



Nonprofit corporations and independent licensees
of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 10/03/2024

Breyanzi® (lisocabtagene maraleucel)

HCPCS: Q2054

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
- a. FDA approved indications
 - b. FDA approved age
 - c. Prescribed by on in consultation with an oncologist
 - d. Diagnosis of relapsed or refractory non-Hodgkin's lymphoma
 - i. Treatment of patients with relapsed or refractory Non-Hodgkin's lymphoma of the following subtypes:
 1. Diffuse large B-cell lymphoma (DLBCL)
 2. Primary mediastinal B-cell lymphoma (PMBCL)
 3. Follicular lymphoma, grade 3B
 - ii. Received ≥ 2 lines of chemotherapy, including rituximab and anthracycline
OR
 - iii. Refractory disease or relapse within 12 months of first-line anti-CD20 and anthracycline therapy
OR
 - iv. Refractory disease to first-line chemoimmunotherapy or relapse after first-line therapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age
 - v. Patients must meet all of the following
 1. ECOG performance status of 0 - 2
 2. Creatinine clearance greater than 30 mL/min
 3. Alanine aminotransferase less than 5 times the upper limit of normal
 4. Left ventricular ejection fraction greater than 40%
 5. No known active CNS involvement by primary malignancy (secondary CNS involvement is allowed)
 6. No history of another primary malignancy that has not been in remission for at least 2 years prior to consideration of CAR-T therapy
 7. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy
 8. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable
 9. No presence of graft-vs-host disease (GVHD)

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

10. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months
 11. No thromboembolic events within 6 months
 12. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening
 13. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis
- e. Diagnosis of relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)
- i. Must have received at least 2 prior lines of therapy including all of the following
 1. A Bruton tyrosine kinase (BTK) inhibitor
 2. A B-cell lymphoma 2 (BCL-2) inhibitor
 - ii. Patients must meet all of the following
 1. ECOG performance status of 0 - 2
 2. No known active central nervous system malignancy
 3. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable
 4. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy
 5. Creatinine clearance greater than 30 mL/min
 6. Alanine aminotransferase less than 5 times upper limit of normal
 7. Left ventricular ejection fraction greater than 40%
 8. Platelets greater than 50,000/mm³
 9. No second malignancies in addition to CLL or SLL if the second malignancy has required therapy in the last 2 years or is not in complete remission
 10. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months
 11. No thromboembolic events within 6 months
 12. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening
 13. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis
- f. Diagnosis of relapsed or refractory follicular lymphoma (FL)
- i. Subjects must have received at least 2 prior lines of therapy including an anti-CD20 monoclonal antibody and an alkylating agent
 - ii. Must have measurable disease
 - iii. Patient must meet all of the following:
 1. No prior allogeneic HSCT
 2. No known active central nervous system malignancy
 3. ECOG performance status 0 - 2
 4. No transformed FL
 5. No histological grade 3b FL
 6. Creatinine clearance greater than 30 mL/min
 7. Hepatic transaminases less than 5 times the upper limit of normal
 8. Cardiac ejection fraction greater than 40%
 9. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable
 10. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy

11. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months
 12. No thromboembolic events within 6 months
 13. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening
 14. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis
- g. Diagnosis of relapsed or refractory mantle cell lymphoma (MCL)
- i. Subjects must have received at least two prior line of therapy including all the following:
 1. An anthracycline or bendamustine-containing chemotherapy
 2. An anti-CD20 monoclonal antibody therapy
 3. A Bruton's tyrosine kinase (BTK) inhibitor
 - ii. Must have 1 measurable lesion
 - iii. Patient must meet all of the following:
 1. No known active central nervous system malignancy
 2. ECOG performance status 0 - 2
 3. Creatinine clearance greater than 30 mL/min
 4. Hepatic transaminases less than 5 times the upper limit of normal
 5. Cardiac ejection fraction greater than 40%
 6. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable
 7. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy
 8. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months
 9. No thromboembolic events within 6 months
 10. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening
 11. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis
- h. Have not received prior treatment with any CAR-T therapy despite indication or any other genetically-modified T-cell therapy or are being considered for treatment with any other genetically-modified T-cell therapy
- i. Only to be administered at certified bone marrow/stem cell transplant centers
 - j. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the BCBSM/BCN utilization management medical drug list
 - k. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by BCBSM
 - l. If new diagnoses are FDA approved, coverage will be determined based on the FDA approved indication on a case by case basis until fully evaluated by the BCBSM Pharmacy and Therapeutics Committee
- B. Quantity Limitations, Authorization Period and Renewal Criteria
- a. Quantity Limits: Align with FDA recommended dosing
 - b. Authorization Period: 3 months with the allowance of only one dose per lifetime
 - c. Renewal Criteria: Not applicable as no further authorization will be provided

