# Breyanzi® Coding & Billing Information

Cell Therapy 360®

## INDICATIONS

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

- adult patients with large B-cell lymphoma (LBCL), 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, who have:
  - refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or
  - refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age; or
  - relapsed or refractory disease after two or more lines of systemic therapy.

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

- adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least 2 prior lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
- adult patients with relapsed or refractory follicular lymphoma (FL) who have received 2 or more prior lines of systemic therapy. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
- adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have received at least 2 prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor.

## SELECT IMPORTANT SAFETY INFORMATION

**WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, AND SECONDARY HEMATOLOGICAL MALIGNANCIES**

- **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.**
- **T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies, including BREYANZI.**
- **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 additional Important Safety Information on pages 15-19 and full Prescribing Information, including Boxed WARNINGS and Medication Guide.

Breyanzi™ (lisocabtagene maraleucel) SUSPENSION FOR IV INFUSION

# Introduction

Bristol Myers Squibb is committed to delivering optimal patient and customer experience with cellular therapies.

Breyanzi® is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of[1]:

- adult patients with large B-cell lymphoma (LBCL), 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, who have:
  - refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or
  - refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age; or
  - relapsed or refractory disease after two or more lines of systemic therapy.

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

- adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least 2 prior lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
- adult patients with relapsed or refractory follicular lymphoma (FL) who have received 2 or more prior lines of systemic therapy. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
- adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have received at least 2 prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor.

Breyanzi is for autologous use only and is administered intravenously, as a one-time treatment.[1]*
A single dose of Breyanzi contains CAR-positive viable T cells that consist of CD8 and CD4 components, with each component supplied separately in one to four single-dose vials[1]:

- For R/R LBCL after 1 line of therapy, 3L+ CLL or SLL, FL, or MCL, a single dose contains 90 to 110 x $10^6$ CAR-positive viable T cells
- For R/R LBCL after ≥2 lines of therapy, a single dose contains 50 to 110 x $10^6$ CAR-positive viable T cells

Please see **Boxed WARNINGS**, including cytokine release syndrome (CRS), neurologic toxicities, and T cell malignancies, on previous page.

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.

*This is part of a larger CAR T process that includes apheresis, manufacturing, administration, and monitoring.
3L+=third or subsequent line; CAR=chimeric antigen receptor; R/R=relapsed or refractory.

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

# ICD-10-CM Diagnosis Codes

The ICD-10-CM codes listed below 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.

## FDA-Approved Indications

| Adult Patients With R/R LBCL* After First-Line Chemoimmunotherapy or ≥2 Lines of Systemic Therapy | |
|---|---|
| **ICD-10-CM Code Range[2]** | **Description** |
| **C82.4_** | Follicular lymphoma grade IIIb |
| **C83.3_†** | Diffuse large B-cell lymphoma |
| **C83.9_** | Non-follicular (diffuse) lymphoma, unspecified |
| **C85.1_** | Unspecified B-cell lymphoma |
| **C85.2_** | Mediastinal (thymic) large B-cell lymphoma |
| **C85.8_** | Other specified types of non-Hodgkin lymphoma |

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.

**For questions about coding and billing information, contact your Bristol Myers Squibb Account Representative or call Cell Therapy 360® Patient Support at 1-888-805-4555 (choose option 2, then 3)**

*Including DLBCL NOS, PMBCL, HGBCL, FL3B, and DLBCL transformed from indolent lymphomas including FL, MCL, and RT CLL. Limitations of Use: Breyanzi is not indicated for the treatment of patients with primary central nervous system lymphoma. Please refer to page 1 and page 15 for the complete FDA-approved indications.

†C83.39 end date is effective September 30, 2024 and C83.390 is not applicable.[3]

DLBCL=diffuse large B-cell lymphoma; FDA=US Food and Drug Administration; FL=follicular lymphoma; FL3B=follicular lymphoma grade IIIb; HGBCL=high grade B-cell lymphoma; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; MCL=mantle cell lymphoma; NOS=not otherwise specified; PMBCL=primary mediastinal large B-cell lymphoma; R/R LBCL=relapsed or refractory large B-cell lymphoma; RT CLL=Richter transformation of chronic lymphocytic leukemia.

