Medical Policy

Zynlonta™ (loncastuximab tesirine)	
MEDICAL POLICY NUMBER	Med_Clin_Ops_068
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

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PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Zynlonta™ (loncastuximab tesirine) therapy.

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

Coverage for Zynlonta will be provided for 12 months and may be renewed.

1. Patient is 18 years of age or older; **AND**
2. Zynlonta is prescribed by, or in consultation with, an oncologist; **AND**
3. Patient has a documented diagnosis 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; **AND**
4. The B-cells must be CD19-positive as confirmed by testing or analysis; **AND**

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5. Patient has tried at least two systemic regimens (e.g., GemOx (gemcitabine/oxaliplatin) ± rituximab, Polivy (polatuzumab vedotin intravenous injection) ± bendamustine ± rituximab, Monjuvi (tafasitamab-cxix) + Revlimid (lenalidomide).

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

BACKGROUND

Zynlonta is indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low-grade lymphoma, and high-grade B-cell lymphoma.

This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

DEFINITIONS

1. ZYNLONTA™ (loncastuximab tesirine-lpyl) for injection, for intravenous use. Initial U.S. Approval: 2021
    a. ZYNLONTA (loncastuximab tesirine-lpyl) for injection is a sterile, preservative-free, white to off-white lyophilized powder, which has a cake-like appearance
    b. Supplied in a single-dose vial for reconstitution and further dilution. Each carton (NDC 79952-110-01) contains one 10 mg single-dose vial.

CODING

Applicable NDC Codes	
79952-0110-01	10 mg of loncastuximab tesirine-lpyl as a lyophilized powder in a single-dose vial for reconstitution and dilution

Applicable Procedure Code	
J9359	Injection, loncastuximab tesirine-lpyl, 0.075 mg

Applicable ICD-10 Codes	
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

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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

EVIDENCE BASED REFERENCES

1. Product Information: ZYNLONTA(TM) intravenous injection, loncastuximab tesirine-lpyl intravenous injection. ADC Therapeutics America (per FDA), Murray Hill, NJ, 2021

POLICY HISTORY

Original Effective Date	July 19, 2021
Revised Date	• November 1, 2021 – no changes made. • July 2022 – Added J code (J9359) Injection, loncastuximab tesirine-lpyl, 0.075 mg; Effective 4/1/2022 • March 1, 2023 – Adopted by MA UM Committee (no policy revisions made) • January 1, 2024

Approved by the Pharmacy and Therapeutics Committee 7/26/22

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