Draft New Policy: Do Not Implement

Allogeneic Regulatory T Cell Immunotherapy with HSPC and T cells-vldq (Tregzi™)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Tregzi is indicated for use in matched donor hematopoietic stem cell transplantation with myeloablative preparative regimen, for hematopoietic and immunologic reconstitution and to improve chronic graft-versus-host disease (cGVHD)-free survival, in the treatment of adults with hematological malignancies.
All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: chart notes or medical record documenting previous lines of therapy and response.

COVERAGE CRITERIA

Prevention of Chronic Graft-versus-Host Disease (cGVHD)

Authorization of 3 months (one dose) may be granted for hematopoietic and immunologic reconstitution and to improve cGVHD-free survival in the treatment of hematological malignancies when all of the following criteria are met:

- The member has one of the following:
  - Acute lymphoblastic leukemia (ALL) in complete remission or complete remission with incomplete count recovery.
  - Acute myelogenous leukemia (AML) in complete remission or complete remission with incomplete count recovery.
  - Mixed phenotype acute leukemia (MPAL) in complete remission or complete remission with incomplete count recovery.
  - Undifferentiated acute leukemia in complete remission or complete remission with incomplete count recovery.
  - Myelodysplastic syndrome (MDS) with no circulating blasts and less than 10 percent blasts in the bone marrow and member is eligible for allogeneic transplant, has poor risk genetic features, or has failed nontransplant therapies (e.g., erythropoietin-stimulating agents [ESAs], lenalidomide, hypomethylating agents [HMAs]), or chemotherapies.
  - Therapy-related/secondary MDS.

- The member is planned to undergo a human leukocyte antigen (HLA)-matched donor hematopoietic stem cell transplantation (HSCT).
- The member will receive a myeloablative preparative regimen (e.g., etoposide, cyclophosphamide, or fludarabine-thiotepa-busulfan).
- The requested medication will be used in combination with tacrolimus.
- The member is 18 years of age or older.
- The member has a hematopoietic cell transplantation-specific comorbidity index (HCT-CI) less than or equal to 4.
- The member is classified as disease risk index (DRI) category intermediate or high.
- The member has a Karnofsky performance score of greater than or equal to 70.
- The member has not received a previous treatment course of the requested medication.
- The member has adequate and stable kidney, liver, pulmonary, and cardiac function.
- The member does not have clinically significant active infection.
- The member does not have active GVHD.
- The member does not have an active inflammatory disorder.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Tregzi [package insert]. Sacramento, CA: Orca Biosystems Inc.; June 2026.
2. Meyer EH, Salhotra A, Gandhi AP, et al. Orca-T vs allogeneic hematopoietic stem cell transplantation (Precision-T): a multicenter, randomized phase 3 trial. Blood. 2026;147(11):1168-1177.
3. Precision-T: A Study of Orca-T in Recipients Undergoing allogeneic Transplantation for Hematologic Malignancies. Available at: https://clinicaltrials.gov/study/NCT04013685. Accessed July 9, 2026.

EFFECTIVE DATE

ID_CHS_75272026_0926