

Prior Authorization Criteria <u>Tzield (teplizumab-mzwv)</u>

All requests for Tzield (teplizumab-mzwv) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage may be provided with a diagnosis of **Type 1 diabetes** (**T1D**) and the following criteria is met:

- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.
- Must be age-appropriate according to FDA-approved labeling, nationally recognized compendia, or evidence-based practice guidelines
- Documentation the member has Stage 2 T1D confirmed by one of the following:
 - o At least 2 positive pancreatic islet autoantibodies
 - 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)
 - 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 must be documented)
- Documentation Type 2 diabetes has been ruled out based on clinical history
- Documentation the member has had a complete blood count and liver enzyme tests
- **Initial Duration of Approval:** 1 month
- Reauthorization criteria
 - o None one time infusion over 14 days

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.



TZIELD (TEPLIZUMAB-MZWV) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Wholecare Pharmacy Services. **FAX:** (888) 245-2049

1.1	ole to Highmark Wholecare l	•					
If needed, you may call to speak to a Pharmacy Services Representative. PHONE : (800) 392-1147 Mon – Fri 8:30am to 5:00pm PROVIDER INFORMATION							
Requesting Provider: Provider NPI:							
Provider Specialty:			Office Contact:				
State license #:			Office NPI:				
Office Address:			Office Phone:				
			Office Fax:				
MEMBER INFORMATION							
Member Name:	DOB:						
Member ID:		Member weight:	Height:				
REQUESTED DRUG INFORMATION							
Medication: Streng			th:				
Directions:		Quantity:	ity: Refills:				
Is the member currently receiving rec	quested medication? Yes	☐ No Date	e Medication Initiated:				
		nformation					
		ically, JCODE:					
Place of Service: Hospital		per's home Other					
	Place of Serv	vice Information					
Name:			NPI:				
Address:		Phone:	Phone:				
	ACEDICAL INGENIA						
D	MEDICAL HISTORY (equests)				
Diagnosis:		ICD Code:					
Please mark all that apply:	C-11	dib a di a a					
1. The members is positive for the	<u> </u>	tibodies					
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)							
2. The member has decolerance without event hymeral vector and always telegrape test							
2. The member has dysglycemia without overt hyperglycemia using an oral glucose tolerance test Yes No (if an oral glucose tolerance test is not available, an alternative method for diagnosing dysglycemia without							
overt hyperglycemia must be documented)							
Jr . g J	,						
3. Type 2 diabetes has been ruled out (please submit documentation)							
Ŭ Yes □ No							
4. The member has had a complete blood count and liver enzyme test							
☐ Yes ☐ No CURRENT or PREVIOUS THERAPY							
Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)				



VV FIOLECAKE SUPPORTING INFORMATION or CLINICAL RATIONALE				
Prescribing Provider Signature	Date			



DRUG NAME

PRIOR AUTHORIZATION FORM (CONTINUED)- PAGE 2 of 2

1		as applicable to Highmark Wholecare Pharmacy Services. FAX: (888) 245-2049						
If needed, you may call to speak to a Pharmacy Services Representative. PHONE : (800) 392-1147 Mon – Fri 8:30am to 5:00pm								
MEMBER INFORMATION								
Member Name:		DOB:						
Member ID:		Member weight:	Height:					
MEDICAL HISTORY (Complete for ALL requests)								
Add questions or options for providing information as needed.								
Yes No								
☐ Yes ☐ No								
Yes No								
CURRENT or PREVIOUS THERAPY								
Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)					
REAUTHORIZATION								
Add questions as needed								
Has the member experienced an improvement with treatment? \[Yes \[No \]								
SUPPORTING INFORMATION or CLINICAL RATIONALE								
Prescribing Provider Signature			Date					
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