

Teprotumumab

Goal(s):

- To ensure appropriate use of teprotumumab in patients with Thyroid Eye Disease (TED)

Length of Authorization:

- 8 total lifetime doses (approve for 9 months)

Requires PA:

- Teprotumumab (pharmacy and provider administered claims)

Covered Alternatives:

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

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code. Go to #2	
2. Is the patient an adult (18 years or older)?	Yes: Go to #3	No: Pass to RPh. Deny; medical appropriateness
3. Is the medication being ordered by, or in consultation with, an ophthalmologist or specialized ophthalmologist (e.g. neuro-ophthalmologist or ocular facial plastic surgeon)?	Yes: Go to #4	No: Pass to RPh. Deny; medical appropriateness
4. Does the patient have moderate, severe, or sight-threatening TED? <ul style="list-style-type: none"> Defined by the Graves' Orbitopathy Severity Assessment. Possible severity ratings are mild, moderate, severe, and sight-threatening. 	Yes: Go to #5	No: Pass to RPh. Deny; medical appropriateness
5. Does the patient have active TED? <ul style="list-style-type: none"> Defined as Clinical Activity Score (CAS) of 4 or higher on 7 point scale within past 3 months. 	Yes: Go to #6 CAS score: _____ Score date: _____	No: Go to #8

Approval Criteria

<p>6. Does the patient have <u>any</u> of the following:</p> <ul style="list-style-type: none"> • active viral hepatitis, chronic liver disease, or a significant chronic infection <u>or</u> • a contraindication or severe side effect* to intermediate or high dose* corticosteroids <u>or</u> • failed to respond to 6 weeks of low-dose corticosteroid prophylaxis after radioactive iodine treatment <u>or</u> • failed to respond/relapsed after at least 3 weeks of intermediate or high dose* (IV or oral) corticosteroids <p>*Note:</p> <ul style="list-style-type: none"> • Teprotumumab is associated with hyperglycemia which may necessitate diabetic medication changes and may not be an appropriate alternative when avoiding steroids in patients with uncontrolled diabetes mellitus. • Steroid regimens may vary. Example intermediate steroid regimen: 0.5 g/week for 6 weeks then 0.25 g/week for additional 6 weeks for cumulative dose 4.5 g IV methylprednisolone over ~ 3 months. Example high-dose steroid regimen: IV methylprednisolone 0.75 g/week for 6 weeks then 0.5 g/week for 6 weeks. 	<p>Yes: Go to #9</p>	<p>No: Go to #7</p>
<p>7. Does the patient have documentation of diplopia or significant proptosis*?</p> <p>*Note: significant proptosis is defined as ≥ 3 mm above the upper limit for race and sex or < 3 mm but of sufficient severity to impact daily quality of life.</p>	<p>Yes: Go to #9</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>8. Does the patient have inactive TED?</p>	<p>Yes: Go to #9</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>

Approval Criteria

<p>9. Is the patient of childbearing potential?</p> <p>Not considered of childbearing potential any of the following:</p> <ul style="list-style-type: none"> • Onset of menopause >2 years before current date <u>or</u> • Non-therapy-induced amenorrhea >12 months before current date <u>or</u> • Surgically sterile (absence of ovaries and/or uterus, or tubal ligation) <u>or</u> • Not sexually active 	<p>Yes: Go to #10</p>	<p>No: Go to #12</p>
<p>10. Is there documentation of negative pregnancy test within past 4 weeks?</p>	<p>Yes: Go to #11</p> <p>Type of test (urine or serum): _____</p> <p>Date of test: _____</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>11. Has the provider attested that the patient has been counselled on risk of fetal harm AND agreed to use <u>at least</u> one reliable form of contraceptive for entire duration of drug therapy <u>and</u> for 180 days (6 months) after final dose?</p> <ul style="list-style-type: none"> • Reliable forms of birth control have less than 1% failure rate/year with consistent and correct use • Examples include: implants, injectables, combined oral/intravaginal/transdermal contraceptives, intrauterine devices, sexual abstinence, or vasectomized partner • Hormonal methods should be started at least one full menstrual cycle prior to initiation of teprotumumab. 	<p>Yes: Go to #12</p> <p>Contraceptive method: _____</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>12. Is there documentation that there has been a risk/benefit discussion with the patient related to risk of potentially permanent hearing impairment with teprotumumab AND documentation of a plan to assess/monitor hearing before, during, and after treatment?</p>	<p>Yes: Go to #13</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>

Approval Criteria

13. Has the patient previously received any doses of teprotumumab?

Yes: Approve balance to allow 8 total lifetime doses[†]

(8 doses – previous # doses = current approval #)

Previous number of doses _____

No: Approve 8 doses[†]

[†] All approvals will be referred for and offered optional case management

*P&T/DUR Review : 4/24 (SF); 12/20 (SF)
Implementation: 5/1/24; 1/1/2021*