

# YESCARTA®

## COMMUNITY CODING AND BILLING GUIDE



### // Information about reimbursement for YESCARTA and its administration

The use of the information in this guide does not guarantee reimbursement or that any reimbursement received will cover your costs. The information in this guide is subject to change. Payer coding requirements may vary or change over time. Healthcare providers should ensure they are using the latest coding information available. It is the responsibility of the healthcare provider to determine and submit the appropriate codes, charges, and modifiers for services that were rendered, and for these codes, charges, and modifiers to be supported by documentation in the patient's medical records. Always check with each payer for payer-specific requirements before submitting any claims, and always provide complete and accurate information when submitting claims for YESCARTA. Kite, a Gilead Company, and its agents disclaim any and all liability as a result of denied claims or incorrect codes.

### INDICATIONS

YESCARTA® is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of:

- Adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy.
- Adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

Limitations of Use: YESCARTA is not indicated for the treatment of patients with primary central nervous system lymphoma.

- Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Please see full Prescribing Information, including **BOXED WARNING** and Medication Guide.

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CAR=chimeric antigen receptor.

Please see full Prescribing Information, including **BOXED WARNING** and Medication Guide.

 **YESCARTA**<sup>®</sup>  
(axicabtagene ciloleuce)<sup>®</sup> Suspension  
for IV infusion

# // CODING AND BILLING GUIDE OVERVIEW

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# // Coding and Billing Guide Overview

This resource provides an overview of the current relevant codes, as of January 2024, that may be potential options for use with YESCARTA®.

Coverage and coding guidelines for YESCARTA and its administration may differ by insurer and may be updated regularly. In addition, reimbursement methodologies and rates may vary by payer and treatment setting and are guided by the specific contract the Authorized Treatment Center (ATC)\* has with a given payer. Always contact each patient's health insurance company directly to ensure that you have the most recent billing, coding, and coverage policy information, as well as discuss any reimbursement inquiries.

**Due to risk of neurologic toxicity and Cytokine Release Syndrome (CRS), YESCARTA availability is only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS. Further information is available at: [www.YescartaTecartusREMS.com](http://www.YescartaTecartusREMS.com) or 1-844-454-KITE (5483).<sup>1</sup>**

The information available within is compiled from sources believed to be accurate as of January 2024. Responsibility for properly submitting claims lies with the healthcare provider. Kite and its agents make no warranties or guarantees, expressed or implied, concerning the accuracy or appropriateness of this information for your particular use given the frequent changes in public and private payer billing. The use of this information does not guarantee reimbursement or that any reimbursement received will cover your costs. The information in this guide is subject to change. Healthcare providers should ensure they are using the latest coding information available. Payer coding requirements may vary or change over time, so it is important to regularly check with each payer for payer-specific requirements before submitting any claims.

\*Authorized Treatment Centers are independent facilities certified to dispense Kite CAR T therapies. Choice of an Authorized Treatment Center is within the sole discretion of the physician and patient. Kite does not endorse any individual treatment sites.

CAR=chimeric antigen receptor.

## IMPORTANT SAFETY INFORMATION

### WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, and SECONDARY HEMATOLOGICAL MALIGNANCIES

- Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving YESCARTA. Do not administer YESCARTA to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.
- Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving YESCARTA, including concurrently with CRS or after CRS resolution. Monitor for neurologic toxicities after treatment with YESCARTA. Provide supportive care and/or corticosteroids as needed.
- T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies, including YESCARTA.
- YESCARTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS.

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# // THE CAR T PATIENT-CARE PROCESS

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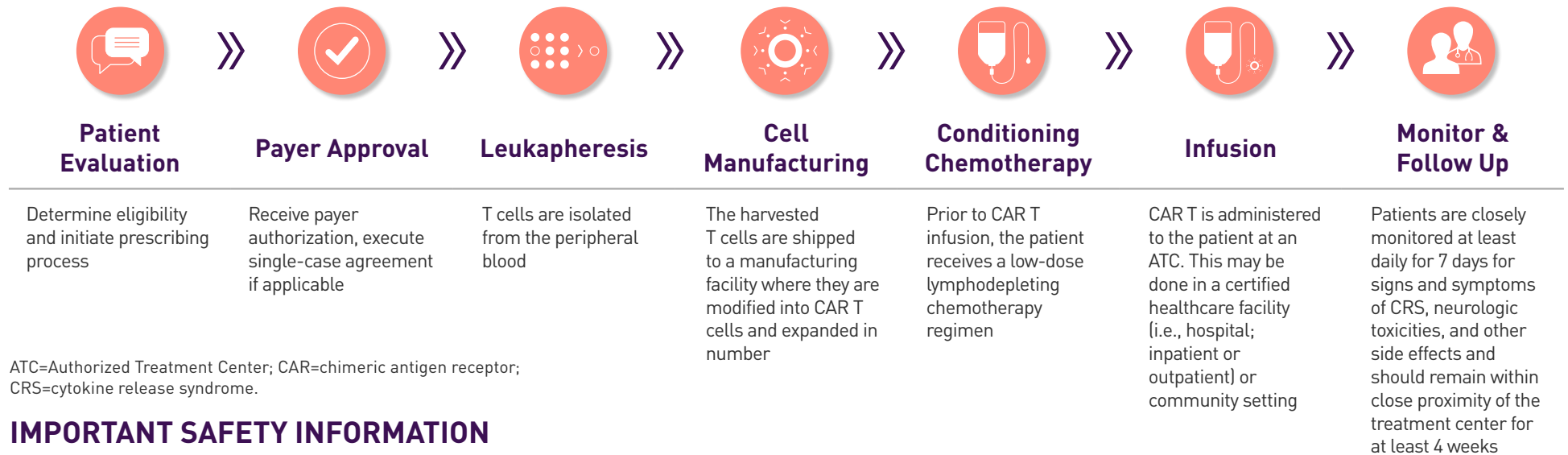
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# The CAR T Patient-Care Process

YESCARTA® is administered as a one-time infusion at an ATC.<sup>1</sup>



ATC=Authorized Treatment Center; CAR=chimeric antigen receptor; CRS=cytokine release syndrome.

