PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Zynlonta Prior Authorization Policy
- Zynlonta® (loncastuximab tesirine-lpyl intravenous infusion – Teva)

REVIEW DATE: 05/18/2022

OVERVIEW
Zynlonta, a CD19-directed antibody and alkylating agent conjugate, is indicated for the treatment of adults with relapsed or refractory **large B-cell lymphoma** (DLBCL) [including DLBCL not otherwise specified and DLBCL arising from low grade lymphoma and high grade B-cell lymphoma], 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 3.2022 – April 25, 2022) recommend Zynlonta as a third-line and subsequent therapy option only after two or more line 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) would have a negative impact on the clinical efficacy of subsequent anti-CD19 CAR T-cell therapy.[2]

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Zynlonta. 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

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

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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.

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; April 2021.
2. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 3.2022 – April 25, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 16, 2022.

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