SENTARA COMMUNITY PLAN
(MEDICAID)

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 1-844-305-2331**. 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 Sentara #: _____ **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:** _____

- ❑ 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

(Continued on next page)

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, stage 2, delay onset of symptomatic disease**

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

- ❑ Provider will confirm that member is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy
- ❑ Member does not have an active infection including clinically important localized infections
- ❑ Member has been evaluated for the absence of active Epstein-Barr virus (EBV) or cytomegalovirus (CMV) infection
- ❑ Provider will confirm that member will not receive live or live-attenuated vaccines within 8 weeks OR inactivated or mRNA vaccines within 2 weeks, prior to or during treatment
- ❑ Provider will confirm that therapy will not be used as a disease modifying therapy in non-autoimmune dysglycemic conditions
- ❑ Member has a confirmed diagnosis of Stage 2 Type 1 Diabetes as documented by the following:
  - ❑ Confirmation that the member's diagnosis is of autoimmune origin and does not suggest insulin resistance due to obesity, type 2 diabetes or dysglycemia due to other forms of diabetes (including, but not limited to, genetic forms of diabetes, maturity-onset diabetes of the young [MODY], latent autoimmune diabetes in adults [LADA], or diabetes secondary to medications or surgery)
- ❑ Member will receive treatment to delay the onset of Stage 3 type I diabetes
  - ❑ For members ≥ 1 year of age to < 18 years of age:
    - ❑ Confirmation of two or more of the following pancreatic islet cell autoantibodies:

(Continued on next page)

- ❑ Glutamic acid decarboxylase 65 (GAD65) autoantibodies
- ❑ Insulin autoantibody (IAA)
- ❑ Insulinoma-associated antigen 2 autoantibody (IA-2A)
- ❑ Zinc transporter 8 (ZnT8A) autoantibody
- ❑ Islet cell autoantibody (ICA)

❑ Confirmation of dysglycemia without overt hyperglycemia using an oral glucose tolerance test (if an oral glucose tolerance test is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be appropriate) defined as one of the following:

- ❑ Fasting 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
- ❑ A1C 5.7-6.4% or ≥ 10% increase in A1C

❑ For members ≥ 18 years of age to < 45 years of age:

❑ Confirmation of dysglycemia without overt hyperglycemia using an OGTT (if an OGTT is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be appropriate) defined as one of the following:

- ❑ 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
- ❑ A1C 5.7-6.4% or ≥ 10% increase in A1C

❑ Member does **NOT** have any of the following laboratory indices:

- 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

❑ Member has not received prior therapy with teplizumab

(Continued on next page)

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

Coverage will be provided for 12 doses for initial approval, may be renewed for one additional treatment course for a total of 12 doses.

- ❑ Member is between the ages of 8 and 17
- ❑ Member has been recently (i.e., within the previous 8 weeks) diagnosed with Stage 3 type 1 diabetes (T1D)
- ❑ Member will receive treatment to delay the decline in endogenous insulin production based on confirmation of **BOTH** of the following:
  - ❑ Confirmation of at least one of the following pancreatic islet cell autoantibodies:
    - ❑ Glutamic acid decarboxylase 65 (GAD) autoantibodies
    - ❑ Islet antigen 2 (IA-2) autoantibodies
    - ❑ Zinc transporter 8 (ZnT8) autoantibodies
    - ❑ Islet cell cytoplasmic autoantibodies (ICA)
    - ❑ Insulin autoantibodies (if testing obtained within the first 14 days of insulin treatment)
  - ❑ 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 has **NOT** received a prior course of teplizumab (Tzield™)
- ❑ Provider will confirm member is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy
- ❑ Provider will confirm that 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, including clinically important localized infections
- ❑ Member has been evaluated for the absence of active Epstein-Barr virus (EBV) or cytomegalovirus (CMV) infection
- ❑ Member does **NOT** have any of the following laboratory indices:
  - 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

(Continued on next page)

- ❑ 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

Reauthorization: 12 additional doses. All criteria that apply must be checked for approval. To support each line checked, all documentation (lab results, diagnostics, and/or chart notes) must be provided or request may be denied.

- ❑ Member continues to meet the relevant criteria identified in the initial criteria
- ❑ Member is being continuously monitored for a beneficial response to therapy
- ❑ Member has an absence of unacceptable toxicity from the drug

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 Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan'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**
REVISED/UPDATED/REFORMARTTED: ~~3/9//2023; 5/14/2024; 6/5/2024; 6/15/2026;~~ **8/11/2026**