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 **active** TED? • Defined as Clinical Activity Score (CAS) of 4 or higher on 7 point scale within past 3 months.	**Yes:** Go to #5 CAS score:_____ Score date:_____	**No:** Pass to RPh. Deny; medical appropriateness
5. Does the patient have **moderate**, **severe**, or **sight-threatening** TED? • Defined by the Graves' Orbitopathy Severity Assessment • Possible severity ratings are mild, moderate, severe, and sight-threatening.	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Is the patient currently euthyroid (thyroid hormone levels no more than 50% above or below of normal range) within past 3 months?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
7. Does the patient have any of the following: • a contraindication or severe side effect* to corticosteroids or • failed to respond to 6 weeks of low-dose corticosteroid prophylaxis after radioactive iodine treatment or • failed to respond/relapsed after at least 3 weeks of high-dose (IV or oral) corticosteroids *Note: • 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.	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness
8. Is the patient of childbearing potential? Not considered of childbearing potential any of the following: • Onset of menopause >2 years before current date or • Non-therapy-induced amenorrhea >12 months before current date or • Surgically sterile (absence of ovaries and/or uterus, or tubal ligation) or • Not sexually active	**Yes:** Go to #9	**No:** Go to #11
9. Is there documentation of negative pregnancy test within past 4 weeks?	**Yes:** Go to #10 Type of test (urine or serum): _____ Date of test:_____	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
10. Has patient 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? • 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.	**Yes:** Go to #11 Date of Counselling: _____ Contraceptive method:_____	**No:** Pass to RPh. Deny; medical appropriateness
11. 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