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- CAR-T therapy is a type of treatment that utilizes the body's own immune system to fight cancer. T-cells are collected from the patient via apheresis and are genetically engineered in the laboratory to produce chimeric antigen receptors on the cell surface, allowing the T-cells to recognize an antigen on target cancer cells. Once the tumor cells are identified, they are attacked and killed by the CAR-T therapy.
- CAR-T therapy has not been studied when given following prior treatment with any CAR-T therapy or following any other genetically-modified T-cell therapy.
- Due to the risk of cytokine release syndrome and neurological toxicities, CAR-T therapies are only allowed to be given at treatment centers certified by their REMS programs. CAR-T REMS programs require certified hospitals and their clinics to have on-site, immediate access to tocilizumab and an understanding of how to manage the risks of the associated CAR-T side effects.
- Breyanzi is indicated for the treatment of adult patients with relapsed or refractory 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. Breyanzi is not indicated for the treatment of patients with primary central nervous system lymphoma. Breyanzi is also indicated for the treatment of 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; adult patients with relapsed or refractory follicular lymphoma (FL) who have received 2 or more prior lines of systemic therapy; and adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have received at least 2 prior lines of systemic therapy, including a BTK inhibitor.
- Safety and efficacy as third-line therapy were established in the TRANSCEND trial, an open-label, multicenter, single-arm study of 268 patients with relapsed or refractory large B-cell Non-Hodgkin's lymphoma. Subjects must have been treated with an anthracycline and rituximab (or other CD20-targeted agent) and have relapsed or refractory disease after at least 2 lines of systemic therapy or after allogeneic HSCT. For patients who received previous CD19-targeted therapy, CD19-positive lymphoma confirmed on a biopsy had to be confirmed since completing the prior CD19-targeted therapy. Patients were excluded from the study if they had an ECOG performance status of greater than 2, a creatinine clearance less than 30 mL/min, alanine aminotransferase greater than 5 times the upper limit of normal, left ventricular ejection fraction (LVEF) less than 40%, active CNS involvement by primary malignancy, history of another primary malignancy that has not been in remission for at least 2 years prior to consideration of CAR-T therapy, had active infection, or the presence of graft-vs-host disease. The primary endpoints were complete response (CR) rate and duration of response (DOR). Seventy-three percent of patients achieved a response (95% CI: 67% - 80%), including 54% who experienced CR (95% CI: 47% - 61%) and 19% who achieved a partial response (PR; 95% CI: 14% - 26%). Median duration of response was 16.7 months in all responders (95% CI: 5.3 – not reached (NR)). For patients who achieved a CR, median duration of response was not reached (95% CI: 16.7 – NR). For patients achieving a PR, median duration of response was 1.4 months (95% CI: 1.1 – 2.2). Of 104 patients treated with Breyanzi who achieved a CR, 65% had remission lasting at least six months and 62% had remission lasting at least nine months.

- Safety and efficacy as second-line therapy were established in the TRANSFORM trial, a randomized, open-label, parallel-group, multicenter study of 184 patients with relapsed or refractory large B-cell Non-Hodgkin's lymphoma. Subjects must have been treated with an anthracycline and rituximab (or other CD20-targeted agent) and have relapsed or refractory disease after first-line therapy. Patients were excluded from the study if they had an ECOG performance status of greater than 1, a creatinine clearance less than 45 mL/min, alanine aminotransferase greater than 5 times the upper limit of normal, LVEF less than 40%, active CNS involvement by primary malignancy, history of another primary malignancy that has not been in remission for at least 2 years prior to consideration of CAR-T therapy, or had active infection. The primary endpoint was event free survival (EFS). Breyanzi significantly improved median EFS compared with standard therapy (10.1 months vs. 2.3 months; HR = 0.34; p-value < 0.0001) and also significantly increased median progression free survival (PFS) (14.8 months vs. 5.7 months; HR = 0.4; p-value = 0.0001). Sixty-six percent of patients assigned Breyanzi achieved complete response to therapy compared with 39% of patients assigned standard treatment (p-value < 0.0001).
- Safety and efficacy for use in CLL or SLL were established in the TRANSCEND-CLL 004, a phase 1/2, open-label, multicenter study of 65 patients with relapsed or refractory CLL or SLL who had received at least 2 prior lines of therapy including a BTK inhibitor and a BCL-2 inhibitor. Patients were excluded from the study if they had an ECOG performance status of greater than 1, a creatinine clearance less than 30 mL/min, alanine aminotransferase greater than 5 times the upper limit of normal, LVEF less than 40%, active CNS involvement by primary malignancy, history of another primary malignancy that has not been in remission for at least 2 years prior to consideration of CAR-T therapy, or had active infection. Of the evaluable patients, 45% and 20% achieved overall and complete responses, respectively. Of 13 MRD-evaluable patients, 100% and 92% achieved undetectable MRD in blood and marrow, respectively.
- Safety and efficacy for use in FL were established in the TRANSCEND-FL trial, a phase II, open-label, multicenter, single-arm study of 94 patients with relapsed or refractory FL following at least 2 prior lines of therapy including an anti-CD20 monoclonal antibody and an alkylating agent. Patients must have had measurable disease. Patients were excluded from the study if they had an ECOG performance status of greater than 1, a creatinine clearance less than 30 mL/min, alanine aminotransferase greater than 5 times the upper limit of normal, LVEF less than 40%, active CNS involvement by primary malignancy, history of another primary malignancy that has not been in remission for at least 2 years prior to consideration of CAR-T therapy, or had active infection. The primary endpoint was overall response rate (ORR). The ORR was 95.7% (95% CI: 89.5–98.8). The CR rate was 73.4% (95% CI: 63.3–82.0). The median DOR was not reached after a median follow-up of 16.8 months.
- Safety and efficacy for use in MCL were established in the TRANSCEND-MCL trial, a phase II, open-label, multicenter, single-arm study of 68 patients with relapsed or refractory MCL who had received at least two prior lines of therapy including a BTK inhibitor, an alkylating agent, and an anti-CD20 agent. Patients must have had measurable disease. Patients were excluded from the study if they had an ECOG performance status of greater than 1, a creatinine clearance less than 30 mL/min, alanine aminotransferase greater than 5 times the upper limit of normal, LVEF less than 40%, active CNS involvement by primary malignancy, history of another primary malignancy that has not been in remission for at least 2 years prior to consideration of CAR-T therapy, or had active infection. The primary endpoint was ORR. The ORR was 85.3% (95% CI: 74.6, 92.7) and 67.6% (95% CI: 55.2, 78.5) achieved a CR. The median DOR was 13.3 months (95% CI: 6.0, 23.3) with a median follow-up of 22.2 months (95% CI: 16.7, 22.8).
- Disease should be measured/staged with PET-CT. Focal uptake in nodal and extranodal sites is considered involvement with lymphoma, including spleen, liver, bone, thyroid, and so on. A measurable node must have a longest diameter (LDi) greater than 1.5 cm. A measurable extranodal lesion should have an LDi greater than 1.0 cm. All other lesions (including nodal, extranodal, and assessable disease) should be followed as nonmeasured disease (eg, cutaneous, GI, bone, spleen, liver, kidneys, pleural or pericardial effusions, ascites).

- A provider portal platform is used to capture clinical outcome information for patients on select high-cost treatments, such as gene and cellular therapies. If a patient meets medical necessity as defined by this policy and is approved for treatment, the requesting physician must attest to providing clinical outcome information within the appropriate provider portal at the requested cadence.

References:

1. Breyanzi [prescribing information]. Bothell, WA: Bristol Myers Squibb; May 2024.
2. National Comprehensive Cancer Network. B-cell lymphomas (Version 2.2024). 2024 April 30. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed on May 23, 2024.
3. Lee DW et al. Current concepts in the diagnosis and management of cytokine release syndrome. *Blood*. 2014 Jul 10; 124 (2): 188 - 195.
4. Abramson JS, Palomba ML, Gordon LI, et al. Lisocabtagene maraleucel for patients with relapsed or refractory large B-cell lymphomas (TRANSCEND NHL 001): a multicenter seamless design study. *Lancet*. 2020 Sep 19; 396 (10254): 839 – 52.
5. Clinicaltrials.gov. A phase 1, multicenter, open-label study of JCAR017, CD19-targeted chimeric antigen receptor (CAR) t-cells, for relapsed and refractory (R/R) b-cell non-hodgkin lymphoma (NHL) (NCT02631044). Available at: <https://clinicaltrials.gov/ct2/show/NCT02631044>. Accessed on February 8, 2021.
6. Cheson BD, Fisher RI, Barrington SF, et al. Recommendations for initial evaluation, staging, and response assessment of hodgkin and non-hodgkin lymphoma: the lugano classification. *J Clin Oncol*. 2014 Sep 20; 32 (27): 3059 – 68.
7. Clinicaltrials.gov. A global randomized multicenter phase 3 trial of JCAR017 compared to standard of care in adult subjects with high-risk, second-line, transplant-eligible relapsed or refractory aggressive b-cell Non-hodgkin lymphomas (TRANSFORM) (NCT03575351). Available at: <https://clinicaltrials.gov/ct2/show/NCT03575351>. Accessed on May 31, 2022.
8. Amorosi D. Liso-cel significantly improves outcomes in second-line DLBCL. 2021 Dec 11. Available at: <https://www.healio.com/news/hematology-oncology/20211211/lisocel-significantly-improves-outcomes-in-secondline-dlbcl>. Accessed on May 21, 2022.
9. Healio.com. FDA grants priority review to Breyanzi for second-line treatment of large B-cell lymphoma. 2022 Feb 17. Available at: <https://www.healio.com/news/hematology-oncology/20220217/fda-grants-priority-review-to-breyanzi-for-secondline-treatment-of-large-bcell-lymphoma>. Accessed on May 31, 2022.
10. U.S. Department of Health and Human Services. Common terminology criteria for adverse events (Version 5.0). 2017 Nov 27. Available at: https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_8.5x11.pdf. Accessed on July 6, 2022.
11. National Comprehensive Cancer Network. Chronic lymphocytic leukemia/small lymphocytic lymphoma (Version 3.2024). 2024 March 26. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed on March 27, 2024.
12. Siddiqi T, Soumerai JD, Dorrith KA, et al. Phase 1 TRANSCEND CLL 004 study of lisocabtagene maraleucel in patients with relapsed/refractory CLL or SLL. *Blood*. 2022 Mar 24; 139 (12): 1794 - 1806.
13. Clinicaltrials.gov. Study evaluating safety and efficacy of JCAR017 in subjects with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) (NCT03331198). Available at: <https://classic.clinicaltrials.gov/ct2/show/NCT03331198>. Accessed on December 18, 2023.
14. Bristol Myers Squibb. Bristol Myers Squibb announces TRANSCEND CLL 004 trial of Breyanzi (lisocabtagene maraleucel) met primary endpoint of complete response rate in patients with relapsed or refractory chronic lymphocytic leukemia. 2023 Jan 26. Available at: <https://news.bms.com/news/corporate-financial/2023/Bristol-Myers-Squibb-Announces-TRANSCEND-CLL-004-Trial-of-Breyanzi-lisocabtagene-maraleucel-Met-Primary-Endpoint-of-Complete-Response-Rate-in-Patients-with-Relapsed-or-Refractory-Chronic-Lymphocytic-Leukemia/default.aspx>. Accessed on December 18, 2023.

Policy History												
#	Date	Change Description										
2.0	Effective Date: 10/03/2024	Updated criteria under CLL and SLL indication to read no central nervous system involvement of the malignancy and no second malignancies in addition to CLL or SLL if the second malignancy has required therapy in the last 3 years or is not in complete remission										
1.9	Effective Date: 06/06/2024	Updated to include new indications for use in relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), follicular lymphoma (FL), and mantle cell lymphoma (MCL)										
1.8	Effective Date: 02/08/2024	Updated to add preliminary criteria for use in relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)										
1.7	Effective Date: 06/08/2023	Updated to require physicians provide clinical outcomes data using the Audaire Health platform										
1.6	Effective Date: 08/04/2022	Updated to align criteria across all CAR-T policies and include new indication for use as second-line therapy in DLBCL										
1.5	Effective Date: 06/09/2022	Updated to add preliminary criteria for use as second-line therapy in DLBCL										
1.4	Effective Date: 04/14/2022	Updated to remove CD19 requirement as NCCN guidelines state CAR-T can work without being positive for CD19 disease										
1.3	Effective Date: 08/12/2021	New policy - this policy replaces previously approved criteria that was embedded in Chimeric Antigen Receptor-T Cell Class policy which will be retired										
1.2	Effective Date: 03/15/2021	UM medical management system update for BCBS <table border="1" data-bbox="483 884 1365 1094"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <tr> <td>BCBS</td> <td>Yes</td> </tr> <tr> <td>BCN</td> <td>Yes</td> </tr> <tr> <td>MAPPO</td> <td>Yes</td> </tr> <tr> <td>BCNA</td> <td>Yes</td> </tr> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
BCN	Yes											
MAPPO	Yes											
BCNA	Yes											
1.1	Effective Date: 03/08/2021	UM medical management system update for BCN <table border="1" data-bbox="483 1167 1365 1388"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <tr> <td>BCBS</td> <td>No</td> </tr> <tr> <td>BCN</td> <td>Yes</td> </tr> <tr> <td>MAPPO</td> <td>Yes</td> </tr> <tr> <td>BCNA</td> <td>Yes</td> </tr> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	Yes	MAPPO	Yes	BCNA	Yes
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	No											
BCN	Yes											
MAPPO	Yes											
BCNA	Yes											
1.0	Effective Date: 02/11/2021	UM medical management system update for BCNA and MAPPO <table border="1" data-bbox="483 1461 1365 1671"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <tr> <td>BCBS</td> <td>No</td> </tr> <tr> <td>BCN</td> <td>No</td> </tr> <tr> <td>MAPPO</td> <td>Yes</td> </tr> <tr> <td>BCNA</td> <td>Yes</td> </tr> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	No	MAPPO	Yes	BCNA	Yes
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	No											
BCN	No											
MAPPO	Yes											
BCNA	Yes											

* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

Blue Cross Blue Shield/Blue Care Network of Michigan Medication Authorization Request Form



This form is to be used by participating physicians to obtain coverage for **drugs covered under the medical benefit**. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	Name
ID Number	Specialty
D.O.B. <input type="checkbox"/> Male <input type="checkbox"/> Female	Address
Diagnosis	City /State/Zip
Drug Name	Phone/Fax: P: () - F: () -
Dose and Quantity	NPI
Directions	Contact Person
Date of Service(s)	Contact Person Phone / Ext.

STEP 1: DISEASE STATE INFORMATION

1. Is this request for: Initiation Continuation *Date patient started therapy:* _____
2. Administered by patient or a medical professional? patient (self) health care professional (physician, nurse, etc.)
3. Site of administration? Provider office/Home infusion Other: _____
 Hospital outpatient facility (go to #4) *Reason for Hospital Outpatient administration:* _____
 Hospital inpatient facility for Car-T therapy only (for example: Kymriah, Yescarta, or Tecartus) (go to #5)
4. Please specify location of administration if hospital outpatient infusion: _____
5. Please specify location of administration if hospital inpatient infusion: _____
6. Please provide the NPI number for the place of administration: _____
7. **Initiation AND Continuation of therapy:**
 - a. What is the patient's diagnosis? _____
 - b. What other medication has the patient received for their condition? Please list _____
 - i. Please describe the response to previous therapies:

 - c. Will the patient be receiving any other treatment for the listed condition while on this medication? Please list:

 - d. Please list any labs values important for diagnosing or monitoring this patient's condition:

8. **Continuation of therapy:**
 - a. Has the patient progressed while on this medication? yes no
 - b. How has the patient's condition changed while on this medication?
 Improved; Please describe: _____
 Stable; please describe: _____
 Worsened; Please describe: _____
 Other; Please describe: _____

Chart notes are required for the processing of all requests. Please add any other supporting medical information necessary for our review (required)

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name	Physician Signature	Date
Step 2: Checklist	<input type="checkbox"/> Form Completely Filled Out <input type="checkbox"/> Provide chart notes	<input type="checkbox"/> Attach test results
Step 3: Submit	By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979	By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320

Confidentiality notice: This transmission contains confidential information belonging to the sender that is legally privileged. This information is intended only for use of the individual or entity named above. The authorized recipient of this information is prohibited from disclosing this information to any other party. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or action taken in reliance on the contents of this document is strictly prohibited. If you have received this in error, please notify the sender to arrange for the return of this document.