Louisiana Medicaid
Teplizumab-mzwv (Tzield™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for teplizumab-mzwv (Tzield™).

Additional Point-of-Sale edits may apply.

*This agent may have a **Black Box Warning**, and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety Regulations. Please refer to individual prescribing information for details.*

Approval Criteria

- The recipient is 8 years of age or older on date of the request; **AND**
- The recipient has a diagnosis of Stage 2 type 1 diabetes; **AND**
- The recipient has at least **TWO** of the following pancreatic islet autoantibodies (must be **stated on the request):**
    - 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); **AND**
- The recipient has dysglycemia defined by **ONE** of the following: (Confirmation of dysglycemia must be conducted within the 7-week period before the date of the request, and results with associated dates must be **stated on the request**)
    - Fasting blood glucose greater than 110mg/dL and less than 126 mg/dL; **OR**
    - Oral glucose tolerance test (OGTT) resulting in a 2-hour plasma glucose level greater than or equal to 140 mg/dL and less than 200 mg/dL; **OR**
    - Oral glucose tolerance test (OGTT) resulting in a 30-, 60-, or 90-minute plasma glucose level greater than or equal to 200 mg/dL; **AND**
- This medication is prescribed by an endocrinologist; **AND**
- The following are true and **stated on the request**:
    - The recipient does not have a clinical history that suggests type 2 diabetes; **AND**
    - The recipient does not have Stage 3 type 1 diabetes, whether previously diagnosed or detected at screening (fasting glucose greater or equal to 126 mg/dL or 2-hour plasma glucose greater than or equal to 200 mg/dL); **AND**
    - The recipient has never completed a 14-day treatment course of teplizumab-mzwv (Tzield™); **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, prior treatment requirements and required storage and handling procedures; **AND**

- All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
- The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of approval: 14 days – ONE 14-day treatment course allowed per lifetime

References

ClinicalTrials.gov. Teplizumab for Prevention of Type 1 Diabetes In Relatives "At-Risk". https://clinicaltrials.gov/ct2/show/NCT01030861

Tzield (teplizumab-mzwv) [package insert]. Red Bank, NJ: Provention Bio, Inc; November 2022. https://static1.squarespace.com/static/5f4574ed93f3456c76f3a95d/t/638f76b5ec1e430049cf4cd9/1670346457470/tzield-full-prescribing-information.pdf

Revision / Date	Implementation Date
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