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: Tzield™ (teplizumab) (J9381) (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: _____ **Height:** _____ **BSA:** _____ **Date:** _____

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.

Quantity Limits:

- Stage 2, Type 1 Diabetes: 1 single dose vial daily for 14 days
- Stage 3, Type 1 Diabetes: 1 single dose vial daily for 12 days and repeated 6 months later

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Recommended Dosage:

Stage 2, Type 1 Diabetes	
Day(s)	**Daily Dosage**
1	65 mcg/m^2
2	125 mcg/m^2
3	250 mcg/m^2
4	500 mcg/m^2
5 through 14	1030 mcg/m^2

Stage 3, Type 1 Diabetes	
Day(s)	**Daily dosage**
1	106 mcg/m^2
2	425 mcg/m^2
3 through 12	850 mcg/m^2

- Premedicate prior to each of the first 5 days of infusion: (1) nonsteroidal anti-inflammatory drug (NSAID) or acetaminophen, (2) an antihistamine, and/or (3) an antiemetic. Additional doses may be administered if needed.

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.

❑ **DIAGNOSIS: Diabetes mellitus, type 1, delay onset of symptomatic disease (stage 3)**

Coverage will be provided for one 14-day treatment course and may not be renewed.

- ❑ Member is ≥ 1 year of age
- ❑ Prescribed by or in consultation with an endocrinologist
- ❑ Member has a confirmed diagnosis of Stage 2 Type 1 Diabetes as documented by **BOTH** of the following:
  - ❑ Member has at least **TWO** of the following pancreatic islet cell autoantibodies:
    - ❑ Glutamic acid decarboxylase 65 (GAD) autoantibodies
    - ❑ Insulin autoantibody (IAA)
    - ❑ Insulinoma-associated antigen 2 autoantibody (IA-2A)
    - ❑ Zinc transporter 8 autoantibody (ZnT8A)
    - ❑ Islet cell autoantibody (ICA)
  - ❑ Dysglycemia without overt hyperglycemia using oral glucose test defined by **ONE** of the following as:
    - ❑ Fasting glucose 100-125 mg/dL
    - ❑ 2-hour postprandial plasma glucose 140-199 mg/dL
    - ❑ An intervening postprandial glucose level at 30, 60, or 90 minutes of ≥ 200 mg/dL
- ❑ Member does **NOT** have Stage 1 or Stage 3 Type 1 Diabetes

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- ❑ Member does **NOT** have Type 2 Diabetes
- ❑ Member is up to date with all vaccinations prior to initiating therapy
- ❑ Member will **NOT** receive live or live-attenuated vaccines within 8 weeks **OR** inactivated or mRNA vaccines within 2 weeks before or during treatment
- ❑ Member does **NOT** have an active infection
- ❑ Member has been evaluated for acute infection with Epstein-Barr virus (EBV) or cytomegalovirus (CMV)
- ❑ Member does **NOT** have any of the following:
  - Lymphocyte count < 1,000 lymphocytes/mcL
  - Hemoglobin < 10 g/dL
  - Platelet count < 150,000 platelet/mcL
  - Absolute neutrophil count < 1,500 neutrophils/mcL
  - Elevated ALT or AST > 2 times the upper limit of normal (ULN)
  - Bilirubin > 1.5 times ULN
- ❑ Requested medication will be used as single agent therapy

❑ **DIAGNOSIS: Diabetes mellitus, type 1, recently diagnosed with symptomatic disease (stage 3)**

Coverage will be provided for two 12-day treatment courses and may not be renewed.

- ❑ Member is between the ages of 8 and 17
- ❑ Prescribed by or in consultation with an endocrinologist
- ❑ Member has a confirmed diagnosis of Stage 3 Type 1 Diabetes as documented by **BOTH** of the following:
  - ❑ Member must meet **BOTH** of the following:
    - ❑ Presence of at least **ONE** of the following pancreatic islet cell autoantibody
      - ❑ Glutamic acid decarboxylase 65 (GAD) autoantibodies
      - ❑ Insulin autoantibody (IAA)
      - ❑ Insulinoma-associated antigen 2 autoantibody (IA-2A)
      - ❑ Zinc transporter 8 autoantibody (ZnT8A)
      - ❑ Islet cell autoantibody (ICA)
    - ❑ Peak C-peptide ≥ 0.2 pmol/mL on a mixed-meal tolerance test (if a mixed meal tolerance test is not available, an alternative method for measuring peak C-peptide ≥ 0.2 pmol/mL may be appropriate).
  - ❑ Member is newly diagnosed with Stage 3 Type 1 Diabetes (within 8 weeks of request):
    - Date of diagnosis: _____

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- ❑ Member does **NOT** have Stage 1 or Stage 2 Type 1 Diabetes
- ❑ Member does **NOT** have Type 2 Diabetes
- ❑ Member has **NOT** received a prior course of teplizumab (Tzield™) or donislecel (Lantidra™)
- ❑ Member is up to date with all vaccinations prior to initiating therapy
- ❑ Member will **NOT** receive live or live-attenuated vaccines within 8 weeks **OR** inactivated or mRNA vaccines within 2 weeks before or during treatment
- ❑ Member does **NOT** have an active infection
- ❑ Member has been evaluated for acute infection with Epstein-Barr virus (EBV) or cytomegalovirus (CMV)
- ❑ Member does **NOT** have any of the following:
  - Lymphocyte count < 1,000 lymphocytes/mcL
  - Hemoglobin < 10 g/dL
  - Platelet count < 150,000 platelet/mcL
  - Absolute neutrophil count < 1,500 neutrophils/mcL
  - Elevated ALT or AST > 2 times the upper limit of normal (ULN)
  - Bilirubin > 1.5 times ULN
- ❑ Requested medication will be used as single agent therapy
- ❑ Requested medication will be administered in accordance with the Food and Drug Administration dosing guidelines including a total of two 12-day courses given 6 months apart

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: ~~2/16/2023; 5//23/2024; 5/28/2026;~~ **9/24/2026**
REVISED/UPDATED/REFORMATTED: ~~3/9//2023; 5/14/2024; 6/5/2024; 7/10/2026;~~ **10/16/2026**