Billing and Coding Information

TECARTUS® (brexucabtagene autoleucel) Suspension for IV infusion

Below is an overview of current relevant codes as of October 2021, including codes for MCL and ALL. These codes may be potential options for use when billing for TECARTUS®.

HOW SUPPLIED[1]

TECARTUS is supplied in an infusion bag containing ≈68 mL of frozen suspension of genetically modified autologous T cells in 5% DMSO and human serum albumin.

ICD-10-PCS CODES[2]

XW033M7–Introduction of brexucabtagene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7

XW043M7–Introduction of brexucabtagene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 7

NDC[1]

For MCL: **71287-0219-01***

For ALL: **71287-0220-01***

BILLING UNIT[1]

1 billing unit is equal to 1 TECARTUS infusion bag.

HCPCS PRODUCT CODE[3]

Q2053–Brexucabtagene autoleucel; up to 200 million autologous anti-CD19 CAR-positive viable T cells, including leukapheresis and dose preparation procedures per therapeutic dose

WAC[4]

$399,000

ICD-10-CM DIAGNOSIS CODES[5]

C83.10-C83.19	C91.00	C91.02	Z00.6†	Z51.12‡
Mantle cell lymphoma	Acute lymphoblastic leukemia not having achieved remission	Acute lymphoblastic leukemia, in relapse	Encounter for examination for normal comparison and control in clinical research program	Encounter for antineoplastic immunotherapy

CURRENT PROCEDURAL TERMINOLOGY CODE[6]

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 (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

Effective for services on or after October 1, 2021, qualified facilities that report an appropriate diagnosis and ICD-10-PCS code for the inpatient administration of TECARTUS to Medicare beneficiaries may be eligible for an NTAP.[7]

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.

INDICATION

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

- Adult patients with relapsed or refractory mantle cell lymphoma (MCL).

This indication is approved under accelerated approval based on overall response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

- Adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

IMPORTANT SAFETY INFORMATION

BOXED WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITIES

- **Cytokine Release Syndrome (CRS), including life-threatening reactions, occurred in patients receiving TECARTUS. Do not administer TECARTUS to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.**
- **Neurologic toxicities, including life-threatening reactions, occurred in patients receiving TECARTUS, including concurrently with CRS or after CRS resolution. Monitor for neurologic toxicities after treatment with TECARTUS. Provide supportive care and/or corticosteroids as needed.**
- **TECARTUS 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 brochure.

*The NDC has been "zero-filled" to create an 11-digit code that meets Health Insurance Portability and Accountability Act (HIPAA) standards. The zero-fill location is indicated in teal font.[1]

†This code should be reported only for clinical trial cases or with standardized drug charges of less than $373,000.[7]

‡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.[8]

ALL=acute lymphoblastic leukemia; CAR=chimeric antigen receptor; 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; MCL=mantle cell lymphoma; NDC=National Drug Code; NTAP=New Technology Add-On Payment; WAC=wholesale acquisition cost.

Important Safety Information (continued)

Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred following treatment with TECARTUS. CRS occurred in 91% (75/82) of patients with MCL, including ≥ Grade 3 CRS in 18% of patients. CRS occurred in 92% (72/78) of patients with ALL, including ≥ Grade 3 CRS in 26% of patients. The median time to onset of CRS was 3 days (range: 1 to 13 days) and the median duration of CRS was 10 days (range: 1 to 50 days) for patients with MCL. Three patients with ALL had ongoing CRS events at the time of death. The median time to onset of CRS was 5 days (range: 1 to 12 days) and the median duration of CRS was 8 days (range: 2 to 63 days) for patients with ALL. Among patients with CRS, the key manifestations (>10%) were similar in MCL and ALL and included fever (93%), hypotension (62%), tachycardia (59%), chills (32%), hypoxia (31%), headache (21%), fatigue (20%), and nausea (13%). Serious events associated with CRS in MCL and ALL combined (≥ 2%) included hypotension, fever, hypoxia, tachycardia, and dyspnea.

Ensure that a minimum of 2 doses of tocilizumab are available for each patient prior to infusion of TECARTUS. Following infusion, monitor patients for signs and symptoms of CRS daily for at least 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, including those that were fatal or life-threatening, occurred following treatment with TECARTUS. Neurologic events occurred in 81% (66/82) of patients with MCL, including ≥ Grade 3 in 37% of patients. The median time to onset for neurologic events was 6 days (range: 1 to 32 days) with a median duration of 21 days (range: 2 to 454 days) in patients with MCL. Neurologic events occurred in 87% (68/78) of patients with ALL, including ≥ Grade 3 in 35% of patients. The median time to onset for neurologic events was 7 days (range: 1 to 51 days) with a median duration of 15 days (range: 1 to 397 days) in patients with ALL. The onset of neurologic events can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. 91% of all treated patients experienced the first CRS or neurological event within the first 7 days after TECARTUS infusion.

The most common neurologic events (>10%) were similar in MCL and ALL and included encephalopathy (57%), headache (37%), tremor (34%), confusional state (26%), aphasia (23%), delirium (17%), dizziness (15%), anxiety (14%), and agitation (12%). Serious events including encephalopathy, aphasia, confusional state, and seizures occurred after treatment with TECARTUS. Monitor patients daily for at least 7 days for patients with MCL and at least 14 days for patients with ALL at the certified healthcare facility and for 4 weeks following infusion for signs and symptoms of neurologic toxicities and treat promptly.

