Reference number(s)
4467-A

Standard Medicare Part B Management Gazyva

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Gazyva	obinutuzumab

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[1]

Chronic Lymphocytic Leukemia (CLL)

Gazyva, in combination with chlorambucil, is indicated for the treatment of patients with previously untreated CLL.

Follicular Lymphoma

- 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.
- 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.

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Lupus Nephritis (LN)

Gazyva is indicated for the treatment of adult patients with active lupus nephritis who are receiving standard therapy.

Compendial Uses[2,3]

- Chronic lymphocytic leukemia/ small lymphocytic lymphoma (CLL/ SLL)
- Follicular lymphoma
- Marginal zone lymphomas
    - Extranodal (gastric and non-gastric MALT lymphoma) marginal zone lymphoma
    - Nodal marginal zone lymphoma
    - Splenic marginal zone lymphoma
- Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
- Mantle cell lymphoma (MCL)
- 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
- HIV-related B-cell lymphomas
- Post-transplant lymphoproliferative disorders
- Castleman's disease
- Hairy Cell Leukemia

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

Submission of the following information must be available, upon request, for all submissions:

- For TP53-mutated MCL: documentation of the presence of TP53-mutation.
- For lupus nephritis:
    - Initial requests: medical records (e.g., chart notes, lab reports) documenting the presence of autoantibodies relevant to SLE (e.g., antinuclear antibodies [ANA] by immunofluorescence [IFA] 1:80 or higher, anti-double-stranded DNA [anti-ds DNA], anti-Smith [anti-Sm], antiphospholipid antibodies, low complement proteins), or kidney biopsy supporting diagnosis (where applicable).
    - Continuation requests: medical records (e.g., chart notes, lab reports) documenting disease stability or improvement.

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Coverage Criteria[1-5]

Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL)

Authorization of 12 months may be granted for the treatment of CLL/SLL as a single agent or in combination with acalabrutinib, venetoclax, acalabrutinib and venetoclax, chlorambucil, bendamustine, high-dose methylprednisolone (HDMP), or ibrutinib.

Follicular Lymphoma (FL)

Authorization of 12 months, up to 30 months total, may be granted for the treatment of follicular lymphoma when any of the following criteria are met:

- The requested medication will be used in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone) regimen, CVP (cyclophosphamide, vincristine and prednisone) regimen, bendamustine, or lenalidomide as first line therapy.
- 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.
- The requested medication will be used as maintenance therapy as a single agent.
- 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.
- The requested medication will be used in combination with zanubrutinib (Brukinsa) as third line and subsequent therapy.

Active Lupus Nephritis

Authorization of 12 months may be granted for treatment of active lupus nephritis when both of the following criteria are met:

- The member meets either of the following:
  - Lupus nephritis is confirmed on kidney biopsy
  - If a kidney biopsy is not feasible or if the member is not a candidate for kidney biopsy, prior to initiating therapy, the member is positive for autoantibodies relevant to SLE (e.g., ANA by IFA 1:80 or higher, anti-ds DNA, anti-Sm, antiphospholipid antibodies, low complement proteins)
- Member is receiving a standard therapy regimen (e.g., cyclophosphamide, mycophenolate mofetil, azathioprine, hydroxychloroquine, glucocorticoids) or has a clinical reason to avoid treatment with standard therapy regimen.

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Extranodal Marginal Zone Lymphoma and Splenic Marginal Zone Lymphoma

Authorization of 12 months may be granted for the treatment of extranodal marginal zone lymphoma (gastric and non-gastric MALT lymphoma) or splenic marginal zone lymphoma when any of the following criteria are met:

- The requested medication will be used as subsequent therapy in combination with bendamustine, or lenalidomide.
- The requested medication will be used as maintenance therapy when the member has been previously treated with the requested medication and bendamustine.
- 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.

Nodal Marginal Zone Lymphoma

Authorization of 12 months may be granted for the treatment of nodal marginal zone lymphoma when any of the following criteria are met:

- 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.
- The requested medication will be used as subsequent therapy in combination with bendamustine, or lenalidomide.
- The requested medication will be used as maintenance therapy when the member has been previously treated with the requested medication and bendamustine.
- 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.

