TREGZI™
(allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq) Suspension For IV infusion

Billing and Coding Guide

INDICATIONS AND USAGE[1]
TREGZI 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-free survival, in the treatment of adults with hematological malignancies.

IMPORTANT SAFETY INFORMATION[1]
WARNINGS AND PRECAUTIONS
Graft Failure: Graft failure has occurred after TREGZI administration. Screen TREGZI recipients for antidonor antibodies that may prevent engraftment. Monitor patients closely for laboratory evidence of hematopoietic recovery.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

Reference: 1. TREGZI™ (allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq). Prescribing information. Orca Biosystems, Inc; 2026.

TREGZI billing and coding guide overview

The billing and coding information contained herein was compiled from sources believed to be accurate as of July 2026. Orca Bio and its agents make no warranties or guarantees, expressed or implied, concerning the accuracy or appropriateness of this information for your particular use, given the frequent changes in public and private payer billing requirements.

Treatment centers may use this guide as a reference when navigating payer access considerations for TREGZI, which is administered through an alloHSCT procedure. Healthcare providers are responsible for ensuring the accuracy of all claim submissions. The information in this guide is subject to change. Payer coding requirements may vary and change over time; therefore, providers should regularly verify payer-specific requirements with each payer prior to submitting claims.

Within this guide, you will find:

TREGZI overview

- Patient treatment journey
- Dosing and administration
- Container transport and storage requirements

Coding and billing

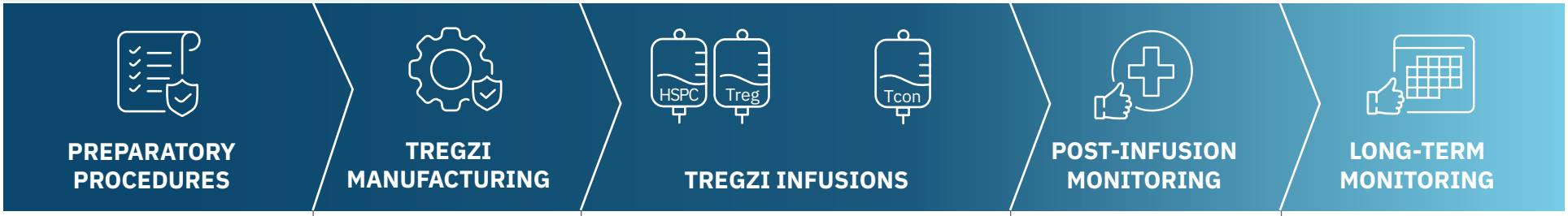
- Diagnosis codes (ICD-10-CM)
- Procedure codes (ICD-10-PCS)
- CPT/Revenue codes
- HCPCS and NDC codes

alloHSCT=allogeneic hematopoietic stem cell transplantation; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; ICD-10-PCS=International Classification of Diseases, Tenth Revision, Procedure Coding System; NDC=National Drug Code.

TREGZI patient journey[1,2]

The patient journey for TREGZI is similar to conventional alloHSCT

A vein-to-vein time of ≤72 hours



Patient

Myeloablative conditioning
- **Days -10 to -2**

Donor Cell Acquisition

Mobilization and apheresis
- **Days -6 to -2**

orcabio

Product manufacturing at the Orca Bio facility in the US
- **Vein-to-vein time: ≤72 hours**

Patient

HSPC and Treg component infusions
- **Day 0**

Tcon component infusion
- **Day +2 or +3**

Safety monitoring and patient follow-up
- **Days 0 to +100**

Safety monitoring and patient follow-up
- **Post Day +100**

An ICD-10-PCS code for the administration of TREGZI should be reported only after all 3 bags of the drug product have been completely infused

alloHSCT=allogeneic hematopoietic stem cell transplantation; HSPC=hematopoietic stem and progenitor cell; ICD-10-PCS=International Classification of Diseases, Tenth Revision, Procedure Coding System; Tcon=conventional T cell; Treg=regulatory T cell; US=United States.

References: 1. Putnam A, Tang S, Chaddock K, et al. High precision Orca-T: optimized for scalable production and distribution. Poster presented at: Tandem Meetings Transplantation & Cellular Therapy Meetings of ASTCT® CIBMTR® February 2026; Salt Lake City, UT. **2.** Meyer E, et al. *Blood*. 2026;147(11)(suppl):1168-1177.

