

# TECARTUS® COMMUNITY CODING AND BILLING GUIDE

### Information about reimbursement for TECARTUS 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 TECARTUS. Kite, a Gilead Company, and its agents disclaim any and all liability as a result of denied claims or incorrect codes.

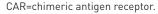
#### **INDICATIONS**

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).

# **CONTENTS**

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



Please see full  $\underline{\text{Prescribing Information}}$ , including  $\underline{\text{BOXED WARNING}}$  and  $\underline{\text{Medication Guide}}$ .



# Coding and Billing Guide Overview

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



**Overview** 

# Coding and Billing Guide Overview

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

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

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

The information available within is compiled from sources believed to be accurate as of January 2024. Responsibility for properly submitting claims lies with the healthcare provider. Kite and its agents make no warranties or quarantees, 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 quarantee 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.

CAR=chimeric antigen receptor.

#### IMPORTANT SAFETY INFORMATION

**Overview** 

#### WARNING: CYTOKINE RELEASE SYNDROME. NEUROLOGIC TOXICITIES. AND SECONDARY HEMATOLOGICAL MALIGNANCIES

- 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.
- T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies.
- TECARTUS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS.



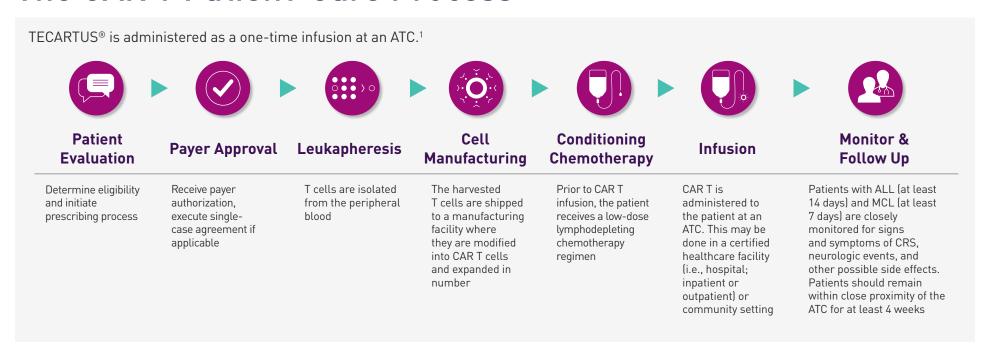
<sup>\*</sup>Authorized Treatment Centers are independent facilities certified to dispense Kite CAR T therapies. Choice of an Authorized Treatment Center is within the sole discretion of the physician and patient. Kite does not endorse any individual treatment sites.

# The CAR T Patient-Care Process

CAR=chimeric antigen receptor.



### The CAR T Patient-Care Process



 $ALL = acute\ lymphoblastic\ lymphoma;\ ATC = Authorized\ Treatment\ Center;\ CAR = chimeric\ antigen\ receptor;\ CRS = cytokine\ release\ syndrome;\ MCL = mantle\ cell\ lymphoma.$ 

#### IMPORTANT SAFETY INFORMATION

#### CYTOKINE RELEASE SYNDROME (CRS)

CRS, including fatal or life-threatening reactions, occurred following treatment with TECARTUS. CRS occurred in 91% (75/82) of patients with MCL, including  $\geq$  Grade 3 CRS in 18% of patients. Among the patients with MCL who died after receiving TECARTUS, one patient had a fatal CRS event. 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. CRS occurred in 92% (72/78) of patients with ALL, including  $\geq$  Grade 3 CRS in 26% of patients. 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 ( $\geq$  2%) included hypotension, fever, hypoxia, tachycardia, and dyspnea.

