

Medical Policy Manual

Draft New Policy: Do Not Implement

Veligrotug-vvze (Lumvoa)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

**The proposal is to add text/statements in red and to delete text/statements with strikethrough:
POLICY**

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Lumvoa is indicated for the treatment of thyroid eye disease regardless of thyroid eye disease activity or duration. All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
Supporting chart notes or medical record indicating moderate-to-severe disease.

EXCLUSIONS

- Coverage will not be provided for repeat series of Lumvoa infusions.
- Member will not use Lumvoa in combination with Tepezza.

PRESCRIBER SPECIALITIES

This medication must be prescribed by or in consultation with an ophthalmologist and endocrinologist.

COVERAGE CRITERIA

Thyroid Eye Disease (TED)

Authorization of 6 months may be granted for treatment of TED when all of the following criteria are met:

- Member is 18 years of age or older.
- Member has moderate-to-severe (active or inactive) disease (see Appendix A).
- Member will not exceed a one-time treatment course consisting of 5 infusions given once every 3 weeks at a dose of 10 mg/kg.
- Member is receiving appropriate management to achieve or maintain euthyroid status, if applicable.

APPENDIX

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Appendix A: Disease Severity Assessment

- Mild disease, at least one of the following:
 - Minor lid retraction (<2 mm)
 - Mild soft-tissue involvement
 - Exophthalmos <3 mm above normal for race and gender
 - No or intermittent diplopia
 - Corneal exposure responsive to lubricants
- Moderate-to-severe disease, at least one of the following:
 - Lid retraction ≥2 mm
 - Moderate or severe soft-tissue involvement
 - Exophthalmos ≥3 mm above normal for race and gender
 - Inconstant or constant diplopia
- Sight-threatening disease, at least one of the following:
 - Dysthyroid optic neuropathy (DON)
 - Corneal breakdown

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

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3. Burch HB, Perros P, Bednarczuk T, Cooper DS, et al. Management of Thyroid Eye Disease: A Consensus Statement by the American Thyroid Association and the European Thyroid Association. *Thyroid*. 2022 Dec;32(12):1439-1470.
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6. Yen MT, Cockerham K, Saeed P, Leibowitz S, Mudumbai RC, Schittkowski MP, et al. THRIVE: a phase 3, randomized, double-masked, placebo-controlled study of veligrotug for active thyroid eye disease. *Ophthalmology*. 2026 Sep;133(9):1085-1096. doi:10.1016/j.ophtha.2026.04.022.

EFFECTIVE DATE

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