

YESCARTA®

HOSPITAL BILLING AND CODING 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.

Please see Important Safety Information, including **BOXED WARNING**, throughout this guide.

// CONTENTS

- Helpful Reminders for Submitting Claims
- Review of Relevant Codes
 - ICD-10-CM Diagnosis Codes
 - ICD-10-PCS Codes
 - Hospital Revenue Codes
 - Level I HCPCS CPT Codes
 - Level II HCPCS Product Code
 - NDC

- Sample CMS-1450/UB-04 Claim Form: Hospital Inpatient

- Sample CMS-1450/UB-04 Claim Form: Hospital Outpatient

CAR T=chimeric antigen receptor T cell; CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; ICD-10-PCS=International Classification of Diseases, 10th Revision, Procedure Coding System; NDC=National Drug Code.

Please see Important Safety Information throughout this guide.

 **YESCARTA**[®]
(axicabtagene ciloleucel) Suspension
for IV infusion



// BILLING AND CODING GUIDE OVERVIEW

Please see Important Safety Information throughout this guide.



// Billing and Coding Guide Overview

This resource provides an overview of the current relevant codes, as of October 2022, that may be potential options for use with YESCARTA®. The information within covers both hospital inpatient and hospital outpatient settings of care.

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.

The information available within is compiled from sources believed to be accurate as of October 2022. 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 T=chimeric antigen receptor T cell.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITIES

- 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.
- YESCARTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS Program.

Please see additional Important Safety Information throughout this guide.

 **YESCARTA**®
(axicabtagene ciloleucel) Suspension
for IV infusion



// THE CAR T PATIENT-CARE PROCESS

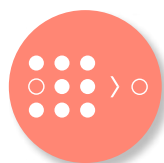
CAR T=chimeric antigen receptor T cell.

Please see Important Safety Information throughout this guide.

 **YESCARTA**[®]
(axicabtagene ciloleucel) Suspension
for IV infusion

The CAR T Patient-Care Process

YESCARTA® is administered as a one-time infusion at an Authorized Treatment Center (ATC). The entire treatment process consists of **5 distinct steps**¹:



Leukapheresis

Leukapheresis is performed. T cells are isolated from the peripheral blood.



Cell Manufacturing

The harvested T cells are shipped to Kite where they are modified into chimeric antigen receptor (CAR) T cells and expanded in number.



Conditioning Chemotherapy

The patient undergoes a 3-day lymphodepleting chemotherapy regimen. This regimen is started prior to the planned infusion of YESCARTA.



Infusion

YESCARTA is administered to the patient at an ATC. This may be done in a hospital inpatient or hospital outpatient setting.



Monitoring & Follow-up

Patients will be monitored for 7 days at the ATC following infusion of YESCARTA. This is done to identify any signs and symptoms of complications such as cytokine release syndrome (CRS), neurologic toxicities, and other possible side effects. Patients are instructed to remain within proximity of the ATC for at least 4 weeks following YESCARTA infusion.

IMPORTANT SAFETY INFORMATION

CYTOKINE RELEASE SYNDROME (CRS)

CRS, including fatal or life-threatening reactions, occurred. CRS occurred in 90% (379/422) of patients with non-Hodgkin lymphoma (NHL), including ≥ Grade 3 in 9%. CRS occurred in 93% (256/276) of patients with large B-cell lymphoma (LBCL), including ≥ 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 ≥ Grade 3 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 (≥ 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.

Please see additional Important Safety Information throughout this guide.

 **YESCARTA®**
(axicabtagene ciloleucel) Suspension
for IV infusion



// OVERVIEW OF CODING FOR PREPARATION AND ADMINISTRATION

Please see Important Safety Information throughout this guide.