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

Claim Form for

Office Billing

# Overview of Coding for Diagnosis, Preparation, and Administration





# **Overview of Coding**

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

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

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



# **Diagnosis Coding**

### **Diagnosis Coding for Product Indications**

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

ICD-10-CM Diagnosis Code <sup>2-4</sup>	Description <sup>2-4</sup>
C83.11-C83.19	Mantle cell lymphoma
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.02	Acute lymphoblastic leukemia, in relapse
Z51.12*	Encounter for antineoplastic immunotherapy

This information is provided for your background and not intended as comprehensive or directive. Payer coding requirements may vary or change over time. It is the responsibility of the healthcare provider to determine and submit the appropriate codes, charges, and modifiers for medically necessary services rendered. This information is in no way a guarantee of reimbursement or coverage for any product or service. CAR=chimeric antigen receptor; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

#### IMPORTANT SAFETY INFORMATION

#### CYTOKINE RELEASE SYNDROME (continued)

**Overview** 

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 for patients with MCL and at least 14 days for patients with ALL 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. **TECARTUS®** 

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

Codina



(brexucabtagene autoleucel) Suspension for IV infusion

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

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

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

#### Level I HCPCS CPT Codes

Level I HCPCS Current Procedural Terminology (CPT®) codes were established to better identify the work, effort, and charges associated with the various steps required to collect and prepare CAR T cells. For Medicare, community practices may choose from 2 billing options: (1) to include the charges for the various steps in the charge submitted for the biological<sup>5</sup>; or (2) to report these charges separately for tracking purposes (documented under 38225, 38226, and 38227).<sup>5,6</sup> For non-Medicare payers, it is the provider's responsibility to contact each payer for payer-specific coding requirements before submitting any claims.

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

#### IMPORTANT SAFETY INFORMATION

#### **NEUROLOGIC TOXICITIES**

Neurologic toxicities including immune effector cell-associated neurotoxicity syndrome (ICANS) that were fatal or life-threatening, occurred following treatment with TECARTUS. Neurologic events occurred in 81% (66/82) of patients with MCL, including  $\geq$  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  $\geq$  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. Neurologic events resolved for 119 out of 134 (89%) patients treated with TECARTUS. The onset of neurologic events can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Ninety-one percent 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 associated with neurologic toxicities in MCL and ALL combined ( $\geq$ 2%) 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.



### Cell Collection and Cell Processing Services

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

Level I HCPCS CPT Code <sup>2,6</sup>	Description <sup>2,6</sup>	Notes
38225	Chimeric antigen receptor T-cell (CAR T) therapy; harvest of blood-derived T lymphocytes for development of genetically modified autologous CAR T cells, per day	Medicare guidance gives several options for how to report charges for cell collection and processing services for CAR T-cell therapy. It is important to review and select the most appropriate billing option for these services. <sup>5*</sup>
38226	Chimeric antigen receptor T-cell (CAR T) therapy; preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation, storage)	New Category I CPT codes for cell collection and processing: leukapheresis (38225), preparation (38226), receipt and preparation for administration (38227) are assigned status
38227	Chimeric antigen receptor T-cell (CAR T) therapy; receipt and preparation of CAR T cells for administration	indicator "B," indicating that CMS considers these codes to be "bundled" for MPFS.6

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

#### IMPORTANT SAFETY INFORMATION

**Overview** 

#### **REMS**

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. The required components of the YESCARTA and TECARTUS REMS are:

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

Further information is available at www.YescartaTecartusREMS.com or 1-844-454-KITE (5483).

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



<sup>\*</sup>As of March 15, 2019, CMS issued the following billing code options for CAR T-cell therapy.5

#### Administration

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

Level I HCPCS CPT Code <sup>2,6</sup>	Description <sup>2,6</sup>	Notes
38228	Chimeric antigen receptor (CAR) T-cell therapy, CAR T-cell administration, autologous	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. **  CPT code 38228 is considered payable by Medicare and is used to document TECARTUS® administration. 5,6 When using 38228 for Medicare, it is important to append the modifier KX to the code, because this is the mechanism that tells your Medicare Administrative Contractor (MAC) that CAR T-cell therapy is administered in a REMS-certified facility. 7

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

#### **IMPORTANT SAFETY INFORMATION**

#### HEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS/MACROPHAGE ACTIVATION SYNDROME (HLH/MAS)

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.

