



Nonprofit corporations and independent licensees
of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 08/13/2026

Lumvoa™ (veligrotug-vvze)

HCPCS: J3590

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA approved indication
 - b. FDA approved age
 - c. Prescribed by or in consultation with an endocrinologist or ophthalmologist
 - d. Must have treated thyroid disease defined as:
 - i. Euthyroid function with free triiodothyronine (T3) and thyroxine (T4) within the normal limits for the range of the laboratory
OR
 - ii. Thyroid function is normalizing with both T3 and T4 levels being less than 50% above or 50% below the normal limits for the range of the laboratory
 - e. For those with active disease in the absence of significant diplopia or proptosis defined as greater than or equal to 3 mm above normal for race and gender: Treatment with an adequate course of oral or intravenous (IV) corticosteroids (for example 30 mg/day prednisone for 4 weeks) has been ineffective, not tolerated, or is contraindicated
 - f. Physician attestation a discussion has been had with the member to stop smoking if they are a current smoker
 - g. Must not be used in combination with or following any previous treatment with other insulin-like growth factor-1 receptor antagonist for the treatment of TED
 - h. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's medical utilization management drug list
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limits: Align with FDA recommended dosing
 - b. Authorization Period: 6 months
 - c. Renewal Criteria: Not applicable as no further authorization will be provided

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***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Thyroid eye disease is a complex orbital inflammatory disease, which can be sight threatening, debilitating, and disfiguring. It is caused by antibodies directed against receptors in the thyroid cells and also on the surface of the cells behind the eyes. Muscles and fatty tissues behind the eye become inflamed leading to proptosis (eye bulging), strabismus (misalignment of the eyes), and diplopia (double vision) and in some cases can lead to blindness. Risk factors for the disease include female gender, middle age, and smoking. Active TED lasts for up to three years with the disease only responding to pharmacotherapy while it is active and inflammation is ongoing.
- Lumvoa is an insulin-like growth factor-1 receptor antagonist indicated for the treatment of thyroid eye disease (TED) regardless of thyroid eye disease activity or duration.
- Goals of treatment in thyroid disease consists of achieving a euthyroid state and symptom management. The majority of patients with thyroid eye disease have mild to moderate disease and require primarily supportive care with ocular lubrication, topical cyclosporine, and lifestyle modification, such as, smoking cessation, sodium restriction, and sunglasses.
- The current mainstay of treatment for moderate to severe thyroid eye disease is oral or intravenous corticosteroids. Treatment can be initiated at doses of oral prednisone 30 mg daily for four weeks or methylprednisolone 500 mg once weekly for weeks 1 to 6, then 250 mg once weekly for weeks 7 to 12 with cumulative dose 4.5 to 5 g over 12 weeks. The European Thyroid Association recommends initial treatment with IV glucocorticoids for moderate-to-severe, active orbitopathy, citing several studies that suggest it is more efficacious and associated with fewer side effects than oral therapy. Similar trials have not been performed in the United States, where initiation with oral glucocorticoids remains the most common first-line treatment. Treatment for thyroid eye disease should start in the early months of the active inflammatory phase, as treatment becomes less effective as the disease progresses.
- There are no clinical head to head studies that compare steroids and Lumvoa for the treatment TED. The 2021 European Group on Graves' orbitopathy (EUGOGO) clinical practice guidelines for the medical management of Graves' orbitopathy state insulin-like growth factor-1 receptor antagonists' incorporation into routine clinical practice is currently limited by the lack of comprehensive long-term efficacy and safety data and the absence of head-to-head comparison trials with intravenous glucocorticoids. However, a 2022 joint consensus statement by the American Thyroid Association and the European Thyroid Association state intravenous corticosteroids are the preferred treatment for active moderate-to-severe TED when disease activity is the prominent feature in the absence of either significant proptosis, defined as greater than or equal to 3 mm above normal for race and gender, or diplopia. In the presence of significant proptosis or diplopia, an insulin-like growth factor-1 receptor antagonist is the preferred treatment option.
- Safety and efficacy were evaluated in the THRIVE and THRIVE-2 trials, two randomized, double-masked, placebo-controlled studies of 301 patients with active or chronic TED. The patients in THRIVE had a clinical diagnosis of active TED with onset within 15 months and a clinical activity score of 3 or more. Participants in THRIVE-2 had a clinical diagnosis of chronic TED with onset greater than 15 months and any clinical activity score (0 - 7). Subjects were randomized 2:1 to receive 10 mg/kg Lumvoa every 3 weeks for 15 weeks. Primary endpoints included proptosis responder rate, mean change in proptosis from baseline, resolution of diplopia, change in clinical activity score (CAS), and overall response. The proptosis responder rate at week 15 was defined as the percentage of patients with ≥ 2 mm reduction in proptosis in the study eye from baseline, without deterioration in proptosis (≥ 2 mm

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increase) in the non-study eye. The proptosis responder rate at week 15 was 70% in THRIVE and 57% for THRIVE-2 which was statistically significant compared to placebo (p-value < 0.01). In both clinical trials, improvement of proptosis was observed as early as 3 weeks and proptosis continued to improve through week 15 in both active and chronic TED. Lumvoa also led to improvement in the less severely impacted non-study eye and a reduction in extraocular muscle volume in both eyes.

