Drug Policy:
Zynlonta™ (loncastuzimab tesirine-Ipyl)

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<tr>
<th>POLICY NUMBER</th>
<th>SUBJECT</th>
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<tr>
<td>UM ONC_1434</td>
<td>Zynlonta™ (loncastuzimab tesirine-Ipyl)</td>
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<th>EFFECTIVE DATE</th>
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<tbody>
<tr>
<td>06/09/21</td>
<td>June 9, 2021</td>
<td>June 25, 2021</td>
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<tr>
<th>PRIMARY BUSINESS OWNER: UM</th>
<th>COMMITTEE/BOARD APPROVAL</th>
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<tr>
<td>UM</td>
<td>Utilization Management Committee</td>
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<tr>
<th>URAC STANDARDS</th>
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<tr>
<th>CMS REQUIREMENTS</th>
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<td>Commercial, Exchange, Medicaid</td>
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I. PURPOSE

To define and describe the accepted indications for Zynlonta (loncastuzimab tesirine-Ipyl) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR

2. When health plan Exchange coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR
3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND

4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND

5. When applicable, generic alternatives are preferred over brand-name drugs.

B. Diffuse Large B-Cell Lymphoma (DLBCL)

1. NOTE: Per NCH Policy & NCH Pathway, Zynlonta (loncastuzimab tesirine-lpyl) is non-preferred for relapsed or refractory DLBCL. This recommendation is based on a lack of level 1 evidence (clinical trial and/or meta-analysis) comparing Zynlonta (loncastuzimab tesirine-lpyl) to other available therapies.

2. Zylonta (loncastuzimab tesirine-lpyl) may be used as monotherapy in members as follows:
   a. The member has relapsed or refractory diffuse large B-cell lymphoma-NOS (DLBCL not otherwise specified), DLBCL arising from low-grade lymphoma, or high-grade B-cell lymphoma, AND
   b. The member has had disease progression on two or more lines of systemic therapies (e.g., R-ICE, R-DHAP, R-ESHAP, R-EPOCH, or R-GDP).

III. EXCLUSION CRITERIA

A. Disease progression while taking Zynlonta (loncastuzimab tesirine-lpyl) or previous CD19-directed therapy [e.g., Monjuvi (tafasitamab-cxix)] .

B. Dosing exceeds single dose limit of Zynlonta (loncastuzimab tesirine-lpyl) 0.15 mg/kg.

C. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES


B. Zynlonta PI prescribing information. ADC Therapeutics America, Murray Hill, New Jersey 2021.