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



<sup>\*</sup>As of March 15, 2019, CMS issued the following billing code options for CAR T-cell therapy.<sup>5</sup>

# Remote Patient Monitoring Services Coding<sup>8</sup>

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

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

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

#### IMPORTANT SAFETY INFORMATION

#### **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.

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



# **Product Coding**

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

#### Level II HCPCS Product Code

A Level II HCPCS product code is used to report the use of the biological product TECARTUS® in the outpatient setting for Medicare. The TECARTUS code, Q2053, 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 Q2053. Providers should contact each payer to clarify the specific coding requirements before submitting any claims. <sup>5,9</sup>

HCPCS Product Code <sup>2</sup>	Description <sup>2</sup>
Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-CD19 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.

CAR=chimeric antigen receptor; CPT=Current Procedural Terminology; FDA=US Food and Drug Administration; HCPCS=Healthcare Common Procedure Coding System.

#### **IMPORTANT SAFETY INFORMATION**

**Overview** 

#### SEVERE INFECTIONS (continued)

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, hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines before collection of cells for manufacturing.

\*\*TECARTUS\*\*

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

(brexucabtagene autoleucel) Suspension for IV infusion

### **NDC**

TECARTUS® has 4 separate National Drug Codes (NDCs); 2 for the infusion bag with cells and 2 for the cassette in which the infusion bag is shipped.<sup>1</sup> Only utilize the infusion bag NDC for billing purposes. Include "N4" before the 11-digit TECARTUS NDC number when completing outpatient claims forms. It is the provider's responsibility to contact each payer for payer-specific coding requirements before submitting any claims.

Product NDC <sup>1,10</sup>	Description <sup>1</sup>	Notes <sup>10,11</sup>
71287-0219-01 for MCL	<b>11-digit NDC</b> for TECARTUS infusion bag containing approximately 68 mL of frozen suspension of genetically modified	Many payers may require the TECARTUS 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
71287-0220-01 for ALL	autologous T cells in 5% DMSO and human serum albumin.	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

**Overview** 

#### 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.

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

Codina

**TECARTUS®** 

# Unique Medicare Billing Instructions for **Community Practices**



**Overview** 

# Unique Medicare Billing Instructions for Community Practices

CMS has issued billing instructions for submitting professional claims for CAR T product and administration for Places of Service\* 11 (community practices/physician offices) and 49 (independent clinics). 12

CAR T-related HCPCS codes cannot be processed in the current Medicare Multi Carrier System because it was set up to allow a maximum of 7 digits for the dollar amount (line item on total maximum of 99999.99). This means nothing greater than \$99999.99 can be reported, while CAR T-cell products need to bill as 1 unit with a dollar amount of 8 digits. Providers will need to utilize a new modifier, -LU to allow for fractionated billing of the HCPCS code. 12

Providers bill in 0.2-unit or 0.1-unit fractions based on the allowed amount.12 TECARTUS® should be billed in fractions of 0.1.1

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

Modifier <sup>12</sup>	Purpose <sup>12</sup>	
Modifier -LU	Fractionated payment for CAR T	
Modifier -76	Repeat procedure or service by the same physician or other qualified HCP <sup>‡</sup>	
Modifier -KX	Attest the community practice is a REMS-approved facility§	

<sup>\*</sup>Place of service codes are reported on the 1500 professional claim to specify the entity where service(s) were rendered.13

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

#### IMPORTANT SAFETY INFORMATION

#### **HYPOGAMMAGLOBULINEMIA**

B-cell aplasia and hypogammaglobulinemia 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.

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

Coding

(brexucabtagene autoleucel) Suspension for IV infusion

<sup>\*</sup>If the allowed amount is <\$500,000, providers will be able to submit 5 separate claims for 0.2-unit fractions on each claim; if the allowed amount is >\$500,000, providers will be able to submit 10 separate claims for 0.1-unit fractions on each claim. 12

<sup>&</sup>lt;sup>‡</sup>Not appropriate for use on the first claim. <sup>12</sup>

<sup>§</sup>Not required for clinical trial billing. 12

# Claim Form for Office Billing

The TECARTUS® product-specific HCPCS code, effective April 1, 2021, is Q2053 (brexucabtagene autoleucel, up to 200 million autologous anti-CD19 CAR-positive viable T cells, including leukapheresis and dose preparation procedures per therapeutic dose).² This code can be used for Medicare outpatient claims. This information is provided for your background and not intended as comprehensive or directive. Payer coding requirements may vary or change over time. It is the responsibility of the healthcare provider to determine and submit the appropriate codes, charges, and modifiers for medically necessary services rendered. This information is in no way a guarantee of reimbursement or coverage for any product or service.

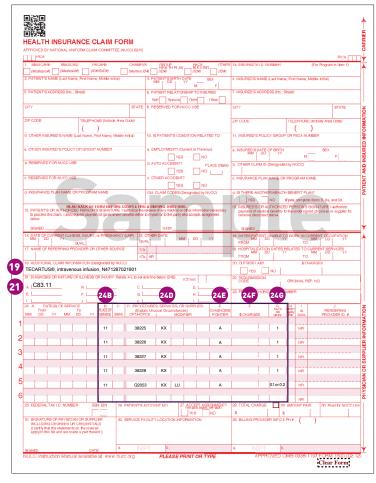
CAR=chimeric antigen receptor; HCPCS=Healthcare Common Procedure Coding System.



# First Claim

### Sample CMS-1500 Claim Form

This sample form is for information purposes only.



This sample form is for information purposes only. It is not intended to be directive, nor does use of the codes listed quarantee 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.

#### **ADDITIONAL CLAIM INFORMATION**

Enter drug name (TECARTUS®), route of administration, 11-digit NDC (N471287021901 for MCL or N471287022001 for ALL, with no dashes), and/or dosage. 1,8

#### **DIAGNOSIS OR NATURE OF ILLNESS OR INJURY**

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

#### 24B PLACE OF SERVICE

Enter appropriate code for place of service; CAR T-cell products will only be reimbursed in place of service 11 (office) or 49 (independent clinic).12

#### PROCEDURES, SERVICES, OR SUPPLIES

Indicate appropriate HCPCS CPT code.

For cell harvesting, storage, and preparation - Use HCPCS Level I CPT codes 38225, 38226, and 38227.6

For TECARTUS product charges - Enter Q2053 to indicate TECARTUS. Use code 38228 to report TECARTUS administration.6

Enter the appropriate modifiers – Use modifier -LU for fractionated payment (TECARTUS should be billed in fractions of 0.1 or 0.2. Providers can submit separate claims for 0.1- or 0.2-unit fractions on each claim) and modifier -KX for attesting the practice is REMS-approved. 12

#### **DIAGNOSIS POINTER**

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

#### **CHARGES**

Enter the total Medicare-allowed payment amount.<sup>12</sup>

#### **DAYS OR UNITS**

Enter the appropriate number of TECARTUS units used (0.1 or 0.2).

ALL=acute lymphoblastic leukemia; CAR=chimeric antigen receptor; CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; MCL=mantle cell lymphoma: NDC=National Drug Code: REMS=Risk Evaluation and Mitigation Strategy. **TECARTUS®** 

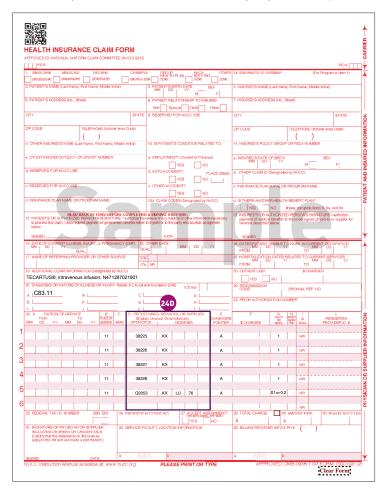
Please see full Prescribing Information, including BOXED WARNING and Medication Guide.



(brexucabtagene autoleucel) Suspension for IV infusion

# **Subsequent Claims** Sample CMS-1500 Claim Form

This sample form is for information purposes only.



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

#### PROCEDURES, SERVICES, OR SUPPLIES

Indicate appropriate HCPCS CPT code.

