

POLICY Document for Gazyva

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 2: Oncology Clinical Policy

- Policy information specific to regimen review per NCCN Guidelines.

Section 1: Clinical Criteria

Specialty Guideline 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
- 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.

- **Compendial Uses**

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

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

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Documentation of the presence of TP53-mutation (for TP53-mutated Mantle cell lymphoma).

Coverage Criteria

- **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.

Authorization of 6 months may be granted in combination with high-dose methylprednisolone for the treatment of CLL/SLL when Bruton Tyrosine Kinase inhibitor (e.g. acalabrutinib) and venetoclax are not available or contraindicated or rapid disease de-bulking is needed.

- **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:

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.

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.

- **Extranodal Marginal Zone Lymphoma and Splenic Marginal Zone Lymphoma**

Authorization of 6 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 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 6 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 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 6 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 diffuse large B-cell lymphoma, high-grade B-cell lymphomas, histologic transformation of indolent lymphomas to diffuse 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 6 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 6 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

- 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-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 for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

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.

Section 2: Oncology Clinical Policy

PURPOSE

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Novologix LLC_NCCN Oncology Clinical Policy_9.2024

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The purpose of this policy is to define the Novologix NCCN® Regimen Prior Authorization Program.

SCOPE

This policy applies to clients who have implemented the Novologix NCCN® Program as a part of their medical and/or pharmacy prior authorization solution.

PROGRAM DESCRIPTION

The National Comprehensive Care Network® (NCCN®) is an alliance of leading cancer centers devoted to patient care, research and education dedicated to improving the quality, effectiveness, and efficiency of cancer care so patients can live better lives.¹ It is comprised of oncology experts who convene regularly to establish the best treatments for patients. NCCN develops various resources for use by stakeholders in the health care delivery system. These resources include, but are not limited to, the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), the NCCN Drugs & Biologics Compendium (NCCN Compendium®) and the NCCN Chemotherapy Order Templates (NCCN Templates®).

NCCN Templates® are based on NCCN Guidelines® and NCCN Compendium®. The NCCN Compendium lists the appropriate drugs and biologics as treatment options for specific cancers using U.S. Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category.

NCCN Categories of Evidence and Consensus²

- Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
- Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

POLICY

Policy for Regimen Prior Authorization

A regimen prior authorization allows submission of a single prior authorization request for all oncology drugs or biologics within an NCCN template that require prior authorization.

PROCEDURE

This policy provides coverage of a regimen review when all of the following criteria are met:

1. Regimen prior authorization reviews, based on NCCN templates, are initiated through the provider portal.
 - If the prior authorization request is submitted via phone or fax, each drug or biologic will need to be submitted and reviewed as a separate prior authorization request for review with drug-specific criteria.
2. The prior authorization review is requested for an oncology drug or biologic.
3. The member is eligible for regimen review.
4. The indication is for a cancer that is eligible for regimen review. Currently, the cancer types in scope for regimen review include the following:
 - o Ampullary Adenocarcinoma
 - o Anal Carcinoma
 - o B-Cell Lymphomas
 - o Basal Cell Skin Cancer
 - o Biliary Tract Cancers
 - o Bone Cancer
 - o Breast Cancer
 - o Bladder Cancer
 - o Central Nervous System Cancers
 - o Cervical Cancer
 - o Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
 - o Chronic Myeloid leukemia
 - o Colon Cancer
 - o Dermatofibrosarcoma Protuberans
 - o Esophageal Cancer
 - o Gastric Cancer
 - o Gastrointestinal Stromal Tumors
 - o Gestational Trophoblastic Neoplasms
 - o Hairy Cell Leukemia
 - o Head and Neck Cancers
 - o Histiocytic Neoplasms
 - o Hodgkin Lymphoma
 - o Hepatocellular Carcinoma
 - o Kaposi Sarcoma
 - o Kidney Cancer

- o Melanoma: Cutaneous
- o Melanoma: Uveal
- o Merkel Cell Carcinoma
- o Mesothelioma: Peritoneal
- o Mesothelioma: Pleural
- o Multiple Myeloma
- o Myelodysplastic Syndromes
- o Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions
- o Myeloproliferative Neoplasms
- o Neuroendocrine and Adrenal Tumors
- o Non-Small Cell Lung Cancer
- o Occult Primary
- o Ovarian Cancer
- o Pancreatic Cancer
- o Penile Cancer
- o Primary Cutaneous Lymphomas
- o Prostate Cancer
- o Rectal Cancer
- o Small Bowel Adenocarcinoma
- o Small Cell Lung Cancer
- o Soft Tissue Sarcoma
- o Squamous Cell Skin Cancer
- o Systemic Mastocytosis
- o Systemic Light Chain Amyloidosis
- o T-Cell Lymphomas
- o Testicular Cancer
- o Thymomas and Thymic Carcinomas
- o Thyroid Carcinoma
- o Uterine Neoplasms
- o Vaginal Cancer
- o Vulvar Cancer
- o Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma
- o Wilms Tumor (Nephroblastoma)

In addition, the following criteria must be met for approval:

1. The requested regimen for the drug(s) or biologic(s) and indication is consistent with an NCCN recommendation with a level of evidence category of 1 or 2A.
2. The NCCN template must be accepted by the provider without modification.

Further review may be indicated when the above criteria are not met.

Authorizations may be granted for 12 months or as medically required, based on the member's condition and provider's assessment.

Supportive Care: Myeloid Growth Factor Therapy

Granulocyte colony stimulating factors are recommended for primary prophylaxis based on the febrile neutropenia risk of the chemotherapy regimen. Febrile neutropenia risk levels vary by NCCN Chemotherapy Order template and are listed at the top of the template. Regimens associated with a high or intermediate risk of febrile neutropenia may include a granulocyte colony stimulating factor as part of the prior authorization.

Continuation of Therapy

To submit a request for continuation of therapy, a new regimen prior authorization review must be requested. Upon template selection, the template must be modified to include the appropriate therapies being used for maintenance treatment. The regimen request will be submitted for further review.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and evidence-based practice guidelines.

REFERENCES:

SECTION 1

1. Gazyva [package insert]. South San Francisco, CA: Genentech, Inc.; July 2022.
2. Columvi [package insert]. South San Francisco, CA: Genentech, Inc.; June 2023.
3. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed May 28, 2024.

SECTION 2

1. National Comprehensive Cancer Network. About NCCN website. <https://www.nccn.org/home/about>, accessed September 9, 2024.
2. National Comprehensive Cancer Network. NCCN Categories of Evidence and Consensus website, <https://www.nccn.org/guidelines/guidelines-process/development-and-update-of-guidelines>, accessed September 9, 2024.

3. National Comprehensive Cancer Network. NCCN Guidelines website. https://www.nccn.org/guidelines/category_1, accessed September 9, 2024. (Note: An account may be required.)
4. National Comprehensive Cancer Network. NCCN Drugs and Biologics Compendium website <https://www.nccn.org/compendia-templates/compendia/drugs-and-biologics-compendia>, accessed September 9, 2024. (Note: A subscription may be required.)
5. National Comprehensive Cancer Network. NCCN Chemotherapy Order Templates (NCCN Templates) website. <https://www.nccn.org/compendia-templates/nccn-templates-main/browse-by-cancer-type>, accessed September 9, 2024. (Note: A subscription may be required.)