## IMPORTANT SAFETY INFORMATION

### CYTOKINE RELEASE SYNDROME (CRS)

CRS, including fatal or life-threatening reactions, occurred following treatment with YESCARTA. CRS occurred in 90% (379/422) of patients with non-Hodgkin lymphoma (NHL), including  $\geq$  Grade 3 CRS in 9%. CRS occurred in 93% (256/276) of patients with large B-cell lymphoma (LBCL), including  $\geq$  Grade 3 in 9%. Among patients with LBCL who died after receiving YESCARTA, 4 had ongoing CRS events at the time of death. For patients with LBCL in ZUMA-1, the median time to onset of CRS was 2 days following infusion (range: 1-12 days) and the median duration was 7 days (range: 2-58 days). For patients with LBCL in ZUMA-7, the median time to onset of CRS was 3 days following infusion (range: 1-10 days) and the median duration was 7 days (range: 2-43 days).

CRS occurred in 84% (123/146) of patients with indolent non-Hodgkin lymphoma (iNHL) in ZUMA-5, including  $\geq$  Grade 3 CRS in 8%. Among patients with iNHL who died after receiving YESCARTA, 1 patient had an ongoing CRS event at the time of death. The median time to onset of CRS was 4 days (range: 1-20 days) and median duration was 6 days (range: 1-27 days) for patients with iNHL.

Key manifestations of CRS ( $\geq 10\%$ ) in all patients combined included fever (85%), hypotension (40%), tachycardia (32%), chills (22%), hypoxia (20%), headache (15%), and fatigue (12%). Serious events that may be associated with CRS include, cardiac arrhythmias (including atrial fibrillation and ventricular tachycardia), renal insufficiency, cardiac failure, respiratory failure, cardiac arrest, capillary leak syndrome, multi-organ failure, and hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS).

Please see full [Prescribing Information](#), including **BOXED WARNING** and Medication Guide.



# // OVERVIEW OF CODING FOR DIAGNOSIS, PREPARATION, AND ADMINISTRATION

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# // Overview of Coding

This section presents an overview of code sets for diagnosis, preparation, administration, and remote patient monitoring services in community practices. Please check with each payer for payer-specific requirements before submitting any claims for YESCARTA®.

Diagnosis Coding	
Diagnosis Coding for Product Indications	
Procedure Coding	
Cell Collection and Cell Processing Services	
Administration	
Remote Patient Monitoring Services Coding	
Product Coding	

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System;  
ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NDC=National Drug Code.

Please see full [Prescribing Information](#), including **BOXED WARNING** and Medication Guide.



# // Diagnosis Coding

## Diagnosis Coding for Product Indications

The following table lists the possible International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes applicable for YESCARTA® treatment. It is important that providers assess individual payer diagnosis coding requirements for each patient. It is the provider's responsibility to contact payers to clarify coverage and coding requirements. Providers must ensure that the most appropriate codes are selected for diagnosis (to the highest level of specificity).

ICD-10-CM Diagnosis Code <sup>2</sup>	Description <sup>2</sup>
C82.01-C82.09	Follicular lymphoma grade I
C82.11-C82.19	Follicular lymphoma grade II
C82.31-C82.39	Follicular lymphoma grade IIIa
C82.41-C82.49	Follicular lymphoma grade IIIb
C82.51-C82.59	Diffuse follicle center lymphoma
C82.61-C82.69	Cutaneous follicle center lymphoma

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## IMPORTANT SAFETY INFORMATION

### CYTOKINE RELEASE SYNDROME (CRS) (continued)

The impact of tocilizumab and/or corticosteroids on the incidence and severity of CRS was assessed in 2 subsequent cohorts of LBCL patients in ZUMA-1. Among patients who received tocilizumab and/or corticosteroids for ongoing Grade 1 events, CRS occurred in 93% (38/41), including 2% (1/41) with Grade 3 CRS; no patients experienced a Grade 4 or 5 event. The median time to onset of CRS was 2 days (range: 1-8 days) and the median duration of CRS was 7 days (range: 2-16 days). Prophylactic treatment with corticosteroids was administered to a cohort of 39 patients for 3 days beginning on the day of infusion of YESCARTA. Thirty-one of the 39 patients (79%) developed CRS and were managed with tocilizumab and/or therapeutic doses of corticosteroids with no patients developing ≥ Grade 3 CRS. The median time to onset of CRS was 5 days (range: 1-15 days) and the median duration of CRS was 4 days (range: 1-10 days). Although there is no known mechanistic explanation, consider the risk and benefits of prophylactic corticosteroids in the context of pre-existing comorbidities for the individual patient and the potential for the risk of Grade 4 and prolonged neurologic toxicities.