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

## FDA-Approved Indications (cont'd)

| Adult Patients With R/R CLL or SLL After ≥2 Prior Lines of Therapy, Including a BTKi and BCL2i* | |
|---|---|
| **ICD-10-CM Code Range[2]** | **Description** |
| **C83.0_** | Small cell B-cell lymphoma |
| **C91.10** | Chronic lymphocytic leukemia of B-cell type not having achieved remission |
| **C91.12** | Chronic lymphocytic leukemia of B-cell type in relapse |

| Adult Patients With R/R FL After ≥2 Lines of Systemic Therapy* | |
|---|---|
| **ICD-10-CM Code Range[2]** | **Description** |
| **C82.0_** | Follicular lymphoma grade I |
| **C82.1_** | Follicular lymphoma grade II |
| **C82.2_** | Follicular lymphoma grade III, unspecified |
| **C82.3_** | Follicular lymphoma grade IIIa |
| **C82.5_** | Diffuse follicle center lymphoma |
| **C82.6_** | Cutaneous follicle center lymphoma |
| **C82.8_** | Other types of follicular lymphoma |
| **C82.9_** | Follicular lymphoma, unspecified |

| Adult Patients With R/R MCL After ≥2 Prior Lines of Systemic Therapy, Including a BTKi | |
|---|---|
| **ICD-10-CM Code Range[2]** | **Description** |
| **C83.1_** | Mantle cell lymphoma |

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*This indication is approved under accelerated approval based on response rate and duration or response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

BCL2i=B-cell lymphoma 2 inhibitor; BTKi=Bruton tyrosine kinase inhibitor; FDA=US Food and Drug Administration; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; R/R CLL or SLL=relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma; R/R FL=relapsed or refractory follicular lymphoma; R/R MCL=relapsed or refractory mantle cell lymphoma.

**Please see Important Safety Information on pages 15-19 and full Prescribing Information, including Boxed WARNINGS and Medication Guide.**

Breyanzi™ (lisocabtagene maraleucel) SUSPENSION FOR IV INFUSION

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

## Encounter Type

| Code | Description |
|---|---|
| **Z00.6*** | Encounter for examination for normal comparison and control in clinical research program |
| **Z51.12** | Encounter for antineoplastic immunotherapy |
| Medicare requires all clinical trial claims to report Z00.6 diagnosis code, condition code 30, value code D4 with the 8-digit National Clinical Trial number.[4†‡] For inpatient and outpatient claims with expanded access use (EAU) of a CAR T product, providers may enter condition code 90. Use of the code will apply a payment adjustment for inpatient claims only.[5,6] Note that MACs will pay for covered clinical trial services furnished to Medicare Advantage beneficiaries.[4§] | |

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*This code should be reported only for clinical trial cases.

†For outpatient claims, Medicare also requires reporting HCPCS modifier Q0 for all lines containing an investigational item/service and Q1 for all lines containing a routine service.[4]

‡If a CAR T product is purchased in the usual manner but is being used for a clinical trial involving a different product (ie, the clinical trial is for a non-CAR T product), the provider may enter a Billing Note NTE02 ("Diff Prod Clin Trial") on the electronic claim form 837I (or a remark "Diff Prod Clin Trial" on a paper CMS-1450 claim form).[4,5]

§For Medicare Advantage patients, providers should not bill outpatient clinical trial services and non-clinical trial services on the same claim. Only covered clinical trial services should be submitted to Part A/B MACs; any outpatient services unrelated to the clinical trial should be billed to the patient's Medicare Advantage plan.[4]

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

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

## CAR T Complications

To properly report CRS and ICANS conditions due to CAR T infusions, coders will have to use at least 2 codes – the code for the underlying condition, represented by a complication "T" code, in addition to a code from the CRS or ICANS code range based on the grade (if documented) or the selection of unspecified (if the grade is not documented).[7]

| Complications Codes[7] | |
|---|---|
| **ICD-10-CM 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 |

| CRS Codes[7] | |
|---|---|
| **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[7] | |
|---|---|
| **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 |

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.

