Cell Therapy 360™

Breyanzi® Coding & Billing Information

For questions about coding & billing information, call Cell Therapy 360® at 1-888-805-4555

Indication: BREYANZI is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.

Limitation of Use: Breyanzi is not indicated for the treatment of patients with primary central nervous system lymphoma.

Important Safety Information

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITIES

- **Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving BREYANZI. Do not administer BREYANZI to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab with or without corticosteroids.**
- **Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving BREYANZI, including concurrently with CRS, after CRS resolution or in the absence of CRS. Monitor for neurologic events after treatment with BREYANZI. Provide supportive care and/or corticosteroids as needed.**
- **BREYANZI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the BREYANZI REMS.**

This information is provided for educational purposes only. Bristol Myers Squibb cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care, and is subject to frequent change. It is the sole responsibility of the healthcare provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

Please see Important Safety Information on pages 14-17 and full Prescribing Information, including Boxed WARNINGS and Medication Guide.

Breyanzi™
(lisocabtagene maraleucel) SUSPENSION FOR IV INFUSION

Breyanzi® is a new CAR T cell therapy for adults with relapsed or refractory (R/R) large B-cell lymphoma (LBCL) after two or more lines of systemic therapy, including diffuse large B cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.[1] Breyanzi is not indicated for the treatment of patients with primary CNS lymphoma. Breyanzi is for autologous use only and is administered intravenously, as a one-time treatment.[1,*] A single dose of BREYANZI contains 50 to 110 × 10^6 CAR-positive viable T cells (consisting of 1:1 CAR-positive viable T cells of the CD8 and CD4 components), with each component supplied separately in one to four single-dose vials. Coding and billing for CAR T cell therapies will vary based on patient's condition, provided services, payer-specific requirements, and selected site/setting of care. Use this guide to review relevant codes and sample claim forms for Breyanzi.

Table of Contents

CAR T = chimeric antigen receptor-modified T cell; CMS = Centers for Medicare and Medicaid Services; 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.

* This is part of a larger CAR T process that includes apheresis, manufacturing, administration, and monitoring.

ICD-10-CM Diagnosis Codes

The ICD-10-CM codes listed below for the approved indication for Breyanzi® are provided by Bristol Myers Squibb and should be verified with a patient's payer. Some payers may specify which codes are covered under their policies. Please code to the level of specificity documented in the medical record.

ICD-10-CM Code[2]	Description
C83.30	Diffuse large B-cell lymphoma, unspecified site
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites
C83.90	Non-follicular (diffuse) lymphoma, unspecified, unspecified site
C83.91	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of head, face, and neck
C83.92	Non-follicular (diffuse) lymphoma, unspecified, intrathoracic lymph nodes
C83.93	Non-follicular (diffuse) lymphoma, unspecified, intra-abdominal lymph nodes
C83.94	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of axilla and upper limb
C83.95	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of inguinal region and lower limb
C83.96	Non-follicular (diffuse) lymphoma, unspecified, intrapelvic lymph nodes
C83.97	Non-follicular (diffuse) lymphoma, unspecified, spleen
C83.98	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of multiple sites
C83.99	Non-follicular (diffuse) lymphoma, unspecified, extranodal and solid organ sites
C82.40	Follicular lymphoma grade IIIb, unspecified site
C82.41	Follicular lymphoma grade IIIb, lymph nodes of head, face, and neck
C82.42	Follicular lymphoma grade IIIb, intrathoracic lymph nodes

Continued on next page

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Breyanzi™ (lisocabtagene maraleucel) SUSPENSION FOR IV INFUSION

ICD-10-CM Diagnosis Codes (cont'd)

ICD-10-CM Code[2]	Description
C82.43	Follicular lymphoma grade IIIb, intra-abdominal lymph nodes
C82.44	Follicular lymphoma grade IIIb, lymph nodes of axilla and upper limb
C82.45	Follicular lymphoma grade IIIb, lymph nodes of inguinal region and lower limb
C82.46	Follicular lymphoma grade IIIb, intrapelvic lymph nodes
C82.47	Follicular lymphoma grade IIIb, spleen
C82.48	Follicular lymphoma grade IIIb, lymph nodes of multiple sites
C82.49	Follicular lymphoma grade IIIb, extranodal and solid organ sites
C82.50	Diffuse follicle center lymphoma, unspecified site
C82.51	Diffuse follicle center lymphoma, lymph nodes of head, face, and neck
C82.52	Diffuse follicle center lymphoma, intrathoracic lymph nodes
C82.53	Diffuse follicle center lymphoma, intra-abdominal lymph nodes
C82.54	Diffuse follicle center lymphoma, lymph nodes of axilla and upper limb
C82.55	Diffuse follicle center lymphoma, lymph nodes of inguinal region and lower limb
C82.56	Diffuse follicle center lymphoma, intrapelvic lymph nodes
C82.57	Diffuse follicle center lymphoma, spleen
C82.58	Diffuse follicle center lymphoma, lymph nodes of multiple sites
C82.59	Diffuse follicle center lymphoma, extranodal and solid organ sites
C85.20	Mediastinal (thymic) large B-cell lymphoma, unspecified site
C85.21	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of head, face, and neck
C85.22	Mediastinal (thymic) large B-cell lymphoma, intrathoracic lymph nodes
C85.23	Mediastinal (thymic) large B-cell lymphoma, intra-abdominal lymph nodes
C85.24	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of axilla and upper limb
C85.25	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.26	Mediastinal (thymic) large B-cell lymphoma, intrapelvic lymph nodes
C85.27	Mediastinal (thymic) large B-cell lymphoma, spleen
C85.28	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of multiple sites
C85.29	Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites
Z51.12	Encounter for antineoplastic immunotherapy

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HCPCS Level II Product Codes

As a newly approved biologic, Breyanzi® does not have a unique HCPCS code at this time. Until a unique HCPCS code is assigned by CMS, Breyanzi may be reported by using one of the following unclassified/miscellaneous HCPCS codes per payer requirements.

HCPCS Code[3]	Description	Notes
C9399	Unclassified drugs or biologicals	MEDICARE FFS*: • Required for claims billed by outpatient hospital facilities under the Outpatient Prospective Payment System (OPPS)[4,†]
J3490	Unclassified drugs	ALL PAYERS: • Requirements may vary; refer to the specific payer policy
J3590	Unclassified biologics	

Although specific payer requirements may vary, additional information is typically required for claims with unclassified/miscellaneous HCPCS codes, including:

- Product name
- Dosage
- NDC number
- Route of administration

FFS = fee-for-service.

* For Medicare Advantage patients, CAR T products and their administration will be paid by A/B MACs under Medicare FFS until the end of 2020. For more information, please see Medicare Learning Network Matters Article SE19024.[5]

† For Medicare FFS claims billed by outpatient hospital facilities under the OPPS or those billed by off-campus provider-based departments (PBDs) under the Physician Fee Schedule, an appropriate modifier should be reported if Breyanzi has been acquired under the 340B drug pricing program. A JG modifier is required if a provider is subject to the 340B payment adjustment; a TB modifier is required if a provider is exempted from the 340B payment adjustment (eg, IPPS-exempt hospital).[6,7]

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Breyanzi™ (lisocabtagene maraleucel) SUSPENSION FOR IV INFUSION

NDC Information

Breyanzi® consists of genetically modified autologous T cells, supplied in vials as separate frozen suspensions of each CD8 component and CD4 component.[1] A single dose of Breyanzi contains 50 to 110 × 10^6 CAR-positive viable T cells (consisting of 1:1 CAR-positive viable T cells of the CD8 and CD4 components), with each component supplied separately in one to four single-dose vials.[1]

10-digit Format[1]	11-digit Format		Description
73153-900-01	**73153-0900-01**		Outer carton containing: • Carton for CD8 component, with up to 4 single-dose vials • Carton for CD4 component, with up to 4 single-dose vials

Payers may require that the NDC number is documented on medical claims submitted for provider-administered therapies, including drugs and biologics billed with an unclassified/miscellaneous code or those with an assigned code.

Specific requirements for NDC reporting may vary; however, the 11-digit format is generally preferred for medical claims. Some payers may require reporting the 11-digit NDC number, along with the NDC qualifier, basis of measure, and quantity.[8] For example, Breyanzi NDC reported in this format would include:

NDC Qualifier	11-digit NDC	Quantity Qualifier	Quantity for a Single Dose
N4	**73153-0900-01**	UN	1

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Breyanzi™ (lisocabtagene maraleucel) SUSPENSION FOR IV INFUSION

ICD-10-PCS Inpatient Procedure Codes*

For Medicare FFS,† the following CAR T designated ICD-10-PCS codes may be reported for inpatient facility services associated with Breyanzi® administration.

ICD-10-PCS Code[9]	Description	Notes for Medicare FFS†
XW23376	Transfusion of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 6	Under the Inpatient Prospective Payment System (IPPS) for FY 2021, these codes are assigned to MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy), with the average national base payment rate of $239,928 (the exact rate may vary widely based on hospital-specific adjustments)[10,‡,§]
XW24376	Transfusion of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology group 6	

For commercial plans and other payers, depending on specific policies, in addition to the codes listed above, the following ICD-10-PCS codes may apply.

ICD-10-PCS Code[9]	Description	Notes for Commercial Plans & Other Payers
6A550Z1	Pheresis of leukocytes, single	Requirements may vary; refer to the specific payer policy.
6A551Z1	Pheresis of leukocytes, multiple	

FY = fiscal year; MS-DRG = Medicare Severity Diagnosis Related Group.

* Site/Setting of care decisions are the sole discretion of the treating physician/institution.

† For Medicare Advantage patients, CAR T products and their administration will be paid by A/B MACs under Medicare FFS until the end of 2020. For more information, please see Medicare Learning Network Matters Article SE19024.[5]

‡ The estimated average base rate reflects a weighted arithmetic mean for the wage indexes, indirect medical, disproportionate share, and geographic adjustment factor, based on the total number of Medicare cases submitted to CMS by the provider. It does not include outlier, pass-through payments, or other applicable adjustments including but not limited to geographic adjustment.[11]

§ CAR T cell therapies are not eligible for NTAP in FY 2021[12]; for FY 2022, NTAP eligibility decisions will be made on a case-by-case basis.