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## Diagnosis Coding for Product Indications (continued)

ICD-10-CM Diagnosis Code <sup>2</sup>	Description <sup>2</sup>
<b>C82.81-C82.89</b>	Other types of follicular lymphoma
<b>C82.91-C82.99</b>	Follicular lymphoma, unspecified
<b>C83.31-C83.39</b>	Diffuse large B-cell lymphoma
<b>C83.91-C83.99</b>	Non-follicular (diffuse) lymphoma, unspecified
<b>C85.21-C85.29</b>	Mediastinal (thymic) large B-cell lymphoma
<b>C85.81-C85.89</b>	Other specified types of non-Hodgkin lymphoma
<b>Z51.12*</b>	Encounter for antineoplastic immunotherapy

\*If the purpose of a visit is for the administration of CAR T, ICD-10-CM diagnosis code Z51.12 (Encounter for antineoplastic immunotherapy) should be reported as the principal diagnosis, and the malignancy for which CAR T therapy is being administered should be assigned as the secondary diagnosis.<sup>2</sup>

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CAR=chimeric antigen receptor; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

## IMPORTANT SAFETY INFORMATION

### CYTOKINE RELEASE SYNDROME (CRS) (continued)

Ensure that 2 doses of tocilizumab are available prior to YESCARTA infusion. Monitor patients for signs and symptoms of CRS following infusion at least daily for 7 days at the certified healthcare facility, and for 4 weeks thereafter. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time. At the first sign of CRS, institute treatment with supportive care, tocilizumab, or tocilizumab and corticosteroids as indicated.

### NEUROLOGIC TOXICITIES

Neurologic toxicities including immune effector cell-associated neurotoxicity syndrome (ICANS) that were fatal or life-threatening occurred following treatment with YESCARTA. Neurologic toxicities occurred in 78% (330/422) of patients with NHL receiving YESCARTA, including ≥ Grade 3 in 25%.

Neurologic toxicities occurred in 87% (94/108) of patients with LBCL in ZUMA-1, including ≥ Grade 3 in 31% and in 74% (124/168) of patients in ZUMA-7 including ≥ Grade 3 in 25%. The median time to onset was 4 days (range: 1-43 days) and the median duration was 17 days for patients with LBCL in ZUMA-1. The median time to onset for neurologic toxicity was 5 days (range: 1-133 days) and median duration was 15 days in patients with LBCL in ZUMA-7. Neurologic toxicities occurred in 77% (112/146) of patients with iNHL, including ≥ Grade 3 in 21%.

Please see full [Prescribing Information](#), including **BOXED WARNING** and Medication Guide.



# // Procedure Coding: Cell Collection, Cell Processing, and Administration

Delivering CAR T episode of care requires coordination across several departments and accurate ordering, documentation, and coding in order for the community practice to receive reimbursement. This section focuses on coding of different procedural services associated with administration of CAR T products — **Cell Collection, Cell Processing Services, and Administration** of CAR T. After a service is completed, it is the provider's responsibility to ensure assigning the most appropriate procedure codes.<sup>2</sup>

## Level I HCPCS CPT Codes

Level I HCPCS Current Procedural Terminology (CPT®) codes were established to better identify the work, effort, and charges associated with the various steps required to collect and prepare CAR T cells. For Medicare, community practices may choose from 2 billing options: (1) to include the charges for the various steps in the charge submitted for the biological<sup>3</sup>; or (2) to report these charges separately for tracking purposes (documented under 38225, 38226, and 38227).<sup>3,4</sup> For non-Medicare payers, it is the provider's responsibility to contact each payer for payer-specific coding requirements before submitting any claims.

CAR=chimeric antigen receptor; HCPCS=Healthcare Common Procedure Coding System.

## IMPORTANT SAFETY INFORMATION

### NEUROLOGIC TOXICITIES (continued)

The median time to onset was 6 days (range: 1-79 days) and the median duration was 16 days. Ninety-eight percent of all neurologic toxicities in patients with LBCL and 99% of all neurologic toxicities in patients with iNHL occurred within the first 8 weeks of YESCARTA infusion. Neurologic toxicities occurred within the first 7 days of infusion in 87% of affected patients with LBCL and 74% of affected patients with iNHL.

The most common neurologic toxicities (≥ 10%) in all patients combined included encephalopathy (50%), headache (43%), tremor (29%), dizziness (21%), aphasia (17%), delirium (15%), and insomnia (10%). Prolonged encephalopathy lasting up to 173 days was noted. Serious events, including aphasia, leukoencephalopathy, dysarthria, lethargy, and seizures occurred. Fatal and serious cases of cerebral edema and encephalopathy, including late-onset encephalopathy, have occurred.

The impact of tocilizumab and/or corticosteroids on the incidence and severity of neurologic toxicities was assessed in 2 subsequent cohorts of LBCL patients in ZUMA-1. Among patients who received corticosteroids at the onset of Grade 1 toxicities, neurologic toxicities occurred in 78% (32/41) and 20% (8/41) had Grade 3 neurologic toxicities; no patients experienced a Grade 4 or 5 event. The median time to onset of neurologic toxicities was 6 days (range: 1-93 days) with a median duration of 8 days (range: 1-144 days). Prophylactic treatment with corticosteroids was administered to a cohort of 39 patients for 3 days beginning on the day of infusion of YESCARTA. Of those patients, 85% (33/39) developed neurologic toxicities; 8% (3/39) developed Grade 3 and 5% (2/39) developed Grade 4 neurologic toxicities. The median time to onset of neurologic toxicities was 6 days (range: 1-274 days) with a median duration of 12 days (range: 1-107 days). Prophylactic corticosteroids for management of CRS and neurologic toxicities may result in higher grade of neurologic toxicities or prolongation of neurologic toxicities, delay the onset, and decrease the duration of CRS.

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# Cell Collection and Cell Processing Services

The table below shows the recommended CPT codes for reporting cell collection and cell processing services.