// Coding for YESCARTA® Preparation and Administration

Helpful Reminders for Submitting Claims

Verify patient's eligibility with all payers they are enrolled with, verify the patient's benefits with the payer(s), and seek prior authorization

Clarify coding and clinical documentation requirements by payer, as there may be variations in payer requirements

For Medicare, become familiar with the National Coverage Decisions on CAR T-cell therapy and billing transmittals for CAR T-cell therapy cases

Outside of fee-for-service Medicare, determine any prior authorization (PA) requirements for all payers before the patient undergoes leukapheresis

Kite Konnect® is a Kite-sponsored resource committed to supporting healthcare providers (HCPs) and patients throughout each step of treatment with Kite therapy. Support for eligible individuals may include assistance with Kite Konnect referrals, information on Authorized Treatment Centers (ATCs), reimbursement support, and programs to help cover the cost of Kite therapy. To learn more about the program, visit [KiteKonnect.com](https://www.kitekonnect.com) or call **1-844-454-KITE** [5483], Monday–Friday, 5 AM–6 PM PT.

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.

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.

Ensure that 2 doses of tocilizumab are available prior to YESCARTA infusion. Monitor patients for signs and symptoms of CRS 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.

Please see additional Important Safety Information throughout this guide.





// Review of Relevant Codes

ICD-10-CM Diagnosis Codes

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 ²	Description
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

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.

IMPORTANT SAFETY INFORMATION

NEUROLOGIC TOXICITIES

Neurologic toxicities (including immune effector cell-associated neurotoxicity syndrome) that were fatal or life-threatening occurred. Neurologic toxicities occurred in 78% (330/422) of patients with NHL receiving YESCARTA, including \geq Grade 3 in 25%. Neurologic toxicities occurred in 87% (94/108) of patients with LBCL in ZUMA-1, including \geq Grade 3 in 31% and in 74% (124/168) of patients in ZUMA-7 including \geq 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 \geq Grade 3 in 21%. 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 for 87% of affected patients with LBCL and 74% of affected patients with iNHL.

Please see additional Important Safety Information throughout this guide.

 **YESCARTA**[®]
(axicabtagene ciloleucel) Suspension
for IV infusion



ICD-10-CM Diagnosis Codes (Continued)

ICD-10-CM Diagnosis Code ²	Description
C82.81-C82.89	Other types of follicular lymphoma
C83.31-C83.39	Diffuse large B-cell lymphoma
C85.11-C85.19	Unspecified B-cell lymphoma
C85.21-C85.29	Mediastinal (thymic) large B-cell lymphoma
C85.81-C85.89	Other specified types of non-Hodgkin lymphoma
Z00.6*	Encounter for examination for normal comparison and control in clinical research program
Z51.12†	Encounter for antineoplastic immunotherapy

*This code should be reported only for clinical trial cases. It also requires condition code 30 and the National Clinical Trial number for the relevant trial to be reported on the claim.³ For cases provided under an expanded access program for CAR T-cell therapy, providers should report condition code 90 to indicate it is an expanded access claim.⁴ 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.³

†If a patient admission/encounter is solely for the administration of immunotherapy, assign ICD-10-CM diagnosis code Z51.12, "Encounter for antineoplastic immunotherapy" as the first-listed/principal diagnosis.⁵

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.

IMPORTANT SAFETY INFORMATION

NEUROLOGIC TOXICITIES (continued)

The most common neurologic toxicities ($\geq 10\%$) 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.

Please see additional Important Safety Information throughout this guide.



ICD-10-CM Diagnosis Codes (Continued)

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).¹

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 should 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:

ICD-10-CM Diagnosis Code ²	Description
T80.82XA	Complication of immune effector cellular therapy, initial encounter
T80.82XD	Complication of immune effector cellular therapy, subsequent encounter
T80.82XS	Complication of immune effector cellular therapy, sequela

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.

IMPORTANT SAFETY INFORMATION

NEUROLOGIC TOXICITIES (continued)

Monitor patients for signs and symptoms of neurologic toxicities 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 called the YESCARTA and TECARTUS REMS Program which requires that: Healthcare facilities that dispense and administer YESCARTA must be enrolled and comply with the REMS requirements and must have on-site, immediate access to a minimum of 2 doses of tocilizumab for each patient for infusion within 2 hours after YESCARTA infusion, if needed for treatment of CRS. Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense, or administer YESCARTA are trained about the management of CRS and neurologic toxicities. Further information is available at www.YescartaTecartusREMS.com or 1-844-454-KITE (5483).

Please see additional Important Safety Information throughout this guide.





ICD-10-CM Diagnosis Codes (Continued)

Then, code the appropriate complication and grade from the table below:

ICD-10-CM Diagnosis Code ²	Description
D89.831	Cytokine release syndrome, grade 1
D89.832	Cytokine release syndrome, grade 2
D89.833	Cytokine release syndrome, grade 3
D89.834	Cytokine release syndrome, grade 4
D89.835	Cytokine release syndrome, grade 5
D89.839	Cytokine release syndrome, grade unspecified
G92.00	Immune effector cell-associated neurotoxicity syndrome, grade unspecified
G92.01	Immune effector cell-associated neurotoxicity syndrome, grade 1
G92.02	Immune effector cell-associated neurotoxicity syndrome, grade 2
G92.03	Immune effector cell-associated neurotoxicity syndrome, grade 3
G92.04	Immune effector cell-associated neurotoxicity syndrome, grade 4
G92.05	Immune effector cell-associated neurotoxicity syndrome, grade 5

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.

IMPORTANT SAFETY INFORMATION

HYPERSENSITIVITY REACTIONS

Allergic reactions, including serious hypersensitivity reactions or anaphylaxis, may occur with the infusion of YESCARTA.

Please see additional Important Safety Information throughout this guide.





ICD-10-PCS Codes

International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) codes are used to identify inpatient hospital procedures. Medicare has assigned new ICD-10-PCS codes for YESCARTA®, which will be effective for dates of service on or after October 1, 2021. Medicare has also redefined the hospital inpatient CAR T-cell therapy payment, effective for services on or after October 1, 2021: MS-DRG 018 - Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies. Applying the appropriate ICD-10-PCS code for YESCARTA as listed will align inpatient admissions to MS-DRG 018 for payment.^{6,7} It is the provider's responsibility to contact each payer for payer-specific coding requirements before submitting any claims.

ICD-10-PCS Code ⁶	Description
XW033H7	Introduction of axicabtagene ciloleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7
XW043H7	Introduction of axicabtagene ciloleucel immunotherapy into central vein, percutaneous approach, new technology group 7

Medicare applies a reimbursement adjustment factor to claims that group to MS-DRG 018 where no CAR T-cell therapy product cost was incurred, such as clinical trial and expanded access cases.⁶ For cases where commercial CAR T-cell therapy is administered and the provider incurs a product cost but there is a clinical trial diagnosis Z00.6 code on the claim to indicate something other than CAR T-cell therapy is under study, Medicare will pay the normal MS-DRG 018 amount rather than applying an adjustment factor, as long as providers follow CMS instructions to use the remarks field on the claim to identify these cases.^{6,8*}

Non-Medicare payers may vary on the methodology used to reimburse for inpatient YESCARTA cases. Therefore, it is important to verify payer billing requirements before submitting claims.

*The adjustment is not applicable to cases where YESCARTA is purchased in the usual manner.⁸

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.

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

Severe or life-threatening infections occurred. Infections (all grades) occurred in 45% of patients with NHL. ≥ Grade 3 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.

Please see additional Important Safety Information throughout this guide.





Hospital Revenue Codes

Payers utilize revenue codes to align services with specific departments within a hospital.⁹ A series of revenue codes specific to cell therapy were developed to capture information for services related to cell collection, storage, preparation, administration, and the charges for the CAR T-cell therapy product.³ These codes are used in conjunction with Level I and II Healthcare Common Procedure Coding System (HCPCS) codes to document the clinical management of YESCARTA® therapy. It is the provider's responsibility to contact each payer for payer-specific coding requirements before submitting any claims.¹⁰

Revenue Code ¹¹	Description	Notes ¹⁰
0871	Cell/Gene Therapy Cell Collection	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. [†]
0872	Cell/Gene Therapy Specialized Biologic Processing and Storage - Prior to Transport	
0873	Cell/Gene Therapy Storage and Processing after Receipt of Cells from Manufacturer	
0874	Cell/Gene Therapy Infusion of Modified Cells	
0891*	Special Processed Drugs - FDA (Food and Drug Administration) Approved Cell Therapy - Charges for Modified cell therapy	

*Charges for drugs and biologics for modified cell therapy requiring specific identification as required by the payer. If using an HCPCS code to describe the cells, enter the HCPCS code in the appropriate HCPCS column.¹¹

†As of March 15, 2019, CMS issued the following [billing code options for CAR T-cell therapy](#).¹⁰

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.