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Breyanzi™ (lisocabtagene maraleucel) SUSPENSION FOR IV INFUSION

Hospital Revenue Codes

For Medicare FFS,* the following CAR T designated revenue codes may be reported with accompanying line items billed for services associated with Breyanzi®.

Revenue Code[13]	Description	Notes for Medicare FFS*
0871	Cell/gene therapy – cell collection	Charges for services associated with cell collection and cell processing/storage can be reported under 0871, 0872, and 0873, as separate line items for tracking purposes only. Alternatively, these charges can be reported with Breyanzi charges under 0891, as a single line item.[14,†,‡]
0872	Cell/gene therapy – specialized biologic processing and storage – prior to transport	
0873	Cell/gene therapy – storage and processing after receipt of cells from manufacturer	
0874	Cell/gene therapy – infusion of modified cells	
0891	Pharmacy – specialized processed drugs – FDA approved cell therapy	

For commercial plans and other payers, depending on specific policies, the following revenue codes may be reported, as an alternative to the codes listed above.

Revenue Code[15]	Description	Notes for Commercial Plans & Other Payers
0300	Laboratory – general classification	Requirements may vary; refer to the specific payer policy
0305	Laboratory – hematology	
0310	Laboratory pathology – general classification	
0260	IV therapy – general classification	
0510	Clinic – general classification	
0250	Pharmacy – general classification	
0258	Pharmacy – IV solutions	
0636	Pharmacy – drugs requiring detailed coding	

* For Medicare Advantage patients, CAR T products and their administration will be paid by A/B MACs under Medicare FFS until the end of 2020. For more information, please see Medicare Learning Network Matters Article SE19024.[5]

† For Medicare FFS patients, when the charges for collection and preparation of the CAR T cells are included with the charges for the CAR T product (as a single line item under 0891), the reported date of service must be based on the date of CAR T administration. When cell collection and/or cell processing/storage services are initiated and furnished in the hospital outpatient setting, but the CAR T cell therapy is administered in the inpatient setting, all related charges must be reported on the inpatient claim with the date of CAR T administration as the date of service (reported as separate line items for tracking purposes under 0871, 0872, and 0873 or as a single line item along with CAR T product charges under 0891). For more information, please see Medicare Learning Network Matters Article SE19009.[14]

‡ For Medicare FFS patients, 3-day payment window policy applies to outpatient services furnished by a hospital or an entity wholly owned or wholly operated by the hospital. Note that for IPPS-exempt hospitals, 1-day payment window applies.[16]

The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol Myers Squibb makes no guarantee regarding reimbursement for any service or item.

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Breyanzi™ (lisocabtagene maraleucel) SUSPENSION FOR IV INFUSION

CPT® Category III Codes for Physician and Outpatient Hospital Services*

For Medicare FFS,† the following CAR T designated CPT Category III codes may be reported for outpatient hospital facility services or physician services associated with Breyanzi®. Please note that only one of these CPT Category III codes (CPT code 0540T) is separately payable by Medicare under the Hospital Outpatient Prospective Payment System (OPPS) and the Physician Fee Schedule (PFS).[6,17]

CPT Category III Code[6]	Description	Hospital Revenue Code‡	Medicare FFS Reimbursement Status in CY 2020†	
			OPPS	PFS
Apheresis and Preparation				
0537T	Chimeric antigen receptor T-cell (CAR T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR T cells, per day	**0871**	Not recognized by OPPS§ (status indicator B)	Bundled code, not separately paid§ (status indicator B)
0538T	Chimeric antigen receptor T-cell (CAR T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)	**0872**		
0539T	Chimeric antigen receptor T-cell (CAR T) therapy; receipt and preparation of CAR T cells for administration	**0873**		
Administration				
0540T	Chimeric antigen receptor T-cell (CAR T) therapy; CAR T cell administration, autologous	**0874**	Paid under APC 5694 (status indicator S, CY 2020 national average payment rate is $309.56)	Contractor-priced code** (status indicator C)

For commercial plans and other payers, depending on specific policies, the above listed codes may be reported. CMS has not assigned relative value units to these Category III CPT codes, with the exception of the CPT code 0540T under the OPPS.[17,18] As such, they may not be payable by non-Medicare payers.

APC = Ambulatory Payment Classification.

* Site/Setting of care decisions are the sole discretion of the treating physician/institution.

† For Medicare Advantage patients, CAR T products and their administration will be paid by A/B MACs under Medicare FFS until the end of 2020. For more information, please see Medicare Learning Network Matters Article SE19024.[5]

‡ See previous page for revenue code descriptions.

§ CPT Category III codes 0537T, 0538T, and 0539T can be reported for tracking purposes only, as non-covered charges. For more information, please see Medicare Learning Network Matters Article SE19009.[14]

** Medicare Administrative Contractors typically require additional documentation for contractor-priced codes.

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Breyanzi™ (lisocabtagene maraleucel) SUSPENSION FOR IV INFUSION

CPT® Category I Codes for Physician and Outpatient Hospital Services

For commercial plans and other payers, depending on specific policies, the following CPT Category I codes may be reported for apheresis and intravenous administration services associated with Breyanzi®, as an alternative to the CPT Category III codes listed on the previous page.

CPT Category I Code[19]	Description	Notes for Commercial Plans & Other Payers
Apheresis		Requirements may vary; refer to the specific payer policy
36511	Therapeutic apheresis; for white blood cells	
IV administration*		
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	
96413	Chemotherapy administration; intravenous infusion technique; up to 1 hour, single or initial substance/drug	

Breyanzi is for autologous use only and is administered intravenously, as a one-time treatment.[1] A single dose of BREYANZI contains 50 to 110 × 10^6 CAR-positive viable T cells (consisting of 1:1 CAR-positive viable T cells of the CD8 and CD4 components), with each component supplied separately in one to four single-dose vials. This is part of a larger CAR T process that includes apheresis, manufacturing, administration, and monitoring. The CD8 and CD4 components are administered separately; CD8 component is administered first, immediately followed by the CD4 component.[1] The time for infusion will vary, but will usually be less than 15 minutes for each component.[1]

* These codes refer to intravenous infusion of chemotherapy and other highly complex drugs or highly complex biologic agents.

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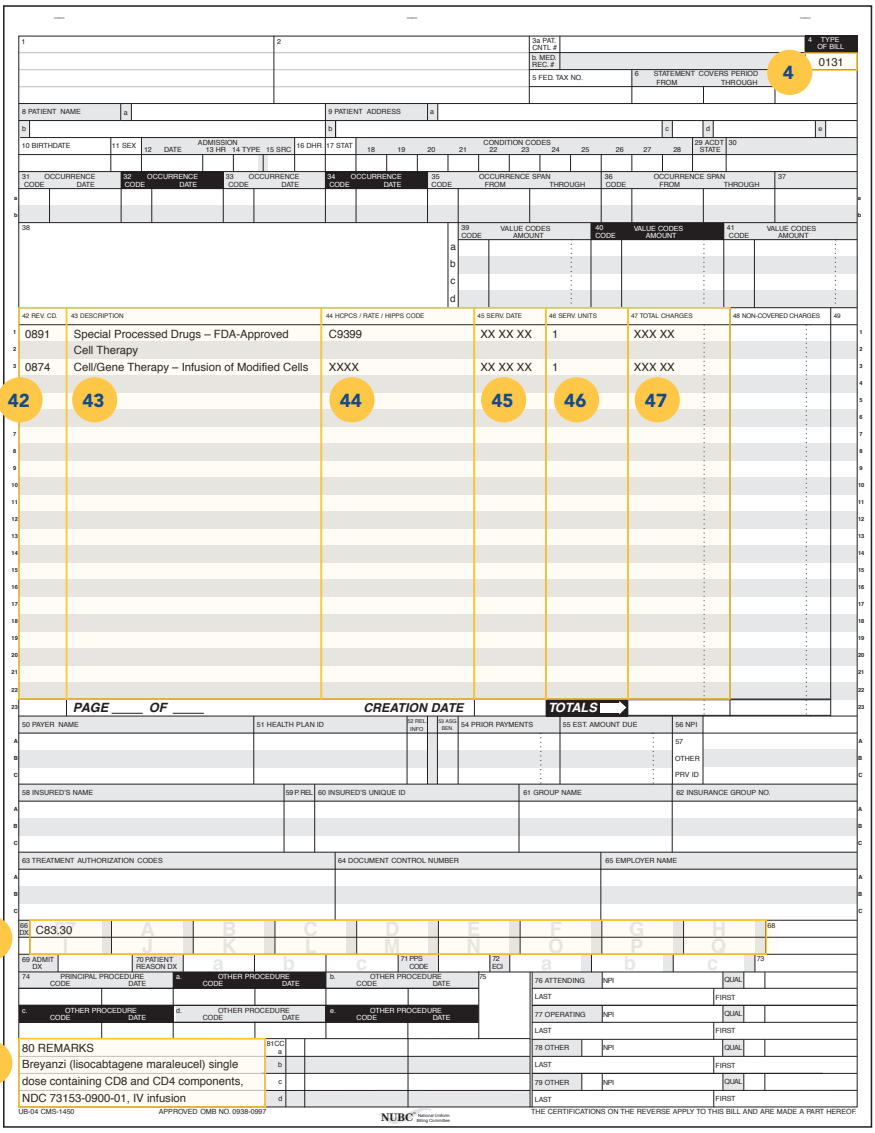
Breyanzi™ (lisocabtagene maraleucel) SUSPENSION FOR IV INFUSION

Sample CMS 1450 (UB-04) Claim Form For Outpatient Hospital Facilities[20]



4 **Form Locator (FL) 4:** Enter the appropriate type of bill code. For example[21]:

- 0131 for an outpatient hospital facility

42 **FL 42:** Enter the appropriate revenue code for each reported line. For example[13,15]:

- 0874 or 0260 for CAR T infusion
- 0891 or 0636 for Breyanzi®

43 **FL 43:** Enter the description for the corresponding revenue code in FL 42.

