

Specialty Pharmacy Watch:

High-Cost Thyroid Eye Disease Treatment

Thyroid eye disease (TED), also called Graves' orbitopathy, is an autoimmune condition in which the immune system attacks the tissue surrounding the eye, resulting in inflammation. TED most commonly occurs in patients with thyroid overactivity due to Graves' disease; however, it also can occur in people with normally functioning or underactive thyroid glands. TED can be sight-threatening in its most severe form. In January 2020, Tepezza® became the first FDA approved medication for TED. Since then, HM Insurance Group has seen multiple claims for Tepezza®, averaging **\$410,000 per full treatment course**.

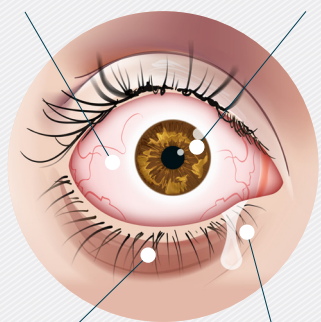
CLINICAL FEATURES OF THYROID EYE DISEASE

DRY AND GRITTY
OCULAR SENSATION

DOUBLE
VISION

PROPTOSIS
(BULGING OF THE EYES)

EXCESSIVE
TEARING



HOW IS TED TREATED?

- **IF HYPERTHYROID:** Medical, radiation or surgical treatment until normal thyroid function is achieved
- **TEPEZZA®** (teprotumumab), a biologic infusion therapy, is the **only FDA approved treatment**
- **OFF-LABEL TREATMENTS:**
 - Systemic steroids (\$)
 - Rituximab (J9312, \$\$)
 - Actemra® (tocilizumab, J3262, \$\$)

TED'S PHASES

There is an **active inflammatory phase**, along with an **inactive phase**.

- Medications only work during the active phase
- Active phase may last between 6 months to 3 years
- During the inactive phase, surgery is the only treatment to reduce eye bulging

WHO IS AFFECTED?

- Incidence rate of **19 per 100,000**
- Higher prevalence in **women** than in men
- Median age is **43 years old** with a range from 8 to 88
- Patients diagnosed **over 50 have a worse prognosis**



WHO TREATS TED?

- **Endocrinologist** or **Ophthalmologist**

TED PRIMARY DIAGNOSIS CODE

- E05.00 – Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm (hyperthyroidism)



ABOUT TEPEZZA®

- FDA approved in **January 2020**
- Indicated for active, moderate-severe TED
- Associated codes: J3590 & J3490 (unclassified), J3241 (assigned), C8957
- Use: Administered **every 3 weeks for 8 total lifetime infusions**
- **Average cost seen is \$410,000 / full treatment course**
 - Cost may range from \$340,000 to \$646,000
- **Must be administered by a health care provider:** in-home, at an outpatient facility or in a hospital
- Billed to medical benefits
 - Most claims seen are home infusions

COMMON CLINICAL CRITERIA FOR TEPEZZA®

- Active TED confirmed by a clinical active score (CAS) of 3 or greater
- Onset of TED symptoms within 9 months of request for treatment
- Prescribed by, or in consultation with, an ophthalmologist, endocrinologist or physician that specializes in TED
- More uncommonly, some plans may require:
 - Clinical diagnosis of Graves' disease
 - Failed treatment with steroids, rituximab, and/or lubricating eye drops

COVERAGE CONSIDERATION: If Tepezza® is being prescribed, be sure to require "site of care" once it is available through the administrator.

Specialty Pharmacy Watch provides important information about pharmaceutical cost-drivers that can impact the growing claims trend in the self-funded insurance market. Awareness is the first step in working to better manage the impact of high-cost pharmaceuticals and therapies, along with their associated administration.