



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.

**P&T Date: 04/16/2026**

**Aucatzyl® (obecabtagene autoleucel)**

**HCPCS: Q2058**

**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 indication<sup>a,b</sup>
  - b. FDA approved age
  - c. Prescribed by or in consultation with an oncologist
  - d. Patients with Philadelphia chromosome positive (Ph+) ALL are eligible if they are intolerant to, or have failed 2 lines of and tyrosine kinase inhibitor therapy (TKI), or have failed 1 line of a second generation TKI, or if TKI therapy is contraindicated
  - e. Patient must meet all of the following:
    - i. ECOG performance status 0 – 2
    - ii. The member has no active infection (e.g. viral, bacterial, fungal) such as CMV, HIV, active hepatitis B or active hepatitis
    - iii. Creatinine clearance greater than 30 mL/min
    - iv. Cardiac ejection fraction greater than 40%
    - v. Has not received allogeneic cellular therapy, such as donor lymphocyte infusion within 6 weeks prior to Aucatzyl infusion
    - vi. No known active central nervous system malignancy
  - f. 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
  - g. Only to be administered at certified bone marrow/stem cell transplant centers
  - h. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the BCBSM/BCN utilization management medical drug list
  - i. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by BCBSM
  - j. 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

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**B. Quantity Limitations, Authorization Period and Renewal Criteria**

- a. Quantity Limits: Align with FDA recommended dosing
- b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time with the allowance of only one dose per lifetime
- c. Renewal Criteria: Not applicable as no further authorization will be provided

<sup>a</sup> Refractory (resistant) disease is defined as those patients who fail to obtain complete response with induction therapy, ie, failure to eradicate all detectable leukemia cells (<5% blasts) from the bone marrow and blood with subsequent restoration of normal hematopoiesis (>25% marrow cellularity and normal peripheral blood counts).

<sup>b</sup> Relapsed disease describes the reappearance of leukemia cells in the bone marrow or peripheral blood after the attainment of a complete remission with chemotherapy and/or allogeneic stem cell transplant

\*\*\*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.
- Aucatzyl is indicated for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).
- Safety and efficacy for use in acute lymphoblastic leukemia were established in the FELIX trial, a multicenter, phase II trial of 112 adult patients with relapsed or refractory ALL. If patients were Philadelphia chromosome positive they had to be intolerant to a tyrosine kinase inhibitor (TKI), had failed 2 previous lines of treatment with any TKI or 1 line of a second-generation TKI, or had a contraindication to a TKI. Patients with prior allogeneic SCT within 100 days of therapy, any active central nervous system malignancy, ECOG performance status of 2 or greater, or active serious infection were excluded. The primary end point was complete response (CR) and CR with incomplete count recovery (CRi). Secondary end points included event-free survival, overall survival (OS), safety, and duration of response (DOR). Of the 65 patients evaluable for efficacy, 27 patients (42%; 95% CI: 29%, 54%) achieved CR within 3 months. The median duration of CR achieved within 3 months was 14.1 months (95% CI: 6.1, not reached).
- Use of Aucatzyl required adequate kidney function. Other CAR-T therapies have been studied in subjects with a creatinine clearance of 30 mL/minute. The National Institute of Health/National Cancer Institute Common Terminology Criteria of Adverse Events (CTCAE) classify grade 2 chronic kidney disease as a creatinine clearance of 30 – 59 mL/minute. As the classification system uses 30 mL/minute as a cutoff for grade 2 disease and data from other CAR-T therapies support their use in these patients, Aucatzyl should be able to be tolerated in this population. As there is no data to support administration of CAR-T at levels lower than 30 mL/minute, therapy should not be given in patients not meeting the 30 mL/minute threshold.

- The CTCAE recommendations set the grade 2 cutoff for left ventricular ejection fraction (LVEF) at 40%. There is data from other CAR-T therapies to support use in those with a LVEF of 40% or greater. Therefore, Aucatzyl should be tolerated in these patients as well. There is no data supporting use at LVEF levels less than 40%.
- Provider portal platforms allow the capture of 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. Aucatzyl [prescribing information]. Gaithersburg, MD: Autolus Inc.; February 2026.
2. Clinicaltrials.gov. A study of CD19 targeted CAR-T cell therapy in adult patients with relapsed or refractory b-cell acute lymphoblastic leukemia (NCT04404660). Available at: <https://clinicaltrials.gov/study/NCT04404660>. Accessed on November 11, 2024.
3. National Comprehensive Cancer Network. Acute lymphoblastic leukemia (Version 2.2025). 2025 June 27. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/all.pdf](https://www.nccn.org/professionals/physician_gls/pdf/all.pdf). Accessed on March 1, 2026.

| Policy History   |                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                  |                                                   |      |     |     |     |       |     |      |     |
|------------------|--------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|---------------------------------------------------|------|-----|-----|-----|-------|-----|------|-----|
| #                | Date                                                         | Change Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                  |                                                   |      |     |     |     |       |     |      |     |
| 1.4              | Effective Date:<br>06/01/2026<br><br>P&T Date:<br>04/16/2026 | Updated to remove no diagnosis of Burkitt's lymphoma, no graft versus host disease, liver function test, no HIV, hepatitis C or B infection, no uncontrollable infection or infection requiring long term antibiotics, no significant cardiac events, no thomboemolic events within 6 months, no pulmonary disease, and no clinically significant CNS disease. Also added requirements of no active infection, must be administered at a certified treatment center, and updated the approval length to 6 months |                  |                                                   |      |     |     |     |       |     |      |     |
| 1.3              | Effective Date:<br>12/04/2025                                | Annual review of criteria was performed, no changes were made                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                  |                                                   |      |     |     |     |       |     |      |     |
| 1.2              | Effective Date:<br>12/12/2024                                | New policy - this criteria replaces previously approved preliminary criteria                                                                                                                                                                                                                                                                                                                                                                                                                                     |                  |                                                   |      |     |     |     |       |     |      |     |
| 1.1              | Effective Date:<br>11/21/2024                                | UM medical management system update for BCBS, BCN, MAPPO, and BCNA <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><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></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                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                  |                                                   |      |     |     |     |       |     |      |     |
| 1.0              | Effective Date:<br>10/03/2024                                | Preliminary Drug Review <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>                                                                                                                                                                                                                                          | Line of Business | PA Required in Medical Management System (Yes/No) | BCBS | No  | BCN | No  | MAPPO | No  | BCNA | No  |
| Line of Business | PA Required in Medical Management System (Yes/No)            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                  |                                                   |      |     |     |     |       |     |      |     |
| BCBS             | No                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                  |                                                   |      |     |     |     |       |     |      |     |
| BCN              | No                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                  |                                                   |      |     |     |     |       |     |      |     |
| MAPPO            | No                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                  |                                                   |      |     |     |     |       |     |      |     |
| BCNA             | No                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                  |                                                   |      |     |     |     |       |     |      |     |

\* 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>.

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# 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.

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| 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<br>Phone / Ext.                       |

### STEP 1: DISEASE STATE INFORMATION

- Is this request for: ☐ Initiation ☐ Continuation Date patient started therapy: \_\_\_\_\_
- Administered by patient or a medical professional? ☐ patient (self) ☐ health care professional (physician, nurse, etc.)
- 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)
- Please specify location of administration if hospital outpatient infusion: \_\_\_\_\_
- Please specify location of administration if hospital inpatient infusion: \_\_\_\_\_
- Please provide the NPI number for the place of administration: \_\_\_\_\_
- Initiation AND Continuation of therapy:**
  - What is the patient's diagnosis? \_\_\_\_\_
  - What other medication has the patient received for their condition? Please list \_\_\_\_\_  
    - Please describe the response to previous therapies: \_\_\_\_\_
  - Will the patient be receiving any other treatment for the listed condition while on this medication? Please list: \_\_\_\_\_
  - Please list any labs values important for diagnosing or monitoring this patient's condition: \_\_\_\_\_
- Continuation of therapy:**
  - Has the patient progressed while on this medication? ☐ yes ☐ no
  - 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                                                                                               |
|-----------------------------|-----------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| <b>Step 2:</b><br>Checklist | <input type="checkbox"/> Form Completely Filled Out<br><input type="checkbox"/> Provide chart notes | <input type="checkbox"/> Attach test results                                                       |
| <b>Step 3:</b><br>Submit    | <b>By Fax: BCBSM Specialty Pharmacy Mailbox</b><br><b>1-877-325-5979</b>                            | <b>By Mail: BCBSM Specialty Pharmacy Program</b><br><b>P.O. Box 312320, Detroit, MI 48231-2320</b> |

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7/26/2018, 9/18/2018; 1/31/2020; 3/17/2020; 8/9/2021