References:

1. Lumvoa [prescribing information]. Waltham, MA: Viridian Therapeutics, Inc; June 2026.
2. Clinicaltrials.gov. A safety, tolerability and efficacy study of veligrotug (VRDN 001) in healthy volunteers and participants with thyroid eye disease (THRIVE) (NCT05176639). Available at: <https://www.clinicaltrials.gov/study/NCT05176639?spons=Viridian%20Therapeutics,%20Inc.&rank=2&page=1&limit=10#participation-criteria>. Accessed on June 29, 2026.
3. Clinicaltrials.gov. An efficacy, safety, and tolerability study of veligrotug (VRDN-001), in participants with chronic thyroid eye disease (THRIVE-2) (NCT06021054). Available at: <https://www.clinicaltrials.gov/study/NCT06021054?spons=Viridian%20Therapeutics,%20Inc.&rank=1&page=1&limit=10>. Accessed on June 29, 2026.
4. Abrams J, Leibowitz S, Yen MT, et al. Efficacy and safety of veligrotug (VRDN-001), a full antagonist monoclonal antibody to IGF-1 receptor, in active thyroid eye disease: THRIVE phase 3 topline results. Available at: <https://www.viridiantherapeutics.com/wp-content/uploads/2025/05/viridian-therapeutics-AACE-2025-Oral-presentation-thrive-top-level-data.pdf>. Accessed on June 29, 2026.
5. McAlinden C. An overview of thyroid eye disease. *Eye and Vision*. 2014; 1: 9 – 12.
6. Ross DS, Burch HB, Cooper DS, et al. 2016 american thyroid association guidelines for diagnosis and management of hyperthyroidism and other causes of thyrotoxicosis. *Thyroid*. 2016; 26 (10): 1343 - 1421.
7. Bartalena L, Baldeschi L, Boboridis K, et al. The 2016 european thyroid association/european group on graves' orbitopathy guidelines for the management of graves' orbitopathy. *Eur Thyroid J*. 2016 Mar; 5 (1): 9 - 26.
8. Bartalena L, Kahaly GJ, Baldeschi L, et al. The 2021 european group on graves' orbitopathy (EUGOGO) clinical practice guidelines for the medical management of graves' orbitopathy. *Eur J Endocrinol*. 2021 Aug 27; 185 (4): G43.

Policy History												
#	Date	Change Description										
1.3	Effective Date: 08/13/2026	New policy - this criteria replaces previously approved preliminary criteria										
1.2	Effective Date: 08/03/2026	UM medical management system update for MAPPO and BCNA <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
BCN	Yes											
MAPPO	Yes											
BCNA	Yes											
1.1	Effective Date: 07/13/2026	UM medical management system update for BCBS and BCN <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	No	BCNA	No
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BCBS	Yes											
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MAPPO	No											
BCNA	No											
1.0	Effective Date: 02/12/2026	Preliminary Drug Review <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	No	MAPPO	No	BCNA	No
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MAPPO	No											
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* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.

Blue Cross Blue Shield/Blue Care Network of Michigan

Medication Authorization Request Form



This form is to be used by participating physicians to obtain coverage for **drugs covered under the medical benefit**. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

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PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	Name
ID Number	Specialty
D.O.B. ☐ Male ☐ Female	Address
Diagnosis	City /State/Zip
Drug Name	Phone/Fax: P: () - F: () -
Dose and Quantity	NPI
Directions	Contact Person
Date of Service(s)	Contact Person Phone / Ext.

STEP 1: DISEASE STATE INFORMATION

- Is this request for: ☐ Initiation ☐ Continuation Date patient started therapy: _____
- Administered by patient or a medical professional? ☐ patient (self) ☐ health care professional (physician, nurse, etc.)
- Site of administration? ☐ Provider office/Home infusion ☐ Other: _____
☐ Hospital outpatient facility (go to #4) Reason for Hospital Outpatient administration: _____
☐ Hospital inpatient facility for Car-T therapy only (for example: Kymriah, Yescarta, or Tecartus) (go to #5)
- Please specify location of administration if hospital outpatient infusion: _____
- Please specify location of administration if hospital inpatient infusion: _____
- Please provide the NPI number for the place of administration: _____
- Initiation AND Continuation of therapy:**
 - What is the patient's diagnosis? _____
 - What other medication has the patient received for their condition? Please list _____
 - Please describe the response to previous therapies: _____
 - Will the patient be receiving any other treatment for the listed condition while on this medication? Please list: _____
 - Please list any labs values important for diagnosing or monitoring this patient's condition: _____
- Continuation of therapy:**
 - Has the patient progressed while on this medication? ☐ yes ☐ no
 - How has the patient's condition changed while on this medication?

☐ Improved: Please describe: _____
 ☐ Stable: please describe: _____
 ☐ Worsened; Please describe: _____
 ☐ Other; Please describe: _____

Chart notes are required for the processing of all requests. Please add any other supporting medical information necessary for our review (required)

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name	Physician Signature	Date
Step 2: Checklist	☐ Form Completely Filled Out ☐ Provide chart notes	☐ Attach test results
Step 3: Submit	By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979	By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320

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7/26/2018, 9/18/2018; 1/31/2020; 3/17/2020; 8/9/2021