Tregzi™ (allogeneic regulatory T-cell immunotherapy with HSPC and T-cells-vldq)
(Intravenous)

Document Number: IC-0872

Last Review Date: 09/01/2026
Date of Origin: 09/01/2026
Dates Reviewed: 09/2026

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 1 dose.
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

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

- One dose/infusion only

III. Initial Approval Criteria

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:

Matched Donor HSCT for the treatment of hematological malignancies - for hematopoietic and immunologic reconstitution and to improve Chronic Graft-Versus-Host Disease (cGVHD) † Φ [1,3]

- Member is at least 18 years of age; **AND**
- Treatment will be used with an appropriate myeloablative preparative regimen as part of an allogeneic hematopoietic stem cell transplant procedure (allo-HSCT); **AND**
- Used for hematopoietic and immunologic reconstitution and to improve cGVHD-free survival; **AND**
- Member has one of the following histo-pathologically confirmed diagnoses*;

    - Acute leukemias (i.e., lymphoid or myeloid lineage or mixed phenotype/undifferentiated) in complete remission (CR) or CR with incomplete hematologic recovery (CRi); **OR**
    - Myelodysplastic Syndrome (MDS) with no circulating blasts and <10% blasts in the bone marrow; **AND**
- Member must be matched to an 8/8 HLA-matched related or unrelated donor; **AND**
- Member has been screened for anti-donor antibodies prior to receiving therapy; **AND**
- Member has not had a prior allogeneic HCT; **AND**
- Treatment will be used in combination with a single agent calcineurin inhibitor (e.g., tacrolimus) as GVHD prophylaxis; **AND**
- Member will be monitored for malignancies of donor origin and secondary malignancies; **AND**
- Member will be monitored for severe hypersensitivity reactions including anaphylaxis which may occur due to DMSO, human serum albumin (HSA), Dextran or murine protein, during and after treatment infusion; **AND**
- Member does not have any clinically important infections prior to transplant and will be monitored for signs and symptoms of infections and treated as clinically indicated

Note: Requests for alternative diagnoses will be reviewed on a case-by-case basis.

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

IV. Renewal Criteria [1]

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

V. Dosage/Administration [1]

<table>
<tr><th>Indication</th><th>Dose</th></tr>
<tr><td>Hematopoietic and immunologic reconstitution and to improve
chronic GVHD-free survival</td><td>A single dose of TREGZI consists of hematopoietic stem and progenitor cells (HSPCs), regulatory T-cells (Tregs), conventional T-cells (T-cons), and T-con diluent provided in 4 separate infusion bags labeled for the specific patient. Each patient-specific infusion bag of TREGZI contains a batch dependent concentration of allogeneic cells.
<table>
<tr><th>Component</th><th>Dose Regimen</th><th>Target Viable Cell Dose Range (cells/kg)</th></tr>
<tr><td>HSPCs</td><td>IV once on Day 0</td><td>≥1.0 x 10^6</td></tr>
<tr><td>T-regs</td><td>IV once on Day 0 immediately after administration of HSPCs</td><td>1.3 x 10^6 to 3.5 x 10^6</td></tr>
<tr><td>T-cons</td><td>IV once on Day +2 to +3 (after the start of HSCP infusion on Day 0)</td><td>1.3 x 10^6 to 6.9 x 10^6</td></tr>
<tr><td>T-con diluent</td><td>IV once administered with T-cons on Day +2 to +3 (after the start of HSCP infusion on Day0)</td><td>30 mL</td></tr>
</table></td></tr>
<tr><td colspan="2">– <u>Abbreviations</u>: HSPCs, hematopoietic stem and progenitor cells; T-regs, regulatory T-cells; T-cons, conventional T cells.
– Tregzi contains human blood cells. Follow universal precautions and local biosafety guidelines for handling and disposal to avoid potential transmission of infectious diseases.</td></tr>
</table>

VI. Billing Code/Availability Information

<u>HCPCS(s) code</u>:

- J3590 – Unclassified biologics
- C9399 – Unclassified drugs or biologicals

<u>NDC</u>:

Bag (Container) and Carton (Package) Name	NDC
TREGZI	NDC 85866-223-04
HSPC Infusion Bag Label	NDC 85866-124-01
Treg Infusion Bag Label	NDC 85866-125-01
Tcon Infusion Bag Label	NDC 85866-126-01
Tcon Diluent Infusion Bag Label	NDC 85866-127-01
Carton for Treg and HSPC	NDC 85866-123-02
Cassette Label for Tcon	NDC 85866-126-02
Carton for Tcon Diluent	NDC 85866-127-02

VII. References

1. Tregzi [package insert]. Sacramento, CA; Orca Biosystems, Inc.; July 2026. Accessed July 2026.

2. Precision-T: a randomized study of Orca-T in recipients undergoing allogeneic transplantation for hematologic malignancies (Orca-T). ClinicalTrials.gov. Updated September 26, 2025. Accessed October 6, 2025. https://clinicaltrials.gov/study/NCT05316701
3. 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 Mar 12;147(11):1168-1177. doi: 10.1182/blood.2025031313.
4. de Witte T, Bowen D, Robin M, et al. Allogeneic hematopoietic stem cell transplantation for MDS and CMML: recommendations from an international expert panel. Blood. 2017;129(13):1753-1762. doi:10.1182/blood-2016-06-724500
5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Hematopoietic Cell Transplantation. Version 2.2026. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. 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 Compendium, go online to NCCN.org. Accessed July 2026.

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	No: PA not a priority
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
D89.811	Chronic graft-versus-host disease
Z29.89	Encounter for other specified prophylactic measures
Z94.81	Bone marrow transplant status
Z94.84	Stem cells transplant status
Z94.9	Transplanted organ and tissue status, unspecified

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