PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 04/28/2021

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 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 not yet addressed in guidelines from the National Comprehensive Cancer Network (NCCN) [version 3.2021 – March 16, 2021].[2] For second-line or subsequent treatment of relapsed or refractory DLBCL, preferred regimens in patients who are ineligible for transplantation include GemOx (gemcitabine/oxaliplatin) ± rituximab and Polivy® (polatuzumab vedotin intravenous injection) ± bendamustine ± rituximab. Monjuvi (tafasitamab-cxix intravenous infusion), a CD19-directed antibody-drug conjugate, + Revlimid® (lenalidomide capsules) is among the other recommended regimens for second-line and subsequent therapy. For transplant candidates, various chemotherapy regimens are among the preferred regimens. Xpovio® (selinexor tablets), a nuclear export inhibitor, is listed for third-line or subsequent use.

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 Indications

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 include GemOx (gemcitabine/oxaliplatin) ± rituximab, Polivy (polatuzumab vedotin intravenous injection) ± bendamustine ± rituximab, Monjuvi (tafasitamab-cxix intravenous injection) + Revlimid (lenalidomide capsules).

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. Monjuvi® intravenous infusion [prescribing information]. Murray Hill, NJ: ADC Therapeutics; April 2021.
2. The NCCN B-cell Lymphomas Clinical Practice Guidelines in Oncology (Version 3.2021 – March 16, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 26, 2021.