Hairy Cell Leukemia

Authorization of 12 months may be granted in combination with vemurafenib as initial therapy for treatment of hairy cell leukemia in members who are unable to tolerate purine analogs.

B-Cell Lymphomas when used as pre- treatment with glofitamab (Columvi)

Authorization of 1 month may be granted for treatment of mantle cell lymphoma, diffuse large B-cell lymphoma, high-grade B-cell lymphomas, histologic transformation of indolent lymphomas to diffuse

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large B-cell lymphoma, HIV-related B-cell lymphomas and post-transplant lymphoproliferative disorders when used as single agent pre-treatment for up to 1 dose in cycle 1 of glofitamab therapy.

Mantle Cell Lymphoma

Authorization of 12 months may be granted for mantle cell lymphoma when either of the following criteria are met:

- The requested medication will be used as induction therapy for TP53 mutated disease and in combination with Venclexta (venetoclax) and Brukinsa (zanubrutinib).
- 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.

Histologic Transformation of indolent Lymphomas to Diffuse Large B-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, HIV-Related B-Cell Lymphomas, Post-Transplant Lymphoproliferative Disorders, and Castleman's Disease

Authorization of 12 months may be granted for the treatment of histologic transformation of indolent lymphomas to diffuse large B-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, HIV-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.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

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Follicular Lymphoma (FL)

Authorization of 12 months, up to 30 months total may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat follicular lymphoma.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen and
    - No evidence of disease progression while on the current regimen

Lupus Nephritis

Authorization of 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat lupus nephritis.
- The member is receiving benefit from therapy. Benefit is defined as disease stability or improvement.

B-Cell Lymphomas when Used as Pre- Treatment with Glofitamab (Columvi)

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

All Other Indications

Authorization of 12 months, may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication listed in the coverage criteria section.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen and
    - No evidence of disease progression while on the current regimen

Appendix[3]

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.

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Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Gazyva.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Hairy cell leukemia
- NCCN Guideline: Chronic lymphocytic leukemia/small lymphocytic lymphoma
- NCCN Guideline: B-cell lymphomas
- 2024 American College of Rheumatology (ACR) Guideline for the Screening, Treatment, and Management of Lupus Nephritis

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Gazyva are covered in addition to the following:

- Chronic lymphocytic leukemia/ small lymphocytic lymphoma (CLL/ SLL)
- Follicular lymphoma
- Marginal zone lymphomas
    - Extranodal (gastric and non-gastric MALT lymphoma) marginal zone lymphoma
    - Nodal marginal zone lymphoma
    - Splenic marginal zone lymphoma
- Histologic transformation of indolent lymphomas 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
- HIV-related B-cell lymphomas
- Post-transplant lymphoproliferative disorders
- Castleman's disease
- Hairy Cell Leukemia

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for the additional indications listed in Summary of Evidence can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label

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use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

According to the 2024 ACR guideline for lupus nephritis, it is strongly recommended to initiate and continue hydroxychloroquine to manage and prevent extra-renal manifestations, unless contraindicated.

References

1. Gazyva [package insert]. South San Francisco, CA: Genentech, Inc.; December 2025.
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3. Bajema IM, Wilhelmus S, Alpers CE, et al. Revision of the International Society of Nephrology/Renal Pathology Society classification for lupus nephritis: clarification of definitions, and modified National Institutes of Health activity and chronicity indices. Kidney Int. 2018;93(4):789-796. https://www.sciencedirect.com/science/article/pii/S0085253817308591. Accessed February 10, 2026.
4. Sammaritano LR, Askanase A, Bermas BL, et al. 2024 American College of Rheumatology (ACR) Guideline for the Screening, Treatment, and management of Lupus Nephritis. Arthritis and Rheumatology. 2025;1115-1135.
5. Fanouriakis A, Kostopoulou M, Alunno A, et al. EULAR recommendations for the management of systemic lupus erythematosus with kidney involvement: 2025 update. Ann Rheum Dis. January 2026;85(1):75-90. URL: https://ard.eular.org/article/S0003-4976%2825%2904412-7/fulltext. Accessed March 14, 2026.

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