REMS Program: Because of the risk of CRS and neurologic toxicities, TECARTUS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS Program which requires that:

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

Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS), including life-threatening reactions, occurred following treatment with TECARTUS. HLH/MAS occurred in 4% (3/78) of patients with ALL. Two patients experienced Grade 3 events and 1 patient experienced a Grade 4 event. The median time to onset for HLH/MAS was 8 days (range: 6 to 9 days) with a median duration of 5 days (range: 2 to 8 days). All 3 patients with HLH/MAS had concurrent CRS symptoms and neurologic events after TECARTUS infusion. Treatment of HLH/MAS should be administered per institutional standards.

Hypersensitivity Reactions: Serious hypersensitivity reactions, including anaphylaxis, may occur due to dimethyl sulfoxide (DMSO) or residual gentamicin in TECARTUS.

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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 TECARTUS®. Kite and its agents disclaim any and all liability as a result of denied claims or incorrect codes.

Important Safety Information (continued)

Severe Infections: Severe or life-threatening infections occurred in patients after TECARTUS infusion. Infections (all grades) occurred in 56% (46/82) of patients with MCL and 44% (34/78) of patients with ALL. Grade 3 or higher infections, including bacterial, viral, and fungal infections, occurred in 30% of patients with ALL and MCL. TECARTUS 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 6% of patients with MCL and 35% of patients with ALL after TECARTUS infusion 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, life-threatening and fatal opportunistic infections have been reported. The possibility of rare infectious etiologies (e.g., fungal and viral infections such as HHV-6 and progressive multifocal leukoencephalopathy) should be considered in 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 TECARTUS infusion. In patients with MCL, Grade 3 or higher cytopenias not resolved by Day 30 following TECARTUS infusion occurred in 55% (45/82) of patients and included thrombocytopenia (38%), neutropenia (37%), and anemia (17%). In patients with ALL who were responders to TECARTUS treatment, Grade 3 or higher cytopenias not resolved by Day 30 following TECARTUS infusion occurred in 20% (7/35) of the patients and included neutropenia (12%) and thrombocytopenia (12%); Grade 3 or higher cytopenias not resolved by Day 60 following TECARTUS infusion occurred in 11% (4/35) of the patients and included neutropenia (9%) and thrombocytopenia (6%). Monitor blood counts after TECARTUS infusion.

Hypogammaglobulinemia and B-cell aplasia can occur in patients receiving treatment with TECARTUS. Hypogammaglobulinemia was reported in 16% (13/82) of patients with MCL and 9% (7/78) of patients with ALL. Monitor immunoglobulin levels after treatment with TECARTUS and manage using infection precautions, antibiotic prophylaxis, and immunoglobulin replacement. The safety of immunization with live viral vaccines during or following TECARTUS 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 treatment, and until immune recovery following treatment with TECARTUS.

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 TECARTUS infusion. Advise patients to refrain from driving and engaging in hazardous activities, such as operating heavy or potentially dangerous machinery, during this period.

Adverse Reactions: The most common adverse reactions (incidence ≥ 20%) in MCL patients were fever, CRS, hypotension, encephalopathy, fatigue, tachycardia, arrhythmia, infection with pathogen unspecified, chills, hypoxia, cough, tremor, musculoskeletal pain, headache, nausea, edema, motor dysfunction, constipation, diarrhea, decreased appetite, dyspnea, rash, insomnia, pleural effusion, and aphasia.

The most common adverse reactions (incidence ≥ 20%) in ALL patients were fever, cytokine release syndrome, hypotension, encephalopathy, tachycardia, nausea, chills, headache, fatigue, febrile neutropenia, diarrhea, musculoskeletal pain, hypoxia, rash, edema, tremor, infection with pathogen unspecified, constipation, decreased appetite, and vomiting.

Please see additional Important Safety Information throughout this brochure and full Prescribing Information, including BOXED WARNING and Medication Guide.

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References: 1. TECARTUS® (brexucabtagene autoleucel). Prescribing information. Kite Pharma, Inc; 2021. **2.** ICD-10-CM/PCS MS-DRG v39.0 Definitions Manual. Centers for Medicare & Medicaid Services. Accessed October 1, 2021. https://www.cms.gov/icd10m/version39-fullcode-cms/fullcode_cms/P0038.html. **3.** April 2021 alpha-numeric HCPCS file. Centers for Medicare & Medicaid Services. Accessed October 1, 2021. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update. **4.** Truven Health Analytics Inc [database online]. Red Book—TECARTUS pricing. October 1, 2021. **5.** International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM). Centers for Disease Control and Prevention. Updated April 1, 2020. Accessed October 1, 2021. https://icd10cmtool.cdc.gov/?fy=FY2021. **6.** Optum 360 [database online]. CPT® Code Section (0537T-0540T). July 15, 2021. **7.** 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. Final rule. Accessed October 1, 2021. https://www.cms.gov/medicare/acute-inpatient-pps/fy-2022-ipps-final-rule-home-page . **8.** ICD-10-CM official guidelines for coding and reporting. Centers for Disease Control and Prevention. Accessed October 1, 2021. https://www.cdc.gov/nchs/data/icd/10cmguidelines-FY2020_final.pdf.

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