VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Zynlonta Utilization Management Medical Policy
- Zynlonta® (loncastuximab tesirine-lpyl intravenous infusion – Teva)

REVIEW DATE: 05/31/2023

OVERVIEW

Zynlonta, a CD19-directed antibody and alkylating agent conjugate, is indicated for the treatment of relapsed or refractory **large B-cell lymphoma** (including diffuse large B-cell lymphoma [DLBCL] not otherwise specified, DLBCL arising from low grade lymphoma, and high grade B-cell lymphoma) in adults, after two or more lines of systemic therapy.[1] Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Guidelines

Zynlonta is discussed in the guidelines from the National Comprehensive Cancer Network (NCCN):

- **B-Cell Lymphoma**: NCCN guidelines (version 3.2023 – May 11, 2023) recommend Zynlonta as a third-line and subsequent therapy option only after two or more lines of systemic therapy.[2] For second-line or subsequent treatment of relapsed or refractory DLBCL, a variety of chemotherapy-based regimens ± rituximab are preferred regimens. Allogeneic stem cell transplantation is also an option for selected patients, as consolidation after alternate second-line therapy. NCCN notes that it is unclear if any CD-19 therapy (including Zynlonta and Monjuvi® [tafasitamab intravenous infusion]) would have a negative impact on the clinical efficacy of subsequent anti-CD19 CAR T-cell therapy.[2,3]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Zynlonta. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Zynlonta as well as the monitoring required for adverse events and long-term efficacy, approval requires Zynlonta to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Zynlonta is recommended in those who meet the following criteria:

FDA-Approved Indication

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1. **Large B-Cell Lymphoma.** Approve for 1 year if the patient meets the following criteria (A, B, and C):

Note: This includes diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma.

A) Patient is ≥ 18 years of age; AND

B) Patient has tried at least two systemic regimens; AND
Note: Examples of systemic therapies containing one or more of the following products include gemcitabine, oxaliplatin, rituximab, Polivy (polatuzumab vedotin intravenous infusion), bendamustine, Monjuvi (tafasitamab-cxix intravenous infusion), or Revlimid (lenalidomide capsules). Autologous stem cell transplant and chimeric antigen receptor (CAR) T-cell therapy also count as a systemic regimen.

C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 0.15 mg/kg given intravenously once every 3 weeks for two cycles, followed by 0.075 mg/kg given intravenously once every three weeks for subsequent cycles.
Note: If the patient has a body mass index ≥ 35 kg/m^2, the dose is calculated based on the adjusted body weight in kg. To calculate adjusted body weight, use the following equation: adjusted body weight kg = 35 kg/m^2 x (height in meters)^2.

Other Uses with Supportive Evidence

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2. Human Immunodeficiency Virus-Related B-Cell Lymphoma. Approve for 1 year if the patient meets the following criteria (A, B, and C):
Note: This includes human immunodeficiency virus-related diffuse large B-cell lymphoma (DLBCL), primary effusion lymphoma, and human herpes virus 8 (HHV8)-positive DLBCL not otherwise specified.

A) Patient is ≥ 18 years of age; AND

B) Patient has tried at least two systemic regimens; AND
Note: Examples of systemic therapies include R-EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin, rituximab) and RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone).

C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 0.15 mg/kg given intravenously once every 3 weeks for two cycles, followed by 0.075 mg/kg given intravenously once every three weeks for subsequent cycles.
Note: If the patient has a body mass index ≥ 35 kg/m^2, the dose is calculated based on the adjusted body weight in kg. To calculate adjusted body weight, use the following equation: adjusted body weight kg = 35 kg/m^2 x (height in meters)^2.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Zynlonta is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Zynlonta® intravenous infusion [prescribing information]. Murray Hill, NJ: ADC Therapeutics; October 2022.
2. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 3.2023 – May 11, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 15, 2023.

3. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Search term: loncastuximab. Accessed on May 15, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	05/18/2022
Annual Revision	**Large B-Cell Lymphoma:** Removed the descriptor diffuse from the condition of approval and added a Note with examples of large B-cell lymphomas. **Human Immunodeficiency Virus-Related B-Cell Lymphoma:** New condition of approval added.	05/31/2023