For cell harvesting, storage, and preparation – Use HCPCS Level 1 CPT codes 38225, 38226, and 38227.6

For TECARTUS® product charges - Enter Q2053 to indicate TECARTUS. Use code 38228 to report TECARTUS administration.6

Enter the appropriate modifiers – Use modifier -LU for fractionated payment (TECARTUS should be billed in factors of 0.1 or 0.2. Providers can submit separate claims for 0.1- or 0.2-unit fractions on each claim), modifier -KX for attesting the practice is REMS-approved, and modifier -76\* for repeat procedure or service by same physician. 12

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.

CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; REMS=Risk Evaluation and Mitigation Strategy.



<sup>\*</sup>Not appropriate for use on the first claim.

# Helpful Reminders

The following pages contain lists of helpful reminders to consider while coding and billing for TECARTUS®. Remember to always check each payer's requirements before submitting any claims.

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

Please see full <u>Prescribing Information</u>, including **BOXED WARNING** and Medication Guide.



**Overview** 

# Helpful Reminders

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

#### **Prior to Service Delivery**

Determine eligibility and insurance plan priority

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

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

Review published coverage policies for primary diagnosis and ICD-10-CM code, relevant disease-related characteristics, prior lines of therapy, and clinical fitness Submit the prior authorization request following payer instructions

Determine whether an expedited prior authorization process is available

Confirm prior authorization for each step of the treatment

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

#### IMPORTANT SAFETY INFORMATION

**Overview** 

#### HYPOGAMMAGLOBULINEMIA (continued)

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.

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

**TECARTUS®** 

(brexucabtagene autoleucel) Suspension for IV infusion

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

#### **Concurrent With Service Delivery**

Confirm written, authenticated clinician order for cell collection

Confirm nursing/cell lab documentation of cell collection procedure

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

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

Confirm nursing/cellular lab documentation of the administration procedure

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

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

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

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MAR=medication administration record.



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

#### **After Service Provision**

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

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

Review HCPCS Level II and NDC reporting requirements

Review for correct CPT codes on outpatient claims

Review to ensure the accuracy of units billed, that the prior authorization number is on the claim (if applicable), and that correct dates of services are reported Consider tracking claims post-submission and reviewing the remittances carefully

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

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

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

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

#### IMPORTANT SAFETY INFORMATION

**Overview** 

#### **SECONDARY MALIGNANCIES**

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

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



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

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

Confirm if payer-provider contracts are joint or separate

Confirm point of contact for payer case manager

Confirm party billing the payer

Confirm terms of cost and reimbursement sharing between parties

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HCP=healthcare professional.

#### **IMPORTANT SAFETY INFORMATION**

**Overview** 

#### **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 initial period.

Please see full <u>Prescribing Information</u>, including **BOXED WARNING** and Medication Guide.

Coding



### **Diagnosis Coding for Complications**

Certain complications and toxicities may occur with the use of TECARTUS®. 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 may be coded.

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

Complications Codes <sup>2</sup>	
ICD-10-CM Diagnosis Code	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

Code the appropriate complication and grade from the table below:

CRS Codes <sup>2</sup>	
ICD-10-CM Diagnosis Code  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

ICANS Codes <sup>2</sup>	
ICD-10-CM Diagnosis Code	Description
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.

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



# Medicare Clinical Trial and Expanded Access Billing

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



Unique Medicare

**Billing Instructions** 

# Clinical Trial and Expanded Access Billing

### Medicare Clinical Trial Billing

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

### Medicare Expanded Access Billing

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

Medicare pays an adjusted rate for CAR T-cell therapy cases where a product cost is not incurred, such as for clinical trial and CAR T-cell therapy provided under an expanded access program. For non-Medicare, providers must check with the payer regarding any special billing requirements for clinical trial or expanded access cases. 15

CAR=chimeric antigen receptor.

#### IMPORTANT SAFETY INFORMATION

#### **ADVERSE REACTIONS**

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

Unique Medicare

**Billing Instructions** 

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

**TECARTUS®** 

(brexucabtagene autoleucel) Suspension for IV infusion

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Coding



**Overview** 



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 $\textbf{Please see full } \underline{\textbf{Prescribing Information}}, \textbf{including } \textbf{BOXED WARNING} \textbf{ and } \textbf{Medication Guide}.$