CLINICAL GUIDELINES FOR MEDICAL NECESSITY

MEDICAL POLICY

Glofitamab-gxbm (Columvi®)

Version: 1.0

EFFECTIVE DATE: 1/1/2024

NantHealth® | Eviti®

Please note the following:

Glofitamab-gxbm (Columvi®)

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Please refer to the CMS website at http://www.cms.gov for additional information.

Note: For Medicaid members/enrollees, circumstances when state Medicaid coverage provisions conflict with the coverage provisions within this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Glofitamab-gxbm (Columvi): Discussion

Non-Hodgkin's lymphomas (NHL) are a heterogeneous group of lymphoproliferative disorders originating in B-lymphocytes, T-lymphocytes, or natural killer (NK) cells (NK/T-cell lymphomas are rare).[1] Glofitamab-gxbm is a bispecific antibody (has two distinct binding domains) that binds to CD20 expressed on the surface of B cells, and to CD3 receptors expressed on the surface of T cells. It causes T-cell activation and growth, the release of cytokines (proteins that function as chemical messengers in your immune system), and the destruction of CD20-expressing B cells.[2]

Glofitamab-gxbm is approved by the FDA for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS), or large B-cell lymphoma (LBCL) arising from follicular lymphoma after two or more lines of systemic therapy.[2]

NCCN has endorsed glofitamab-gxbm for the following indications: diffuse large B-cell lymphoma (DLBCL), histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma, high-grade B-cell lymphomas, HIV-related diffuse large B-cell lymphoma, HHV8-positive diffuse large B-cell lymphoma, and post-transplant lymphoproliferative disorders.[1]

Note:

1. Cytokine release syndrome (CRS), including serious or fatal reactions, can occur in patients receiving glofitamab-gxbm. Premedicate before each dose, and initiate treatment with the glofitamab-gxbm step-up dosing schedule to reduce the risk of CRS.
2. Individuals should be hospitalized for the 2.5 mg step-up dose and for subsequent infusions as recommended. [2]

Glofitamab-gxbm: Definitions

- **Food and Drug Administration (FDA) -** The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary

drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

- **National Comprehensive Cancer Network (NCCN) -** An alliance of thirty-two leading cancer centers devoted to patient care, research, and education. The NCCN guidelines are utilized for Radiation Therapy and Medical Oncology standards. NCCN consensus clinical standards are periodically updated and NantHealth, Inc. reviews these and updates its policies within a timely manner.
- **Cytokine Release Syndrome -** A condition that may occur after treatment with some types of immunotherapies, such as monoclonal antibodies and CAR-T cells. Cytokine release syndrome is caused by a large, rapid release of cytokines into the blood from immune cells affected by the immunotherapy. [3]
- **Tumor Lysis Syndrome -** A potentially serious complication of anticancer therapy characterized by metabolic and electrolyte abnormalities caused by the disintegration of malignant cells by anticancer therapy and rapid release of intracellular contents into the peripheral blood. It is usually observed within 12 to 72 hours after the start of chemotherapy. [1]

Glofitamab-gxbm: Policy

Glofitamab-gxbm will be considered for coverage when the following criteria are met:

Diffuse Large B-Cell Lymphoma (DLBCL) or High-Grade B-Cell Lymphomas (High-Grade B-Cell Lymphomas with Translocations of MYC and BCL2 and/or BCL6 or High-Grade B-Cell Lymphomas)

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Third line and subsequent therapy (only after at least two lines of systemic therapy) as a single agent for a partial response, no response, progressive, relapsed, or refractory disease [1]

Histologic Transformation of Indolent Lymphomas to Diffuse Large B-Cell Lymphoma

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Single-agent (only after at least 2 lines of systemic therapy) for disease that was previously treated with an anthracycline-based regimen and with no intention to proceed to transplant for histologic transformation of follicular or nodal marginal zone lymphoma with a partial response, no response, progressive, relapsed, or refractory disease [1]

HIV-Related B-Cell Lymphomas (Diffuse large B-cell lymphoma, primary effusion lymphoma, and HHV8-positive diffuse large B-cell lymphoma, not otherwise specified)

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Third line and subsequent therapy (only after at least two lines of systemic therapy) as a single agent for a partial response, no response, relapsed, progressive, or refractory disease [1]

Post-Transplant Lymphoproliferative Disorders (PTLD) and Monomorphic PTLD B-cell type

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Third line and subsequent therapy (only after at least two lines of systemic therapy) as a single agent for a partial response, no response, relapsed, progressive, or refractory disease [1]

Note: All of the above indications also include patients with disease progression after transplant or CAR T-cell therapy.[1]

Authorization Period and Renewal Criteria

1. Initial Authorization Period: 12 months
2. Renewal Criteria: No evidence of disease progression or unacceptable toxicity
3. Renewal Authorization Period: 12 months

Glofitamab-gxbm: References

1. National Comprehensive Cancer Network Guidelines. B-Cell Lymphomas (Version 5.2023). https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed August 16, 2023.
2. Glofitamab-gxbm (Columvi) Package Insert. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761309s000lbl.pdf. Accessed August 16, 2023.
3. Cytokine Release Syndrome. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/cytokine-release-syndrome. Accessed August 16, 2023.

Glofitamab-gxbm: Coding (CPT®, ICD 10 and HCPCS) *

*Procedure codes appearing in medical policy documents are only included as a general reference. This list may not be all-inclusive and is subject to updates. In addition, the codes listed are not a guarantee of payment. CPT codes are available through the AMA.

CODE	DESCRIPTION
B21.2	HIV Non-Hodgkin's lymphoma
C83.3	Diffuse large B-cell lymphoma, unspecified site
D47. Z1	Post-transplant lymphoproliferative disorder
J9999	Glofitamab-gxbm

Glofitamab-gxbm: Revision and Review History

NO.	DESCRIPTION	DATE(S)
1	Original Effective Date:	1/1/2024
2	Policy Review Dates:	8/28/2023
3	Policy Revision Dates:	
4	Department Owner:	Medical Affairs
5	NH Advisory Committee:	9/29/2023
6	Revision Changes:	