YESCARTA®
HOSPITAL BILLING AND CODING GUIDE

YESCARTA® (axicabtagene ciloleucel) Suspension for IV infusion

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 additional Important Safety Information throughout this guide.

CONTENTS

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.

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// BILLING AND CODING GUIDE OVERVIEW

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Billing and Coding Guide Overview

This resource provides an overview of the current relevant codes, as of April 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 April 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.

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THE CAR T PATIENT-CARE PROCESS

CAR T=chimeric antigen receptor T cell.

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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	Cell Manufacturing	Conditioning Chemotherapy	Infusion	Monitoring & Follow-up
Leukapheresis is performed. T cells are isolated from the peripheral blood.	The harvested T cells are shipped to Kite where they are modified into chimeric antigen receptor (CAR) T cells and expanded in number.	The patient undergoes a 3-day lymphodepleting chemotherapy regimen. This regimen is started prior to the planned infusion of YESCARTA.	YESCARTA is administered to the patient at an ATC. This may be done in a hospital inpatient or hospital outpatient setting.	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.

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// OVERVIEW OF CODING FOR PREPARATION AND ADMINISTRATION

Please see Important Safety Information throughout this guide.

YESCARTA® (axicabtagene ciloleucel) Suspension for IV infusion

Coding for YESCARTA® Preparation and Administration

Helpful Reminders for Submitting Claims

- [ ] Clarify coding and clinical documentation requirements by payer, as there may be variations in payer requirements
- [ ] For Medicare, become familiar with the published guidance on coding
- [ ] 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 or call **1-844-454-KITE** [5483], Monday–Friday, 5 AM–6 PM PT.

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IMPORTANT SAFETY INFORMATION

CYTOKINE RELEASE SYNDROME (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.

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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

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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 ≥ 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%. 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.

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.

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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 or with standardized drug charges of less than $373,000.[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.[4]

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IMPORTANT SAFETY INFORMATION

NEUROLOGIC TOXICITIES (continued)

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.

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.

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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 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 above will align inpatient admissions to MS-DRG 018 for payment.[3,5] It is the provider's responsibility to contact each payer for payer-specific coding requirements before submitting any claims.

ICD-10-PCS Code[3]	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 and include ICD-10-CM diagnosis code Z00.6 (Encounter for examination for normal comparison and control in clinical research program).[3,5]*

Non-Medicare payers may vary on their coding and subsequent reimbursement for YESCARTA when it is administered during an inpatient admission and may or may not utilize the ICD-10-PCS codes. Therefore, it is important to determine the appropriate coding requirements for each payer before submitting any claims.

*This adjustment will also apply to Medicare hospital inpatient admissions that integrate YESCARTA obtained for expanded access use where the claim contains standardized YESCARTA charges of less than $373,000. The adjustment is not applicable to cases where YESCARTA is purchased in the usual manner.[3]

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Hospital Revenue Codes

Payers utilize revenue codes to align services with specific departments within a hospital.[6] A series of revenue codes specific to cell therapy were developed to capture information for services related to cell collection, storage, and preparation.[7] These codes will align 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.[8]

Revenue Code[9]	Description	Notes[8]
0871	Cell/Gene Therapy Cell Collection	Medicare guidance outlines that providers should not report the same charge twice under the drug revenue code 0891 and under the pre-infusion cell preparation revenue codes 0871, 0872, and 0873.
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.[9]

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IMPORTANT SAFETY INFORMATION

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).

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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. Hospitals may choose to include the charges for these various steps in the charge submitted for the biological or report these charges separately for tracking purposes (documented under 0537T, 0538T, and 0539T). It is the provider's responsibility to contact each payer for payer-specific coding requirements before submitting any claims.[8]

HCPCS CPT Code[7]	Description	Notes[7,8]
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 codes for services furnished in the hospital outpatient setting by Medicare. 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.
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 reviewed. That alignment for reporting is as follows[8,9]:

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

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Level II HCPCS Product Code

A Level II HCPCS product code is used to document administration of YESCARTA® in the hospital outpatient setting for Medicare. The YESCARTA code, Q2041, has an inclusive definition that encompasses the administration of YESCARTA, leukapheresis, and all cell preparation. 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.[7,8]

HCPCS Product Code[7,10]	Description[10]	Notes[7,8]
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anticd 19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	Medicare coding guidance states that if cell preparation is conducted in the hospital outpatient setting but CAR T cells are administered in the inpatient setting, the Q2041 code should NOT be entered on the Centers for Medicare & Medicaid Services (CMS) 1450 claim form for the inpatient admission. Q2041 is, however, appropriate to enter on a hospital outpatient Medicare claim when YESCARTA is administered in the hospital outpatient setting.

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IMPORTANT SAFETY INFORMATION

HYPERSENSITIVITY REACTIONS

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

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.

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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.[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[11,12]
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.

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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.

PROLONGED CYTOPENIAS

Patients may exhibit cytopenias for several weeks following lymphodepleting chemotherapy and YESCARTA infusion. ≥ 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.

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// 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.

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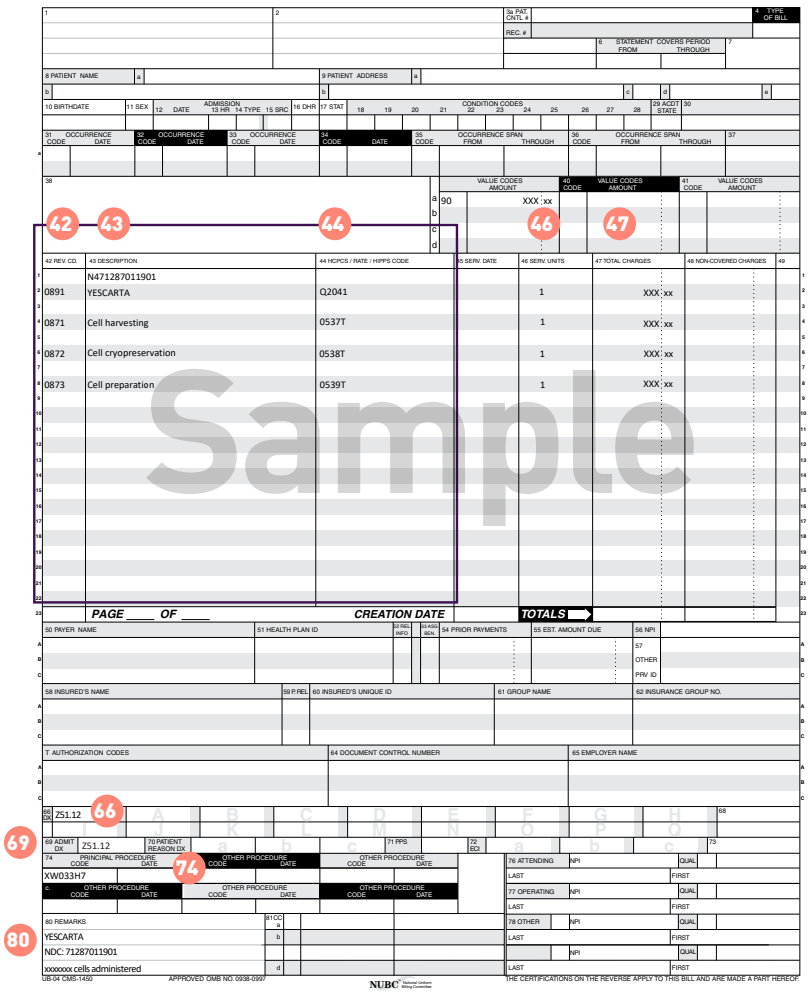
YESCARTA® (axicabtagene ciloleucel) Suspension for IV infusion

References

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

This sample form is for information purposes only.



42 REVENUE CODES

For YESCARTA® cell infusion – For Medicare, use either revenue code ***0891 or 0874***.[9]

For cell harvesting, storage, and preparation – For Medicare, use revenue codes ***0871, 0872, and 0873***.[9]

Hospitals should confirm revenue coding requirements for other payers.

43 DESCRIPTION

Include the brand name ***YESCARTA***. In the row above, enter the YESCARTA NDC as ***N471287011901, with no dashes***.[1,11,12] Only the YESCARTA NDC for the infusion bag should be used for billing purposes.

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 13 of this guide for detailed information).[8,10]

44 HCPCS CODES

For YESCARTA cell infusion – For Medicare, guidance states to not use code ***Q2041*** when cell preparation takes place in the outpatient setting and YESCARTA administration takes place in the inpatient setting. Instead, use code ***0540T*** and its corresponding revenue code. Other payers may accept and prefer the ***Q2041*** code. However, that information should be confirmed by payer.[8,10]

For cell harvesting, storage, and preparation – Enter the appropriate HCPCS CPT code for the service provided (see page 13 of this guide for detailed information). The date of service should be the date that YESCARTA was administered, not the date cells were collected.[7,8]

FIELDS 42 - 44

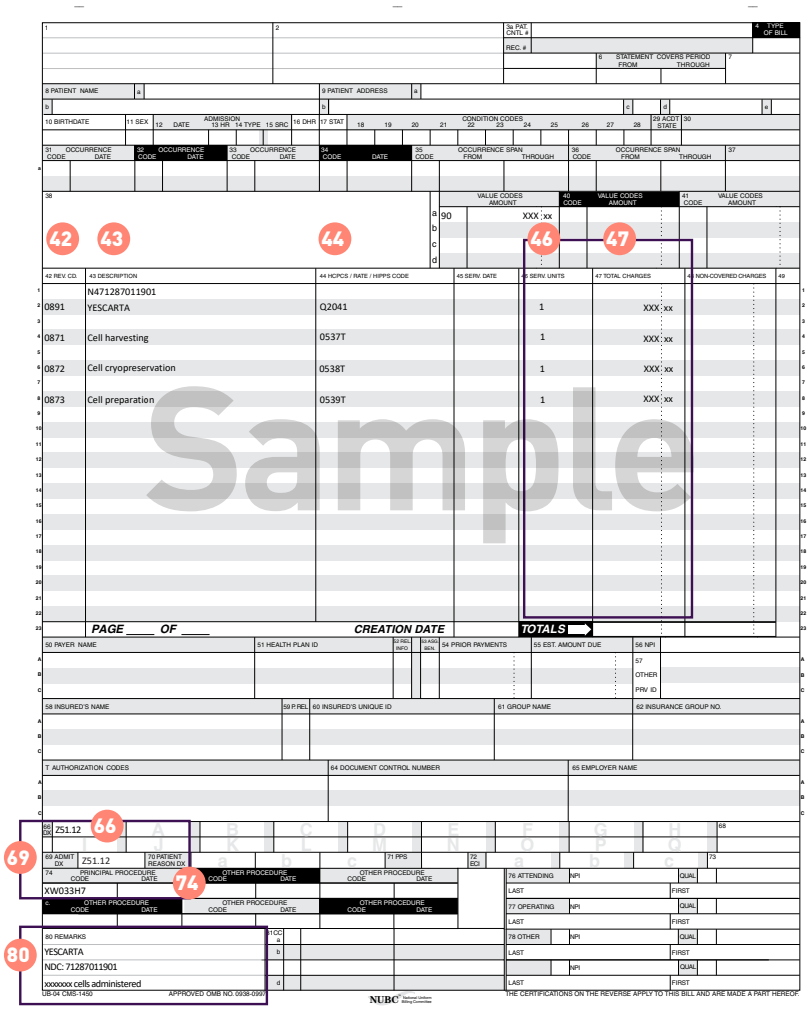
This sample form is for information purposes only. It is not intended to be directive, nor does use of the codes listed guarantee reimbursement. Healthcare providers and staff may find other codes more appropriate. It is the responsibility of providers to select the coding options that best reflect internal 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.

YESCARTA® (axicabtagene ciloleucel) Suspension for IV infusion

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

This sample form is for information purposes only.



FIELDS 46 - 80

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 ***Z51.12*** (Encounter for antineoplastic immunotherapy) as the first-listed or principal diagnosis.[2]

69 ADMIT DIAGNOSIS

Enter ***Z51.12*** (Encounter for antineoplastic immunotherapy) as the admit diagnosis.[2]

74 PRINCIPAL PROCEDURE

Enter the appropriate ICD-10-PCS code from the 2 dedicated to CAR T–specific codes (***XW033H7* or *XW043H7***).[3] Other payers may also utilize these codes to establish the reimbursement methodology for YESCARTA® admissions.

80 REMARKS

Enter the ***YESCARTA*** name and the ***11-digit NDC represented with no dashes: 71287011901***.[1] Confirm any additional documentation requirements for YESCARTA inpatient claims with each payer.

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.

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YESCARTA® (axicabtagene ciloleucel) Suspension for IV infusion

HOSPITAL OUTPATIENT ADMINISTRATION

The YESCARTA® product-specific Healthcare Common Procedure Coding System (HCPCS) code is Q2041 (axicabtagene ciloleucel, up to 200 million autologous anticd 19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose).[9]

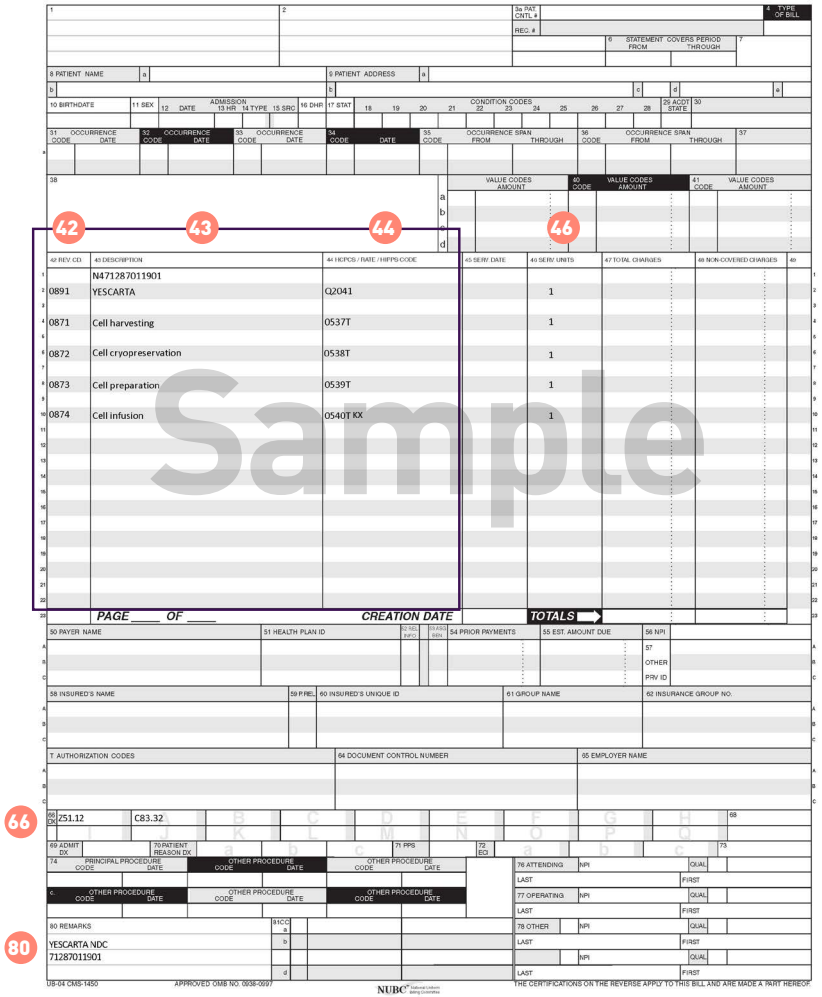
Medicare requires this code on hospital outpatient claims when cells are delivered in that setting. Other payers may apply the Q2041 code for outpatient and other settings of care. It is important for providers to confirm billing and coding requirements with each payer before submitting claims.

