

Medical Policy:

Zynlonta[®] (loncastuximab tesirine) Intravenous

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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
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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.