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 additional Important Safety Information throughout this guide.





Level I HCPCS CPT Codes

The following series of 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, hospitals may choose from 3 billing options: 1) to include the charges for these various steps in the charge submitted for the biological; 2) to report these charges separately for tracking purposes (documented under 0537T, 0538T, and 0539T); or 3) if the CAR T-cell therapy product is administered to the patient as a hospital inpatient, hold the charges for these services and report them under the appropriate revenue codes in the inpatient CAR T-cell therapy claim. For non-Medicare payers, it is the provider's responsibility to contact each payer for payer-specific coding requirements before submitting any claims.¹⁰

HCPCS CPT Code ³	Description	Notes ^{10,12,13}
0537T	Chimeric antigen receptor T-cell (CAR T) therapy; collection/handling of genetically modified CAR-T cells	0537T, 0538T, and 0539T are considered non-payable services when furnished by hospital outpatient departments under Medicare's Outpatient Prospective Payment System (OPPS). However, other payers may accept these codes as payable. Providers may still use these codes to track cell preparation steps for YESCARTA®. CPT code 0540T is considered payable by Medicare and is used to document YESCARTA administration. When using 0540T 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.*
0538T	Chimeric antigen receptor T-cell (CAR T) therapy; preparation for transport of genetically modified CAR-T cells	
0539T	Chimeric antigen receptor T-cell (CAR T) therapy; receipt and preparation of CAR-T cells for administration	
0540T	Chimeric antigen receptor T-cell (CAR T) therapy, CAR T-cell administration, autologous	

The Level I HCPCS CPT codes must be reported with the appropriate revenue code for the claim to be accepted and adjudicated. The mapping for reporting is as follows^{10,11}:

CPT Code 0537T	»	Revenue Code 0871 (Cell/Gene Therapy Cell Collection)
CPT Code 0538T	»	Revenue Code 0872 (Cell/Gene Therapy Specialized Biologic Processing and Storage – Prior to Transport)
CPT Code 0539T	»	Revenue Code 0873 (Cell/Gene Therapy Storage and Processing After Receipt of Cells From Manufacturer)
CPT Code 0540T	»	Revenue Code 0874 (Cell/Gene Therapy Infusion of Modified Cells)

*See billing code options for Medicare.

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 Important Safety Information throughout this guide.

 **YESCARTA®**
(axicabtagene ciloleucel) Suspension
for IV infusion



Level II HCPCS Product Code

A Level II HCPCS product code is used to report the use of the biological product YESCARTA® in the hospital outpatient setting for Medicare. The YESCARTA code, Q2041, has a description that includes the services of leukapheresis, and all cell preparation. 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. For Medicare claims, the Q2041 code should only be designated on a CMS 1450 claim form when YESCARTA is delivered in the hospital outpatient setting. Other payers outside Medicare may, however, utilize the Q2041 code for inpatient claims as well. Providers should contact each payer to clarify the specific coding requirements before submitting any claims.³

HCPCS Product Code ¹³	Description ³
Q2041	Axicabtagene ciloleucel, up to 200 million autologous antcd 19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose

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.

IMPORTANT SAFETY INFORMATION

PROLONGED CYTOPENIAS

Patients may exhibit cytopenias for several weeks following lymphodepleting chemotherapy and YESCARTA infusion. \geq Grade 3 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. 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.

Please see additional Important Safety Information throughout this guide.





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.¹ **Only utilize the infusion bag NDC for billing purposes.** Include “N4” before the 11-digit YESCARTA NDC number when completing hospital inpatient and outpatient claims forms. It is the provider’s responsibility to contact each payer for payer-specific coding requirements before submitting any claims.

Product NDC ¹	Description ¹	Notes ^{14,15}
71287-0119-01	11-digit NDC 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.

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.

IMPORTANT SAFETY INFORMATION

SECONDARY MALIGNANCIES

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

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 additional Important Safety Information throughout this guide.





// HOSPITAL INPATIENT ADMINISTRATION

Outside of Medicare, other payers may apply different payment methodologies for inpatient admissions related to administration of YESCARTA®. Providers should work directly with each payer to confirm both claims coding and documentation, as well as payment methodology. Payer coding requirements may vary or change over time. It is the provider's responsibility to check the coding and clinical documentation requirements with each payer before submitting any claims.

Please see Important Safety Information throughout this guide.





Sample CMS-1450/UB-04 Claim Form: Hospital Inpatient

This sample form is for information purposes only.

Sample

42 43 44 46 47

69 74

UB-04 CMS-1450

APPROVED: OMB NO. 0938-0397

NUBC® National Uniform Billing Committee

THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF

42 REVENUE CODES

For reporting the YESCARTA product charge – Use revenue code **0891**.¹¹

For YESCARTA® cell infusion – Use revenue code **0874**.¹¹

For cell harvesting, storage, and preparation – Use revenue codes **0871, 0872, and 0873**.¹¹

43 DESCRIPTION

If the payer requests or requires NDC information to be reported, enter the YESCARTA NDC as **N471287011901, with no dashes**.^{1,15} Only the YESCARTA NDC for the infusion bag should be used for billing purposes.

Confirm any additional documentation requirements for YESCARTA inpatient claims with each payer.

44 REPORTING THE YESCARTA PRODUCT

For YESCARTA cell infusion – For Medicare, HCPCS codes are not reported in inpatient claims; but the charge for the YESCARTA product is reported using revenue code **0891**, which is an extension of pharmacy. Other payers may request the use of the YESCARTA HCPCS code **Q2041**. However, that information should be confirmed by payer.^{10,13}

FIELDS 42 - 44

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 Important Safety Information throughout this guide.



Sample CMS-1450/UB-04 Claim Form: Hospital Inpatient

This sample form is for information purposes only.

Sample

42 43 44 46 47

69 66 74

UB-04 CMS-1450

APPROVED: OMB NO. 0938-0397

NUBC® National Uniform Billing Committee

THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

FIELDS 46 - 74

46 SERVICE UNITS

For all services, enter "1" to denote the single encounter process for each.

47 TOTAL CHARGES

Enter total charges for all steps.

66 DIAGNOSIS CODES

Enter the ICD-10-CM diagnosis code that appropriately describes the principal and secondary diagnoses

69 ADMIT DIAGNOSIS

Enter the ICD-10-CM diagnosis code that appropriately describes the admitting diagnosis

74 PRINCIPAL PROCEDURE

Enter the appropriate ICD-10-PCS code from the 2 dedicated to CAR T-specific codes (**XW033H7** or **XW043H7**).⁶

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 Important Safety Information throughout this guide.



// HOSPITAL OUTPATIENT ADMINISTRATION

The YESCARTA® product-specific Healthcare Common Procedure Coding System (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).¹⁰

Medicare requires this code on hospital outpatient claims when cells are delivered in that setting. Other payers may apply the Q2041 code for outpatient and other settings of care. It is important for providers to confirm billing and coding requirements with each payer before submitting claims.

Please see Important Safety Information throughout this guide.





Sample CMS-1450/UB-04 Claim Form: Hospital Outpatient

This sample form is for information purposes only.

Sample

42 43 44 46 66

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC® National Uniform Billing Committee THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

FIELDS 42 - 44

*As of March 15, 2019, CMS issued the following billing code options for CAR T-cell therapy.¹⁰

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 Important Safety Information throughout this guide.

42 REVENUE CODES

For YESCARTA® cell infusion – Use revenue code **0874**.¹¹

For YESCARTA product charges – Use revenue code **0891** with HCPCS code **Q2041**.^{10,13}

For cell harvesting, storage, and preparation – Use revenue codes **0871, 0872, or 0873**.¹¹

For Medicare, there are billing options for how to report the charges for cell harvesting, storage, and preparation on hospital outpatient claims. It is important to review these options.^{10,11*}

43 DESCRIPTION

Medicaid programs require the reporting of NDC information, and other payers may also request or require NDC information to be reported. If so, enter the YESCARTA NDC as **N471287011901**, with no dashes.^{1,15} Only the YESCARTA NDC for the infusion bag should be used for billing purposes. These payers may also have additional requirements on reporting the unit of measurement in this field.