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

# HCPCS Level II Product Codes

Effective October 1, 2021, Breyanzi® has been assigned a unique Q-code for use in all sites of care and by all payers.[8]

| HCPCS Code/ Modifier | Description | Notes |
|---|---|---|
| **Q2054** | Lisocabtagene maraleucel, up to 110 million autologous anti-CD19 CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose | FOR MEDICARE FFS OPPS HOSPITAL CLAIMS* AND OTHER PAYER CLAIMS:<br>• 1 billing unit[8] |
| **-JZ** | Zero drug amount discarded/not administered to any patient | • Required on all claims for separately payable drugs under Medicare Part B when there is no discarded amount from single-dose containers eligible for payment (effective July 1, 2023)[9] |

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.

*Note that effective January 2025, the -TB modifier will be required for all OPPS claims for products acquired under the 340B Drug Pricing Program.[10]

CAR=chimeric antigen receptor; FFS=fee for service; HCPCS=Healthcare Common Procedure Coding System; OPPS=Outpatient Prospective Payment System.

# 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 CAR-positive viable T cells that consist of CD8 and CD4 components, with each component supplied separately in one to four single-dose vials.[1]

- For R/R LBCL after 1 line of therapy, CLL or SLL, FL, or MCL, a single dose contains 90 to 110 x $10^6$ CAR-positive viable T cells
- For R/R LBCL after ≥2 lines of therapy, a single dose contains 50 to 110 x $10^6$ CAR-positive viable T cells

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

Payers may require that the NDC number(s) is (are) documented on medical claims submitted for provider-administered therapies.

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.[11] 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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CAR=chimeric antigen receptor; CLL or SLL=chronic lymphocytic leukemia or small lymphocytic lymphoma; FL=follicular lymphoma; MCL=mantle cell lymphoma; NDC=National Drug Code; R/R LBCL=relapsed or refractory large B-cell lymphoma; WAC=wholesale acquisition cost.

# ICD-10-PCS Inpatient Procedure Codes*

Effective for discharges on or after October 1, 2021, the following CAR T-designated ICD-10-PCS codes may be reported for inpatient facility services associated with Breyanzi® administration.

| ICD-10-PCS Code[12] | Description | Notes for Medicare FFS Under the IPPS† |
|---|---|---|
| XW033N7 | Introduction of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7 | For FY 2025:<br>• Assigned to MS-DRG 018 (Chimeric Antigen Receptor [CAR] T cell and Other Immunotherapies), with the average national base payment rate of $269,138.53 (the exact rate may vary widely based on hospital-specific adjustments)[13‡]<br>• The base rate for MS-DRG 018 will be reduced by an adjustor of 0.33 for CAR T clinical trial/expanded access use cases.[14§] Note that MACs will pay for covered clinical trial services furnished to Medicare Advantage beneficiaries.[4] |
| XW043N7 | Introduction of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology group 7 | |

**For questions about coding and billing information, contact your Bristol Myers Squibb Account Representative or call Cell Therapy 360® Patient Support at 1-888-805-4555 (choose option 2, then 3)**

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.

*Site/setting-of-care decisions are at the sole discretion of the treating physician/institution.

†For MA patients, billing requirements and reimbursement methodology may vary by plan.

‡The estimated average does not include outlier, pass-through payments, or other applicable hospital-specific adjustments.

