Draft Revision Policy: Do Not Implement

Mosunetuzumab-axgb (Lunsumio™)

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 Indication

Lunsumio is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.

Compendial Uses

- Follicular Lymphoma
- Diffuse Large B-cell Lymphoma
- High-Grade B-cell Lymphoma
- Human Immunodeficiency Virus (HIV)-Related B-cell Lymphomas
- Post-transplant Lymphoproliferative Disorders (B-cell type)

All other indications are considered experimental/investigational and not medically necessary.

COVERAGE CRITERIA

Follicular Lymphoma

Authorization of 12 months may be granted for treatment of follicular lymphoma when both of the following criteria are met:

- The disease had a partial response or no response to treatment or the disease is relapsed or progressive.
- The member has tried at least 2 prior lines of systemic therapy.

Diffuse Large B-cell Lymphoma or High-Grade B-cell Lymphoma

Authorization of 12 months may be granted for subsequent treatment of relapsed or refractory diffuse large B-cell lymphoma or high-grade B-cell lymphoma when used in combination with polatuzumab vedotin.

HIV-Related B-cell Lymphomas

Authorization of 12 months may be granted for subsequent treatment of relapsed or refractory HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma, or HIV-related plasmablastic lymphoma when used in combination with polatuzumab vedotin.

Post-Transplant Lymphoproliferative Disorders (PTLD)

Authorization of 12 months may be granted for subsequent treatment of relapsed or refractory monomorphic post-transplant lymphoproliferative disorders (B-cell type) when used in combination with polatuzumab vedotin.

CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

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

1. Lunsumio [package insert]. South San Francisco, CA: Genentech, Inc.; November 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 4, 2025.

EFFECTIVE DATE

ID_CHS_2025