AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

Drug Requested: Tregzi™ (allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq) **(J3490/C9399) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

Requested Medication is ONE of the following:

- ❑ New Start
- ❑ Continuation of therapy – provide therapy start date: _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Maximum Dose: 1 treatment per lifetime (single dose of four infusions)

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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	1.3×10^6 to 3.5×10^6
Tcons	Intravenous, once, on Day +2 or +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 or +3 (after HSPC infusion on Day 0)	30 mL

HSPC – Hematopoietic stem and progenitor cells; Tregs – Regulatory T-cells; Tcons – Conventional T-cells.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Coverage will be provided for one treatment course (single dose of four infusions) and may NOT be renewed.

- ❑ Member is 18 years of age or older
- ❑ Medication is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center
- ❑ Member is diagnosed with **ONE** of the following: Acute myeloid, lymphoid, or mixed phenotype leukemia in complete remission (CR) or CR with incomplete hematologic recovery, with or without the presence of known minimal residual disease; Myelodysplastic syndromes (MDS) and/or have therapy-related/secondary MDS, with ≤ 10% blast burden in the bone marrow **(submit documentation)**
- ❑ Treatment will be used with an appropriate myeloablative preparative regimen (must include BFT or other busulfan-based regimen, cyclophosphamide/total body irradiation [TBI], or etoposide/TBI) as part of an allogeneic hematopoietic stem cell transplant procedure (allo-HSCT)
- ❑ Member has an intermediate- or high-risk Disease Risk Index (DRI)
- ❑ Medication is being used for the prevention of chronic graft-versus-host disease
- ❑ Member has **NOT** had a prior allogeneic HSCT and has not had prior treatment with Tregzi
- ❑ Member must be matched to an 8/8 HLA-matched related or unrelated donor
- ❑ Member has been screened for anti-donor antibodies prior to receiving therapy
- ❑ Member will receive concomitant therapy with oral tacrolimus starting on the day following Tcon infusion **(verified by chart notes and/or pharmacy paid claims)**
- ❑ Member will be monitored for malignancies of donor origin and secondary malignancies

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- ❑ Member will be monitored for severe hypersensitivity reactions including anaphylaxis which may occur due to DMSO, human serum albumin (HSA), Dextran or murine protein, during and after treatment infusion
- ❑ Member does **NOT** have any clinically important infections prior to transplant and will be monitored for signs and symptoms of infections and treated as clinically indicated
- ❑ Member is **NOT** currently receiving corticosteroids or other immunosuppressive therapy [**Note: Topical corticosteroids or oral systemic corticosteroid doses < 10 mg/day are allowed]**

Reauthorization Criteria – Coverage cannot be renewed. Tregzi is indicated as a one-time infusion only. Repeat administration has not been studied and safety and efficacy of additional doses have not been established; additional infusions are therefore **NOT** authorized.

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR
- ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: 9/24/2026
REVISED/UPDATED/REFORMATTED: 10/16/2026