

PA Criteria	Criteria Details						
<b>Covered Uses (FDA approved indication)</b>	Tzield injection is a CD3-directed antibody indicated to delay the onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric patients aged 8 years and older with Stage 2 T1D, to be given with dosing based on body surface area and administered once daily for 14 days. Currently, there are no compendia supported uses for this therapy outside the FDA-indication(s).						
<b>Exclusion Criteria</b>	Must not have a history of type 2 diabetes.						
<b>Required Medical Information</b>	<p>Medical records supporting the request must be provided, including autoantibody test results – AND – Must provide patient’s current weight and height.</p> <p>For approval, the following must be met:</p> <ul style="list-style-type: none"> <li>• Must have documentation of at least two of the following autoantibodies: <ul style="list-style-type: none"> <li>» Glutamic acid decarboxylase 65 (GAD) autoantibody:</li> <li>» Insulin autoantibody (IAA)</li> <li>» Insulinoma-associated antigen 2 autoantibody (IA-2A)</li> <li>» Zinc transporter 8 autoantibody (ZnT8A)</li> <li>» Islet cell autoantibody (ICA)</li> </ul> </li> <li>• Must have documentation of dysglycemia defined as meeting one of the following: <ul style="list-style-type: none"> <li>» A fasting glucose level of 110 to 125 mg/dL – or –</li> <li>» A two-hour postprandial plasma glucose level of at least 140 mg/dL but less than 200 mg/dL – or – A postprandial glucose level more than 200 mg/dL on two occasions</li> </ul> </li> </ul>						
<b>Age Restriction</b>	Must be 8 years of age or older.						
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, an endocrinologist.						
<b>Coverage Duration</b>	One, 14-day course in accordance with the FDA-approved labeling.						
<b>Other Criteria/Information</b>	<p>Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.</p> <table border="1" data-bbox="496 1444 1511 1585"> <thead> <tr> <th>HCPCS</th> <th>Description</th> <th>Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td>J9381</td> <td>Tzield (teplizumab-mzww) injection</td> <td><b>Billing unit: 5 mcg</b>  2mg/2mL SDV</td> </tr> </tbody> </table>	HCPCS	Description	Billing Units/How Supplied	J9381	Tzield (teplizumab-mzww) injection	<b>Billing unit: 5 mcg</b>  2mg/2mL SDV
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STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	8/21/2025	Pharmacy & Therapeutics (P&T) Committee	8/21/2025