CENTENE® Corporation

Clinical Policy: Tabelecleucel (Tab-cel)

Reference Number: CP.PHAR.747
Effective Date: FDA Approval Date
Last Review Date: 11.25
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

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

Description

Tabelecleucel (Tab-cel®/™) is an allogeneic Epstein-Barr virus (EBV)-specific T-cell immunotherapy.

FDA Approved Indication(s) [Pending]

Tab-cel is indicated as monotherapy for treatment of adult and pediatric patients 2 years of age and older with Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV^+ PTLD) who have received at least one prior therapy including an anti-CD20 containing regimen.

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**.

It is the policy of health plans affiliated with Centene Corporation® that Tab-cel is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria*

**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. Post-Transplant Lymphoproliferative Disease (must meet all)**:**

1. Diagnosis of PTLD;*
2. Prescribed by or in consultation with an oncologist, hematologist, or transplant specialist;
3. Age ≥ 2 years;*
4. Member has previously received a hematopoietic cell transplantation or a solid organ transplant;
5. Disease is EBV seropositive;
6. One of the following (a or b):
   a. Disease is refractory;
   b. Member has relapsed after at least one line of therapy that includes rituximab or a rituximab biosimilar (*see Appendix B for examples*);*

   **Prior authorization may be required for rituximab or rituximab biosimilar*
7. Tab-cel is not prescribed concurrently with chimeric antigen receptor (CAR) T-cell immunotherapy (e.g., Abecma®, Carvykti®, Breyanzi®, Kymriah™, Tecartus®, Yescarta®);

8. Documentation of member's current body weight in kg;
9. Request meets one of the following (a or b):*
   a. Dose does not exceed 2 x 10^6 viable T cells/kg (per dose) on days 1, 8, and 15 of a 35 day cycle;*
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

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 one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
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 for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy*

**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. Post-Transplant Lymphoproliferative Disease

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Tab-cel for a covered indication and has received this medication for at least 30 days;
2. Member has not switched ≥ 4 times to a Tab-cel lot with a different human leukocyte antigen (HLA) restriction (*see Appendix D*);
3. Member has not achieved 2 consecutive complete responses to the same Tab-cel lot;
4. Member has not achieved 3 consecutive partial responses to the same Tab-cel lot;
5. Member has not received ≥ 15 cycles (45 doses) of Tab-cel;
6. Tab-cel is not prescribed concurrently with CAR T-cell immunotherapy (e.g., Abecma, Carvykti, Breyanzi, Kymriah, Tecartus, Yescarta);
7. If request is for a dose increase, documentation of member's current body weight in kg;
8. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 2 x 10^6 viable T cells/kg (per dose) on days 1, 8, and 15 of a 35 day cycle;*
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

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 one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
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 for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CAR: chimeric antigen recepor
EBV: Epstein-Barr virus
FDA: Food and Drug Administration
HLA: human leukocyte antigen
NCCN: National Comprehensive Cancer Network
PTLD: post-transplant lymphoproliferative disease

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 for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
rituximab (Rituxan®) or rituximab biosimilars (Riabni™, Ruxience™, Truxima®)	Varies	Varies
Examples of rituximab-containing chemotherapy regimens: • RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
• Pola-R-CHP (polatuxumab vedotin-piiq, rituximab, cyclophosphamide, doxorubicin, prednisone) • RCEPP (rituximab, cyclophosphamide, etoposide, prednisone, procarbazine) • RCEOP (rituximab, cyclophosphamide, etoposide, vincristine, prednisone) • RCVP (rituximab, cyclophosphamide, vincristine, prednisone)		

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 [Pending]

- Contraindication(s): pending
- Boxed warning(s): pending

Appendix D: General Information

- The number of cycles of Tab-cel to be administered is determined by the response to treatment. If a complete or partial response is not obtained, patients may be switched to a Tab-cel lot with a different HLA restriction (up to 4 different restrictions) selected from the existing product inventory.
  - If the patient achieves 2 consecutive complete response (maximal response), no further treatment with Tab-cel is recommended.
  - If the patient achieves 3 consecutive partial response (maximal response), no further treatment with Tab-cel is recommended.

V. Dosage and Administration [Pending]

Indication	Dosing Regimen	Maximum Dose
EBV^+-PTLD*	2 x 10^6 viable T cells per kg body weight per dose on days 1, 8, and 15 of a 35 day cycle*	2 x 10^6 viable T cells per kg per dose; 3 doses per cycle; 3 cycles per lot up to a total of 15 cycles (45 doses)*

VI. Product Availability [Pending]

Single-dose vials: frozen suspension of T-cells*

VII. References

1. Brand Name Prescribing Information.
2. National Comprehensive Cancer Network. B-Cell Lymphomas Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed July 31, 2025.

3. Allen UD, Preiksaitis JK; AST Infectious Diseases Community of Practice. Post-transplant lymphoproliferative disorders, Epstein-Barr virus infection, and disease in solid organ transplantation: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. *Clin Transplant*. 2019 Sep;33(9):e13652. doi: 10.1111/ctr.13652.
4. Mahadeo KM, Baiocchi R, Beitinjaneh A, et al. Tabelecleucel for allogeneic haematopoietic stem-cell or solid organ transplant recipients with Epstein-Barr virus-positive post-transplant lymphoproliferative disease after failure of rituximab or rituximab and chemotherapy (ALLELE): a phase 3, multicentre, open-label trial. Lancet Oncol. 2024 Mar;25(3):376-387. doi: 10.1016/S1470-2045(23)00649-6.

Coding Implications [Pending]
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
Pending	Pending

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively	08.26.25	11.25

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. The Health Plan 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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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 the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.