Dosing and administration

TREGZI is administered through an IV infusion. A single dose of TREGZI consists of hematopoetic stem and progenitor cells (HSPCs), regulatory T cells (Tregs), conventional T cells (Tcons), and Tcon diluent provided in 4 separate infusion bags labeled for the specific patient.[1]

TREGZI route of administration, dose regimen, and target dose range[1]

Drug component	Dose regimen	Target viable cell dose range (cells per patient kg)
HSPCs	Intravenous, once, on Day 0	≥1.0×10^6
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 to +3 (after the start of HSPC infusion on Day 0)	1.3×10^6 to 6.9×10^6
Tcon diluent*	Intravenous, once, administered with Tcons drug product on Day +2 to +3 (after HSPC infusion on Day 0)	30 mL

Although multiple NDCs may be associated with the individual components of TREGZI, only 1 billable NDC should be reported for billing of the complete therapy.

TREGZI is provided in 2 transport containers[1]:

1. A refrigerated shipping container at 2 °C to 8 °C (36 °F to 46 °F), containing the HSPC infusion bag and Treg infusion bag in a single protective carton
   - The HSPCs and Tregs are in separate infusion bags labeled for a specific patient
2. A cardboard box containing:
   - A liquid nitrogen dry vapor shipper at below -125 °C (below -193 °F), containing the cryopreserved Tcon infusion bag in a protective metal cassette. The prescribing information is also included in the shipper
   - A protective carton at ambient temperature (20 °C to 25 °C, 68 °F to 77 °F) containing the Tcon diluent infusion bag

HSPC=hematopoietic stem and progenitor cell; IV=intravenous; NDC=National Drug Code; Tcon=conventional T cell; Treg=regulatory T cell.

*Mix the Tcon diluent (30 mL) with the Tcon drug product and administer as a single infusion.

Reference: 1. TREGZI™ (allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq). Prescribing information. Orca Biosystems, Inc; 2026.

Diagnosis and procedure codes

Diagnosis codes: ICD-10-CM

ICD-10-CM codes are diagnosis codes used for medical claims reporting. There are many ICD-10-CM diagnosis codes for hematologic malignancies that may be used to report TREGZI. Providers should report the code that most accurately reflects the patient's diagnosis to the highest level of specificity supported by the medical record documentation.

Procedure coding: ICD-10-PCS

The ICD-10-PCS is used by hospitals to report inpatient procedures and services ordered and provided to patients.

The administration of TREGZI may be reported with 1 of the codes in the table below once the entire therapeutic dose of TREGZI has been administered, which begins with the infusion of HSPCs and ends with the infusion of Tcons.

Procedure codes[1]	
ICD-10-PCS code	**Description**
XW033BA	Introduction of Orca-T Allogeneic T-cell Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 10
XW043BA	Introduction of Orca-T Allogeneic T-cell Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 10

HSPC=hematopoietic stem and progenitor cell; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; ICD-10-PCS=International Classification of Diseases, Tenth Revision, Procedure Coding System; Tcon=conventional T cell.

Reference: 1. Centers for Medicare & Medicaid Services. ICD-10-CM/PCS MS-DRG v43.0 Definitions Manual. Accessed July 1, 2026. https://www.cms.gov/icd10m/FY2026-fr-v43-fullcode-cms/fullcode_cms/P0001.html

Additional procedure codes

In addition to the TREGZI codes shown on the previous page, there may be additional services provided to the patient during the inpatient stay that may also be reported. These services include, but are not limited to, the ICD-10-PCS codes listed in the table below.

ICD-10-PCS codes[1,2]	
Code	**Description**
30233Y2	Transfusion of Allogeneic Related Hematopoietic Stem Cells into Peripheral Vein, Percutaneous Approach
30233Y3	Transfusion of Allogeneic Unrelated Hematopoietic Stem Cells into Peripheral Vein, Percutaneous Approach
30243Y2	Transfusion of Allogeneic Related Hematopoietic Stem Cells into Central Vein, Percutaneous Approach
30243Y3	Transfusion of Allogeneic Unrelated Hematopoietic Stem Cells into Central Vein, Percutaneous Approach
30233U2	Transfusion of Allogeneic Related T-cell Depleted Hematopoietic Stem Cells into Peripheral Vein, Percutaneous Approach
30233U3	Transfusion of Allogeneic Unrelated T-cell Depleted Hematopoietic Stem Cells into Peripheral Vein, Percutaneous Approach
30243U2	Transfusion of Allogeneic Related T-cell Depleted Hematopoietic Stem Cells into Central Vein, Percutaneous Approach
30243U3	Transfusion of Allogeneic Unrelated T-cell Depleted Hematopoietic Stem Cells into Central Vein, Percutaneous Approach
3E033GC	Introduction of Other Therapeutic Substance into Peripheral Vein, Percutaneous Approach
3E043GC	Introduction of Other Therapeutic Substance into Central Vein, Percutaneous Approach

Important Coding Note

The information provided is intended for informational purposes only. Coding and billing decisions should be made by the facility based on the patient's documented clinical circumstances, applicable payer requirements, and current coding guidelines.

ICD-10-PCS=International Classification of Diseases, Tenth Revision, Procedure Coding System.

References: 1. Centers for Medicare & Medicaid Services. ICD-10-CM/PCS MS-DRG v42.0 Definitions Manual. Accessed March 16, 2026. https://www.cms.gov/icd10m/FY2025-NPRM-Version42-fullcode-cms/fullcode_cms/P0003.html **2.** AAPC. ICD-10-PCS Lookup. Accessed March 16, 2026. https://www.aapc.com/codes/icd-10-pcs-codes-range/

Procedure coding: CPT and revenue codes

The following CPT codes (HCPCS Level I) and hospital revenue codes may be used to report services associated with TREGZI.

CPT codes[1]	
Code	**Description**
38204	Management of recipient hematopoietic progenitor cell donor search and cell acquisition
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
38999	Unlisted procedure, hemic or lymphatic system

Hospital revenue codes[2]	
Code*	**Description**
0815†	Acquisition of Body Components—Stem Cells—Allogeneic
0761	Specialty Services—Treatment Room
0891	Special Processed Drugs–FDA-Approved Cell Therapy (Pharmacy–Extension of 025X and 063X)
0940	Other Therapeutic Services—General

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; HSPC=hematopoietic stem and progenitor cell.

*A revenue code is a 3- or 4-digit numeric code used in institutional medical billing (UB-04 forms) to identify a specific accommodation and/or ancillary service. These codes indicate the department or cost center (eg, radiology, emergency department, pharmacy) where a service is provided. For example, many transplant centers map HSPC processing and cryopreservation to laboratory revenue codes (030x series); however, transplant revenue codes can vary based on facility billing structure and setting. This is a sampling of revenue codes and is not meant to be exhaustive or prescriptive.

†According to National Uniform Billing Committee (NUBC) requirements, revenue code 0815 must be reported on the bill for all payers for stem cell transplant acquisition services. For a listing of donor services, see Medicare Claims Processing Manual Chapter 3, Section 90.3.1: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c03.pdf and Chapter 4, Section 231.11: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c04.pdf

References: 1. American Medical Association. Current Procedural Terminology: CPT® 2025: Professional Edition. Chicago, IL: AMA Press; 2025. **2.** Revenue codes. Noridian Medicare. Accessed March 16, 2026. https://med.noridianmedicare.com/web/jfa/topics/claim-submission/revenue-codes

Product coding: HCPCS and NDC codes

HCPCS Level II codes (eg, J-codes) are alphanumeric codes used to report drugs and biologicals. Providers should confirm applicable coding and payer-specific billing requirements prior to claim submission.

Product codes[1]	
HCPCS (Level II) code	**Description**
C9399*†	Unclassified drugs or biologicals
J3490	Unclassified drugs
J3590	Unclassified biologics
J9999	Not otherwise classified, antineoplastic drugs

Payer requirements regarding the use of the 10- or 11-digit NDC may vary. Electronic data interchange (EDI) transactions generally require the use of the 11-digit NDC format. Providers should verify payer requirements for appropriate NDC reporting prior to claim submission.

Billable NDC for TREGZI (all components, located on Certificate of Analysis) [2]	
10-digit NDC	**11-digit NDC**
85866-223-04	85866-0223-04

Non-billable NDCs for individual components[2]	
HSPC: 85866-124-01	**Tcon:** 85866-126-01
Treg: 85866-125-01	**Tcon diluent:** 85866-127-01
Cassette label for Tcon: 85866-126-02	**Carton for Tcon Diluent:** 85866-127-02
Carton for Treg and HSPC: 85866-123-02	

FDA=US Food and Drug Administration; HCPCS=Healthcare Common Procedure Coding System; HSPC=hematopoietic stem and progenitor cell; NDC=National Drug Code; OPPS=Outpatient Prospective Payment System; Tcon=conventional T cell; Treg=regulatory T cell.

