Draft Revised Policy: Do Not Implement

Loncastuximab Tesirine-lpyl (Zynlonta®)

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

I. 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.

A. FDA-Approved Indication
Zynlonta is indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS), DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma.

B. Compendial Uses
1. Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
2. Human immunodeficiency virus (HIV) related B-cell lymphomas
3. Post-transplant lymphoproliferative disorders

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

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
Chart notes, medical record documentation or claims history supporting previous lines of therapy.

III. CRITERIA FOR INITIAL APPROVAL

A. Large B-cell lymphoma
Authorization of 12 months may be granted for treatment of ~~relapsed, progressive or refractory~~ large B-cell lymphoma (e.g., DLBCL NOS, DLBCL arising from low grade lymphoma, high-grade B-cell lymphoma) when the member has partial response, no response, relapsed, progressive or refractory disease and all of the following criteria are met:
1. The member has received two or more prior lines of systemic therapy.
2. The requested medication will be used as a single agent.

B. Histologic Transformation of Indolent Lymphomas to Diffuse Large B-cell Lymphoma
Authorization of 12 months may be granted for treatment of histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma when the member has partial response, no response, progressive or relapsed disease and all of the following criteria are met:
1. The member has received treatment with an anthracycline-based regimen (e.g., doxorubicin)

2. ~~The requested medication will be used as subsequent therapy~~.
3. The member is not a candidate for transplant.

C. HIV-Related B-cell lymphomas

Authorization of 12 months may be granted for treatment of ~~relapsed, progressive or refractory~~ HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma when the member has partial response, relapsed, progressive, or refractory disease and all of the following criteria are met:

1. The member has received two or more lines of systemic therapy.
2. The requested medication will be used as a single agent.

D. Post-Transplant Lymphoproliferative Disorders (PTLD)

Authorization of 12 months may be granted for treatment of monomorphic PTLD (B-cell type) when the member has partial response, relapsed, progressive or refractory disease and all of the following criteria are met:

1. The member has received two or more lines of systemic therapy.
2. The requested medication will be used as a single agent.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III 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. Zynlonta [package insert]. Murray Hill, NJ: ADC Therapeutics America; October 2022.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed April 5, 2023.

EFFECTIVE DATE

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