Please see Important Safety Information throughout this guide.

YESCARTA® (axicabtagene ciloleucel) Suspension for IV infusion

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

This sample form is for information purposes only.



FIELDS 42 - 44

42 REVENUE CODES

For YESCARTA® cell infusion – For Medicare, use revenue codes ***0891 and 0874***.[9]

To track non-payable charges for cell harvesting, storage, and preparation – For Medicare, use revenue codes ***0871, 0872, or 0873***. Do not use these codes if code ***0891*** is used.[9]

Hospitals should confirm revenue coding requirements for other payers.

43 DESCRIPTION

Include the brand name ***YESCARTA***. In the row above, enter the YESCARTA NDC as ***N471287011901, with no dashes***.[1,11,12] Only the YESCARTA NDC for the infusion bag should be used for billing purposes.

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 13 of this guide for detailed information).[8]

44 HCPCS CODES

For YESCARTA cells – Enter ***Q2041*** to indicate YESCARTA. This code and subsequent reimbursement also includes all cell harvesting, storage, and preparation. Use code ***0540T*** to report YESCARTA administration.[8]

To track non-payable charges for cell harvesting, storage, and preparation – Enter the appropriate HCPCS CPT codes for the services provided (see page 13 of this guide for detailed information). Charges for these steps may be reported separately for tracking purposes, or be included in the charge for code ***Q2041***. The date of service should be the date that YESCARTA was administered, not the date cells were collected.[7,8]

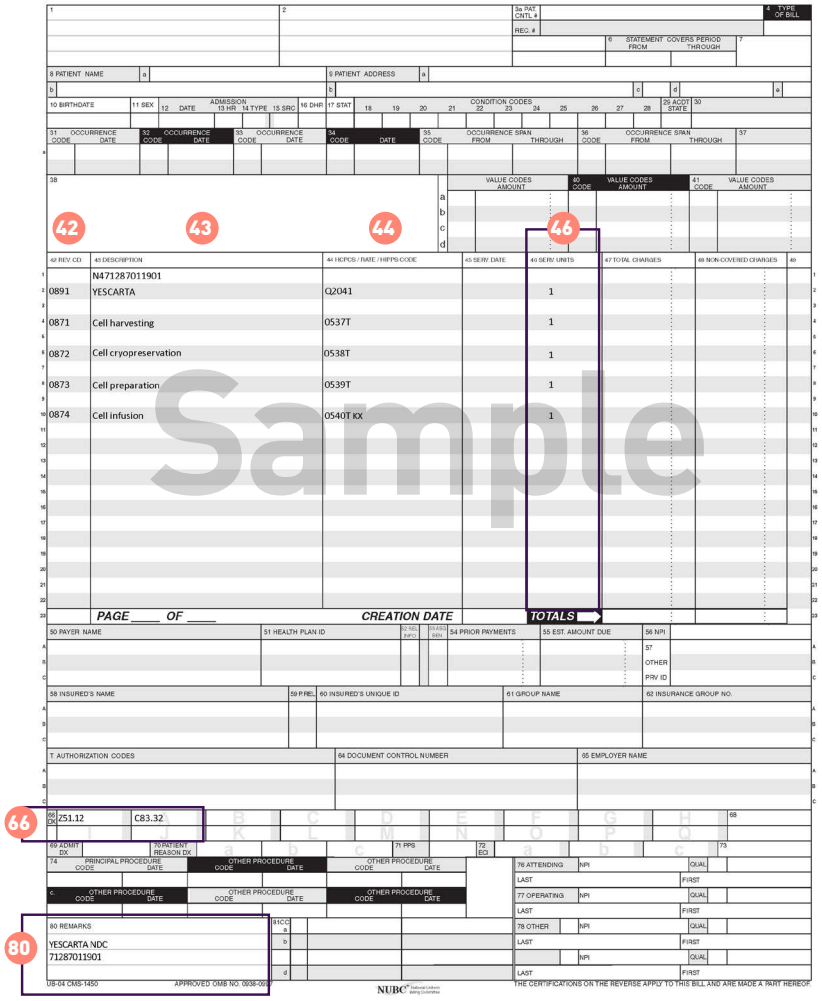
This sample form is for information purposes only. It is not intended to be directive, nor does use of the codes listed guarantee reimbursement. Healthcare providers and staff may find other codes more appropriate. It is the responsibility of providers to select the coding options that best reflect internal 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.

YESCARTA® (axicabtagene ciloleucel) Suspension for IV infusion

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

This sample form is for information purposes only.



FIELDS 46 - 80

46 SERVICE UNITS

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

66 DIAGNOSIS CODES

Enter ***Z51.12 (Encounter for antineoplastic immunotherapy)*** as the first-listed or principal diagnosis.[2]

80 REMARKS

Enter the ***YESCARTA®*** name and the ***11-digit NDC with no dashes: 71287011901***.[1]

IMPORTANT PROVIDER CONSIDERATIONS

The Centers for Medicare & Medicaid Services allows reasonable and necessary chimeric antigen receptor T-cell (CAR T) therapy services, as long as the therapies are furnished in Risk Evaluation and Mitigation Strategy (REMS)–approved facilities and the claims include the appropriate coding.

For outpatient hospital and professional claims, CPT codes are reported for the administration procedure, associated services, and the individual products. Providers are required to denote a KX modifier on a CAR T-cell therapy service to acknowledge that the service is being submitted by or performed in an FDA REMS-approved facility.[7] The provider should indicate a KX modifier on Part A outpatient and Part B claims but not Part A inpatient claims.[13]

Any place that is not located within a hospital but is properly equipped as an infusion center would be considered an "associated clinic" for the purpose of the YESCARTA® REMS. Once a provider has been identified as an FDA REMS-approved facility, they are added to a special edit that allows all inpatient and outpatient claims to automatically process as an FDA REMS-approved facility.[13]

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.

YESCARTA® (axicabtagene ciloleucel) Suspension for IV infusion

References

Dedicated support throughout the treatment journey

Kite Konnect®

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®

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.

CAR T=chimeric antigen receptor T cell.

// 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.

References

Helpful Reminders

Consider the Following Steps When Billing and Coding for YESCARTA

Confirm the appropriate CPT code for leukapheresis associated with T-cell collection

For Medicare, use the Q2041 code only when YESCARTA® is administered in an outpatient setting. Other payers may accept Q2041 on inpatient claims forms. If YESCARTA is administered in the hospital inpatient setting, you will need to use the Level I HCPCS CPT codes and corresponding revenue codes listed on page 13 when completing an inpatient claim for Medicare.[7,8]

Contact your patient's payer to determine if there are any specific coding requirements for the hospital outpatient setting

Determine the correct Medicare reimbursement methodology for the hospital inpatient setting

Effective for YESCARTA Medicare inpatient admissions on or after October 1, 2021, though September 30, 2022, hospitals will receive payment under the new CAR T-specific **Medicare-Severity Diagnosis Related Group** - ***MS-DRG 018 - Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies***.

Contact your patient's payer to identify their DRG assignment or other established reimbursement methodology for YESCARTA

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

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.

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.

Please see additional Important Safety Information throughout this guide.

YESCARTA® (axicabtagene ciloleucel) Suspension for IV infusion

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.

ADVERSE REACTIONS

The most common non-laboratory adverse reactions (incidence ≥ 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 ≥ 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.

The most common non-laboratory adverse reactions (incidence ≥ 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 additional Important Safety Information throughout and 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.
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Please see Important Safety Information throughout this guide.

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Kite A GILEAD Company