TECARTUS®
(brexucabtagene autoleucel) Suspension for IV infusion

TECARTUS® HOSPITAL 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).

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

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CAR=chimeric antigen receptor; CMS=Centers for Medicare & Medicaid Services.

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Hospital 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®. The information within covers both hospital inpatient and hospital outpatient settings of care.

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.

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 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 that 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=chimeric antigen receptor.

IMPORTANT SAFETY INFORMATION

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.**

References

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The CAR T Patient-Care Process

CAR=chimeric antigen receptor.

References

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The CAR T Patient-Care Process

TECARTUS® is administered as a one-time infusion at an ATC.[1]

Patient Evaluation	Payer Approval	Leukapheresis	Cell Manufacturing	Conditioning Chemotherapy	Infusion	Monitor & Follow Up
Determine eligibility and initiate prescribing process	Receive payer authorization, execute single-case agreement if applicable	T cells are isolated from the peripheral blood	The harvested T cells are shipped to a manufacturing facility where they are modified into CAR T cells and expanded in number	Prior to CAR T infusion, the patient receives a low-dose lymphodepleting chemotherapy regimen	CAR T is administered to the patient at an ATC. This may be done in a healthcare facility (i.e., hospital; inpatient or outpatient) or community setting	Patients with ALL (at least 14 days) and MCL (at least 7 days) are closely monitored for signs and symptoms of CRS, neurologic events, and other possible side effects. Patients should remain within close proximity of a healthcare facility for at least 2 weeks

ALL=acute lymphoblastic leukemia; 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 ≥ 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 ≥ 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 (≥ 2%) included hypotension, fever, hypoxia, tachycardia, and dyspnea.

References

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

TECARTUS® (brexucabtagene autoleucel) Suspension for IV infusion

Overview of Coding for Diagnosis, Preparation, and Administration

References

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

TECARTUS® (brexucabtagene autoleucel) Suspension for IV infusion

Overview of Coding

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

	Hospital Outpatient	Hospital Inpatient
Diagnosis Coding		
Diagnosis Coding for Product Indications	ICD-10-CM	ICD-10-CM
Diagnosis Coding for Complications	ICD-10-CM	ICD-10-CM
Procedure Coding		
Cell Collection and Cell Processing Services	Revenue Code; Level I HCPCS CPT Code	Revenue Code; Level I HCPCS CPT Code
Administration	Revenue Code; Level I HCPCS CPT Code	ICD-10-PCS; Level I HCPCS CPT Code; Revenue Code
Remote Patient Monitoring Services Coding		
	HCPCS CPT Code	N/A
Product Coding		
	Revenue Code; Level II HCPCS Product Code; NDC	Revenue Code; NDC

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

References

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

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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[2-4]	Description
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

*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.[2]

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.

IMPORTANT SAFETY INFORMATION

CYTOKINE RELEASE SYNDROME (continued)

Confirm that a minimum of 2 doses of tocilizumab are available for each patient prior to infusion of TECARTUS. Monitor patients daily for at least 7 days following infusion for signs and symptoms of CRS. Monitor patients for signs or symptoms of CRS for 2 weeks after infusion. 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.

References

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

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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[2]	
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

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

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 ≥ 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. 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.

References

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Diagnosis Coding for Complications (continued)

Code the appropriate complication and grade from the table below:

CRS Codes[2]	
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[2]	
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

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CRS=cytokine release syndrome; ICANS=immune effector cell-associated neurotoxicity syndrome; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

IMPORTANT SAFETY INFORMATION

NEUROLOGIC TOXICITIES (continued)

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 (≥2%) including encephalopathy, aphasia, confusional state, and seizures occurred after treatment with TECARTUS.

References

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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 hospital 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.[2]

Revenue Codes

Payers utilize revenue codes to align services with specific departments within a hospital.[5] A series of revenue codes specific to cell therapy were developed to capture information for services related to cell collection, storage, preparation, administration, and the charges for the CAR T-cell therapy product.[6] These codes are used in conjunction with Level I and II Healthcare Common Procedure Coding System (HCPCS) codes to document the clinical management of TECARTUS® therapy.[7] It is the provider's responsibility to contact each payer for payer-specific coding requirements before submitting any claims.

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, hospitals may choose from 3 billing options: 1) to include the charges for the various steps in the charge submitted for the biological[7]; 2) to report these charges separately for tracking purposes (documented under 38225, 38226, and 38227)[7,8]; or 3) if the CAR T-cell therapy product is administered to the patient as a hospital inpatient, hold the charges for these services and report them under the appropriate revenue codes in the inpatient CAR T-cell therapy claim.[7] For non-Medicare payers, it is the provider's responsibility to contact each payer for payer-specific coding requirements before submitting any claims.

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 TECARTUS, which will be effective for dates of service on or after October 1, 2021. Medicare has also redefined the hospital inpatient CAR T-cell therapy payment, effective for services on or after October 1, 2021: MS-DRG 018 - Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies. Applying the appropriate ICD-10-PCS code for TECARTUS as listed will align inpatient admissions to MS-DRG 018 for payment.[9] It is the provider's responsibility to contact each payer for payer-specific coding requirements before submitting any claims.

CAR=chimeric antigen receptor; MS-DRG=Medicare Severity-Diagnosis Related Groups.

References

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

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Cell Collection and Cell Processing Services

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

Revenue Code[2,8]	Level I HCPCS CPT Code[2,8]	Description[2,8]	Notes
0871: Cell/gene therapy – cell collection	**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.[7]* 38225, 38226, and 38227 are considered non-payable services when furnished by hospital outpatient departments under Medicare's Outpatient Prospective Payment System (OPPS). However, other payers may accept these codes as payable. Providers may still use these codes to track cell preparation steps for TECARTUS®.[7,8]
0872: Cell/gene therapy – specialized biologic processing and storage – prior to transport	**38226**	Chimeric antigen receptor T-cell (CAR T) therapy; preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation, storage)	
0873: Cell/gene therapy – storage and processing after receipt of cells from manufacturer	**38227**	Chimeric antigen receptor T-cell (CAR T) therapy; receipt and preparation of CAR T cells for administration	

*As of March 15, 2019, CMS issued the following billing code options for CAR T-cell therapy.[7]

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CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System.

IMPORTANT SAFETY INFORMATION

NEUROLOGIC TOXICITIES (continued)

Monitor patients daily for at least 7 days following infusion for signs and symptoms of neurologic toxicity/ICANS. Monitor patients for signs or symptoms of neurologic toxicities for 2 weeks after infusion and treat promptly. Advise patients to avoid driving for at least 2 weeks following infusion.

References

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Administration

ICD-10-PCS codes are used for reporting inpatient hospital procedures. CPT codes are used for outpatient hospital and professional claims for reporting administration, associated services, and individual products.[2]

ICD-10-PCS Code[2]	Description[2]
XW033M7	Introduction of brexucabtagene autoleucel immunotherapy (peripheral vein approach)
XW043M7	Introduction of brexucabtagene autoleucel immunotherapy (central vein approach)

Revenue Code[2]	Level I HCPCS CPT Code[8]	Description[2]	Notes
0874: Cell/ gene therapy – infusion of modified cells	**38228**	Chimeric antigen receptor T-cell (CAR T) 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.[7]* CPT code 38228 is considered payable by Medicare and is used to document TECARTUS® administration.[8]

*As of March 15, 2019, CMS issued the following billing code options for CAR T-cell therapy.[7]

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CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-PCS=International Classification of Diseases, Tenth Revision, Procedure Coding System.

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.

References

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Remote Patient Monitoring Services Coding[10]

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

HYPERSENSITIVITY REACTIONS

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

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.

References

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

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Product Coding

The NUBC developed revenue codes to report charges for cell and gene therapy products, similar to those for services like cell collection. Additionally, HCPCS Level II product codes were established to describe FDA-approved CAR T products.[2]

Level II HCPCS Product Code

A Level II HCPCS product code is used to report the use of the biological product TECARTUS® in the hospital outpatient setting for Medicare.[6] The TECARTUS code, Q2053, has a description that includes the services of leukapheresis and all cell preparation.[6] 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.[7] For Medicare claims, the Q2053 code should only be designated on a CMS 1450 claim form when TECARTUS is delivered in the hospital outpatient setting.[6,11] Other payers outside Medicare may, however, utilize the Q2053 code for inpatient claims as well.[6] Providers should contact each payer to clarify the specific coding requirements before submitting any claims.

Revenue Code[2]	Level II HCPCS Product Code[6]	Description[2]
0891: Special Processed Drugs – FDA Approved Cell Therapy	**Q2053**	Brexucabtagene autoleucel, up to 200 million autologous anti-CD19 CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose

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CAR=chimeric antigen receptor; CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; FDA=US Food and Drug Administration; HCPCS=Healthcare Common Procedure Coding System; NUBC=National Uniform Billing Committee.

IMPORTANT SAFETY INFORMATION

SEVERE INFECTIONS (continued)

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.

References

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

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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.[1] **Only utilize the infusion bag NDC for billing purposes.** Include "**N4**" before the 11-digit TECARTUS 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[1,12]	Description[1]	Notes[12,13]
71287-0219-01 for MCL **71287-0220-01 for ALL**	**11-digit NDC** for TECARTUS infusion bag containing approximately 68 mL of frozen suspension of genetically modified autologous T cells in 5% DMSO and human serum albumin.	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 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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ALL=acute lymphoblastic leukemia; DMSO=dimethyl sulfoxide; MCL=mantle cell lymphoma.

IMPORTANT SAFETY INFORMATION

SEVERE INFECTIONS (continued)

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.

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.

References

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

TECARTUS® (brexucabtagene autoleucel) Suspension for IV infusion

Hospital Outpatient Administration

The TECARTUS® product-specific HCPCS, 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).[2,6]

Medicare requires this code on hospital outpatient claims when cells are delivered in that setting. Other payers may apply the Q2053 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.[6]

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

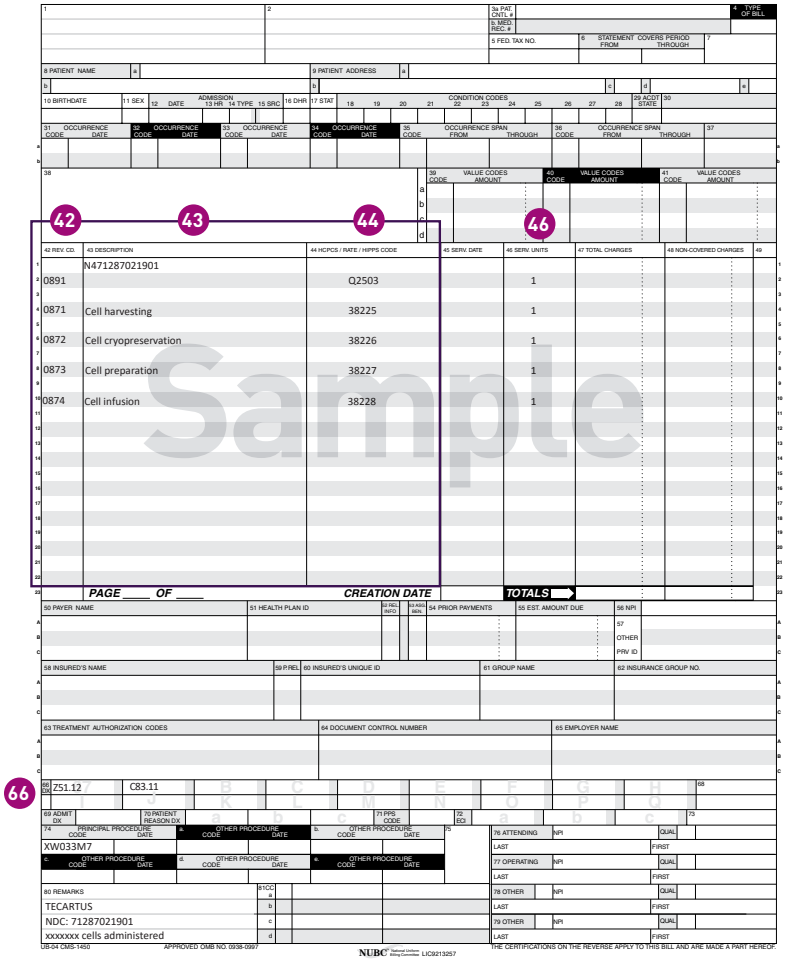
References

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

TECARTUS® (brexucabtagene autoleucel) 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[7]

For TECARTUS® cell infusion – Use revenue code ***0874***.[2]

For TECARTUS product charges – Use revenue code ***0891*** with HCPCS code ***Q2053***.[2,6]

For cell harvesting, storage, and preparation – Use revenue codes ***0871, 0872, or 0873***.[2]

For Medicare, there are billing options for how to report the charges for cell harvesting, storage, and preparation on hospital outpatient claims. It is important to review these options.[7]

43 DESCRIPTION

Medicaid programs require the reporting of NDC information, and other payers may also request or require NDC information to be reported.[1,12] If so, enter the TECARTUS NDC as ***N471287021901 for MCL or N471287022001 for ALL, with no dashes***.[1,12] Only the TECARTUS NDC for the infusion bag should be used for billing purposes. These payers may also have additional requirements on reporting the unit of measurement in this field.

