# Teplizumab

**Goal(s):**
- To promote safe and effective use in populations with established benefit:
  - Teplizumab has benefit for *prevention* of type 1 diabetes mellitus (T1DM) in members with stage 2 disease (defined below based on lab testing).
  - Benefit has not been established for symptomatic (stage 3) T1DM or members who do not meet the definition for stage 2 disease (defined below).

**Length of Authorization:**
- One 14-day treatment course.

**Requires PA:**
- All provider-administered and pharmacy point-of-sale claims for teplizumab

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. Is the request for an FDA approved age (e.g. 8 years of age or older)? | **Yes:** Go to #2 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 2. Has the patient previously been treated with teplizumab (use beyond the original 14 day infusion)? | **Yes:** Pass to RPh. Deny; medical appropriateness. No evidence to support additional doses. | **No:** Go to #3 |
| 3. Is the medication prescribed by or in consultation with an endocrinologist? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 4. Does the patient meet the standard criteria for the diagnosis of type 1 diabetes as determined as having one of the following:<br>- HbA1c of 6.5% or higher **OR**<br>- Fasting plasma glucose (FPG) of 126 mg/dL or higher **OR**<br>- Oral glucose tolerance test (OGTT) of 200 mg/dL or higher? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #5 |
| 5. Have baseline liver function tests and complete blood panel been evaluated in the past 2 months? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 6. Has the patient received, or have contraindications to, all routine immunizations recommended for their age based on provider attestation of immunization history?<br><br>Note:<br>- Teplizumab labeling recommends administration of live-attenuated vaccines at least 8 weeks prior to treatment and inactivated (killed) vaccines or mRNA vaccines at least 2 weeks prior to treatment.<br>- Routine vaccinations for patients at least 8 years of age typically include hepatitis B, hepatitis A, diphtheria, tetanus, pertussis, pneumococcal conjugate, inactivated poliovirus, influenza, and at least 2 doses of measles, mumps, rubella, and varicella. | **Yes:** Go to #7<br><br>Document provider attestation of immunization history. | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is the person at high risk of developing T1DM (e.g. Stage 2 diabetes) as determined by having the following:<br>- Presence of two or more diabetes-related autoantibodies (e.g. insulin autoantibodies (IAA), islet cell antibodies (ICA), glutamic acid decarboxylase 65 (GAD) autoantibodies, insulinoma-associated antigen 2 autoantibody (IA-2A), zinc transporter 8 autoantibody (ZnT8A)) **AND**<br>- Abnormal glucose confirmed within the last 2 months as determined by:<br>  - An abnormal glucose during an OGTT (140-199 mg/dL) **OR**<br>  - FPG 100-125 mg/dL **OR**<br>  - HbA1c 5.7-6.4% or ≥10% increase in HbA1c **OR**<br>  - 2-hour plasma glucose 140-199 mg/dL<br><br>Note: Teplizumab is preventative therapy and not approved at this time for people diagnosed with symptomatic T1DM (e.g. Stage 3) | **Yes:** Approve for one 14-day course. | **No:** Pass to RPh. Deny; medical appropriateness. |