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/ small lymphocytic lymphoma (CLL/ SLL)
2. Follicular lymphoma
3. Marginal zone lymphomas
   a. Gastric mucosa associated lymphoid tissue (MALT) lymphoma
   b. Nongastric MALT lymphoma
   c. Nodal marginal zone lymphoma
   d. Splenic marginal zone lymphoma
4. Histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma
5. Mantle cell lymphoma
6. Diffuse large B-cell lymphoma
7. High-grade B-cell lymphomas (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
8. Burkitt lymphoma
9. AIDS-related B-cell lymphomas
10. Post-transplant lymphoproliferative disorders
11. Castleman's disease

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, bendamustine, 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 as first line therapy.
2. The requested medication will be used as a single agent or in combination with lenalidomide, bendamustine, CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone) or CVP (cyclophosphamide, vincristine, and prednisone) for subsequent therapy.
3. The requested medication will be used as maintenance therapy as a single agent.
4. The requested medication will be used as a substitute for rituximab in members experiencing intolerance or 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, and Splenic Marginal Zone Lymphoma

Authorization of 6 months may be granted for the treatment of gastric MALT lymphoma, non-gastric MALT 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 intolerance or rare complications from rituximab such as mucocutaneous reactions including paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis.

D. Nodal Marginal Zone Lymphoma

Authorization of 6 months may be granted for the treatment of nodal marginal zone lymphoma when any of the following criteria are met:

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

E. Histologic Transformation of Nodal Marginal Zone Lymphoma to Diffuse Large B-Cell Lymphoma, Mantle Cell Lymphoma, Diffuse Large B-Cell Lymphoma, High-Grade B-Cell Lymphomas (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified), 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 (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified), 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 intolerance or 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. APPENDIX

Re-challenge with the same anti-CD20 monoclonal antibody is not recommended and it is unclear if the use of an alternative anti-CD20 monoclonal antibody poses the same risk of recurrence.

V. REFERENCES

1. Gazyva [package insert]. South San Francisco, CA: Genentech, Inc.; January 2021.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed June 1, 2021.