blue california
Promise Health Plan

obinutuzumab (Gazyva)

Medical Benefit Drug Policy

Place of Service
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: ANTINEOPLASTICS
Mechanism of Action: Anti-CD20 monoclonal antibody
HCPCS:
J9301:Injection, obinutuzumab, 10 mg
How Supplied:
1000 mg/40 ml (single-use vial)

Condition(s) listed in policy *(see coverage criteria for details)*

- B-cell Lymphomas
- Castleman Disease
- Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma
- Follicular Lymphoma
- Hairy Cell Leukemia
- Mantle Cell Lymphoma
- Marginal Zone Lymphoma
- Pretreatment with Columvi Therapy

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

B-cell Lymphomas
Meets medical necessity if all the following are met:

1. Diagnosis of B-cell lymphomas (e.g., diffuse Large B-Cell Lymphoma, high-grade B-cell Lymphoma, histologic transformation of indolent Lymphomas to Diffuse Large B-Cell Lymphoma, HIV-related B-Cell Lymphomas, or Post-Transplant Lymphoproliferative Disorders, Burkitt Lymphoma)
2. Being used as a substitute for a NCCN-supported use of rituximab due to an intolerance or contraindication to rituximab (e.g., severe hypersensitivity reactions requiring discontinuation, and rare complications such as mucocutaneous reactions including paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis)

Covered Doses:
Dependent on NCCN supported regimen

Coverage Period:
Dependent on NCCN supported regimen

ICD-10:
B20, C82.00-C82.09, C82.10-C82.19, C82.20-C82.29, C82.30-C82.39, C82.40-C82.49, C82.50-C82.59, C82.60-C82.69, C82.80-C82.89, C82.90-C82.99, C83.07, C83.10-C83.19, C85.20-C85.29, C83.30-C83.38, C83.398, C83.70-C83.79, C83.80-C83.89, C83.90-C83.99, C85.10 - C85.19, C85.80-C85.89, C88.40, D47.Z1

<u>Castleman Disease</u>
Meets medical necessity if all the following are met:
1. Being used as a substitute for a NCCN-supported use of rituximab due to an intolerance or contraindication to rituximab (e.g., severe hypersensitivity reactions requiring discontinuation, and rare complications such as mucocutaneous reactions including paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis)

Covered Doses:
Dependent on NCCN supported regimen

Coverage Period:
Dependent on NCCN supported regimen

ICD-10:
B10.89, D47.Z2

<u>Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma</u>
Meets medical necessity if all the following are met:

Covered Doses:

For cycle 1 (28-day cycle): Up to 100 mg given intravenously (IV) on Day 1, 900 mg on Day 2, followed by 1000 mg on Days 8 and 15
For cycles 2 to 6 (28-day cycles): Up to 1000 mg given IV on Day 1
OR
For cycle 1 (21-day cycle): Up to 100 mg given IV on Day 1, 900 mg on Day 2, followed by 1000 mg on Days 8 and 15
For cycles 2 to 8 (21-day cycles): Up to 1000 mg given IV on Day 1

Coverage Period:
Up to 6-8 cycles depending on drug regimen

ICD-10:
C83-C83.09, C91.10, C91.12

Follicular Lymphoma
Meets medical necessity if all the following are met:
1. Meets ONE of the following:
    a. Diagnosis of follicular lymphoma (including primary cutaneous follicular lymphoma with extracutaneous disease and meets ONE of the following:
        i. Being used as a single-agent for treatment or maintenance therapy
        ii. Being used for treatment in combination with ONE of the following:
            1. Bendamustine
            2. CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone)
            3. CVP (cyclophosphamide, vincristine, and prednisone)
            4. Lenalidomide
            5. Brukinsa (zanubrutinib) and meets both of the following:
                a. Disease is relapsed or refractory or progressive
                b. Patient has received at least two prior lines of systemic therapy
    b. Being used as a substitute for a NCCN-supported use of rituximab due to an intolerance or contraindication to rituximab (e.g., severe hypersensitivity reactions requiring discontinuation, and rare complications such as mucocutaneous reactions including paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis)

Covered Doses:
Single agent treatment:
Cycle 1 (28-day cycle): up to 1000 mg given intravenously (IV) on days 1, 8, 15, 22
Cycles 2-13 (56-day cycles): up to 1000 mg given IV on day 1

Single agent maintenance:
Up to 1000 mg every 2 months up to 12 doses

In combination with Brukinsa or bendamustine for treatment and maintenance:
Cycle 1 (28-day cycle): up to 1000 mg given IV on day 1, 8, 15
Cycle 2-6 (28-day cycles): up to 1000 mg given IV on day 1
Maintenance starts 8 weeks after cycle 6 (56-day cycles): up to 1000 mg given IV on day 1

In combination with CHOP (cyclosphosphamide, doxorubicin, vincristine and prednisone)
Cycle 1 (21-day cycle): up to 1000 mg given IV on day 1, 8, 15
Cycles 2-6 (21-day cycles): up to 1000 mg given IV on day 1

In combination with CVP (cyclosphosphamide, vincristine and prednisone)
Cycle 1 (21-day cycle): up to 1000 mg given IV on day 1, 8, 15
Cycles 2-8 (21-day cycles): up to 1000 mg given IV on day 1

In combination with lenalidomide:
Cycle 1 (28-day cycle): up to 1000 mg given IV on day 1, 8, 15
Cycles 2-6 (28-day cycles): up to 1000 mg given IV on day 1
Cycles 7- 18 (56-day cycles): up to 1000 mg given IV on day 1

Coverage Period:
Single-agent treatment: To complete 13 cycles
Single-agent maintenance: To complete 2 years
Combination with Brukinsa or bendamustine for treatment: To complete 6 cycles
Combination with Brukinsa or bendamustine for maintenance: Indefinite
Combination with CHOP: To complete 6 cycles
Combination with CVP: To complete 8 cycles
Combination with lenalidomide: To complete 18 cycles

ICD-10:
C82.00-C82.69, C82.80-C82.99

Hairy Cell Leukemia
Meets medical necessity if all the following are met:
1. Being used as initial treatment
2. Being used in combination with Vemurafenib (Zelboraf)

Covered Doses:
Cycle 1 (28-day cycle): Vemurafenib only
Cycle 2 (28-day cycle): Up to 1000 mg given intravenously (IV) on Days 1, 8, 15
Cycle 3 to 4 (28-day cycle): Up to 1000 mg given IV on Day 1

Coverage Period:
6 months

ICD-10:
C91.40, C91.42

Mantle Cell Lymphoma
Meets medical necessity if all the following are met:
1. Meets ONE of the following:
   a. Being used as a substitute for a NCCN-supported use of rituximab
   b. Being used in combination with zanubrutinib (Brukinsa) and venetoclax (Venclexta) as induction therapy for TP53-mutated disease

Covered Doses:
Combination with zanubrutinib (Brukinsa) and venetoclax (Venclexta)
Cycle 1 (28-day cycle): up to 1000 mg given intravenously (IV) on Days 1, 8, 15
Cycles 2-8 (28-day cycles): up to 1000 mg given IV on Day 1
OR
Cycle 1 (28-day cycles): 100 mg given IV on Day 1, 900 mg on Day 2, 1000 mg on Days 8 and 15
Cycles 2-8 (28-day cycles): 1000 mg given IV on Day 1

