New Century Health

Drug Policy:

Gazyva™ (obinutuzumab)

POLICY NUMBER UM ONC_1259	**SUBJECT** Gazyva™ (obinutuzumab)		**DEPT/PROGRAM** UM Dept	**PAGE 1 of 3**
DATES COMMITTEE REVIEWED 02/11/14, 11/02/14, 04/11/16, 02/06/17, 02/01/18, 02/07/19, 12/11/19, 01/08/20, 04/08/20, 02/10/21, 11/15/21, 01/12/22, 05/11/22, 07/13/22, 11/09/22, 03/08/23, 05/10/23	**APPROVAL DATE** May 10, 2023	**EFFECTIVE DATE** May 26, 2023	**COMMITTEE APPROVAL DATES** 02/11/14, 11/02/14, 04/11/16, 02/06/17, 02/01/18, 02/07/19, 12/11/19, 01/08/20, 04/08/20, 02/10/21, 11/15/21, 01/12/22, 05/11/22, 07/13/22, 11/09/22, 03/08/23, 05/10/23	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	**NCQA STANDARDS** UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Gazyva (obinutuzumab) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this NCH policy provided:

1. The requested medication was used within the last year, AND
2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

B. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)

1. Gazyva (obinutuzumab) may be used in members with CD20 positive CLL/SLL as a single agent or in combination with chemotherapy as any of the following:
   a. Initial therapy as a single agent OR in combination with chemotherapy OR
   b. Treatment of relapsed or refractory disease in combination with chemotherapy OR
   c. Maintenance therapy, as a single agent, for up to two years.
2. NOTE: The following regimens are not supported by NCH Policy based on the lack of Level 1 Evidence (randomized clinical trials and/or meta-analyses) to show superior outcomes compared to NCH recommended alternatives agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com.
   a. Initial or subsequent therapy with or without del (17p)/ TP53 mutation: Acalabrutinib + Obinutuzumab; Ibrutinib + Obinutuzumab.
   b. The above policy position is based on findings from randomized trials that do not show any additional overall survival benefit of adding an anti-CD-20 antibody such as obinutuzumab to acalabrutinib or to ibrutinib, compared to single agent acalabrutinib or single agent ibrutinib.

C. Follicular Lymphoma

1. Gazyva (obinutuzumab) may be used in members with CD20 positive Follicular Lymphoma as a single agent or in combination with chemotherapy as any of the following:
   a. Initial therapy, in combination with chemotherapy OR
   b. Treatment of relapsed or refractory disease in combination with chemotherapy OR
   c. Maintenance therapy, as a single agent, for up to two years.

III. EXCLUSION CRITERIA

A. Disease progression while taking Gazyva (obinutuzumab).

B. Dosing exceeds single dose limit of Gazyva (obinutuzumab) 1,000 mg.

C. Treatment with Gazyva (obinutuzumab) exceeds the total duration limit of 6 cycles (for initial therapy) and 2 years (for maintenance therapy).

D. Investigational use of Gazyva (obinutuzumab) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
   1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
   2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
   3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
   4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it

may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).

5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Woyach JA, et al. Ibrutinib Regimens versus Chemoimmunotherapy in Older Patients with Untreated CLL. N Engl J Med. 2018 Dec 27;379(26):2517-2528.

B. Sharman JP, et al. Acalabrutinib with or without obinutuzumab versus chlorambucil and obinutuzmab for treatment-naive chronic lymphocytic leukaemia (ELEVATE TN): a randomised, controlled, phase 3 trial. Lancet. 2020 Apr 18;395(10232):1278-1291.

C. Gazyva prescribing information. Genentech, Inc. South San Francisco, CA 2022.

D. Clinical Pharmacology Elsevier Gold Standard 2023.

E. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2023.

F. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.

G. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs Bethesda, MD 2023.

H. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

I. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

J. NCQA UM 2023 Standards and Elements.