Drug Policy:
Gazyva™ (obinutuzumab)

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. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR

2. When health plan Exchange coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR

II. COMMITTEE APPROVAL DATES (latest version listed last)

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

II. PRIMARY BUSINESS OWNER: UM

II. COMMITTEE/BOARD APPROVAL

Utilization Management Committee

II. URAC STANDARDS

HUM 1

II. NCQA STANDARDS

UM 2

II. ADDITIONAL AREAS OF IMPACT

CMS REQUIREMENTS

STATE/FEDERAL REQUIREMENTS

II. APPLICABLE LINES OF BUSINESS

Commercial, Exchange, Medicaid
3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When available, generic alternatives are preferred over brand-name drugs.

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

1. **NOTE:** The preferred agents for requests for Rituxan (rituximab) and Gazyva (obinutuzumab), per NCH Policy & NCH Pathway, are Truxima (rituximab-abbs) & Ruxience (rituximab-pvvr).
2. Please refer to the NCH Pathway document for recommended regimens for initial and subsequent therapy for the above neoplasms.

**III. EXCLUSION CRITERIA**

A. Disease progression while taking Gazyva (obinutuzumab).
B. Dosing exceeds single dose limit of Gazyva (obinutuzumab) 1000 mg.
C. Treatment with Gazyva (obinutuzumab) exceeds the total duration limit of 6 cycles.
D. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

**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**