For cell harvesting, storage, and preparation – Enter the appropriate description of the service provided based on the HCPCS CPT code aligned to the respective revenue codes (see page 15 of this guide for detailed information).¹⁰

44 HCPCS CODES

For YESCARTA cells – Enter **Q2041** to indicate YESCARTA. Use code **0540T** to report YESCARTA administration.¹⁰

Medicare has provided 3 scenarios for how to bill the services described by HCPCS Level I CPT codes **0537T, 0538T, and 0539T**. These codes may be reported for tracking purposes but are non-payable. Another option is to include the charges for these services in the charge of **Q2041**. In this situation, the date of service should be the date that YESCARTA was administered, not the date the cells were collected.^{10*}

// Dedicated support throughout the treatment journey



Logistics Support

Patients can learn about potential resources for transportation and housing assistance.



Reimbursement Support

Help with benefits investigations, claims appeals information, and potential sources of support for eligible uninsured and underinsured patients.



Patient Enrollment

Register a patient for therapy if you are a healthcare professional.



Ongoing Commitment

Kite Konnect Case Managers are available to support healthcare professionals and patients throughout the CAR T treatment journey.

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.

Resources may include referrals to independent third-party nonprofit patient assistance programs. These programs are not operated or controlled by Kite. Nonprofit patient assistance program eligibility requirements may vary and are established solely by each independent organization. Kite makes no guarantee with respect to reimbursement or copay assistance for any item or service.

Cell therapy patient programs are for eligible prescribed patients.



Kite Konnect can help with finding an Authorized Treatment Center and provide information about the support resources that may be available to your patient.
1-844-454-KITE [5483], Monday–Friday, 5 AM–6 PM PT.



// HELPFUL REMINDERS

The following page contains a list of considerations to consider when billing and coding 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 Important Safety Information throughout this guide.

// Helpful Reminders

Consider the Following Steps When Billing and Coding for YESCARTA®

Confirm the appropriate codes for the claim to capture the patient's diagnoses, the correct procedure code, revenue codes, and relevant condition codes and value codes

The appropriate codes for a CAR T-cell therapy claim may vary depending on the patient's status (inpatient or outpatient) and the services provided. It is important to confirm that the charges for YESCARTA appear on the claim, billed under revenue code 0891. For Medicare patients who receive CAR T-cell therapy services such as cell collection as hospital outpatients, Medicare has provided guidance on 3 billing options that providers may use to bill the services represented by HCPCS CPT codes 0537T, 0538T, and 0539T.¹⁰ It is also important to note for Medicare patients that the modifier KX should be appended to HCPCS CPT code 0540T for the administration of CAR T-cell therapy when YESCARTA is administered to hospital outpatients. This tells your Medicare Administration Contractor (MAC) that the administration of YESCARTA has occurred in REMS-certified facility, which is a Medicare requirement for CAR T-cell therapy coverage.¹² For Medicare cases where YESCARTA is provided as part of an expanded access program, condition code 90 should be added to the claim.⁴ Non-Medicare payers may have other billing requirements, such as the use of a value code.

Contact your patient's payer to determine if there are any specific coding requirements

Contact your patient's payer to identify their reimbursement methodology for YESCARTA

For Medicare, YESCARTA cases receive payment under the MS-DRG 018, Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies.

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.

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.

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 additional Important Safety Information throughout this guide and accompanying full Prescribing Information, including **BOXED WARNING and Medication Guide.**

 **YESCARTA®**
(axicabtagene ciloleucel) Suspension
for IV infusion



References

1. YESCARTA® (axicabtagene ciloleucel). Prescribing information. Kite Pharma, Inc; 2022.
2. National Center for Health Statistics – ICD-10-CM. Centers for Disease Control and Prevention. Accessed November 1, 2022. <https://icd10cmtool.cdc.gov/?fy=FY2022>
3. CMS Manual System. Pub 100-04 Medicare claims processing manual: chapter 32 – billing requirements for special services. Section 400 – chimeric antigen receptor (CAR) T-cell therapy. Subsection 400.0 – 400.3. Centers for Medicare & Medicaid Services. Accessed November 1, 2022. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c32.pdf>
4. Medicare program; hospital inpatient prospective payment systems for acute care hospitals and the long-term care hospital prospective payment system and policy changes and fiscal year 2023 rates; quality programs and Medicare promoting interoperability program requirements for eligible hospitals and critical access hospitals; costs incurred for qualified and non-qualified deferred compensation plans; and changes to hospital and critical access hospital conditions of participation. Updated August 10, 2022. Accessed November 1, 2022. <https://www.govinfo.gov/content/pkg/FR-2022-08-10/pdf/2022-16472.pdf>
5. ICD-10-CM official guidelines for coding and reporting. Centers for Disease Control and Prevention. Accessed November 1, 2022. <https://www.cms.gov/files/document/2021-coding-guidelines-updated-12162020.pdf>
6. Medicare program; hospital inpatient prospective payment systems for acute care hospitals and the long-term care hospital prospective payment system and policy changes and fiscal year 2022 rates; quality programs and Medicare promoting interoperability program requirements for eligible hospitals and critical access hospitals; changes to Medicaid provider enrollment; and changes to the Medicare Shared Savings Program. Accessed November 1, 2022. <https://www.govinfo.gov/content/pkg/FR-2021-08-13/pdf/2021-16519.pdf>
7. Medicare program; hospital inpatient prospective payment systems for acute care hospitals and the long-term care hospital prospective payment system and final policy changes and fiscal year 2021 rates; quality reporting and Medicare and Medicaid promoting interoperability programs requirements for eligible hospitals and critical access hospitals. Centers for Medicare & Medicaid Services. Accessed November 1, 2022. <https://www.govinfo.gov/content/pkg/FR-2020-09-18/pdf/2020-19637.pdf>
8. CMS Manual System. Pub 100-04 Medicare claims processing - transmittal 10995. Updated September 16, 2021. Accessed November 1, 2022. <https://www.cms.gov/files/document/r10995cp.pdf>
9. Research Data Assistance Center. Accessed November 1, 2022. <https://www.resdac.org/cms-data/variables/revenue-center-code-ffs>
10. Chimeric antigen receptor (CAR) T-cell therapy revenue code and HCPCS setup revisions. Centers for Medicare & Medicaid Services. Updated May 28, 2019. Accessed November 1, 2022. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE19009.pdf>
11. Summary of gene and cell therapy code changes. National Uniform Billing Committee. Accessed November 1, 2022. <https://www.nubc.org/system/files/media/file/2020/02/Cell-Gene%20Therapy%20Code%20Changes.pdf>
12. National Coverage Determination (NCD 110.24): chimeric antigen receptor (CAR) T-cell therapy - this CR rescinds and fully replaces CR 11783. Centers for Medicare & Medicaid Services. Accessed November 1, 2022. <https://www.cms.gov/files/document/mm12177-national-coverage-determination-ncd-11024-chimeric-antigen-receptor-car-t-cell-therapy-cr.pdf>
13. CMS Manual System. Pub 100-04 Medicare claims processing: April 2019 update of the hospital Outpatient Prospective Payment System (OPPS). Centers for Medicare & Medicaid Services. Accessed November 1, 2022. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4255CP.pdf>
14. Program memorandum intermediaries/carriers. Transmittal AB-01-04. Centers for Medicare & Medicaid Services. January 18, 2001. Accessed November 1, 2022. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/AB0104.pdf>
15. Future format of the National Drug Code; public hearing and request for comments. Food and Drug Administration. Federal Register. Accessed November 1, 2022. <https://www.federalregister.gov/documents/2018/08/07/2018-16807/future-format-of-the-national-drug-code-public-hearing-request-for-comments>
16. CMS Manual System. Pub 100-20 One-Time Notification. Transmittal 11179. Centers for Medicare & Medicaid Services (CMS). Updated January 12, 2022. Accessed November 1, 2022. <https://www.cms.gov/files/document/r11179otn.pdf>

Please see Important Safety Information throughout this guide.

TECARTUS, YESCARTA, the Yescarta Logo, KITE KONNECT, the Kite Konnect Logo, KITE, and the Kite Logo are trademarks of Kite Pharma, Inc. GILEAD is a trademark of Gilead Sciences, Inc. All other trademarks referenced herein are the property of their respective owners.
© 2022 Kite Pharma, Inc. All rights reserved. | US-YESM-0034 12/2022

