Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 162.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Yescarta (axicabtagene ciloleucel)

I. Policy:
Yescarta (axicabtagene ciloleucel)

II. Purpose/Objective:
To provide a policy of coverage regarding Yescarta (axicabtagene ciloleucel)

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:
Yescarta (axicabtagene ciloleucel) is a CD19-directed genetically modified autologous T cell immunotherapy in which a patient's T cells are reprogrammed with a transgene encoding a chimeric antigen receptor (CAR) to identify and eliminate CD19-expressing malignant and normal cells. The CAR is comprised of a murine single-chain antibody fragment which recognizes CD19 and is fused to CD28 and CD3 zeta. CD3 zeta is a critical component for initiating T-cell activation and antitumor activity. After binding to CD19-expressing cells, the CD28 and CD3-zeta co-stimulatory domains activate downstream signaling cascades, which results in T cell activation, proliferation, acquisition of effector functions, and secretion of inflammatory cytokines and chemokines, leading to destruction of CD19-expressing cells. Axicabtagene ciloleucel is prepared from the patient's peripheral blood cells obtained via leukapheresis.

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

Yescarta (axicabtagene ciloleucel) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

Large B-Cell Lymphoma (second-line)
- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of large B-cell lymphoma that is refractory to first-line chemoimmunotherapy OR that relapses within 12 months of first-line chemoimmunotherapy **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

Large B-Cell Lymphoma (third-line or beyond)
- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of one of the following diagnoses:
    - Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified **OR**
    - Relapsed or refractory primary mediastinal large B-cell lymphoma **OR**
    - Relapsed or refractory high-grade B-cell lymphoma **OR**
    - Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) arising from follicular lymphoma

  AND
- Medical record documentation of a therapeutic failure on two or more previous lines of therapy **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

Note: Yescarta is not indicated for the treatment of patients with primary central nervous system lymphoma.

Follicular Lymphoma
- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of relapsed or refractory follicular lymphoma (FL) **AND**
- Medical record documentation of a therapeutic failure on two or more previous lines of therapy **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

AUTHORIZATION DURATION: Yescarta will be approved for a one-time authorization for one administration of Yescarta.

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: 1/16/18

Revised: 1/15/19 (prior CAR-T therapy), 4/29/21 (DLBCL arising from follicular lymphoma), 6/18/21 (Follicular Lymphoma indication), 5/17/22 (added second line lymphoma, Medicaid PARP statement), 5/11/23 (LOB carve out, Medicaid business segment)

Reviewed: 10/31/18, 11/1/19, 9/30/20