# Lumvoa™ (veligrotug-vvze)
## (Intravenous)

Document Number: IC-0873

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## I. Length of Authorization [1]

- Initial: Prior authorization validity will be provided initially for 6 months (180 days) (max total of 5 infusions).
- Renewal: Prior authorization validity may NOT be renewed.*

## II. Dosing Limits

**Max Units (per dose and over time) [HCPCS Unit]:**

- 1,500 mg (3 vials) every 3 weeks for a total of 5 infusions

## III. Initial Approval Criteria [1,9,10]

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**
- Must be prescribed by, or in consultation with, a specialist in ophthalmology, endocrinology, oculoplastic surgery, or neuro-ophthalmology; **AND**
- Patient is euthyroid, or thyroid dysfunction is being actively managed and is clinically stable on current therapy; **AND**
- Member was advised or counseled to refrain from or discontinue tobacco smoking; **AND**
- Member does not have a history of inflammatory bowel disease; **AND**
- Member does not have uncontrolled hyperglycemia or diabetes; **AND**
- Member hearing will be assessed before, during, and after treatment; **AND**
- Used as single agent therapy; **AND**
- Member has not received prior treatment with an insulin-like growth factor-1 receptor inhibitor (anti-IGF-1)*; **AND**

**Thyroid Eye Disease (TED) † [1,9,10,12]**

- Member has a clinical diagnosis of TED based on characteristic clinical signs and features in the context of autoimmune thyroid disease; **AND**
    - Member has moderate-to-severe TED with a Clinical Activity Score (CAS) ≥ 3 **§** and one of the following:

- severe proptosis (≥ 3 mm)
- intermittent or constant diplopia
- moderate or severe soft tissue involvement
- orbital pain and/or pressure; **OR**

▪ Member had an inadequate response, or there is a contraindication or intolerance, to high-dose intravenous glucocorticoids; **OR**

○ Member has moderate-to-severe TED; **AND**

▪ Severe proptosis (≥ 3 mm); **AND**

▪ Proptosis of ≥ 17 mm prior to the start of therapy

| § Assessment of Thyroid Eye Disease (TED): Clinical Activity Score (CAS) Elements [9] |
|---|
| – Spontaneous retrobulbar pain<br>– Pain on attempted upward or downward gaze<br>– Redness of eyelids<br>– Redness of conjunctiva<br>– Swelling of caruncle or plica<br>– Swelling of eyelids<br>– Swelling of conjunctiva (chemosis)<br>– Increase in exophthalmos of ≥2 mm*<br>– Decrease in eye motility of ≥8°*<br>– Decrease in visual acuity in the last 1–3 months* |
| *Note: Each element is assigned a score of one. Elements denoted with a * can be used when a previous assessment is available. A seven-point scale is used when prior assessment is not available.* |

† FDA Approved Indication(s); ‡ Compendium Recommended Indication(s); Φ Orphan Drug

## IV. Renewal Criteria [1]

- Duration of authorization has not been exceeded *(refer to Section I)**

**Re-treatment with Lumvoa will be reviewed on a case-by-case basis via the peer review process.*

## V. Dosage/Administration [1]

| Indication | Dose |
|---|---|
| Thyroid Eye Disease | Administer 10 mg/kg intravenously every three weeks for 5 total infusions. |

## VI. Billing Code/Availability Information

HCPCS Code(s):

- J3590 – Unclassified biologics
- C9399 – Unclassified drugs or biologicals *(Hospital Outpatient Use Only)*

NDC:

- Lumvoa 500/10 mL mg solution in a single-dose vial for injection: 85166-0001-xx

## VII. References


1. Lumvoa [package insert]. Waltham, MA; Viridian Therapeutics, Inc.; June 2026. Accessed June 2026.
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12. Wiersinga WM, Eckstein AK, Žarković M. Thyroid eye disease (Graves' orbitopathy): clinical presentation, epidemiology, pathogenesis, and management. Lancet Diabetes Endocrinol. 2025 Jul;13(7):600-614. doi: 10.1016/S2213-8587(25)00066-X. Epub 2025 May 2. PMID: 40324443.


## Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

| Factor | Conclusion |
|---|---|
| Indication | Yes: Consider for PA |
| Safety and efficacy | No: PA not a priority |
| Potential for misuse/abuse | No: PA not a priority |
| Cost of drug | Yes: Consider for PA |

## Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|---|---|
| E05.00 | Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm (hyperthyroidism) |
| H05.831 | Thyroid orbitopathy, right orbit |
| H05.832 | Thyroid orbitopathy, left orbit |
| H05.833 | Thyroid orbitopathy, bilateral |
| H05.839 | Thyroid orbitopathy, unspecified orbit |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| **Jurisdiction** | **Applicable State/US Territory** | **Contractor** |
| E (1) | CA, HI, NV, AS, GU, CNMI | Noridian Healthcare Solutions, LLC |
| F (2 & 3) | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC |
| 5 | KS, NE, IA, MO | Wisconsin Physicians Service Insurance Corp (WPS) |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| **Jurisdiction** | **Applicable State/US Territory** | **Contractor** |
| 6 | MN, WI, IL | Wellpoint Federal |
| H (4 & 7) | LA, AR, MS, TX, OK, CO, NM | Novitas Solutions, Inc. |
| 8 | MI, IN | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9) | FL, PR, VI | First Coast Service Options, Inc. |
| J (10) | TN, GA, AL | Palmetto GBA |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA |
| L (12) | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc. |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | Wellpoint Federal |
| 15 | KY, OH | CGS Administrators, LLC |