§MS-DRG 018 rate adjustment will not be applied for cases when a CAR T product is purchased in the usual manner but is being used for a clinical trial involving a different product as reported with a Billing Note NTE02 ("Diff Prod Clin Trial") on the electronic claim form 837I (or a remark "Diff Prod Clin Trial" on a paper CMS-1450 claim form).[4,5,15]

CMS=Centers for Medicare & Medicaid Services; FFS=fee for service; FY=fiscal year; ICD-10-PCS=International Classification of Diseases, Tenth Revision, Procedure Coding System; IPPS=Inpatient Prospective Payment System; MA=Medicare Advantage; MAC=Medicare Administrative Contractor; MS-DRG=Medicare Severity Diagnosis Related Group.

# Hospital Revenue Codes*

The following CAR T-designated revenue codes may be reported with accompanying line items billed for services associated with Breyanzi®.

| Revenue Code[16] | 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.[17†‡] |
| **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 | |

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.

*Site/setting-of-care decisions are at the sole discretion of the treating physician/institution.

†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 Chapter 32 of the Medicare Claims Processing Manual.[4]

‡For Medicare FFS patients, a 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, a 1-day payment window applies.[18]

CAR=chimeric antigen receptor; FDA=US Food and Drug Administration; FFS=fee for service; IPPS=Inpatient Prospective Payment System.

# CPT® Codes for Outpatient Hospital and Physician Services*

The following CAR T–designated CPT Category I codes may be reported for outpatient hospital facility services or physician services associated with Breyanzi®. Please note that only one of these CPT Category I codes (CPT code 38228) is separately payable by Medicare under the Hospital OPPS.[19]

| CPT Category I Code[20] | Description | Hospital Revenue Code† | Medicare FFS Reimbursement Status Under OPPS in CY 2025[19]‡ |
|---|---|---|---|
| **Apheresis and Preparation** | | | |
| **38225** | 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) |
| **38226** | Chimeric antigen receptor T cell (CAR T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage) | **0872** | |
| **38227** | Chimeric antigen receptor T cell (CAR T) therapy; receipt and preparation of CAR T cells for administration | **0873** | |
| **Administration** | | | |
| **38228** | Chimeric antigen receptor T cell (CAR T) therapy; CAR T cell administration, autologous | **0874** | Paid under APC 5694 (status indicator S, CY 2025 national average payment rate is $331.69) |

CPT Category III codes were in effect through December 31, 2024. **New CPT Category I codes are effective as of January 1, 2025.**[20]
CMS has instructed MACs that Medicare only covers CAR T therapy when administered in a REMS-certified healthcare facility. When a facility submits a claim, in order to acknowledge that they are REMS-certified, **the claim must have the -KX modifier appended to the CAR T administration code 38228.** In Transmittal 11179 (released in January 2022), CMS clarified that the -KX modifier is only required for CAR T claims submitted by **outpatient hospital facilities** (Part A outpatient claims).[4,20,21¶]

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.

*Site/setting-of-care decisions are at the sole discretion of the treating physician/institution.

†See previous page for revenue code descriptions.

