special Instructions for Clinical Trials and Expanded Access Cases <sup>5</sup>	Payment Implications	Revenue Code <sup>2</sup>	Notes	HCPCS Code	HCPCS Product Code Description	Payment Implications	
<b>PRODUCT REPORTING TO MEDICARE</b>  <i>For Commercial and Medicaid plans, reference individual payer policies and contracts to determine billing indicators for clinical trials and payment</i>	0891 - Special Processed Drugs - FDA Approved Cell Therapy	The charge for the product/drug is typically reported without a HCPCS code on inpatient claims.	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	For CAR-T cases where the hospital does not incur a cost for the product itself, Medicare will pay a reduced amount of MS-DRG 018.	All FDA-approved CAR-T products currently are assigned to MS-DRG 018. Product charges are used to determine outlier payments and used in future rate-setting.	0891 - Special Processed Drugs - FDA Approved Cell Therapy	Report appropriate HCPCS code for the product <sup>6</sup>	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	HCPCS product code generates ASP + 6% reimbursement (excludes sequestration)	
			Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, and dose preparation procedures, per therapeutic dose					Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, and dose preparation procedures, per therapeutic dose		
			Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose					Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose		
			Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose					Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose		
			Q2055	Idecabtagene vicleucel, up to 460 million autologous anti-bcma car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	For an expanded access case, after October 1, 2022, providers are instructed to put condition code 90 on the claim to receive the reduced MS-DRG 018 payment <u>since a CAR-T product cost was not incurred</u> . Prior to October 1, 2022, CMS had instructed providers to enter a Billing Note NTE02 "Expand Acc Use" on the electronic claim 837I or put "Expand Acc Use" in the remarks field on a paper claim (Form Locator 80).				Q2055	Idecabtagene vicleucel, up to 460 million autologous anti-bcma car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose		
			Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose					Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose		
			Q2058	Obecabtagene autoleucel, 10 up to 400 million cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose <sup>6</sup>					Q2058	Obecabtagene autoleucel, 10 up to 400 million cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose <sup>6</sup>		
			C9399 or J3590 and the product NDC until a HCPCS code is released	Other CAR-T products for which there is not an assigned HCPCS code	C9399 or J3590 and the product NDC until a HCPCS code is released				Other CAR-T products for which there is not an assigned HCPCS code			

<sup>1</sup> Medicare Special Edition article SE 19009 published May 28, 2019 updates information in the April 2019 OPPS Update Transmittal 4255 where CMS gives providers the option to include cell collection and cell processing charges with the product charge and report all under revenue code 0891. It can be found at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE19009.pdf>. Value code 86 may be used to report product acquisition cost if requested or allowed by payers.

<sup>2</sup> Revenue code 0891 (an extension of pharmacy 025x or 063x) was created by the National Uniform Billing Committee (NUBC) for reporting special processed drugs - FDA approved cell therapy and includes CAR-T products; see the NUBC manual for more details; <https://www.nubc.org/system/files/media/file/2020/02/Cell-Gen%20therapy%20Code%20Changes.pdf>. All providers and payers have to use the new codes per the HIPAA transaction code set regulation. Additionally, providers should review the instructions released by CMS in Transmittal R10571CP, effective Oct 1, 2020, to better understand how to report certain instances when a CAR-T product is not incurred (such as expanded access use) as well as when a CAR-T product cost is incurred but the patient is involved in a clinical trial of some other drug. This can be found at: <https://www.cms.gov/files/document/110571cp.pdf>

<sup>3</sup> In the FY 2021 and FY 2022 IPPS Final Rules, CMS states that there is nothing to preclude hospitals from setting their product charge in accordance with their hospital's cost-to-charge ratio (CCR). Providers should review this and report an appropriate charge as this will impact future MS-DRG 018 rate-setting.

<sup>4</sup> HCPCS codes do not typically print on inpatient Medicare claims so product Q-codes or C-codes (which likely will change to a Q-code) are not expected to appear on Medicare inpatient claims despite the codes being shown here, unless Medicare instructs differently.

<sup>5</sup> CMS Manual System Pub 100-4 Medicare Claims Processing, Transmittal R10571CP, effective Oct 1, 2020, section 5, "Payment Adjustment for CAR T-cell Clinical Trial and Expanded Access Use Immunotherapy Cases" at <https://www.cms.gov/files/document/110571cp.pdf>, and the FY 2023 IPPS Final Rule, where CMS finalized that providers will use condition code 90 to indicated expanded access cases (<https://www.federalregister.gov/d/2022-16472/p-1006>). For all other Medicare required clinical trial billing indicators, refer to Medicare Claims Processing Manual Chapter 12 – Billing Requirements for Special Services; 69 - Qualifying Clinical Trials: <https://www.cms.gov/regulations-and-guidance/guidance/manuals/download/cmi10432.pdf>.

<sup>6</sup> For more information, please see the CMS Q1 2025 HCPCS Quarterly Decision at <https://www.cms.gov/files/document/2025-hcps-application-summary-quarter-1-2025-drugs-and-biologicals.pdf>, page 15

<sup>7</sup> Determine specifics of reporting requirements from your state's Medicaid program and the specific patient's Medicaid plan.

<sup>8</sup> Also, report applicable modifiers (i.e., TB, AT)

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