NOTE: Some payers may require to report drug NDC number(s) in FL 43.

44 **FL 44:** Enter relevant HCPCS Level II and CPT codes, along with applicable modifiers. For example[3,6,19]:

- 0540T or 96413 for CAR T infusion
- C9399, J3490, or J3590 for Breyanzi

45 **FL 45:** Enter corresponding date(s) of service.

46 **FL 46:** Enter appropriate units of service.

NOTE: For miscellaneous codes, such as C9399, J3490, and J3590, 1 unit of service is typically reported.[23]

47 **FL 47:** Enter total charges for each reported line.

67 **FL 67:** Enter appropriate ICD-10-CM diagnosis code(s) for patient condition(s). For example[2]:

- C83.30 for diffuse large B-cell lymphoma, unspecified site

80 **FL 80:** Enter product information required when reporting a miscellaneous code (eg, drug name, dosage, NDC number, route of administration).[4]

Requirements may vary; refer to specific payer policy*,†

* Billing instructions have been issued for Medicare FFS patients. For more information, please see Medicare Learning Network Matters Article SE19009.[14]

† For Medicare Advantage patients, CAR T products and their administration will be paid by A/B MACs under Medicare FFS until the end of 2020. For more information, please see Medicare Learning Network Matters Article SE19024.[5]

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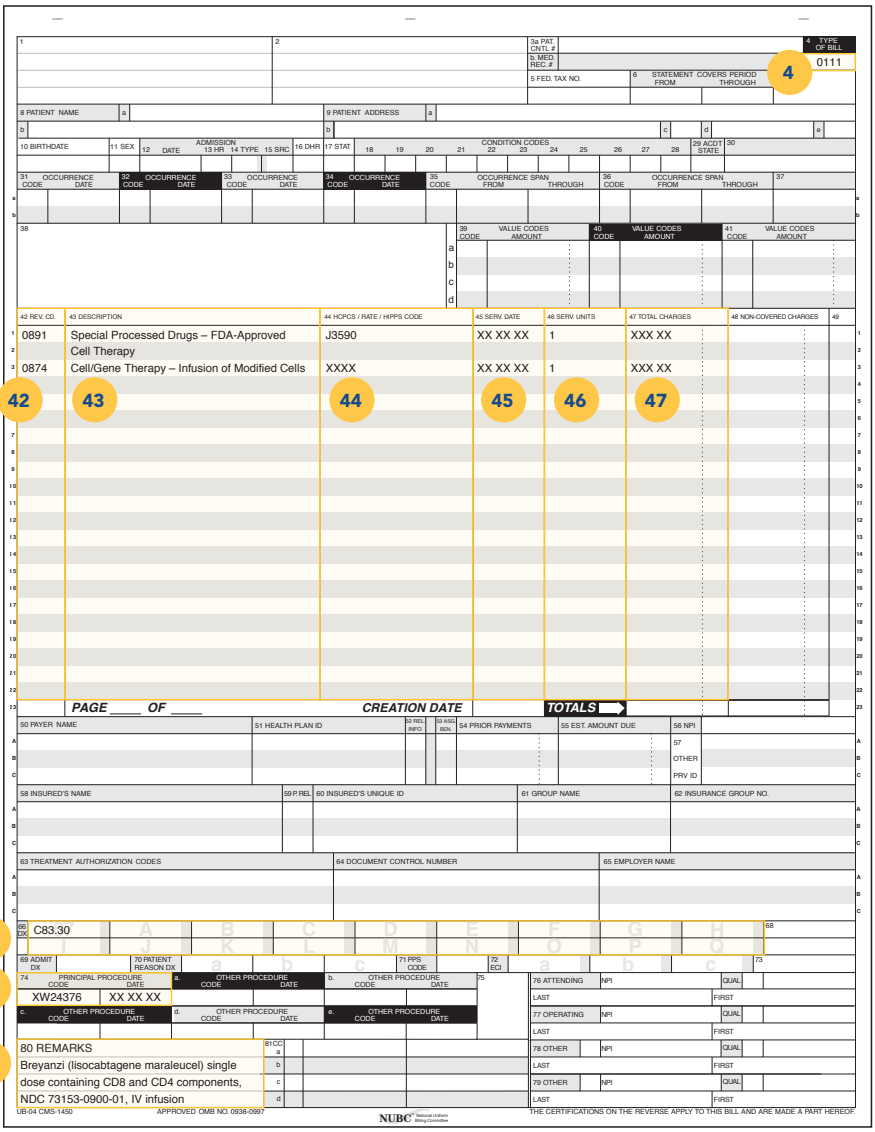
Sample CMS 1450 (UB-04) Claim Form For Inpatient Hospital Facilities[20]



4 **FL 4:** Enter the appropriate type of bill code. For example[21]:
- 0111 for an inpatient hospital facility

42 **FL 42:** Enter the appropriate revenue code for each reported line. For example[13,15]:
- 0874 or 0260 for CAR T infusion
- 0891 or 0636 for Breyanzi®

43 **FL 43:** Enter the description for the corresponding revenue code in FL 42.
NOTE: Some payers may require to report drug NDC number(s) in FL 43.

44 **FL 44:** If required by payer, enter relevant HCPCS Level II code, along with the applicable modifier. For example[3,6,19]:
- 0540T or 96413 for CAR T infusion
- J3490 or J3590 for Breyanzi

45 **FL 45:** Enter corresponding date(s) of service.

46 **FL 46:** Enter appropriate units of service.
NOTE: For miscellaneous codes, such as J3490 and J3590, 1 unit of service is typically reported.[23]

47 **FL 47:** Enter total charges for each reported line.

67 **FL 67:** Enter appropriate ICD-10-CM diagnosis code(s) for patient condition(s). For example[2]:
- C83.30 for diffuse large B-cell lymphoma, unspecified site

74 **FL 74:** Enter relevant ICD-10-PCS procedure code(s) with corresponding date(s) of service. For example[9]:
- XW23376 or XW24376 for Breyanzi infusion

80 **FL 80:** Enter product information required when reporting a miscellaneous code (eg, drug name, dosage, NDC number, route of administration).[4]

Requirements may vary; refer to specific payer policy*,†

* Billing instructions have been issued for Medicare FFS patients. For more information, please see Medicare Learning Network Matters Article SE19009.[14]

† For Medicare Advantage patients, CAR T products and their administration will be paid by A/B MACs under Medicare FFS until the end of 2020. For more information, please see Medicare Learning Network Matters Article SE19024.[5]

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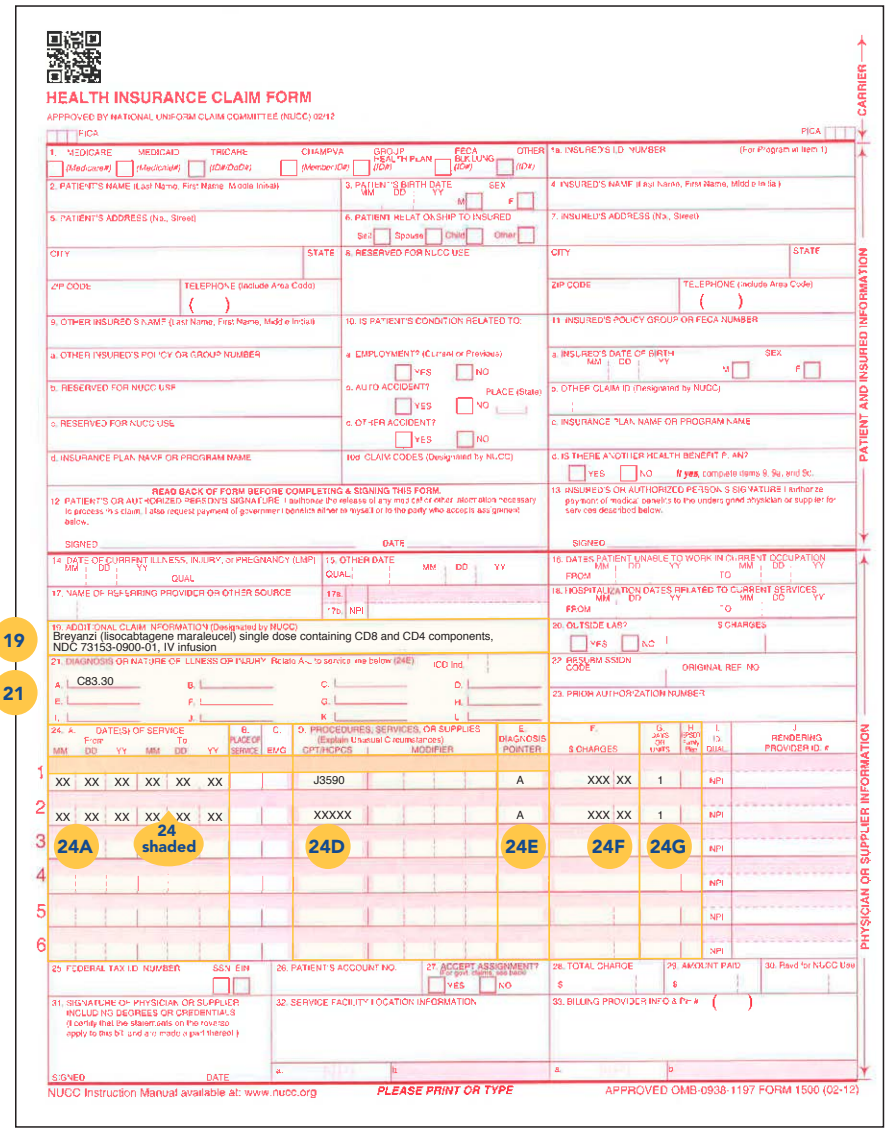
Breyanzi™ (lisocabtagene maraleucel) SUSPENSION FOR IV INFUSION

Sample CMS 1500 Claim Form For Physician Practices/Clinics[24]



19 **Item 19:** Enter product information required when reporting a miscellaneous code *such as J3490 and J3590* (eg, drug name, dosage, NDC number, route of administration).[4]

21 **Item 21:** Enter appropriate ICD-10-CM diagnosis code(s) for patient condition(s). For example[2]:

- C83.30 for diffuse large B-cell lymphoma, unspecified site

24 **Item 24 (shaded area):**

NOTE: Some payers may require to report drug NDC number(s) in the shaded area for item 24.