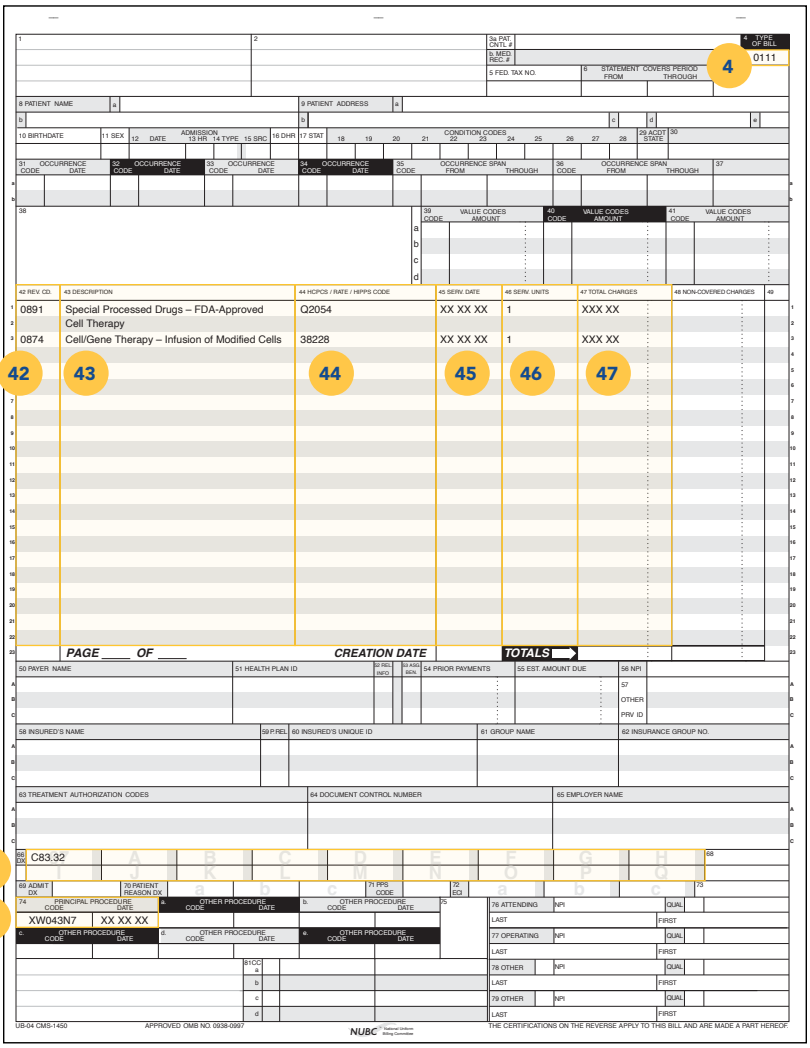
‡For MA patients, billing requirements and reimbursement methodology may vary by plan.

§CPT Category I codes 38225, 38226, 38227 can be reported for tracking purposes only as non-covered charges. For more information, please see Chapter 32 of the Medicare Claims Processing Manual.[4,20]

¶Once a hospital facility is identified by a MAC as an FDA REMS-approved facility for a particular CAR T cell therapy, the facility is added to a special edit that allows their inpatient and outpatient facility claims to process automatically regardless of whether the -KX modifier is present on subsequent claims. This special Medicare edit is not applicable to professional claims billing 38228. For all Medicare professional claims billing this code, the -KX modifier must be present on each CAR T claim.[21]

APC=Ambulatory Payment Classification; CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; CY=calendar year; FDA=US Food and Drug Administration; FFS=fee for service; MA=Medicare Advantage; MAC=Medicare Administrative Contractor; OPPS=Outpatient Prospective Payment System; REMS=Risk Evaluation and Mitigation Strategy.

# Sample CMS-1450 (UB-04) Claim Form For Inpatient Hospital Facilities[22]




**4** **Form Locator (FL) 4:** Enter the appropriate type of bill code. For example[23]:

- 0111 for an inpatient hospital facility

**42** **FL 42:** Enter the appropriate revenue code for each reported line. For example[16,17]:

- 0874 for CAR T infusion
- 0891 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. For example[8,20]:

- 38228 for CAR T infusion
- Q2054 for Breyanzi

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

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

*NOTE: For Q2054, 1 unit of service is reported per therapeutic dose of Breyanzi.*[8]

**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]:

- C83.32 for diffuse large B-cell lymphoma, intrathoracic lymph nodes

**74** **FL 74:** Enter relevant ICD-10-PCS procedure code(s) with corresponding date(s) of service. For example, for Breyanzi infusion[12]:

- XW033N7 or XW043N7

## Requirements may vary; refer to specific payer policy*

These sample forms are for informational purposes only. 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.

