Aucatzyl® (Obecabtagene Autoleucel)
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for one treatment course (1 split dose infusion).
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 1 billable unit on day 1 and day 10

III. Initial Approval Criteria [1,5-8]

Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax**.** Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines.

Prior authorization validity is provided in the following conditions:

- Patient does not have a clinically significant active infection or inflammatory disorder; **AND**
- Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during Obecabtagene autoleucel treatment and until immune recovery following treatment; **AND**
- Patient has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- Prophylaxis for infection will be followed according to local guidelines; **AND**
- Patient has not received prior chimeric antigen receptor (CAR)-T cell therapy; **AND**
- Patient has not received other anti-CD19 therapy (e.g., blinatumomab,) OR patient previously received other anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; **AND**

- Used as single agent therapy (*not applicable to lymphodepleting or bridging chemotherapy while awaiting manufacture*); **AND**

Acute B-Cell Precursor Lymphoblastic Leukemia (ALL) † ‡ Φ [1-11]

- Patient is at least 18 years of age*; **AND**
- Patient has a diagnosis of relapsed or refractory disease; **AND**
  - Patient has Philadelphia chromosome (Ph)-positive disease; **AND**
    - Previous therapy has included tyrosine kinase inhibitors (TKIs) (i.e., bosutinib, dasatinib, imatinib, nilotinib, or ponatinib); **OR**
  - Patient has Philadelphia chromosome (Ph)-negative disease

**NCCN recommendations for ALL may be applicable to adolescent and young adult (AYA) patients 15 to 39 years of age.*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria

Duration of authorization has not been exceeded *(refer to Section I)*

V. Dosage/Administration [1]

Indication	Dose

B-Cell Precursor ALL	**Lymphodepleting chemotherapy:**
	• Administer fludarabine (30 mg/m^2 intravenously daily for 4 days) and cyclophosphamide (500 mg/m^2 intravenously daily for 2 days starting with the first dose of fludarabine).
	Aucatzyl Infusion:
	• The total recommended dose of Aucatzyl is 410 × 10^6 CD19 chimeric antigen receptor (CAR)-positive viable T cells supplied in three to five infusion bags. Bags are supplied in three color-coded bag configurations (10 × 10^6, 100 × 10^6, 300 × 10^6) for split dose administration
	• Treatment consists of a split dose infusion to be administered on D1 and D10 (+/- 2 days) and is based upon the tumor burden as assessed by bone marrow blast percentage from a sample obtained within 7 days prior to the start of lymphodepletion
	• Dosing is split based upon the following bone marrow blast percentages:
	  ○ >20%: 10 x 10^6 D1 with 400 x 10^6 D10 (+/- 2 days)
	  ○ ≤ 20%: 100 x 10^6 D1 with 310 x 10^6 D10 (+/- 2 days)

For autologous use only. For intravenous use only. • Aucatzyl contains human blood cells that are genetically modified with a replication-incompetent lentiviral vector. • One treatment course consists of lymphodepleting chemotherapy followed by a split dose infusion. • Confirm Aucatzyl availability prior to starting the lymphodepleting regimen. • Confirm the patient's identity with the patient identifiers on each Aucatzyl infusion bag(s).	
Premedication: • Premedicate with acetaminophen 30 minutes prior to infusion. Avoid prophylactic system corticosteroids which may interfere with Aucatzyl activity. **Monitoring after infusion:**	

- Monitor patients for signs and symptoms of cytokine release syndrome (CRS), neurologic toxicities/ immune effector cell-associated neurotoxicity syndrome (ICANS) and other acute toxicities daily for at least 14 days following the first infusion.
- Instruct patients to remain within proximity of a healthcare facility for at least 2 weeks following each infusion.
- Instruct patients to refrain from driving for at least 2 weeks following infusion.

- See the Release for Infusion Certificate for the actual number of chimeric antigen receptor (CAR)-positive T cells in the product.
- Store infusion bag(s) in the vapor phase of liquid nitrogen (less than or equal to minus 150°C) in a temperature-monitored system. Thaw prior to infusion.
- Tocilizumab must be available on site prior to infusion if needed for the treatment of CRS (2 doses minimum)
- Follow universal precautions and local biosafety guidelines for handling and disposal of Aucatzyl to avoid potential transmission of infectious diseases.

