Clinical Policy: Obecabtagene Autoleucel (Aucatzyl)

Reference Number: LA.PHAR.675
Effective Date: 06.19.25
Last Review Date: 02.19.26~~03.04.25~~
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

Description
Obecabtagene autoleucel (Aucatzyl®) is a CD19-directed chimeric antigen receptor (CAR) T-cell therapy.

FDA Approved Indication(s)
Aucatzyl is indicated for the treatment of adult patients with relapsed or refractory B-cell acute lymphoblastic leukemia (ALL).

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

All requests reviewed under this policy **require** ~~**medical director review**~~**Precision Drug Action Committee (PDAC) Utilization Management Review.**

It is the policy of Louisiana Healthcare Connections that Aucatzyl is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acute Lymphoblastic Leukemia* (must meet all):
**Only for initial treatment dose; subsequent doses will not be covered.*

1. Diagnosis of B-cell precursor ALL;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a or b):
   a. Member has relapsed or refractory disease defined as one of the following (i - iv):
      i. Primary refractory disease;
      ii. First relapse if first remission ≤ 12 months;
      iii. Relapsed or refractory disease after 2 or more lines of systemic therapy;
      iv. Relapsed or refractory disease following allogeneic stem cell transplantation (allo-SCT) and must be 3 months from allo-SCT at the time of Aucatzyl infusion;
   b. Disease is Philadelphia chromosome positive (Ph+), relapsed or refractory, and one of the following (i, ii, or iii):

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i. Member has failed 2 tyrosine kinase inhibitors (e.g., imatinib, Sprycel®, Tasigna®, Bosulif®, Iclusig®);
ii. Member has failed one second-generation tyrosine kinase inhibitor (e.g., Bosulif, Sprycel, Tasigna);
iii. Member has a contraindication to all tyrosine kinase inhibitors;
**Prior authorization may be required for tyrosine kinase inhibitors*

5. If previously treated with Blincyto®, documentation of CD19 tumor expression on blasts obtained from bone marrow or peripheral blood after completion of the most recent prior line of therapy;
6. Member does not have central nervous system (CNS)-3 disease* or have a history or presence of any CNS disorder (e.g., seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, any autoimmune disease with CNS involvement, posterior reversible encephalopathy syndrome, or cerebral edema);
**CNS-3 disease is defined as detectable cerebrospinal blast cells in a sample of CSF with ≥ 5 white blood cells (WBCs) per mm^3*
7. If member has CNS-2 disease*, documentation of no clinically evident neurological changes;
**CNS-2 disease is defined as CSF blast cells with < 5 WBCs/mm^3*
8. Member has not previously received treatment with CAR T-cell immunotherapy (e.g., Abecma®, Breyanzi™, Carvykti™, Kymriah™, Tecartus®, Yescarta™);
9. Aucatzyl is not prescribed concurrently with other CAR T-cell immunotherapy (e.g., Abecma, Breyanzi, Carvykti, Kymriah, Tecartus, Yescarta);
10. Dose does not exceed a total of 410 x 10^6 CAR-positive viable T cells administered as a split dose.

Approval duration: 3 months *(2 doses only, with 8 doses of tocilizumab (Actemra) if requested at up to 800 mg per dose)*

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53.

II. Continued Therapy

A. Acute Lymphoblastic Leukemia
1. Continued therapy will not be authorized as Aucatzyl is indicated as a single treatment course.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy– LA.PMN.53

B. History or presence of any CNS disorder, such as a seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, any autoimmune disease with CNS involvement, posterior reversible encephalopathy syndrome, or cerebral edema;

C. Presence of CNS-3 disease defined as detectable cerebrospinal blast cells in a sample of CSF with ≥ 5 WBCs per mm^3 with or without neurological changes.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALL: acute lymphoblastic leukemia
allo-SCT: allogeneic stem cell transplantation
CAR: chimeric antigen receptor
CNS: central nervous system
CSF: cerebrospinal fluid
FDA: Food and Drug Administration
MRI: magnetic resonance imaging
Ph+: Philadelphia chromosome positive
WBC: white blood cells

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
imatinib mesylate (Gleevec®)	Adults with Ph+ ALL: 600 mg/day Pediatrics with Ph+ ALL: 340 mg/m^2/day	Adults: 800 mg/day Pediatrics: 600 mg/day
Sprycel® (dasatinib)	Ph+ ALL: 140 mg per day	180 mg/day
Iclusig® (ponatinib)	Ph+ ALL: 45 mg per day	45 mg/day
Tasigna® (nilotinib)	Resistant or intolerant Ph+ CML-CP and CML-AP: 400 mg twice per day	800 mg/day
Bosulif® (bosutinib)	Ph+ CML: 500 mg per day	600 mg/day
Various combination regimens that may include the following: daunorubicin, doxorubicin, vincristine, dexamethasone, prednisone, pegaspargase,	Ph- ALL: varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
nelarabine, methotrexate, cyclophosphamide, cytarabine, rituximab, 6-mercaptopurine		

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s):
  - Cytokine release syndrome (CRS): do not administer Aucatzyl to patients with active infection or inflammatory disorders. disorders. Prior to administering Aucatzyl, ensure that healthcare providers have immediate access to medications and resuscitative equipment to manage CRS.
  - Immune effector cell-associated neurotoxicity syndrome (ICANS) including fatal or life-threatening reactions, occurred in patients receiving Aucatzyl, including concurrently with CRS or after CRS resolution. Monitor for neurologic signs and symptoms after treatment with Aucatzyl. Prior to administering Aucatzyl, ensure that healthcare providers have immediate access to medications and resuscitative equipment to manage neurologic toxicities.
  - T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies.

Appendix D: General Information

- Refractory disease is defined as an inability to achieve a complete response to therapy.
- The FELIX Phase Ib/II Study in patients with ALL (NCT04404660) excluded patients with:
  - Presence of CNS-3 disease defined as detectable cerebrospinal blast cells in a sample of CSF with ≥ 5 WBCs per mm^3 with or without neurological changes;
  - Presence of CNS-2 disease defined as detectable cerebrospinal blast cells in a sample of CSF with < 5 WBCs per mm^3 with neurological changes;
  - History or presence of clinically relevant CNS pathology

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
ALL	410 x 10^6 CAR-positive viable T cells administered as a split dose on Day 1 and Day 10	410 x 10^6 CAR-positive viable T cells

VI. Product Availability

Single-dose unit infusion bag: frozen suspension of genetically modified autologous T-cells labeled for the specific recipient

VII. References

1. Aucatzyl Prescribing Information. Gaithersburg, MD: Autolus Inc.; ~~November 2024.~~August 2025. Available at: https://www.~~autolus.com/media/aj4olbsd/~~aucatzyl~~-pi-08-nov2024.pdf.~~.com/.Accessed ~~January 6~~October 13, 2025.
2. Autolus Therapeutics. (2023, December 9). Autolus Therapeutics Presents Clinical Data Updates at the American Society of Hematology (ASH) Annual Meeting 2023 [Press release]. Available at: https://autolus.gcs-web.com/news-releases/news-release-details/autolus-therapeutics-presents-clinical-data-updates-american. Accessed ~~January 3, 2024~~November 6, 2025.
3. Obecabtagene Autoleucel (obe-cel, AUTO1) for Relapsed/Refractory Adult B-cell Acute Lymphoblastic Leukemia (R/R B-ALL): Pooled Analysis of the Ongoing FELIX Phase Ib/II Study. December 9, 2023. Abstract #222 - oral presentation: American Society of Hematology (ASH) Annual Meeting 2023. Available at: https://www.autolus.com/media/4xbmrn5p/cr_roddie-et-al_felix-pooled-analysis_oral-presentation_ash23_final2-1dec23.pdf. Accessed ~~January 3, 2024~~November 6, 2025.
4. A Study of CD19 Targeted CAR T Cell Therapy in Adult Patients With Relapsed or Refractory B Cell Acute Lymphoblastic Leukaemia (ALL). Clinicaltrials.gov ID: NCT04404660. Updated August 28, 2023. Available at: https://clinicaltrials.gov/study/NCT04404660. Accessed ~~January 3, 2024~~November 6, 2025.
5. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia Version ~~3.2024~~2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed ~~January~~November 6, 2025.
6. Roddie C, Sandhu KS, Tholouli E, et al. Obecabtagene Autoleucel in Adults with B-Cell Acute Lymphoblastic Leukemia. N Engl J Med. 2024 Nov 27; doi:10.1056/NEJMoa2406526

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Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
~~C9399~~Q2058	~~Unclassified drugs or biologicals~~Obecabtagene autoleucel, 10 up to 400 million cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per infusion
~~J9999~~	~~Not otherwise classified, antineoplastic drugs~~

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Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted to local policy.	03.04.25	05.19.25
Annual review: updated HCPCS code added [Q2058] replacing code [C9301], removed codes [C9399, J9999]; Updated language under Policy/Criteria to effectively redirect prior authorization reviews to Precision Drug Action Committee (PDAC) Utilization Management Review; references reviewed and updated	02.19.26	

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or

withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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