24A **Item 24A:** Enter corresponding date(s) of service.

24D **Item 24D:** Enter relevant HCPCS Level II and CPT codes, along with applicable modifiers. For example[3,6,19]:

- 0540T or 96413 for CAR T infusion
- J3490 or J3590 for Breyanzi®

24E **Item 24E:** Enter the corresponding diagnosis code reference letter from item 21.

24F **Item 24F:** Enter the charges for each reported line.

24G **Item 24G:** Enter appropriate units of service.

NOTE: For miscellaneous codes, 1 unit of service is typically reported.[23]

Requirements may vary; refer to specific payer policy*,†

* Billing instructions have been issued for Medicare FFS patients. For more information, please see Medicare Learning Network Matters Article SE19009.[14]

† For Medicare Advantage patients, CAR T products and their administration will be paid by A/B MACs under Medicare FFS until the end of 2020. For more information, please see Medicare Learning Network Matters Article SE19024.[5]

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Breyanzi™ (lisocabtagene maraleucel) SUSPENSION FOR IV INFUSION

Indication

BREYANZI is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.

Limitation of Use: BREYANZI is not indicated for the treatment of patients with primary central nervous system lymphoma.

Important Safety Information

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITIES

- **Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving BREYANZI. Do not administer BREYANZI to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab with or without corticosteroids.**
- **Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving BREYANZI, including concurrently with CRS, after CRS resolution or in the absence of CRS. Monitor for neurologic events after treatment with BREYANZI. Provide supportive care and/or corticosteroids as needed.**
- **BREYANZI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the BREYANZI REMS.**

Cytokine Release Syndrome (CRS)

CRS, including fatal or life-threatening reactions, occurred following treatment with BREYANZI. CRS occurred in 46% (122/268) of patients receiving BREYANZI, including ≥ Grade 3 (Lee grading system) CRS in 4% (11/268) of patients. One patient had fatal CRS and 2 had ongoing CRS at time of death. The median time to onset was 5 days (range: 1 to 15 days). CRS resolved in 119 of 122 patients (98%) with a median duration of 5 days (range: 1 to 17 days). Median duration of CRS was 5 days (range: 1 to 30 days) in all patients, including those who died or had CRS ongoing at time of death.

Among patients with CRS, the most common manifestations of CRS include fever (93%), hypotension (49%), tachycardia (39%), chills (28%), and hypoxia (21%). Serious events that may be associated with CRS include cardiac arrhythmias (including atrial fibrillation and ventricular tachycardia), cardiac arrest, cardiac failure, diffuse alveolar damage, renal insufficiency, capillary leak syndrome, hypotension, hypoxia, and hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS).

Ensure that 2 doses of tocilizumab are available prior to infusion of BREYANZI.

Sixty-one of 268 (23%) patients received tocilizumab and/or a corticosteroid for CRS after infusion of BREYANZI. Twenty-seven (10%) patients received tocilizumab only, 25 (9%) received tocilizumab and a corticosteroid, and 9 (3%) received corticosteroids only.

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Breyanzi™ (lisocabtagene maraleucel) SUSPENSION FOR IV INFUSION

Important Safety Information (cont'd)

Neurologic Toxicities

Neurologic toxicities that were fatal or life-threatening, occurred following treatment with BREYANZI. CAR T cell-associated neurologic toxicities occurred in 35% (95/268) of patients receiving BREYANZI, including ≥ Grade 3 in 12% (31/268) of patients. Three patients had fatal neurologic toxicity and 7 had ongoing neurologic toxicity at time of death. The median time to onset of the first event was 8 days (range: 1 to 46 days). The onset of all neurologic events occurred within the first 8 weeks following BREYANZI infusion. Neurologic toxicities resolved in 81 of 95 patients (85%) with a median duration of 12 days (range: 1 to 87 days). Three of four patients with ongoing neurologic toxicity at data cutoff had tremor and one subject had encephalopathy. Median duration of neurologic toxicity was 15 days (range: 1 to 785 days) in all patients, including those with ongoing neurologic events at the time of death or at data cutoff.

Seventy-eight (78) of 95 (82%) patients with neurologic toxicity experienced CRS. Neurologic toxicity overlapped with CRS in 57 patients. The onset of neurologic toxicity was after onset of CRS in 30 patients, before CRS onset in 13 patients, same day as CRS onset in 7 patients, and same day as CRS resolution in 7 patients. Neurologic toxicity resolved in three patients before the onset of CRS. Eighteen patients experienced neurologic toxicity after resolution of CRS.

The most common neurologic toxicities included encephalopathy (24%), tremor (14%), aphasia (9%), delirium (7%), headache (7%), dizziness (6%), and ataxia (6%). Serious events including cerebral edema and seizures occurred with BREYANZI. Fatal and serious cases of leukoencephalopathy, some attributable to fludarabine, have occurred in patients treated with BREYANZI.

