Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 237.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Zynlonta (loncastuximab tesirine-lpyl)

I. Policy:
Zynlonta (loncastuximab tesirine-lpyl)

II. Purpose/Objective:
To provide a policy of coverage regarding Zynlonta (loncastuximab tesirine-lpyl).

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Zynlonta is an antibody drug conjugate that contains a humanized IgG_1 monoclonal antibody directed at CD19, conjugated to a pyrrolobenzodiazepine dimer cytotoxic alkylating agent (SG3199) via a protease cleavable linker (the linker with SG3199 attached is the small molecule cytotoxin, SG3249 [tesirine]). The antibody component binds to CD19 (a transmembrane protein expressed on B-cell surfaces). After binding, Zynlonta is internalized and releases SG3199 via proteolytic cleavage. SG3199 then binds to the DNA minor groove and forms highly cytotoxic DNA inter-strand crosslinks and induces cell death.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Zynlonta (loncastuximab tesirine-lpyl) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Medical record documentation that Zynlonta is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation 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**
- Medical record documentation of prior treatment with two or more lines of systemic therapy

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 7/20/21

Revised: 6/27/22 (Medicaid PARP statement), 6/6/23 (LOB carve out, Medicaid business segment)

Reviewed: