



## Drug Coverage Policy

Effective Date .....10/01/2026

Coverage Policy Number.....IP0821

Policy Title.....Tregzi

# Graft-Versus-Host Disease – Tregzi

- Tregzi™ (allogeneic regulatory T cell immunotherapy with HSPS and T cells-vldq injection – Orca)

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### INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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### 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.

## Coverage Policy

### POLICY STATEMENT

Prior Authorization is required for 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.

**Tregzi is considered medically necessary when the following are met:**

### 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  $\geq 18$  years of age; AND
  - B)** Tregzi is being used for the prevention of chronic graft-versus-host disease; AND
  - C)** Patient is receiving 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 Covered**

**Tregzi for any other use is considered not medically necessary. Criteria will be updated as new published data are available.**

**Coding Information**

- 1) This list of codes may not be all-inclusive.
- 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

|             |                    |
|-------------|--------------------|
| HCPCS Codes | Description        |
| J3490       | Unclassified Drugs |

**References**

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

**Revision Details**

| Summary of Changes                                                                                                                                      | Review Date | Effective Date |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|----------------|
| New policy.                                                                                                                                             | 08/27/2026  | 10/01/2026     |
| <b>Graft-Versus-Host Disease – Prevention.</b> A requirement that the patient is receiving allogenic hematopoietic stem cell transplantation was added. | 09/10/2026  | 10/01/2026     |

The policy effective date is in force until updated or retired.

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