Coverage Period:
To complete 8 cycles

ICD-10:
C83.10-C83.19

Marginal Zone Lymphoma
Meets medical necessity if all the following are met:
1. Meets ONE of the following:
   a. Diagnosis of marginal zone lymphoma [nodal, splenic, gastric mucosa-associated lymphoid tissue (MALT), non-gastric mucosa-associated lymphoid tissue (MALT)] and primary cutaneous with extracutaneous disease and given in combination with an NCCN-supported regimen [e.g., bendamustine, CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone), CVP (cyclophosphamide, vincristine, prednisone), lenalidomide]
   b. Being used as a substitute for a NCCN-supported use of rituximab due to an intolerance or contraindication to rituximab (e.g., severe hypersensitivity reactions requiring discontinuation, and rare complications such as mucocutaneous reactions including paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis

Covered Doses:
In combination with bendamustine or lenalidomide

Cycle 1 (28-day cycle): up to 1000 mg given intravenously (IV) on day 1, 8, 15
Cycles 2-6 (28-day cycles): up to 1000 mg given IV on day 1
Maintenance
Cycle 7 to 18 (56-day cycles): Up to 1000 mg given IV on Day 1

In combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone)
Cycle 1 (21-day cycle): up to 1000 mg given IV on day 1, 8, 15
Cycles 2 to 6 (21-day cycles): up to 1000 mg given IV on day 1

In combination with CVP (cyclophosphamide, vincristine and prednisone)
Cycle 1 (21-day cycle): up to 1000 mg given IV on day 1, 8, 15
Cycles 2 to 8 (21-day cycles): up to 1000 mg given IV on day 1

Coverage Period:
Combination treatment: up to 6-8 cycles depending on drug regimen
Maintenance: up to 2 years

ICD-10:
C83.08, C83.09, C83.80-C83.89, C85.80-C85.89, C88.4

Pretreatment with Columvi Therapy
Meets medical necessity if all the following are met:
1. Being used as single dose pretreatment prior to initiation of Columvi therapy
2. Meets the following for coverage of Columvi therapy:
    a. One of the following B-cell lymphomas:
        i. Diffuse large B-cell lymphoma (DLBCL, including histologic transformation of follicular lymphoma or nodal marginal zone lymphoma to DLBCL)
        ii. High-grade B-cell lymphomas (HGBL)
        iii. HIV-related B-cell lymphomas: HIV-related DLBCL, primary effusion lymphoma, HHV8-positive DLBCL not otherwise specified
        iv. Monomorphic post-transplant lymphoproliferative disorders (PTLD)
        v. Large B-cell lymphoma (LBCL) arising from follicular lymphoma (FL)
    b. Columvi is being used as a single agent
    c. Columvi is being used as third-line and subsequent therapy

Covered Doses:
A single 1,000 mg dose given intravenously 7 days before starting Columvi (Cycle 1 Day 1)

Coverage Period:
To allow for 1 dose

ICD-10:

B20, C83.30-C83.39, C83.80-C83.89, C83.90-C83.99, C85.10-C85.19, C85.20-C85.29, C85.80-C85.89, D47.Z1

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Gazyva (Obinutuzumab) Prescribing Information. Genentech, Inc., South San Francisco, CA: 7/2022.
4. National Comprehensive Cancer Network Drugs & Biologics Compendium. Gazyva (2024). Available by subscription at: www.nccn.org.
5. National Comprehensive Cancer Network. B-cell Lymphomas. (Version 1.2025). Available at www.nccn.org.
6. National Comprehensive Cancer Network. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (Version 1.2025). Available by subscription at: www.nccn.org.
7. National Comprehensive Cancer Network. Hairy Cell Leukemia (Version 1.2025). Available by subscription at: www.nccn.org.
8. National Comprehensive Cancer Network. Primary Cutaneous Lymphoma (Version 1.2025). Available by subscription at: www.nccn.org.

Review History

Date of Last Annual Review: 1Q2025

Changes from previous policy version:

- Mantle cell lymphoma: Expanded coverage to include combination therapy with zanubrutinib (Brukinsa) and venetoclax (Venclexta) for TP53-mutated cancer (Rationale: NCCN category 2A support)

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee