Medical Drug Clinical Criteria

Subject:	Lumvoa (veligrotug-vvze)		
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Overview

This document addresses the use of Lumvoa (veligrotug-vvze). Lumvoa is a fully human monoclonal antibody that targets and inhibits the insulin-like growth factor-1 receptor (IGF-1R). It is approved for adults with Thyroid Eye Disease (TED) regardless of thyroid eye disease activity or duration.

Thyroid Eye Disease is a rare, vision-threatening autoimmune condition characterized by inflammation and expansion of orbital tissues. Clinical manifestations include dry or irritated eyes, proptosis (forward displacement of the eye), diplopia (double vision), and, in severe cases, optic nerve compression. TED is most commonly associated with Graves' disease, the leading cause of hyperthyroidism, and occurs in approximately 40% of affected individuals. While many patients have abnormal thyroid function (e.g., low TSH with elevated free thyroxine [T4] and/or triiodothyronine [T3]), thyroid status does not directly determine disease severity. A subset of patients (~10%) are euthyroid but still develop TED due to elevated thyroid autoantibodies. The disease course is variable and may include an active inflammatory phase followed by stabilization or a chronic phase with persistent structural changes. Many individuals experience mild, self-limited disease managed with conservative measures such as smoking cessation, ocular lubrication, and head elevation.
Guidelines from the American Thyroid Association (ATA) emphasize the importance of achieving and maintaining euthyroidism in patients with TED or those at risk of developing orbitopathy. Historically, treatment of TED has been limited, with surgery reserved for inactive disease to address proptosis, strabismus, or eyelid abnormalities. More recent consensus statements recognize IGF-1R–targeting therapies as important treatment options in moderate-to-severe TED, particularly in patients with significant proptosis and/or diplopia. Guidelines and consensus statements were published prior to the expanded approval of Tepezza in inactive TED and prior to FDA approval of Lumvoa. Both Tepezza and Lumvoa are approved for TED regardless of disease activity or duration.

Lumvoa's mechanism of action is based on inhibition of IGF-1R signaling, which is implicated in the pathogenesis of TED through stimulation of fibroblasts, increased hyaluronan production, and cytokine-mediated inflammation leading to orbital tissue expansion. Lumvoa has been evaluated in multiple clinical trials, including the THRIVE (active TED) and THRIVE-2 (chronic TED) phase 3 studies. These trials enrolled adults with moderate-to-severe TED, including both active and long-duration, low-activity disease. Participants were required to have proptosis ≥3 mm above normal, and eligibility was not restricted by clinical activity score in THRIVE-2, allowing inclusion of patients in the chronic phase. Across studies, efficacy has been primarily assessed using proptosis response, typically defined as a ≥2 mm reduction in proptosis in the study eye without worsening in the fellow eye. Lumvoa demonstrated clinically meaningful reductions in proptosis compared with placebo. Improvements in diplopia and quality-of-life measures have also been reported. There are no head-to-head trials evaluating Lumvoa and Tepezza. To date, published study results for Lumvoa include only those from THRIVE (active TED), whereas both studies investigating Tepezza's role in active and inactive, chronic TED have been published (Dougal 2020, 2023). Long-term efficacy, durability of response, and the role of retreatment with either Lumvoa or Tepezza have not yet been fully established. Both Tepezza and Lumvoa have warnings for exacerbation of preexisting inflammatory bowel disease, hyperglycemia, and hearing impairment including hearing loss.

Degree of Proptosis: Upper limit of Normal for Race/Sex		
	Female	Male
African American	23 mm	24 mm
White	19 mm	21 mm

Asian	16 mm (Thai) 16 mm (Chinese)	17 mm (Thai) 18.6 mm (Chinese)

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Lumvoa (veligrotug-vvze)

Requests for one course* of Lumvoa (veligrotug-vvze) may be approved if the following criteria are met:

I. Individual has a diagnosis of Thyroid Eye Disease; **AND**
II. Lumvoa is prescribed by, or in consultation with an endocrinologist AND an ophthalmologist; **AND**
III. Documentation is provided that individual has moderate to severe disease defined by proptosis ≥ 3 mm above normal values for race and sex (NCT06021054, Yen 2026);
IV. Documentation is provided that one of the following applies:
    A. Thyroid function tests are provided and are within normal limits as defined by laboratory standard (i.e. individual is euthyroid); **OR**
    B. Thyroid function tests are provided which show *both* free thyroxine (T4) and free triiodothyronine (T3) levels less than 50% above or below normal limits as defined by laboratory standard; **OR**
    C. Individual is starting Lumvoa concomitantly with attempts to achieve euthyroid status (Yen 2026).

Lumvoa (veligrotug-vvze) may not be approved for the following:

I. More than one course* of treatment; **OR**
II. Individual is using Lumvoa to reduce proptosis for cosmetic reasons alone; **OR**
III. Individual is using in combination with Tepezza (teprotumumab-trbw); **OR**
IV. When the above criteria are not met and for all other indications.

***Approval Duration:** One course of treatment; defined as a total of 5 intravenous infusions of Lumvoa administered every 3 weeks.

Quantity Limits

Lumvoa (veligrotug-vvze) Quantity Limits

Drug	Limit
Lumvoa (veligrotug-vvze) 500 mg vial	10 mg/kg every 3 weeks for five (5) infusions

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

C9399	Unclassified drugs or biologicals [when specified as Lumvoa (veligrotug-vvze)]
J3590	Unclassified biologics [when specified as Lumvoa (veligrotug-vvze)]

ICD-10 Diagnosis

E05.00	Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm
H05.241-H05.249	Constant exophthalmos [when specified due to thyrotoxicosis]
H05.831-H05.839	Thyroid orbitopathy

Document History

New: 05/15/2025
Document History:

- 05/15/2025 – Select Review: New clinical criteria, step therapy, and quantity limit for Lumvoa. Coding Reviewed: Added HCPCS NOC C9399, J3590, and ICD-10-CM E05.00, H05.241-H05.249, H05.831-H05.839.

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