CRS and Neurologic Toxicities Monitoring

Monitor patients daily at a certified healthcare facility during the first week following infusion, for signs and symptoms of CRS and neurologic toxicities. Monitor patients for signs and symptoms of CRS and neurologic toxicities for at least 4 weeks after infusion; evaluate and treat promptly. Counsel patients to seek immediate medical attention should signs or symptoms of CRS or neurologic toxicity occur at any time. At the first sign of CRS, institute treatment with supportive care, tocilizumab or tocilizumab and corticosteroids as indicated.

BREYANZI REMS

Because of the risk of CRS and neurologic toxicities, BREYANZI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the BREYANZI REMS. The required components of the BREYANZI REMS are:

- Healthcare facilities that dispense and administer BREYANZI must be enrolled and comply with the REMS requirements.
- Certified healthcare facilities must have on-site, immediate access to tocilizumab.
- Ensure that a minimum of 2 doses of tocilizumab are available for each patient for infusion within 2 hours after BREYANZI infusion, if needed for treatment of CRS.
- Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense, or administer BREYANZI are trained on the management of CRS and neurologic toxicities.

Further information is available at www.BreyanziREMS.com, or contact Bristol-Myers Squibb at 1-888-423-5436.

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Important Safety Information (cont'd)

Hypersensitivity Reactions

Allergic reactions may occur with the infusion of BREYANZI. Serious hypersensitivity reactions, including anaphylaxis, may be due to dimethyl sulfoxide (DMSO).

Serious Infections

Severe infections, including life-threatening or fatal infections, have occurred in patients after BREYANZI infusion. Infections (all grades) occurred in 45% (121/268) of patients. Grade 3 or higher infections occurred in 19% of patients. Grade 3 or higher infections with an unspecified pathogen occurred in 16% of patients, bacterial infections occurred in 5%, and viral and fungal infections occurred in 1.5% and 0.4% of patients, respectively. Monitor patients for signs and symptoms of infection before and after BREYANZI administration and treat appropriately. Administer prophylactic antimicrobials according to standard institutional guidelines.

Febrile neutropenia has been observed in 9% (24/268) of patients after BREYANZI 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.

Avoid administration of BREYANZI in patients with clinically significant active systemic infections.

Viral reactivation: 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. Ten of the 11 patients in the TRANSCEND study with a prior history of HBV were treated with concurrent antiviral suppressive therapy to prevent HBV reactivation during and after treatment with BREYANZI. Perform screening for HBV, HCV, and HIV in accordance with clinical guidelines before collection of cells for manufacturing.

Prolonged Cytopenias

Patients may exhibit cytopenias not resolved for several weeks following lymphodepleting chemotherapy and BREYANZI infusion. Grade 3 or higher cytopenias persisted at Day 29 following BREYANZI infusion in 31% (84/268) of patients, and included thrombocytopenia (26%), neutropenia (14%), and anemia (3%). Monitor complete blood counts prior to and after BREYANZI administration.

Hypogammaglobulinemia

B-cell aplasia and hypogammaglobulinemia can occur in patients receiving treatment with BREYANZI. The adverse event of hypogammaglobulinemia was reported as an adverse reaction in 14% (37/268) of patients; laboratory IgG levels fell below 500 mg/dL after infusion in 21% (56/268) of patients. Hypogammaglobulinemia, either as an adverse reaction or laboratory IgG level below 500 mg/dL after infusion, was reported in 32% (85/268) of patients. Monitor immunoglobulin levels after treatment with BREYANZI and manage using infection precautions, antibiotic prophylaxis, and immunoglobulin replacement as clinically indicated.

Live vaccines: The safety of immunization with live viral vaccines during or following BREYANZI 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 BREYANZI treatment, and until immune recovery following treatment with BREYANZI.

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Important Safety Information (cont'd)

Secondary Malignancies

Patients treated with BREYANZI may develop secondary malignancies. Monitor lifelong for secondary malignancies. In the event that a secondary malignancy occurs, contact Bristol-Myers Squibb at 1-888-805-4555 for reporting and to obtain instructions on collection of patient samples for testing.

Effects on Ability to Drive and Use Machines

Due to the potential for neurologic events, including altered mental status or seizures, patients receiving BREYANZI are at risk for altered or decreased consciousness or impaired coordination in the 8 weeks following BREYANZI administration. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, during this initial period.

Adverse Reactions

Serious adverse reactions occurred in 46% of patients. The most common nonlaboratory, serious adverse reactions (> 2%) were CRS, encephalopathy, sepsis, febrile neutropenia, aphasia, pneumonia, fever, hypotension, dizziness, and delirium. Fatal adverse reactions occurred in 4% of patients.

The most common nonlaboratory adverse reactions of any grade (≥ 20%) were fatigue, CRS, musculoskeletal pain, nausea, headache, encephalopathy, decreased appetite, diarrhea, hypotension, tachycardia, dizziness, cough, constipation, abdominal pain, vomiting, edema, and infections (pathogen unspecified).

Please see full Prescribing Information, including Boxed WARNINGS and Medication Guide.

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