Reference number(s)
4698-A

STANDARD MEDICARE PART B MANAGEMENT

ZYNLONTA (loncastuximab tesirine-lpyl)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
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 (NOS), DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma.

B. Compendial Uses
1. Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
2. AIDS-related B-cell lymphomas

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions: Chart notes, medical record documentation or claims history supporting previous lines of therapy.

III. CRITERIA FOR INITIAL APPROVAL

A. Large B-cell lymphoma
Authorization of 12 months may be granted for treatment of relapsed, progressive or refractory large B-cell lymphoma (e.g., DLBCL NOS, DLBCL arising from low grade lymphoma, high-grade B-cell lymphoma) when all of the following criteria are met:
1. The member has received two or more prior lines of systemic therapy.
2. The requested medication will be used as a single agent.

B. Histologic Transformation of Indolent Lymphomas to Diffuse Large B-cell Lymphoma
Authorization of 12 months may be granted for treatment of histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma when all of the following criteria are met:
1. The requested medication will be used as subsequent therapy.

2. The member is not a candidate for transplant.

C. AIDS-Related B-cell lymphomas

Authorization of 12 months may be granted for treatment of relapsed, progressive or refractory AIDS-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma when all of the following criteria are met:

1. The member has received two or more lines of systemic therapy.
2. The requested medication will be used as a single agent.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

1. The member is currently receiving therapy with Zynlonta.
2. Zynlonta is being used to treat an indication enumerated in Section III.
3. The member is receiving benefit from therapy. Benefit is defined as:
   a. No evidence of unacceptable toxicity while on the current regimen, and
   b. No evidence of disease progression while on the current regimen

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Zynlonta.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology
3. NCCN Guideline: B-cell lymphomas

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Zynlonta are covered in addition to the following:

1. Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
2. AIDS-related B-cell lymphomas

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Zynlonta to treat histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support Zynlonta to treat AIDS-related B-cell lymphomas can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

VII. REFERENCES

1. Zynlonta [package insert]. Murray Hill, NJ: ADC Therapeutics America; September 2021.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed April 5, 2022.