

## 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

### 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.<sup>1</sup>

### 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.<sup>1</sup> 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.<sup>1</sup>**

| 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                                  | $1.3 \times 10^6$ to $3.5 \times 10^6$          |
| Tcons        | Intravenous, once, on Day +2 or +3 (after the start of HSPC infusion on Day 0)                         | $1.3 \times 10^6$ to $6.9 \times 10^6$          |
| Tcon diluent | Intravenous, once, administered with Tcons drug product on Day +2 or +3 (after HSPC infusion on Day 0) | 30 mL                                           |

HSPC – Hematopoietic 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:

### 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, and D):
  - A) Patient is  $\geq 18$  years of age; AND
  - B) Tregzi is being used for the prevention of chronic graft-versus-host disease; AND
  - C) Patient is receiving concomitant tacrolimus; AND
  - D) 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  |