Medical Policy:

Zynlonta® (loncastuximab tesirine) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.333	January 2, 2025	June 9, 2021

Definitions

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.

Length of Authorization

Coverage will be provided for 1 year and may be renewed.

Dosing Limits [Medical Benefit]

The recommended dosage is 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.

Guideline

I. INITIAL APPROVAL CRITERIA

Coverage will be provided when the following criteria are met:

Relapsed or refractory large B-cell lymphoma

1. Patient is 18 years of age or older; **AND**
2. Patient has a diagnosis of relapsed or refractory large B-cell lymphoma (may include diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low-grade lymphoma, and high-grade B-cell lymphoma); **AND**
3. Zynlonta is prescribed by, or in consultation with, an oncologist or hematologist; **AND**
4. Zynlonta is initiated after two or more lines of systemic therapy; **AND**
5. The requested use is supported by FDA-approved prescribing information OR the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

II. RENEWAL APPROVAL CRITERIA

Coverage can be renewed for 1 year based on the following:

1. Stabilization of disease or absence of disease progression; **AND**
2. Absence of unacceptable toxicity from the drug.

Applicable Procedure Codes

Code	Description
J9359	Injection, loncastuximab tesirine-lpyl, 0.075 mg

Applicable NDCs

Code	Description
79952-0110-01	Zynlonta 10mg, single-dose vial

ICD-10 Diagnoses

Code	Description
C83.3	Diffuse large B-cell lymphoma
C83.30	Diffuse large B-cell lymphoma, unspecified site
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites

Revision History

Company(ies)	DATE	REVISION

EmblemHealth & ConnectiCare	1/2/2025	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	1/2/2024	Annual Review- No revisions
EmblemHealth & ConnectiCare	3/3/2023	Annual Review- No revisions
EmblemHealth & ConnectiCare	09/28/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	6/9/2021	New Policy

References

1. 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 May 21, 2021.
2. ZYNLONTA™ Prescribing Information. ADC Therapeutics SA. May 2021.