VI. Billing Code/Availability Information

HCPCS Code:

- Q2058 – Obecabtagene autoleucel, 10 up to 400 million cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per infusion

NDC(s):

- Aucatzyl 410 × 10^6 CD19 CAR-positive viable T cells is supplied in three to five infusion bags: 83047-0410-xx
  - 10 × 10^6 CD19 CAR-positive viable T cells in one 50mL infusion bag (Blue) - 83047-0010-xx
  - 100 × 10^6 CD19 CAR-positive viable T cells in one 50mL infusion bag (Orange) - 83047-0100-xx
  - 100 × 10^6 CD19 CAR-positive viable T cells in one 250mL infusion bag (Orange) - 83047-0100-xx
  - 300 × 10^6 CD19 CAR-positive viable T cells in one 250mL infusion bag (Red) - 83047-0300-xx

VII. References

1. Aucatzyl [package insert]. Gaithersburg, MD; Autolus Inc. August 2025. Accessed October 2025.
2. ClinicalTrials.gov. NCT04404660. An Open-Label, Multi-Centre, Phase Ib/II Study Evaluating the Safety and Efficacy of AUTO1, a CAR T Cell Treatment Targeting CD19, in Adult Patients With Relapsed or Refractory B Cell Acute Lymphoblastic Leukaemia. https://clinicaltrials.gov/study/NCT04404660?intr=NCT04404660&rank=1#participation-criteria .
3. Jabbour E, Tholouli E, Sandhu KS, et al., Obecabtagene autoleucel (obe-cel, AUTO1) in adults with relapsed/refractory B-cell acute lymphoblastic leukemia (R/R B-ALL): Overall survival (OS), event-free survival (EFS) and the potential impact of chimeric antigen receptor (CAR)-T cell persistency and consolidative stem cell transplantation (SCT) in the open-label, single-arm FELIX phase Ib/II study.. JCO 42, 6504-6504(2024). DOI:10.1200/JCO.2024.42.16_suppl.6504.
4. Mejstrikova E, Hrusak O, Borowitz MJ, et al. CD19-negative relapse of pediatric B-cell precursor acute lymphoblastic leukemia following blinatumomab treatment. Blood Cancer J. 20177; 659. DOI 10.1038/s41408-017-0023-x

5. Ruella M, Maus MV. Catch me if you can: Leukemia Escape after CD19-Directed T Cell Immunotherapies. Computational and Structural Biotechnology Journal 14 (2016) 357–362.
6. Braig F, Brandt A, Goebeler M, et al. Resistance to anti-CD19/CD3 BiTE in acute lymphoblastic leukemia may be mediated by disrupted CD19 membrane trafficking. Blood; 129:1, 2017 Jan.
7. Majzner RG, Mackall CL. Tumor Antigen Escape from CAR T-cell Therapy. *Cancer Discov* 2018;8:1219-1226.
8. Maude SL, Frey N, Shaw PA, et al. Chimeric antigen receptor T cells for sustained remissions in leukemia. N Engl J Med. 2014;371(16):1507-1517.
9. Fitzgerald JC, Weiss SL, Maude SL, et al. Cytokine release syndrome after chimeric antigen receptor T cell therapy for acute lymphoblastic leukemia. Crit Care Med. 2017;45(2):e124-e131.
10. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Lymphoblastic Leukemia Version 2.2025. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed October 2025.
11. Lee DW et al (2019), ASTCT Consensus Grading for Cytokine Release Syndrome and Neurologic Toxicity Associated with Immune Effector Cells. Biol Blood Marrow Transplant. 2019 Apr; 25(4):625-638.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C83.50	Lymphoblastic (diffuse) lymphoma, unspecified site
C83.51	Lymphoblastic (diffuse) lymphoma, lymph nodes of head, face, and neck
C83.52	Lymphoblastic (diffuse) lymphoma, intrathoracic lymph nodes

C83.53	Lymphoblastic (diffuse) lymphoma, intra-abdominal lymph nodes
C83.54	Lymphoblastic (diffuse) lymphoma, lymph nodes of axilla and upper limb
C83.55	Lymphoblastic (diffuse) lymphoma, lymph nodes of inguinal region and lower limb
C83.56	Lymphoblastic (diffuse) lymphoma, intrapelvic lymph nodes
C83.57	Lymphoblastic (diffuse) lymphoma, spleen
C83.58	Lymphoblastic (diffuse) lymphoma, lymph nodes of multiple sites
C83.59	Lymphoblastic (diffuse) lymphoma, extranodal and solid organ sites
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.02	Acute lymphoblastic leukemia, in relapse

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC