allogeneic regulatory T cell immunotherapy (Tregzi)

Commercial Medical Benefit Drug Policy

1. All requests for this drug must receive authorization prior to drug administration for claim payment.
2. Criteria for coverage is pending P&T Committee approval.
3. In the interim, all requests for coverage will be reviewed for medical necessity.

Drug Details

USP Category: IMMUNOLOGICAL AGENTS
Mechanism of Action: allogeneic regulatory T cell-based immunotherapy with hematopoietic stem and progenitor cells and T cells indicated for use in matched donor hematopoietic stem cell transplantation
HCPCS:
C9399:Unclassified drugs or biologicals
J3490:Unclassified drugs
J3590:Unclassified biologics
How Supplied:
Tregzi is provided in separate infusion bags labeled for the specific patient. A single dose consists of:

- A minimum dose of HSPCs of 1.0 × 10^6 viable cells per patient kilograms.
- A dose of Tregs of 1.3 × 106 to 3.5 × 10^6 viable cells per patient kilograms.
- A dose of Tcons of 1.3 × 106 to 6.9 × 10^6 viable cells per patient kilograms.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

References

1. Tregzi (allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq) Prescribing Information. Orca Biosystems, Inc., Sacramento, CA: 6/2026.

Review History

Date of Last Annual Review: NA
Changes from previous policy version:

- Placeholder

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee