Gazyva (obinutuzumab)

Line(s) of Business: HMO; PPO; QUEST Integration
Akamai Advantage

Effective Date: 10/01/2015

POLICY

A. 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.

FDA-Approved Indications

- Gazyva is a CD20-directed cytolytic antibody and is indicated, in combination with chlorambucil, for the treatment of patients with previously untreated chronic lymphocytic leukemia

Compendial Uses

- Chronic lymphocytic leukemia/Small lymphocytic lymphoma
  - First line therapy in patients greater than, or equal to, 70 years of age with indications for treatment in combination with chlorambucil for disease without del(11q) or del(17p)
  - First line therapy in patients with indications for treatment and significant comorbidities in combination with chlorambucil for disease without del(11q) or del(17p)
  - First line therapy in patients with indications for treatment in combination with chlorambucil for disease with del(11q) or del(17p)
  - Therapy for patients with indications for treatment who are unable to tolerate purine analogs in combination with chlorambucil
  - Relapsed or refractory disease
    - Without del(11q) or del(17p) in patients with indications for treatment
    - With del(11q)

B. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

- Results of testing or analysis positive for the CD20 protein on the surface of the B-cell
- Cancer type/location, tumor histology and grade, staging, new cancer/recurrence, metastases, prior treatments, treatment intent (e.g., initial chemotherapy, neoadjuvant, adjuvant, or palliative)
- Treatment plan with treatment regimen including dose, frequency, length of each cycle, number of cycles, and additional therapies (e.g., other medications, radiation)

C. PRESCRIBER RESTRICTION

The medication must be prescribed by, or in conjunction with, an oncologist or hematologist
D. EXCLUSIONS
- Members who have not been screened for hepatitis B (HBV) infection prior to initiating therapy
- Members whose disease does not possess the CD20 antigen

E. CRITERIA FOR APPROVAL
1. Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL)
   a. Authorization of 6 months may be granted for members greater than, or equal to, 70 years of age with indications for treatment (See Appendix A) who are prescribed Gazyva as first line therapy in combination with chlorambucil
   b. Authorization for 6 months may be granted for members with indications for treatment and significant comorbidities who are prescribed Gazyva as first line therapy in combination with chlorambucil
   c. Authorization for 6 months may be granted for members with indications for treatment and the del(11q) or del(17p) mutation who are prescribed Gazyva in combination with chlorambucil
   d. Authorization for 6 months may be granted for members with indications who are unable to tolerate purine analogs who are prescribed Gazyva in combination with chlorambucil
   e. Authorization for 6 months may be granted for members prescribed Gazyva for relapsed or refractory disease who meet either of the following criteria
      - Without del(11q) or del(17p) in patients with indications for treatment
      - With del(11q)

F. CONTINUATION OF THERAPY
All members, including new members, requesting authorization for therapy must meet ALL initial authorization criteria.

Members who were previously approved for Gazyva by HMSA may request reauthorizations after their initial approval. Approval for an additional 6 months may be granted if the following information is supplied:
- A current oncology note documenting the patient’s response to treatment showing no progression of disease
- Current laboratory reports or other objective measures showing no progression of disease when compared with previous results

G. DOSING AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

H. APPENDIX A
Indications for therapy include severe fatigue, night sweats, weight loss, progressive anemia, progressive thrombocytopenia, threatened end-organ dysfunction

I. IMPORTANT REMINDER
The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.
Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

J. REFERENCES