Glofitamab-gxbm (COLUMVI)
Criteria for Use
November 2024

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at *www.pbm.va.gov* or *http://vaww.pbm.va.gov* for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive glofitamab.

- ☐ Facility is not equipped to monitor and manage Cytokine Release Syndrome (CRS), if necessary
- ☐ Patient unable to be hospitalized for step-up dose on Cycle 1, Day 8 and/or Day 15 followed by 24 hours of monitoring, if any grade of CRS is experienced on either day
- ☐ Absolute Neutrophil Count < 1500/µL, Platelet count < 75,000/µL (if no bone marrow involvement)
- ☐ Total bilirubin > 1.5 times the upper limit of normal (unless Gilbert's syndrome or liver involvement)
- ☐ Alanine transaminase (ALT), aspartate transaminase (AST) and alkaline phosphatase > 3 times the upper limit of normal (unless liver involvement)
- ☐ Creatinine clearance < 50 ml/min
- ☐ Active or uncontrolled infection
- ☐ Unmanageable drug-drug interaction
- ☐ Pregnancy
- ☐ Lactating

Inclusion Criteria

The answers to ALL of the following must be fulfilled in order to meet criteria.

- ☐ Relapsed or refractory, diffuse large B-cell lymphoma (DLBCL) or large B-cell lymphoma (LBCL) arising from follicular lymphoma (FL)
- ☐ Previously treated with ≥ 2 prior lines of therapy (including 1 line with anti-CD20 monoclonal antibody)
- ☐ Care is provided by a VA/VA Community Care oncology or hematology provider
- ☐ Eastern Cooperative Oncology Group (ECOG) performance status 0-1
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented

Additional Inclusion Criteria *Select if applicable*

- ☐ For patients who can become pregnant and patients with partners who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 1 month after stopping treatment.

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Updated version may be found at *PBM INTERnet* or *PBM INTRAnet*