Reference number
2075-A

SPECIALTY GUIDELINE MANAGEMENT

GAZYVA (obinutuzumab)

POLICY

I. 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.

A. FDA-Approved Indications
1. Chronic Lymphocytic Leukemia (CLL)
   Gazyva, in combination with chlorambucil, is indicated for the treatment of patients with previously untreated CLL.

2. Follicular Lymphoma
   a. Gazyva, in combination with bendamustine followed by Gazyva monotherapy, is indicated for the treatment of patients with follicular lymphoma who relapsed after, or are refractory to, a rituximab-containing regimen.
   b. Gazyva, in combination with chemotherapy followed by Gazyva monotherapy in patients achieving at least a partial remission, is indicated for the treatment of adult patients with previously untreated stage II bulky, III or IV follicular lymphoma.

B. Compendial Uses
1. Chronic lymphocytic leukemia in combination with acalabrutinib or venetoclax or as a single agent
2. Small lymphocytic lymphoma (SLL) (managed in the same manner as CLL) in combination with acalabrutinib or venetoclax or as a single agent
3. Follicular lymphoma
4. Gastric MALT lymphoma, second-line or subsequent therapy in combination with bendamustine for recurrent or progressive disease, maintenance therapy, or substitute for rituximab in patients experiencing rare complications from rituximab
5. Non-gastric MALT lymphoma, second-line or subsequent therapy in combination with bendamustine for refractory or progressive disease, maintenance therapy, or substitute for rituximab in patients experiencing rare complications from rituximab
6. Nodal marginal zone lymphoma, second-line or subsequent therapy in combination with bendamustine for refractory or progressive disease, maintenance therapy, or substitute for rituximab in patients experiencing rare complications from rituximab
7. Splenic marginal zone lymphoma, second-line (if prior treatment with rituximab) or subsequent therapy in combination with bendamustine for recurrent disease, maintenance therapy, or substitute for rituximab in patients experiencing rare complications from rituximab
8. Histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma substitute for rituximab in patients experiencing rare complications from rituximab
9. Mantle cell lymphoma, substitute for rituximab in patients experiencing rare complications from rituximab
10. Diffuse large B-cell lymphoma, substitute for rituximab in patients experiencing rare complications from rituximab
11. High-grade B-cell lymphomas, substitute for rituximab in patients experiencing rare complications from rituximab

12. Burkitt lymphoma, substitute for rituximab in patients experiencing rare complications from rituximab [2]
13. AIDS-related B-cell lymphomas, substitute for rituximab in patients experiencing rare complications from rituximab
14. Post-transplant lymphoproliferative disorders, substitute for rituximab in patients experiencing rare complications from rituximab
15. Castleman's disease, substitute for rituximab in patients experiencing rare complications from rituximab

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITAL APPROVAL

A. Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL)
Authorization of 6 months may be granted for the treatment of CLL/SLL as a single agent or in combination with acalabrutinib, venetoclax or chlorambucil.

B. Follicular Lymphoma (FL)
Authorization of 6 months, up to 30 months total, may be granted for the treatment of follicular lymphoma when any of the following criteria are met:

1. The requested medication will be used in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone) regimen, CVP (cyclophosphamide, vincristine and prednisone) regimen, or bendamustine.
2. The requested medication will be used as maintenance therapy
3. The requested medication will be used as a substitute for rituximab in members experiencing rare complications from rituximab such as mucocutaneous reactions including paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis.

C. Gastric MALT Lymphoma, Non-gastric MALT Lymphoma, Nodal and Splenic Marginal Zone Lymphoma
Authorization of 6 months may be granted for the treatment of gastric MALT lymphoma, non-gastric MALT lymphoma, nodal marginal zone lymphoma, or splenic marginal zone lymphoma when any of the following criteria are met:

1. The requested medication will be used as second-line or subsequent therapy in combination with bendamustine.
2. The requested medication be used as maintenance therapy when the member has been previously treated with the requested medication and bendamustine.
3. The requested medication is used as a substitute for rituximab in members experiencing rare complications from rituximab such as mucocutaneous reactions including paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis.

D. Histologic Transformation of Marginal Zone Lymphoma to Diffuse Large B-Cell Lymphoma, Mantle Cell Lymphoma, Diffuse Large B-Cell Lymphoma, High-Grade B-Cell Lymphomas, Burkitt Lymphoma, AIDS-Related B-Cell Lymphomas, Post-Transplant Lymphoproliferative Disorders, and Castleman's Disease
Authorization of 6 months may be granted for the treatment of histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma, mantle cell lymphoma, diffuse large B-cell lymphoma, high-grade B-cell lymphomas, Burkitt lymphoma, AIDS-related B-cell lymphomas, post-transplant lymphoproliferative disorders, or Castleman's disease when the requested medication is used as a substitute for rituximab in members experiencing rare complications from rituximab such as

mucocutaneous reactions including paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis.

III. CONTINUATION OF THERAPY

A. Follicular Lymphoma (FL)

Authorization of 12 months, up to 30 months total, may be granted for continued treatment in members requesting reauthorization for follicular lymphoma when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

B. All other indications

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Gazyva [package insert]. South San Francisco, CA: Genentech, Inc.; March 2020.
2. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. http://www.nccn.org. Accessed July 16, 2020.