Reference number(s)
7527-A

Specialty Guideline Management
Tregzi

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tregzi	allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq

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[1]

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)[1-3]

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.

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.