For cell harvesting, storage, and preparation – Enter the appropriate description of the service provided based on the HCPCS CPT code aligned to the respective revenue codes (see page 13 of this guide for detailed information).[7]

44 HCPCS CODES

For TECARTUS cells - Enter ***Q2053*** to indicate TECARTUS. Use code ***38228*** to report TECARTUS administration.[6-8]

Medicare has provided 3 scenarios for how to bill the services described by HCPCS Level I CPT codes ***38225, 38226, and 38227***.[7,8] These codes may be reported for tracking purposes but are non-payable. Another option is to include the charges for these services in the charge of ***Q2053***. In this situation, the date of service should be the date that TECARTUS was administered, not the date the cells were collected.[6,7]

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; NDC=National Drug Code.

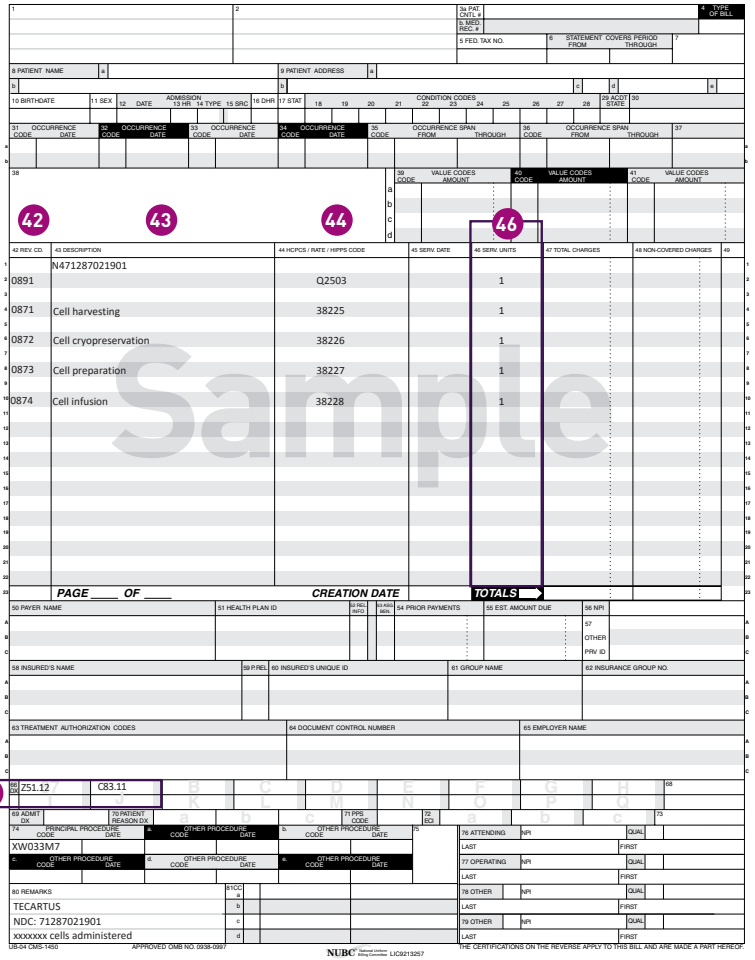
References

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

TECARTUS® (brexucabtagene autoleucel) Suspension for IV infusion

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

This sample form is for information purposes only.



46 SERVICE UNITS

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

66 DIAGNOSIS CODES

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

FIELDS 46 - 66

CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; ICD-10-PCS=International Classification of Diseases, Tenth Revision, Procedure Coding System.

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; ICD-10-PCS=International Classification of Diseases, Tenth Revision, Procedure Coding System.

References

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TECARTUS® (brexucabtagene autoleucel) Suspension for IV infusion

Hospital Inpatient Administration

Outside of Medicare, other payers may apply different payment methodologies for inpatient admissions related to administration of TECARTUS®. 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.

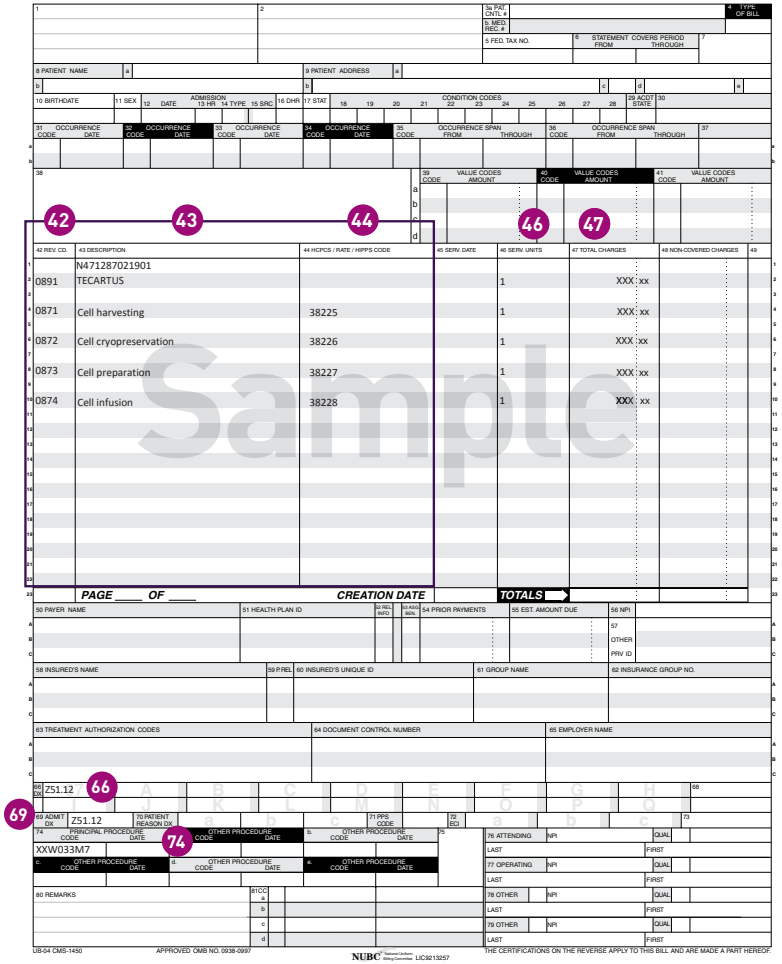
References

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

TECARTUS® (brexucabtagene autoleucel) Suspension for IV infusion

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

This sample form is for information purposes only.



42 REVENUE CODES

For reporting the TECARTUS® product charge - Use revenue code ***0891***.[2]

For TECARTUS cell infusion – Use revenue code ***0874***.[2]

For cell harvesting, storage, and preparation – Use revenue codes ***0871, 0872, and 0873***.[2]

43 DESCRIPTION

If the payer requests or requires NDC information to be reported, enter the TECARTUS NDC as ***N471287021901 for MCL or N471287022001 for ALL, with no dashes***.[1,12] Only the TECARTUS NDC for the infusion bag should be used for billing purposes.

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

44 REPORTING THE TECARTUS PRODUCT

For TECARTUS cell infusion – For Medicare, HCPCS codes are not reported in inpatient claims[7]; but the charge for the TECARTUS product is reported using revenue code ***0891***, which is an extension of pharmacy.[2] Other payers may request the use of the TECARTUS HCPCS code ***Q2053***.[2,6] However, that information should be confirmed by 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.

FIELDS 42 - 44

CMS=Centers for Medicare & Medicaid Services; HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code.

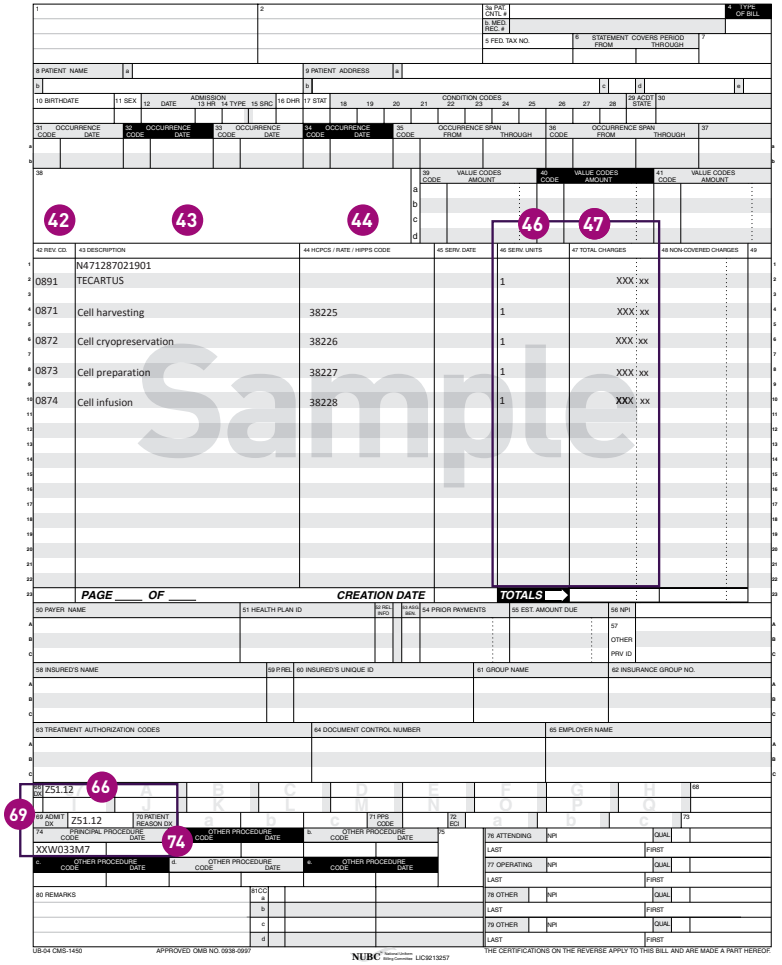
References

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

TECARTUS® (brexucabtagene autoleucel) Suspension for IV infusion

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

This sample form is for information purposes only.



46 SERVICE UNITS

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

47 TOTAL CHARGES

Enter total charges for all steps.

66 DIAGNOSIS CODES

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

69 ADMIT DIAGNOSIS

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

74 PRINCIPAL PROCEDURE

Enter the appropriate ICD-10-PCS code from the 2 dedicated to CAR T-specific codes (***XW033M7 or XW043M7***).[2]

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.

FIELDS 46 - 74

CMS=Centers for Medicare & Medicaid Services; CAR=chimeric antigen receptor; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; ICD-10-PCS=International Classification of Diseases, Tenth Revision, Procedure Coding System.

References

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

TECARTUS® (brexucabtagene autoleucel) Suspension for IV infusion

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.

References

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

TECARTUS® (brexucabtagene autoleucel) Suspension for IV infusion

Helpful Reminders

Consider the Following Steps to Better Ensure Patient Eligibility and Coverage[2]

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

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.

References

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[2]

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 inpatients, confirm presence of the inpatient admission order
- ☐ 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

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.

MAR=medication administration record.

IMPORTANT SAFETY INFORMATION

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.

References

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 (continued)[2]

After Service Provision

- ☐ Confirm payer-specific billing requirements (inpatient or outpatient)
- ☐ Confirm the correct principal and admitting ICD-10-CM diagnosis codes
- ☐ Review HCPCS Level II and NDC reporting requirements (inpatient or outpatient)
- ☐ Review inpatient ICD-10-PCS procedure codes
- ☐ Review for correct revenue codes for the CAR T product charge (0891), product administration charge (0874), cell collection (0871), and cell lab (0872-0873)
- ☐ 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.[14] For commercial payers, identify payment methodology for the payer and whether the patient received CAR T as outpatient or inpatient. Determine applicable payment formula for each claim and each type of CAR T service (such as cell collection and processing, administration, and post-administration management of the patient).[2]

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

References

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

TECARTUS® (brexucabtagene autoleucel) Suspension for IV infusion

Medicare Clinical Trial and Expanded Access Billing

References

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

TECARTUS® (brexucabtagene autoleucel) Suspension for IV infusion

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.[2]

Medicare pays an adjusted rate under MS-DRG 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.[2,15]

CAR=chimeric antigen receptor; MS-DRG=Medicare Severity-Diagnosis Related Groups.

IMPORTANT SAFETY INFORMATION

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.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥ 20%) in:

MCL patients: 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.

ALL patients: 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.

References

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TECARTUS® (brexucabtagene autoleucel) Suspension for IV infusion

References

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TECARTUS®
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Kite
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References

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