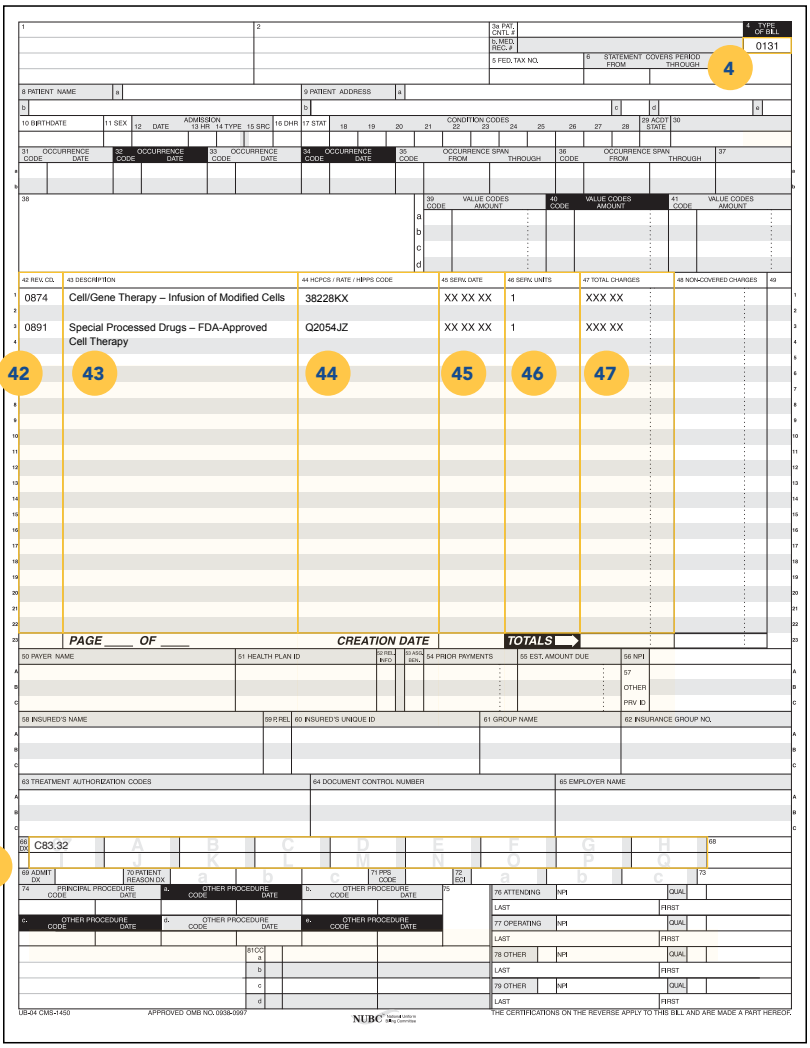
*Billing instructions have been issued for Medicare FFS patients. For more information, please see Chapter 32 of the Medicare Claims Processing Manual, as well as Medicare Transmittals 11179 and 11774.[4,21,24]

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

**Please see Important Safety Information on pages 15-19 and full Prescribing Information, including Boxed WARNINGS and Medication Guide.**

Breyanzi™ (lisocabtagene maraleucel) SUSPENSION FOR IV INFUSION

# Sample CMS-1450 (UB-04) Claim Form For Outpatient Hospital Facilities[22]




**4** **Form Locator (FL) 4:** Enter the appropriate type of bill code. For example[23]:
- 0131 for an outpatient hospital facility

**42** **FL 42:** Enter the appropriate revenue code for each reported line. For example[16,17]:
- 0874 for CAR T infusion
- 0891 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[4,9,19-21]:
- 38228 for CAR T infusion and -KX modifier
- Q2054 for Breyanzi and -JZ modifier

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

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

*NOTE: For Q2054, 1 unit of service is reported per therapeutic dose of Breyanzi.*[8]

**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[21]:
- C83.32 for diffuse large B-cell lymphoma, intrathoracic lymph nodes

## Requirements may vary; refer to specific payer policy*

These sample forms are for informational purposes only. 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.

*Billing instructions have been issued for Medicare FFS patients. For more information, please see Chapter 32 of the Medicare Claims Processing Manual, as well as Medicare Transmittals 11179 and 11774.[4,21,24]

CAR=chimeric antigen receptor; CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; FFS=fee for service; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NDC=National Drug Code.

## INDICATIONS

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

- adult patients with large B-cell lymphoma (LBCL), 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, who have:
  - refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or
  - refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age; or
  - relapsed or refractory disease after two or more lines of systemic therapy.

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

- adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least 2 prior lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
- adult patients with relapsed or refractory follicular lymphoma (FL) who have received 2 or more prior lines of systemic therapy. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
- adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have received at least 2 prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor.

## IMPORTANT SAFETY INFORMATION

**WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, AND SECONDARY HEMATOLOGICAL MALIGNANCIES**

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

Please see next page for additional Important Safety Information and see full Prescribing Information, including Boxed WARNINGS and Medication Guide.

Breyanzi™ (lisocabtagene maraleucel) SUSPENSION FOR IV INFUSION

# IMPORTANT SAFETY INFORMATION (cont'd)

## Cytokine Release Syndrome

Cytokine release syndrome (CRS), including fatal or life-threatening reactions, occurred following treatment with BREYANZI. In clinical trials of BREYANZI, which enrolled a total of 702 patients with non-Hodgkin lymphoma (NHL), CRS occurred in 54% of patients, including ≥ Grade 3 CRS in 3.2% of patients. The median time to onset was 5 days (range: 1 to 63 days). CRS resolved in 98% of patients with a median duration of 5 days (range: 1 to 37 days). One patient had fatal CRS and 5 patients had ongoing CRS at the time of death. The most common manifestations of CRS (≥10%) were fever, hypotension, tachycardia, chills, hypoxia, and headache.

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.

## Neurologic Toxicities

Neurologic toxicities that were fatal or life-threatening, including immune effector cell-associated neurotoxicity syndrome (ICANS), occurred following treatment with BREYANZI. Serious events including cerebral edema and seizures occurred with BREYANZI. Fatal and serious cases of leukoencephalopathy, some attributable to fludarabine, also occurred.

In clinical trials of BREYANZI, CAR T cell-associated neurologic toxicities occurred in 31% of patients, including ≥ Grade 3 cases in 10% of patients. The median time to onset of neurotoxicity was 8 days (range: 1 to 63 days). Neurologic toxicities resolved in 88% of patients with a median duration of 7 days (range: 1 to 119 days). Of patients developing neurotoxicity, 82% also developed CRS.

The most common neurologic toxicities (≥5%) included encephalopathy, tremor, aphasia, headache, dizziness, and delirium.

## CRS and Neurologic Toxicities Monitoring

Monitor patients daily for at least 7 days following BREYANZI infusion at a REMS-certified healthcare facility for signs and symptoms of CRS and neurologic toxicities and assess for other causes of neurological symptoms. Monitor patients for signs and symptoms of CRS and neurologic toxicities for at least 4 weeks after infusion and treat promptly. At the first sign of CRS, institute treatment with supportive care, tocilizumab, or tocilizumab and corticosteroids as indicated. Manage neurologic toxicity with supportive care and/or corticosteroid as needed. Counsel patients to seek immediate medical attention should signs or symptoms of CRS or neurologic toxicity occur at any time.

## 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:

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# IMPORTANT SAFETY INFORMATION (cont'd)

## BREYANZI REMS (cont'd)

- 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.

Further information is available at www.BreyanziREMS.com, or contact Bristol-Myers Squibb at 1-866-340-7332.

## 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. In clinical trials of BREYANZI, infections of any grade occurred in 34% of patients, with Grade 3 or higher infections occurring in 12% of all patients. Grade 3 or higher infections with an unspecified pathogen occurred in 7%, bacterial infections in 3.7%, viral infections in 2%, and fungal infections in 0.7% of patients. One patient who received 4 prior lines of therapy developed a fatal case of John Cunningham (JC) virus progressive multifocal leukoencephalopathy 4 months after treatment with BREYANZI. One patient who received 3 prior lines of therapy developed a fatal case of cryptococcal meningoencephalitis 35 days after treatment with BREYANZI.

Febrile neutropenia developed after BREYANZI infusion in 8% of patients. Febrile neutropenia 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.

Monitor patients for signs and symptoms of infection before and after BREYANZI administration and treat appropriately. Administer prophylactic antimicrobials according to standard institutional guidelines. 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. In clinical trials of BREYANZI, 35 of 38 patients with a prior history of HBV were treated with concurrent antiviral suppressive therapy. Perform screening for HBV, HCV, and HIV in accordance with clinical guidelines before collection of cells for manufacturing. In patients with prior history of HBV, consider concurrent antiviral suppressive therapy to prevent HBV reactivation per standard guidelines.

## Prolonged Cytopenias

Patients may exhibit cytopenias not resolved for several weeks following lymphodepleting chemotherapy and BREYANZI infusion. In clinical trials of BREYANZI, Grade 3 or higher cytopenias persisted at Day 29 following BREYANZI infusion in 35% of patients, and included thrombocytopenia in 25%, neutropenia in 22%, and anemia in 6% of patients. Monitor complete blood counts prior to and after BREYANZI administration.

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# IMPORTANT SAFETY INFORMATION (cont'd)

## Hypogammaglobulinemia

B-cell aplasia and hypogammaglobulinemia can occur in patients receiving BREYANZI. In clinical trials of BREYANZI, hypogammaglobulinemia was reported as an adverse reaction in 10% of patients. Hypogammaglobulinemia, either as an adverse reaction or laboratory IgG level below 500 mg/dL after infusion, was reported in 30% 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.

## Secondary Malignancies

Patients treated with BREYANZI 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, including BREYANZI. Mature T cell malignancies, including CAR-positive tumors, may present as soon as weeks following infusion, and may include fatal outcomes. 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 developing 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, for at least 8 weeks.

## Immune Effector Cell-Associated Hemophagocytic Lymphohistiocytosis-Like Syndrome (IEC-HS)

Immune Effector Cell-Associated Hemophagocytic Lymphohistiocytosis-Like Syndrome (IEC-HS), including fatal or life-threatening reactions, occurred following treatment with BREYANZI. Three of 89 (3%) safety evaluable patients with R/R CLL/SLL developed IEC-HS. Time to onset of IEC-HS ranged from 7 to 18 days. Two of the 3 patients developed IEC-HS in the setting of ongoing CRS and 1 in the setting of ongoing neurotoxicity. IEC-HS was fatal in 2 of 3 patients. One patient had fatal IEC-HS and one had ongoing IEC-HS at time of death. IEC-HS is a life-threatening condition with a high mortality rate if not recognized and treated early. Treatment of IEC-HS should be administered per current practice guidelines.

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## IMPORTANT SAFETY INFORMATION (cont'd)

### Adverse Reactions

The most common adverse reaction(s) (incidence ≥30%) in:

- LBCL are fever, cytokine release syndrome, fatigue, musculoskeletal pain, and nausea. The most common Grade 3-4 laboratory abnormalities include lymphocyte count decrease, neutrophil count decrease, platelet count decrease, and hemoglobin decrease.
- CLL/SLL are cytokine release syndrome, encephalopathy, fatigue, musculoskeletal pain, nausea, edema, and diarrhea. The most common Grade 3-4 laboratory abnormalities include neutrophil count decrease, white blood cell decrease, hemoglobin decrease, platelet count decrease, and lymphocyte count decrease.
- FL is cytokine release syndrome. The most common Grade 3-4 laboratory abnormalities include lymphocyte count decrease, neutrophil count decrease, and white blood cell decrease.
- MCL are cytokine release syndrome, fatigue, musculoskeletal pain, and encephalopathy. The most common Grade 3-4 laboratory abnormalities include neutrophil count decrease, white blood cell decrease, and platelet count decrease.

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