Obinutuzumab (Gazyva®)	Place of Service Office Administration Outpatient Facility Infusion Administration Infusion Center Administration HCPCS: **J9301** per 10 mg

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

- Chronic lymphocytic leukemia
- Follicular lymphoma
- Hairy cell leukemia
- Marginal zone lymphoma
- Small lymphocytic leukemia

AHFS therapeutic class: Antineoplastic agents

Mechanism of action: Anti-CD20 monoclonal antibody

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Gazyva® (obinutuzumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Chronic lymphocytic leukemia or Small lymphocytic lymphoma

Covered dose

28-day cycle for 6 cycles:

- For cycle 1: Up to 100 mg IV on day 1, up to 900 mg on day 2, followed by up to 1000 mg on days 8 and 15
- For cycles 2 through 6: Up to 1000 mg IV once every 28 days.

OR

21-day cycle for 8 cycles:

- For cycle 1: Up to 100 mg IV on day 1, up to 900 mg on day 2, followed by up to 1000 mg on days 8 and 15
- For cycles 2 through 8: Up to 1000 mg IV once every 21 days.

Coverage period

Up to 6-8 cycles depending on dosing schedule

ICD-10:

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

Follicular lymphoma

1. Diagnosis of follicular lymphoma (including primary cutaneous follicular lymphoma with extracutaneous disease), **AND**

2. One of the following:
    a. Being used as a single-agent for treatment or maintenance therapy, OR
    b. Being used for treatment in combination with:
        i. Bendamustine, or
        ii. CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone), or
        iii. CVP (cyclophosphamide, vincristine, and prednisone), or
        iv. Lenalidomide

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

In combination with supported regimens for treatment:
Cycle 1: up to 1000 mg IV on day 1, 8, 15
Then either:
- 21 day cycles (cycles 2-8): up to 1000 mg on day 1, OR
- 28 day cycles (cycles 2-6): up to 1000 mg on day 1

Single agent maintenance:
Up to 1000 mg every 2 months

Coverage period
Single-agent treatment: up to 13 cycles
Combination treatment: up to 6-8 cycles depending on drug regimen
Single-agent maintenance therapy: up to 2 years

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

Hairy cell leukemia

1. Being used as initial treatment, AND
2. Being used in combination with Vemurafenib (Zelboraf)

Covered dose
Cycle 1: Vemurafenib only
Cycle 2: Up to 1000 mg IV on day 1, 8, 15
Cycle 3-4: Up to 1000 mg IV once every 28 days

Coverage period
6 months

ICD-10:
C91.40, C91.42

Marginal zone lymphoma

1. 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**

2. Given in combination with bendamustine Given in combination with an NCCN-supported regimen [e.g., bendamustine, CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone), CVP (cyclophosphamide, vincristine, prednisone), lenalidomide]

Covered dose
In combination with supported regimens for treatment:
Cycle 1: up to 1000 mg IV on day 1, 8, 15
Then either:
21 day cycles (cycles 2-8): up to 1000 mg on day 1, OR
28 day cycles (cycles 2-6): up to 1000 mg on day 1

Single agent maintenance:
Up to 1000 mg every 2 months

Coverage period
Combination treatment: up to 6-8 cycles depending on drug regimen
Single-agent maintenance therapy: up to 2 years

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

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Gazya™ (obinutuzumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

- How supplied:
  1000 mg/40 ml (single-use vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Gazyva® (Obinutuzumab) [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; 7/2022.
- National Comprehensive Cancer Network Drugs & Biologics Compendium. Gazyva (2022). Available by subscription at: www.nccn.org.
- National Comprehensive Cancer Network. B-cell Lymphomas. (Version 5.2022). Available at www.nccn.org.
- National Comprehensive Cancer Network. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (Version 1.2023). Available by subscription at: www.nccn.org.
- National Comprehensive Cancer Network. Hairy Cell leukemia (Version 1.2023). Available by subscription at: www.nccn.org.

- National Comprehensive Cancer Network. Primary Cutaneous Lymphoma (Version 2.2022). Available by subscription at: www.nccn.org.

(7) Policy Update

Date of last review: 1Q2023
Date of next review: 1Q2024
Changes from previous policy version:

- New indication in Section (2): Added coverage for hairy cell leukemia
  Rationale: NCCN category 2A support
- Section (2): Marginal zone lymphoma – Expanded coverage to include combination use with NCCN- supported regimens for marginal zone lymphoma
  Rationale: NCCN category 2A support

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee