Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 283.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Tzield (teplizumab-mzwv)

I. Policy:
Tzield (teplizumab-mzwv)

II. Purpose/Objective:
To provide a policy of coverage regarding Tzield (teplizumab-mzwv)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Tzield (teplizumab-mzwv) binds to CD3 (a cell surface antigen) on both CD4+ and CD8+ T cells, which leads to an increase in the proportion of regulatory T cells and of exhausted CD8+ T cells in peripheral blood. The mechanism behind the delay in progression from stage 2 to stage 3 type 1 diabetes mellitus may involve partial agonistic signaling and deactivation of pancreatic beta cell autoreactive T lymphocytes.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Tzield (teplizumab-mzwv) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Medical record documentation of a diagnosis of Stage 2 Type 1 Diabetes (T1D) confirmed by both of the following:
    - Medical record documentation at least two positive pancreatic islet cell autoantibodies **AND**
    - Medical record documentation of dysglycemia without overt hyperglycemia using an oral glucose tolerance test (OGTT) [if an OGTT is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be appropriate]

  AND
- Medical record documentation or provider attestation that the clinical history of the patient does not suggest Type 2 Diabetes (T2D) **AND**
- Medical record documentation that member is 8 years of age or older **AND**
- Medical record documentation that Tzield is prescribed by or in consultation with an endocrinologist.

Note to reviewer: Pancreatic Islet Autoantibodies include:
- Glutamic Acid Decarboxylase 65 (GAD) Autoantibodies
- Insulin Autoantibodies (IAA)
- Insulinoma-Associated Antigen 2 Autoantibodies (IA-2A)
- Zinc Transporter 8 Autoantibodies (ZnT8A)
- Islet Cell Autoantibodies (ICA)

AUTHORIZATION DURATION: Approval will be for 14 days. Authorization of Tzield should not exceed the FDA-approved treatment duration of 14 days. For requests exceeding the above limit, medical record documentation of the following is required:
- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:
1. Tzield [prescribing information]. Red Bank, NJ: Provention Bio Inc; November 2022.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 5/16/23

Revised: 12/28/23 (references added)

Reviewed: 5/14/24

MA UM Committee approval: 12/31/23