CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Graft-Versus-Host Disease – Tregzi Utilization Management Medical Policy
- Tregzi™ (allogeneic regulatory T cell immunotherapy with HSPS and T cells-vldq injection – Orca)

REVIEW DATE: 07/15/2026; selected revision 09/02/2026

OVERVIEW

Tregzi, an allogeneic regulatory T-cell based immunotherapy with hematopoietic stem and progenitor cells and T cells, 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 (GVHD) free survival, in the treatment of adults with hematologic malignancies.[1]

Dosing Information

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 four separate infusion bags labeled for each specific patient.[1] Each patient-specific infusion bag of Tregzi contains a batch-dependent concentration of allogenic cells. Patient-specific dose information can be found within the Certificate of Analysis. Refer to the Prescribing Information for specific preparation and administration instructions.

Table 1. Tregzi Route of Administration, Dose Regimen, and Target Dose Range.[1]

Component	Dose Regimen	Target Viable Cell Dose Range (cell/patient/kg)
HSPCs	Intravenous, once, on Day 0	$\geq 1.0 \times 10^6$
Tregs	Intravenous, once, on Day 0 immediately after administration of HSPCs	1.3×10^6 to 3.5×10^6
Tcons	Intravenous, once, on Day +2 or +3 (after the start of HSPC infusion on Day 0)	1.3×10^6 to 6.9×10^6
Tcon diluent	Intravenous, once, adminstered with Tcons drug product on Day +2 or +3 (after HSPC infusion on Day 0)	30 mL

HSPC – Hematopoetic stem and progenitor cells; Tregs – Regulatory T-cells; Tcons – Conventional T-cells.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Tregzi. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication(s). Because of the specialized skills required for evaluation and diagnosis of patients treated with Tregzi as well as the monitoring required for adverse events and long-term efficacy, approval requires Tregzi to be prescribed by a physician who specializes in the condition being treated. All approvals are provided for one time (per lifetime) as a single dose of four infusions labeled specifically for each patient. The approval duration is 1 year to allow for an adequate timeframe to prepare and administer one dose of therapy.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tregzi is recommended in those who meet the following criteria:

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FDA-Approved Indication

1. **Graft-Versus-Host Disease – Prevention.** Approve a one time (per lifetime) single dose of four infusions if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Tregzi is being used for the prevention of chronic graft-versus-host disease; AND
   - **C)** Patient is receiving allogenic hematopoietic stem cell transplantation; AND
   - **D)** Patient is receiving concomitant tacrolimus; AND
   - **E)** The medication is prescribed by an oncologist, hematologist, or a physician affiliated with a transplant center.

   Dosing. Approve the four separate intravenous infusion bags labeled for each specific patient.
   Note: Each patient-specific infusion bag of Tregzi contains a batch-dependent concentration of allogenic cells.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tregzi is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Tregzi™ intravenous infusion [prescribing information]. Orca Biosystems: Sacramento, CA; June 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	07/15/2026
Selected Revision	**Graft-Versus-Host Disease – Prevention**. A requirement was added that the patient is receiving allogenic hematopoietic stem cell transplantation.	09/02/2026

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