TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Teplizumab-mzwv (Tzield®)	**CRITERIA ID:** TX.CC.PHAR.23
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy, Medical Directors, Claims
EFFECTIVE DATE: 7/1/2023	**PRODUCT(S):** STAR, STAR PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 04/03/2024, 3/25/2025	**REGULATOR MOST RECENT APPROVAL DATE(S):** N/A

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for Tzield® (teplizumab-mzwv).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

This medication is a non-risk based (NRB) payment drug and should follow state guidance for medical necessity review for Medicaid/CHIP due to the manner in which it is reimbursed. All determinations will be performed by a Medical Director. A pharmacy clinician will review the prior authorization request and make a recommendation to the Medical Director but will not make the ultimate determination on any case.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
T1D – Type 1 diabetes

POLICY:
It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of teplizumab-mzwv (Tzield®); procedure code: J9381.

Description/Mechanism of Action:
Teplizumab-mzwv (Tzield®) is a CD3-direct antibody.

FDA Approved Indication(s):
Teplizumab-mzwv (Tzield®) is indicated:

- To delay the onset of Stage 3 Type 1 diabetes (T1D) in adult and pediatric clients 8 years and above with Stage 2 T1D.

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria:

A. Prevention of Stage 3 Type 1 diabetes (T1D):

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization but ultimate determination will be made by the Medical Director only.
2. The client is 8 years or older.
3. The client has a diagnosis of Stage 2 T1D confirmed by the following (a and b):
    a. Documentation of at least two of the following positive pancreatic islet autoantibodies (i-v):
        i. Islet cell autoantibody (ICA)
        ii. Insulinoma-associated antigen 2 autoantibody (IA-2A)
        iii. Insulin autoantibody (IAA)
        iv. Zinc transporter 8 autoantibody (ZnT8A)
        v. Glutamic acid decarboxylase 65 (GAD) autoantibodies
    b. Documentation of dysglycemia without overt hyperglycemia using oral glucose tolerance test (OGTT) or another appropriate test for dysglycemia may be used if OGTT is not available
4. Clinical history does not suggest the client has Type 2 diabetes.
    Note: Tzield is given to delay the onset of Stage 3 T1D. The use of Tzield is not approved in Type II diabetes or any other stages of Type I diabetes other than Stage 2 T1D
5. Prescriber must obtain and assess a complete blood count and liver enzymes tests before initiating treatment with Tzield.
    Note: Tzield is not recommended in clients with specific lab abnormalities
6. Prescriber must assess the client's history of chronic infection and monitor for any signs of serious active infection while on Tzield. If a serious infection develops, Tzield therapy should be discontinued.

Approval duration: 14 days

REFERENCES:
Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook.

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document	N/A	07/01/23
Ad Hoc review	Updated to TX.CC.PHAR format template Added Centene copyright statement and requirement for NRB policy requiring all final determination by a medical director	04/03/24
Annual review	Correction for TID under criteria 4. to T1D	3/25/2025