Level I HCPCS CPT Code <sup>4</sup>	Description <sup>4</sup>	Notes
38225	Chimeric antigen receptor T-cell (CAR T) therapy; harvest of blood-derived T lymphocytes for development of genetically modified autologous CAR T cells, per day	Medicare guidance gives several options for how to report charges for cell collection and processing services for CAR T-cell therapy. It is important to review and select the most appropriate billing option for these services. <sup>3*</sup>  New Category I CPT codes for cell collection and processing: leukapheresis (38225), preparation (38226), receipt and preparation for administration (38227) are assigned status indicator "B," indicating that CMS considers these codes to be "bundled" for MPFS. <sup>4</sup>
38226	Chimeric antigen receptor T-cell (CAR T) therapy; preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation, storage)	
38227	Chimeric antigen receptor T-cell (CAR T) therapy; receipt and preparation of CAR T cells for administration	

\*As of March 15, 2019, CMS issued the following [billing code options for CAR T-cell therapy](#).<sup>3</sup>

This information is provided for your background and not intended as comprehensive or directive. Payer coding requirements may vary or change over time. It is the responsibility of the healthcare provider to determine and submit the appropriate codes, charges, and modifiers for medically necessary services rendered. This information is in no way a guarantee of reimbursement or coverage for any product or service. CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; MPFS=Medicare physician fee schedule.

## IMPORTANT SAFETY INFORMATION

### NEUROLOGIC TOXICITIES (continued)

Monitor patients for signs and symptoms of neurologic toxicities following infusion at least daily for 7 days at the certified healthcare facility, and for 4 weeks thereafter, and treat promptly.

### REMS

Because of the risk of CRS and neurologic toxicities, YESCARTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS. The required components of the YESCARTA and TECARTUS REMS are:

- Healthcare facilities that dispense and administer YESCARTA must be enrolled and comply with the REMS requirements. Certified healthcare facilities must have on-site, immediate access to tocilizumab, and ensure that a minimum of 2 doses of tocilizumab are available for each patient for infusion within 2 hours after YESCARTA infusion, if needed for treatment of CRS.

Further information is available at [www.YescartaTecartusREMS.com](http://www.YescartaTecartusREMS.com) or 1-844-454-KITE (5483).

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# Administration

CPT codes are used for professional claims to report for administration, associated services, and individual products.<sup>2</sup>

Level I HCPCS CPT Code <sup>4</sup>	Description <sup>4</sup>	Notes
38228	Chimeric antigen receptor T-cell (CAR T) therapy; CAR T cell administration, autologous	<p>Medicare guidance gives several options for how to report charges for cell collection and processing services for CAR T-cell therapy. It is important to review and select the most appropriate billing option for these services.<sup>3*</sup></p> <p>CPT code 38228 is considered payable by Medicare and is used to document YESCARTA<sup>®</sup> administration.<sup>4</sup> When using 38228 for Medicare, it is important to append the modifier KX to the code, because this is the mechanism that tells your Medicare Administrative Contractor (MAC) that CAR T-cell therapy is administered in a REMS-certified facility.<sup>5</sup></p>

\*As of March 15, 2019, CMS issued the following [billing code options for CAR T-cell therapy](#).<sup>3</sup>

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CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; REMS=Risk Evaluation and Mitigation Strategy.

## IMPORTANT SAFETY INFORMATION

### HYPERSENSITIVITY REACTIONS

Allergic reactions may occur with the infusion of YESCARTA. Serious hypersensitivity reactions, including anaphylaxis, may be due to dimethyl sulfoxide (DMSO) or residual gentamicin in YESCARTA.

### SERIOUS INFECTIONS

Severe or life-threatening infections occurred after YESCARTA infusion. Infections (all grades) occurred in 45% of patients with NHL. Grade 3 or higher infections occurred in 17% of patients, including ≥ Grade 3 infections with an unspecified pathogen in 12%, bacterial infections in 5%, viral infections in 3%, and fungal infections in 1%. YESCARTA should not be administered to patients with clinically significant active systemic infections. Monitor patients for signs and symptoms of infection before and after infusion and treat appropriately. Administer prophylactic antimicrobials according to local guidelines.

Febrile neutropenia was observed in 36% of patients with NHL and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad-spectrum antibiotics, fluids, and other supportive care as medically indicated.

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# // Remote Patient Monitoring Services Coding<sup>6</sup>

The following CPT and HCPCS codes are used to bill for remote patient monitoring services.

HCPCS CPT Code	Description	Time
99091	Monthly review of data	30 minutes
99453	RPM device set up	N/A
99454	Monthly review of RPM data	16 or more days over a 30-day period
99457	Patient-provider communication related to RPM data	20 minutes
99458	Patient-provider communication related to RPM data	Additional 20 minutes
98975	RTM device set up and patient education	N/A
98976	RTM monitoring, respiratory	16 or more days over a 30-day period
98977	RTM monitoring, musculoskeletal	16 or more days over a 30-day period
98980	Patient-provider communication related to therapeutic device	20 minutes
98981	Additional time required for 98975-98978 or 90980	Additional 20 minutes

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CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; RPM=remote physiologic monitoring; RTM=remote therapeutic monitoring.

## IMPORTANT SAFETY INFORMATION

### SERIOUS INFECTIONS (continued)

In immunosuppressed patients, including those who have received YESCARTA, life-threatening and fatal opportunistic infections including disseminated fungal infections (e.g., candida sepsis and aspergillus infections) and viral reactivation (e.g., human herpes virus-6 [HHV-6] encephalitis and JC virus progressive multifocal leukoencephalopathy [PML]) have been reported. The possibility of HHV-6 encephalitis and PML should be considered in immunosuppressed patients with neurologic events and appropriate diagnostic evaluations should be performed.

Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, has occurred in patients treated with drugs directed against B cells, including YESCARTA. Perform screening for HBV, HCV, and HIV and management in accordance with clinical guidelines before collection of cells for manufacturing.

Please see full [Prescribing Information](#), including **BOXED WARNING** and Medication Guide.



# // Product Coding

HCPCS Level II product codes have been created to describe FDA-approved CAR T products.<sup>2</sup>

## Level II HCPCS Product Code

A Level II HCPCS product code is used to report the use of the biological product YESCARTA® in the outpatient setting for Medicare.<sup>7</sup> The YESCARTA code, Q2041, has a description that includes the services of leukapheresis, and all cell preparation.<sup>7</sup> Please see the note on Level I HCPCS CPT codes for more information about Medicare's billing options for the leukapheresis and cell processing services that are in the description of Q2041. Providers should contact each payer to clarify the specific coding requirements before submitting any claims.<sup>3</sup>

Level II HCPCS CPT Code <sup>2</sup>	Description <sup>2</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

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CAR=chimeric antigen receptor; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System.

## IMPORTANT SAFETY INFORMATION

### PROLONGED CYTOPENIAS

Patients may exhibit cytopenias for several weeks following lymphodepleting chemotherapy and YESCARTA infusion. Grade 3 or higher cytopenias not resolved by Day 30 following YESCARTA infusion occurred in 39% of all patients with NHL and included neutropenia (33%), thrombocytopenia (13%), and anemia (8%). Monitor blood counts after infusion.

### HYPOGAMMAGLOBULINEMIA

B-cell aplasia and hypogammaglobulinemia can occur in patients receiving YESCARTA. Hypogammaglobulinemia was reported as an adverse reaction in 14% of all patients with NHL. Monitor immunoglobulin levels after treatment and manage using infection precautions, antibiotic prophylaxis, and immunoglobulin replacement.

The safety of immunization with live viral vaccines during or following YESCARTA treatment has not been studied. Vaccination with live virus vaccines is not recommended for at least 6 weeks prior to the start of lymphodepleting chemotherapy, during YESCARTA treatment, and until immune recovery following treatment.

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# NDC

YESCARTA® has 2 separate National Drug Codes (NDCs); one for the infusion bag with cells and a second for the cassette in which the infusion bag is shipped.<sup>1</sup> **Only utilize the infusion bag NDC for billing purposes.** Include “**N4**” before the 11-digit YESCARTA NDC number when completing outpatient claims forms. It is the provider’s responsibility to contact each payer for payer-specific coding requirements before submitting any claims.

Product NDC <sup>1,8</sup>	Description <sup>1</sup>	Notes <sup>8,9</sup>
71287-0119-01	<b>11-digit NDC</b> for YESCARTA infusion bag containing approximately 68 mL of frozen suspension of genetically modified autologous T cells in 5% DMSO and 2.5% albumin (human)	Many payers may require the YESCARTA NDC. When reporting the NDC on claims, use the 11-digit NDC in the 5-4-2 format. Insert a leading zero in the appropriate section to complete the 5-4-2 digit format and remove the dashes prior to entering the NDC on the claim form. The 5-4-2 format is established to comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements for electronic claims transactions.

Payers, including individual Medicare Administrative Contractors (MACs), may request utilization of a value code on the claim form (potentially accompanied by an invoice). Providers should contact each payer to clarify the specific coding requirement before submitting any claims.

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DMSO=dimethyl sulfoxide.

## IMPORTANT SAFETY INFORMATION

### SECONDARY MALIGNANCIES

Patients treated with YESCARTA may develop secondary malignancies. T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies, including YESCARTA. Mature T cell malignancies, including CAR-positive tumors, may present as soon as weeks following infusion, and may include fatal outcomes.

Monitor life-long for secondary malignancies. In the event that a secondary malignancy occurs, contact Kite at 1-844-454-KITE (5483) to obtain instructions on patient samples to collect for testing.

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# // UNIQUE MEDICARE BILLING INSTRUCTIONS FOR COMMUNITY PRACTICES

Please see full [Prescribing Information](#), including **BOXED WARNING** and Medication Guide.



# Unique Medicare billing instructions for community practices

CMS has issued billing instructions for submitting professional claims for CAR T product and administration for Places of Service\* 11 (community practices/physician offices) and 49 (independent clinics).<sup>10</sup>

CAR T-related HCPCS codes cannot be processed in the current Medicare Multi Carrier System because it was set up to allow a maximum of 7 digits for the dollar amount (line item on total maximum of 99999.99). This means nothing greater than \$99999.99 can be reported, while CAR T-cell products need to bill as 1 unit with a dollar amount of 8 digits. Providers will need to utilize a new modifier, -LU to allow for fractionated billing of the HCPCS code.<sup>10</sup>

Providers bill in 0.2-unit or 0.1-unit fractions based on the allowed amount.<sup>10</sup> YESCARTA® should be billed in fractions of 0.1.<sup>†</sup>

**A total of 3 modifiers will be needed on any CAR T-cell claim.**

Modifier <sup>10</sup>	Purpose <sup>10</sup>
<b>Modifier -LU</b>	Fractionated payment for CAR T
<b>Modifier -76</b>	Repeat procedure or service by the same physician or other qualified HCP <sup>‡</sup>
<b>Modifier -KX</b>	Attest the community practice is a REMS-approved facility <sup>§</sup>

\*Place of service codes are reported on the 1500 professional claim to specify the entity where service(s) were rendered.<sup>11</sup>

<sup>†</sup>If the allowed amount is <\$500,000, providers will be able to submit 5 separate claims for 0.2-unit fractions on each claim; if the allowed amount is ≥\$500,000, providers will be able to submit 10 separate claims for 0.1-unit fractions on each claim.<sup>10</sup>

<sup>‡</sup>Not appropriate for use on the first claim.<sup>10</sup>

<sup>§</sup>Not required for clinical trial billing.<sup>10</sup>

This information is provided for your background and not intended as comprehensive or directive. Payer coding requirements may vary or change over time. It is the responsibility of the healthcare provider to determine and submit the appropriate codes, charges, and modifiers for medically necessary services rendered. This information is in no way a guarantee of reimbursement or coverage for any product or service.

CAR=chimeric antigen receptor; CMS=Centers for Medicare and Medicaid Services; HCP=healthcare professional; HCPCS=Healthcare Common Procedure Coding System; REMS=Risk Evaluation and Mitigation Strategy.

## IMPORTANT SAFETY INFORMATION

### EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Due to the potential for neurologic events, including altered mental status or seizures, patients are at risk for altered or decreased consciousness or coordination in the 8 weeks following YESCARTA infusion. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, during this initial period.

Please see full [Prescribing Information](#), including **BOXED WARNING** and Medication Guide.



# // CLAIM FORM FOR OFFICE BILLING

The YESCARTA® product-specific HCPCS code is Q2041 (axicabtagene ciloleucel, up to 200 million autologous anti-CD19 CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose).<sup>2</sup> This code can be used for Medicare outpatient claims. This information is provided for your background and not intended as comprehensive or directive. Payer coding requirements may vary or change over time. It is the responsibility of the healthcare provider to determine and submit the appropriate codes, charges, and modifiers for medically necessary services rendered. This information is in no way a guarantee of reimbursement or coverage for any product or service.

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# // First Claim

## Sample CMS-1500 Claim Form

This sample form is for information purposes only.

This sample form is for information purposes only. It is not intended to be directive, nor does use of the codes listed guarantee reimbursement. Healthcare providers and staff may find other codes more appropriate. It is the responsibility of providers to select the coding options that best reflect internal systems, payer requirements, and medically necessary services rendered. Providers are responsible for the accuracy of billing and claims submitted for reimbursement.

Please see full Prescribing Information, including **BOXED WARNING** and **Medication Guide**.

### 19 ADDITIONAL CLAIM INFORMATION

Enter drug name (**YESCARTA®**), route of administration, 11-digit NDC (N471287011901, with no dashes), and/or dosage.<sup>1,6</sup>

### 21 DIAGNOSIS OR NATURE OF ILLNESS OR INJURY

Enter the ICD-10-CM codes that appropriately describe the principal and any secondary diagnoses.

### 24B PLACE OF SERVICE

Enter appropriate code for place of service; CAR T-cell products will only be reimbursed in place of service 11 (office) or 49 (independent clinic).<sup>10</sup>

### 24D PROCEDURES, SERVICES, OR SUPPLIES

Indicate appropriate HCPCS CPT code.

**For cell harvesting, storage, and preparation** – Use HCPCS Level I CPT codes **38225**, **38226**, and **38227**.<sup>4</sup>

**For YESCARTA product charges** – Enter **Q2041** to indicate YESCARTA. Use code **38228** to report YESCARTA administration.<sup>4</sup>

**Enter the appropriate modifiers** – Use **modifier -LU** for fractionated payment (YESCARTA should be billed in fractions of 0.1. Providers can submit separate claims for 0.1-unit fractions on each claim) and **modifier -KX** for attesting the practice is REMS-approved.<sup>10</sup>

### 24E DIAGNOSIS POINTER

Refer to the diagnosis for this service (see Item 21); enter only 1 diagnosis pointer per line.

### 24F CHARGES

Enter the total Medicare-allowed payment amount.<sup>10</sup>

### 24G DAYS OR UNITS

Enter the appropriate number of YESCARTA units used (0.1).

CAR=chimeric antigen receptor; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NDC=National Drug Code; REMS=Risk Evaluation and Mitigation Strategy.



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# // Subsequent Claims

## Sample CMS-1500 Claim Form

This sample form is for information purposes only.

Subsequent claims are filed identically to the first claim, except for the addition of **modifier -76\*** for repeat procedure or service by the same physician.

### 24D PROCEDURES, SERVICES, OR SUPPLIES

Indicate appropriate HCPCS CPT code.

For cell harvesting, storage, and preparation – Use HCPCS Level 1 CPT codes 38225, 38226, and 38227.<sup>4</sup>

For YESCARTA product charges – Enter Q2041 to indicate YESCARTA. Use code 38228 to report YESCARTA administration.<sup>4</sup>

Enter the appropriate modifiers – Use **modifier -LU** for fractionated payment (YESCARTA should be billed in factors of 0.1. Providers can submit separate claims for 0.1-unit fractions on each claim), **modifier -KX** for attesting the practice is REMS-approved, and **modifier -76\* for repeat procedure or service by same physician**.<sup>10</sup>

\*Not appropriate for use on the first claim.

This sample form is for information purposes only. It is not intended to be directive, nor does use of the codes listed guarantee reimbursement. Healthcare providers and staff may find other codes more appropriate. It is the responsibility of providers to select the coding options that best reflect internal systems, payer requirements, and medically necessary services rendered. Providers are responsible for the accuracy of billing and claims submitted for reimbursement.

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; REMS=Risk Evaluation and Mitigation Strategy.

**HEALTH INSURANCE CLAIM FORM**  
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/22

**1. MEDICARE** (Medicare) ☐ **2. PATIENT'S NAME** (Last Name, First Name, Middle Initial) **3. PATIENT'S ADDRESS** (No., Street) **4. INSURED'S NAME** (Last Name, First Name, Middle Initial) **5. INSURED'S ADDRESS** (No., Street) **6. PATIENT RELATIONSHIP TO INSURED** **7. INSURED'S ADDRESS** (No., Street) **8. RESERVED FOR NUCC USE** **9. OTHER INSURED'S NAME** (Last Name, First Name, Middle Initial) **10. IS PATIENT'S CONDITION RELATED TO:** **11. INSURED'S POLICY GROUP OR FICA NUMBER** **12. PATIENTS OR AUTHORIZED PERSONS SIGNATURE** **13. INSURED'S OR AUTHORIZED PERSONS SIGNATURE** **14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (EMP)** **15. OTHER DATE** **16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION** **17. NAME OF REFERRING PROVIDER OR OTHER SOURCE** **18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES** **19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)** **20. OUTSIDE LAB?** **21. CHARGES** **22. PRIOR AUTHORIZATION NUMBER** **23. PRIOR AUTHORIZATION NUMBER** **24. A. DATE(S) OF SERVICE** **B. PLACE OF SERVICE** **C. PROCEDURE, SERVICE, OR SUPPLY** **D. CHARGE** **E. PORTION** **F. CHARGE** **G. PORTION** **H. QUAL** **I. REFERRING PROVIDER ID #** **25. FEDERAL TAX I.D. NUMBER** **26. PATIENT'S ACCOUNT NO.** **27. ACCOUNT ASSIGNMENT?** **28. TOTAL CHARGE** **29. AMOUNT PAID** **30. PAID BY NUCC/INS** **31. SIGNATURE OF PHYSICIAN OR SUPPLIER** **32. SERVICE FACILITY LOCATION INFORMATION** **33. BILLING PROVIDER INFO & PH #**

Please see full Prescribing Information, including **BOXED WARNING** and Medication Guide.



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# // HELPFUL REMINDERS

The following pages contain lists of considerations when coding and billing for YESCARTA®. Remember to always check each payer's requirements before submitting any claims.

This information is provided for your background and not intended as comprehensive or directive. Payer coding requirements may vary or change over time. It is the responsibility of the healthcare provider to determine and submit the appropriate codes, charges, and modifiers for medically necessary services rendered. This information is in no way a guarantee of reimbursement or coverage for any product or service.

Please see full [Prescribing Information](#), including **BOXED WARNING** and Medication Guide.



## // Helpful Reminders

### Consider the Following Steps to Better Ensure Patient Eligibility and Coverage<sup>2</sup>

#### Prior to Service Delivery

Determine eligibility and insurance plan priority

Submit the prior authorization request following payer instructions

Perform coordination of benefits and confirm benefits for the entire CAR T episode of care

Determine whether an expedited prior authorization process is available

Obtain current out-of-pocket maximums for the patient under each plan

Confirm prior authorization for each step of the treatment

Review published coverage policies for primary diagnosis and ICD-10-CM code, relevant disease-related characteristics, prior lines of therapy, and clinical fitness

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CAR=chimeric antigen receptor; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

## IMPORTANT SAFETY INFORMATION

### ADVERSE REACTIONS

The most common non-laboratory adverse reactions (incidence  $\geq 20\%$ ) in patients with LBCL in ZUMA-7 included fever, CRS, fatigue, hypotension, encephalopathy, tachycardia, diarrhea, headache, musculoskeletal pain, nausea, febrile neutropenia, chills, cough, infection with unspecified pathogen, dizziness, tremor, decreased appetite, edema, hypoxia, abdominal pain, aphasia, constipation, and vomiting.

Please see full [Prescribing Information](#), including **BOXED WARNING** and Medication Guide.



# Consider the Following Steps to Better Ensure Charge Capture, Documentation, and Accurate Claims Reporting and Validation<sup>2</sup>

## Concurrent With Service Delivery

Confirm written, authenticated clinician order for cell collection

Confirm nursing/cell lab documentation of cell collection procedure

Confirm presence of cell laboratory documentation of outbound cell processing according to the applicable manufacturer instructions

Confirm cell laboratory documentation of inbound/receipt of cells and any processing according to applicable manufacturer instructions and clinician orders

Confirm nursing/cellular lab documentation of the administration procedure

Review for orders, medication administration record, and other applicable clinical documentation for any ancillary services

For any hourly observation services provided after administration, confirm presence of clinician order of observation services, and clinician progress notes

Confirm documentation of the administration procedure in the MAR or other record developed by the cell laboratory and/or nursing

This information is provided for your background and not intended as comprehensive or directive. Payer requirements may vary or change over time. It is the responsibility of the healthcare provider to determine and submit the appropriate information for medically necessary services rendered. This information is in no way a guarantee of reimbursement or coverage for any product or service.

MAR=medication administration record.

## IMPORTANT SAFETY INFORMATION

### ADVERSE REACTIONS (continued)

The most common adverse reactions (incidence  $\geq 20\%$ ) in patients with LBCL in ZUMA-1 included CRS, fever, hypotension, encephalopathy, tachycardia, fatigue, headache, decreased appetite, chills, diarrhea, febrile neutropenia, infections with pathogen unspecified, nausea, hypoxia, tremor, cough, vomiting, dizziness, constipation, and cardiac arrhythmias.

Please see full [Prescribing Information](#), including **BOXED WARNING** and Medication Guide.



# Consider the Following Steps to Better Ensure Charge Capture, Documentation, and Accurate Claims Reporting and Validation (continued)<sup>2</sup>

## After Service Provision

Confirm payer-specific billing requirements for outpatient (e.g., Medicare)

Consider tracking claims post-submission and reviewing the remittances carefully

Confirm the correct principal and admitting ICD-10-CM diagnosis codes

Proactively reach out to the patient's payer and understand reimbursement terms for the case

Review HCPCS Level II and NDC reporting requirements

Contact your patient's payer to identify their reimbursement methodology for YESCARTA<sup>®</sup>

Review for correct CPT codes on outpatient claims

For Medicare, YESCARTA cases receive payment under the MS-DRG 018, Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies.<sup>12</sup> For commercial payers, identify payment methodology for the payer and whether the patient received CAR T as outpatient or inpatient. Determine applicable payment formula for each claim and each type of CAR T service (such as cell collection and processing, administration, and post-administration management of the patient).<sup>2</sup>

Review to ensure the accuracy of units billed, that the prior authorization number is on the claim (if applicable), and that correct dates of services are reported

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CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; MS-DRG=Medicare Severity-Diagnosis Related Groups; NDC=National Drug Code.

## IMPORTANT SAFETY INFORMATION

### ADVERSE REACTIONS (continued)

The most common non-laboratory adverse reactions (incidence  $\geq 20\%$ ) in patients with iNHL in ZUMA-5 included fever, CRS, hypotension, encephalopathy, fatigue, headache, infections with pathogen unspecified, tachycardia, febrile neutropenia, musculoskeletal pain, nausea, tremor, chills, diarrhea, constipation, decreased appetite, cough, vomiting, hypoxia, arrhythmia, and dizziness.

Please see full [Prescribing Information](#), including **BOXED WARNING** and Medication Guide.



# Consider the Following Steps to Ensure Coordination Between the Community Practice and Hospital Partner

Confirm in-network vs out-of-network HCP and facility

Confirm if payer-provider contracts are joint or separate

Confirm point of contact for payer case manager

Confirm party billing the payer

Confirm terms of cost and reimbursement sharing between parties

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HCP=healthcare professional.

Please see full [Prescribing Information](#), including **BOXED WARNING** and Medication Guide.



# Diagnosis Coding for Complications

Certain complications and toxicities may occur with the use of YESCARTA®. The most common complications include cytokine release syndrome (CRS) and neurologic toxicities or Immune Effector Cell-Associated Neurotoxicity (ICANS).<sup>1</sup>

There are ICD-10-CM codes that identify that a patient has experienced a complication of immune effector cell therapy, and there are also codes that further specify the grade of either CRS or ICANS. Though, as common complications of immune effector cell therapy, both CRS and ICANS have established diagnosis codes. There may be additional complications or signs of symptoms that may be relevant and may be coded.

To indicate that a patient has CRS and/or ICANS as a complication of YESCARTA treatment, sequence first the appropriate code in the table below:

Complications Codes <sup>2</sup>	
ICD-10-CM Diagnosis Code	Description
<b>T80.82XA</b>	Complication of immune effector cellular therapy, initial encounter
<b>T80.82XD</b>	Complication of immune effector cellular therapy, subsequent encounter
<b>T80.82XS</b>	Complication of immune effector cellular therapy, sequela

Code the appropriate complication and grade from the table below:

CRS Codes <sup>2</sup>	
ICD-10-CM Diagnosis Code	Description
<b>D89.831</b>	Cytokine release syndrome, grade 1
<b>D89.832</b>	Cytokine release syndrome, grade 2
<b>D89.833</b>	Cytokine release syndrome, grade 3
<b>D89.834</b>	Cytokine release syndrome, grade 4
<b>D89.835</b>	Cytokine release syndrome, grade 5
<b>D89.839</b>	Cytokine release syndrome, grade unspecified

ICANS Codes <sup>2</sup>	
ICD-10-CM Diagnosis Code	Description
<b>G92.00</b>	Immune effector cell-associated neurotoxicity syndrome, grade unspecified
<b>G92.01</b>	Immune effector cell-associated neurotoxicity syndrome, grade 1
<b>G92.02</b>	Immune effector cell-associated neurotoxicity syndrome, grade 2
<b>G92.03</b>	Immune effector cell-associated neurotoxicity syndrome, grade 3
<b>G92.04</b>	Immune effector cell-associated neurotoxicity syndrome, grade 4
<b>G92.05</b>	Immune effector cell-associated neurotoxicity syndrome, grade 5

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ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

Please see full [Prescribing Information](#), including **BOXED WARNING** and Medication Guide.



# // MEDICARE CLINICAL TRIAL AND EXPANDED ACCESS BILLING

Please see full [Prescribing Information](#), including **BOXED WARNING** and Medication Guide.



# // Clinical Trial and Expanded Access Billing

## Medicare Clinical Trial Billing

Medicare requires condition code 30 and value code D4, with the National Clinical Trial number and diagnosis code Z00.6 to report all clinical trial claims.<sup>2</sup>

## Medicare Expanded Access Billing

As of October 1, 2022, Medicare requires condition code 90 to report CAR T expanded access cases.<sup>2</sup>

**Medicare pays an adjusted rate for CAR T-cell therapy cases where a product cost is not incurred, such as for clinical trial and CAR T-cell therapy provided under an expanded access program. For non-Medicare, providers must check with the payer regarding any special billing requirements for clinical trial or expanded access cases.<sup>13</sup>**

CAR=chimeric antigen receptor.

Please see full [Prescribing Information](#), including **BOXED WARNING** and Medication Guide.



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