*Medicare Claims Processing Manual (Pub. 100-04), Chapter 17—Drugs and Biologicals—90.3—Hospital Outpatient Payment Under OPPS for New, Unclassified Drugs and Biologicals After FDA Approval But Before Assignment of a Product-Specific Drug or Biological HCPCS Code: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf

†A temporary code used by hospital outpatient departments to report a new or unclassified drug or biological when a product-specific HCPCS code has not yet been assigned.

References: 1. List of CPT/HCPCS codes. Centers for Medicare & Medicaid Services. Accessed October 15, 2025. https://www.cms.gov/medicare/regulations-guidance/physician-self-referral/list-cpt-hcpcs-codes **2.** TREGZI™ (allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq). Prescribing information. Orca Biosystems, Inc; 2026.

IMPORTANT SAFETY INFORMATION AND INDICATION[1]

WARNINGS AND PRECAUTIONS

Graft Failure: Graft failure has occurred after TREGZI administration. Screen TREGZI recipients for antidonor antibodies that may prevent engraftment. Monitor patients closely for laboratory evidence of hematopoietic recovery.

Graft-Versus-Host Disease: Acute and chronic Graft-Versus-Host disease (GVHD), including life-threatening and fatal cases, occurred following treatment with TREGZI. Acute GVHD manifests as maculopapular rash, gastrointestinal symptoms, and elevated bilirubin. Chronic GVHD may include skin rash, mouth sores, dry eyes, liver inflammation, and development of scar tissue in the skin and joints and damage to the lungs. Treat patients with a single agent calcineurin inhibitor as prophylaxis to decrease the risk of GVHD. Monitor for signs and symptoms of GVHD, and treat if GVHD develops.

Infusion Reactions: Infusion reactions (IRs) may occur during or following treatment with TREGZI. Serious hypersensitivity reactions including anaphylaxis may occur to DMSO, human serum albumin (HSA), Dextran or murine protein present in TREGZI. IRs may begin within minutes of the start of TREGZI infusion, although symptoms may continue to intensify and not peak for several hours after the completion of the infusion. Monitor patients for signs and symptoms of IRs during and after TREGZI administration. When a reaction occurs, pause the infusion and institute supportive care as needed. Premedicate patients with antipyretics and histamine antagonists prior to infusion to reduce the incidence and intensity of infusion reactions.

Secondary Malignancies and Malignancies of Donor Origin: Secondary malignancies and malignancies of donor origin may occur following treatment with TREGZI. Development of secondary malignancies, including posttransplantation lymphoproliferative disorder (PTLD) may occur many years after transplantation. PTLD manifests as a lymphoma-like disease favoring non-nodal sites. PTLD is usually fatal if not treated. Serial monitoring of blood for EBV DNA may be warranted in patients with persistent cytopenias. No patient treated with TREGZI has developed PTLD. Monitor for malignancies of donor origin and secondary malignancies. Contact Orca Bio at 1-877-411-6722 if any patient is diagnosed with a secondary malignancy or a malignancy of donor origin.

Transmission of Infectious Agents: Transmission of serious infectious or communicable disease or agents may occur with TREGZI treatment as it is derived from human donor blood and manufactured using animal-derived reagents. Risks of transmission of infectious agents may occur despite screening or testing of donors. Risks of transmission of serious infections include, but are not limited to, human immunodeficiency virus, human T cell lymphotropic virus (HTLV)-1 and -2, hepatitis B virus (HBV), hepatitis C virus (HCV), Treponema pallidum, Trypanosoma cruzi, West Nile virus (WNV), cytomegalovirus, transmissible spongiform encephalopathy agents and vaccinia. Monitor patients for signs and symptoms of infections, perform tests for infectious agents and treat as clinically indicated.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥ 20%) were mucositis, diarrhea, rash, viral infections, infections - pathogen unspecified, abdominal pain, vomiting, nausea, bacterial infections, hemorrhage, aGVHD, edema, and fungal infections.

The most common Grade 3-4 laboratory abnormalities (≥ 20%) are lymphocyte count decreased, platelet count decreased, leukocyte count decreased, neutrophil count decreased and hemoglobin decreased.

INDICATIONS AND USAGE

TREGZI 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-free survival, in the treatment of adults with hematological malignancies.

Please see accompanying full Prescribing Information.

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