TEMPLATE Letter of Appeal for
TREGZI (allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq)

This sample letter is provided for demonstration purposes only and is intended to guide an authorized treatment center (ATC) or hospital in presenting clinical rationale when submitting an appeal to overturn a denial of coverage for TREGZI (allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq). The template outlines suggested language and structure to support clinical decision-making and highlights the types of documentation that can be expected in an appeal submission.

Recommended attachments to accompany the letter of appeal include, but are not limited to, the original prior authorization (PA) form and letter of medical necessity previously submitted, a copy of the denial notice or explanation of benefits (EOB), and any additional clinical or supporting documentation relevant to the appeal.

DISCLAIMERS:
Use of this template does not guarantee coverage or reimbursement and does not replace the independent medical judgment of the ATC or hospital. Orca Bio cannot complete or submit prior authorization forms or write letters of medical necessity or appeal on a patient's behalf but may provide general information, education, and sample templates.

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.

IMPORTANT SAFETY INFORMATION

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 **Prescribing Information**

[Physician's Letterhead]

[Date]

[Name of Payer Contact at Hospital]

[Contact Title]

[Name of Payer][Address]
[City, State, ZIP Code]

RE: Appeal for [Brand Name (generic name)]

Patient: [Patient Name]

Date of Birth: [Date]

Diagnosis: [Diagnosis]

Member ID: [Number]

Group Number: [Number]

Policyholder: [Policyholder Name]

Dear [Payer Reviewer]:

I am writing to request an expedited appeal to the denial of coverage for TREGZI In a letter dated [Date of Denial Letter], [Payer Name] stated that TREGZI is not covered for [Patient Name] due to [Reason(s) for Denial]. I have reviewed this letter and, based on my medical expertise, ask that you reconsider this decision with regard to the following clinical information. I believe TREGZI is medically necessary for my patient, [Patient Name], based on their [Diagnosis] and [Add Other Clinically Relevant Information, such as patient's symptoms and prior treatment(s) history].

Listed below are the patient's diagnosis, medical history, and treatment plan, which confirm the medical necessity and appropriateness of treatment with TREGZI.

Patient's diagnosis, medical history, and treatment plan

[Insert information regarding the patient's diagnosis, medical history, such as prior lines of therapies and the patient's response to those therapies, and treatment plan]

Thank you for your attention on this matter

Sincerely,

[Prescribing Physician Name and Credentials]
[NPI Number]

Enclosed Documents: [Original PA (prior authorization form), Original Letter or Medical Necessity, a copy of the denial notice or explanation of benefits (EOB), Other examples of possible enclosed documents: Phase 3 Manuscript and Supplement, Prescribing Information, Clinical Notes and Patient Medical Records]

IMPORTANT SAFETY INFORMATION (CONT'D)

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.

Please see accompanying full Prescribing Information.