Billing and Coding Information for DLBCL and FL

YESCARTA® (axicabtagene ciloleucel) Suspension for IV infusion

Below is an overview of the current relevant codes, as of November 2020, that may be potential options for use with YESCARTA. Of note, these codes include follicular lymphoma (FL).

How Supplied[1]

YESCARTA is supplied in an infusion bag containing ~68 mL of frozen suspension of genetically modified autologous T cells in 5% DMSO and 2.5% albumin (human)

ICD-10-PCS[2]

XW033C3–Introduction of engineered autologous chimeric antigen receptor T-cell immunotherapy into peripheral vein, percutaneous approach, New Technology Group 3

XW043C3–Introduction of engineered autologous chimeric antigen receptor T-cell immunotherapy into central vein, percutaneous approach, New Technology Group 3

NDC[1]

71287-0119-01
Infusion bag containing approximately 68 mL of frozen suspension of genetically modified autologous T cells in 5% DMSO and 2.5% albumin (human)

Billing Unit[1]

1 billing unit is equal to 1 YESCARTA infusion bag

HCPCS Product Code[3]

Q2041–Axicabtagene ciloleucel, up to 200 million autologous anti-CD19 car-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose

WAC[4]

$373,000

ICD-10-CM Diagnosis Codes[5]

C82.00-C82.49	C82.50-C82.59	C82.60-C82.69	C82.80-C82.89	C82.90-C82.99
Follicular lymphoma	Diffuse follicle center lymphoma	Cutaneous follicle center lymphoma	Other types of follicular lymphoma	Follicular lymphoma, unspecified
C83.30-C83.39	**C85.20-C85.29**	**Z00.6***	**Z51.12†**	
Diffuse large B-cell lymphoma	Mediastinal (thymic) large B-cell lymphoma	Encounter for examination for normal comparison and control in clinical research program	Encounter for antineoplastic immunotherapy	

Current Procedural Terminology (CPT®)[3]

0537T	0538T	0539T	0540T
Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation storage)	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous

INDICATIONS

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

- 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.
  Limitation 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).

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 on the following page.

DLBCL=diffuse large B-cell lymphoma; DMSO=dimethyl sulfoxide; 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; WAC=wholesale acquisition cost.

*This code should be reported only for clinical trial cases or with standardized drug charges of less than $373,000.[2]

†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.[6]

Important Safety Information (continued)

CYTOKINE RELEASE SYNDROME (CRS), including fatal or life-threatening reactions, occurred. CRS occurred in 88% (224/254) of all patients with non-Hodgkin lymphoma (NHL), including Grade ≥3 in 10%. CRS occurred in 94% (101/108) of patients with large B-cell lymphoma (LBCL), including Grade ≥3 in 13%. Among patients with LBCL who died after receiving YESCARTA, 4 had ongoing CRS events at the time of death. The median time to onset of CRS was 2 days (range: 1-12 days) and the median duration was 7 days (range: 2-58 days) for patients with LBCL. CRS occurred in 84% (123/146) of patients with indolent non-Hodgkin lymphoma (iNHL), including Grade ≥3 in 8% (11/146). Among patients with iNHL who died after receiving YESCARTA, 1 patient had ongoing CRS events 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 (80%), hypotension (38%), tachycardia (29%), hypoxia (21%), chills (21%), and headache (13%). Serious events that may be associated with CRS include cardiac arrhythmias (including atrial fibrillation and ventricular tachycardia), cardiac arrest, cardiac failure, renal insufficiency, capillary leak syndrome, hypotension, hypoxia, multi-organ failure and hemophagocytic lymphohistiocytosis/macrophage activation syndrome. Ensure that 2 doses of tocilizumab are available prior to YESCARTA infusion. Following 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.

NEUROLOGIC TOXICITIES that were fatal or life-threatening occurred. Neurologic toxicities occurred in 81% (206/254) of all patients with NHL receiving YESCARTA, including Grade ≥3 in 26%. Neurologic toxicities occurred in 87% (94/108) of patients with LBCL, including Grade ≥3 in 31%. The median time to onset was 4 days (range: 1-43 days) and the median duration was 17 days for patients with LBCL. 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 for patients with iNHL. 98% 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 89% of affected patients with LBCL and 74% of affected patients with iNHL. The most common neurologic toxicities (≥10%) in all patients combined included encephalopathy (53%), headache (45%), tremor (31%), dizziness (20%), delirium (16%), aphasia (15%), and insomnia (11%). Prolonged encephalopathy lasting up to 173 days was noted. Serious events, including leukoencephalopathy and seizures, as well as fatal and serious cases of cerebral edema, have occurred. Following YESCARTA infusion, 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).

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 47% (119/254) of all patients with NHL. Grade ≥3 infections occurred in 19% of patients, Grade ≥3 infections with an unspecified pathogen occurred in 15%, bacterial infections in 5%, viral infections in 2%, 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 anti-microbials according to local guidelines. Febrile neutropenia was observed in 40% of all 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. 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, can occur in patients treated with drugs directed against B cells. Perform screening for HBV, HCV, and HIV 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 30% of all patients with NHL and included neutropenia (22%), thrombocytopenia (13%), and anemia (5%). Monitor blood counts after infusion.

HYPOGAMMAGLOBULINEMIA and B-cell aplasia can occur. Hypogammaglobulinemia occurred in 17% 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 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.

ADVERSE REACTIONS: The most common adverse reactions (incidence ≥20%) in patients with LBCL 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 included fever, CRS, hypotension, encephalopathy, fatigue, headache, infections with pathogen unspecified, tachycardia, febrile neutropenia, musculoskeletal pain, nausea, tremor, chills, diarrhea, constipation, decreased appetite, cough, vomiting, hypoxia, arrhythmia, and dizziness.

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

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The use of the information in this brochure does not guarantee reimbursement or that any reimbursement received will cover treatment costs. This information 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 and its agents disclaim any and all liability as a result of denied claims or incorrect codes.

References: 1. YESCARTA® (axicabtagene ciloleucel). Prescribing information. Kite Pharma, Inc; 2021. **2.** 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 March 5, 2021. https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-19637.pdf. **3.** Medicare program: changes to hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs; revisions of organ procurement organizations conditions of coverage; prior authorization process and requirements for certain covered outpatient department services; potential changes to the laboratory date of service policy; changes to grandfathered children's hospitals-within-hospitals; notice of closure of two teaching hospitals and opportunity to apply for available slots. Centers for Medicare & Medicaid Services. Updated November 12, 2019. Accessed March 5, 2021. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1717-FC. **4.** Truven Health Analytics Inc [database online]. Red Book—YESCARTA Pricing. March 5, 2021. **5.** International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM). Centers for Disease Control and Prevention. Updated April 1, 2020. Accessed March 5, 2021. https://icd10cmtool.cdc.gov/?fy=FY2020. **6.** ICD-10-CM official guidelines for coding and reporting. Centers for Disease Control and Prevention. Accessed March 5, 2021. https://www.cdc.gov/nchs/data/icd/10cmguidelines-FY2020_final.pdf.

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