Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Gazyva (obinutuzumab)

Override(s)	Approval Duration
Prior Authorization	1 year

APPROVAL CRITERIA

Requests for Gazyva (obinutuzumab) may be approved if the following criteria are met:

I. Individual has a diagnosis of chronic lymphocytic leukemia/small lymphocytic lymphoma; **AND**
II. Individual is using for one of the following:
   A. In combination with chlorambucil or bendamustine for first-line treatment in individuals without del (17p) mutations (Label, NCCN 2A); **OR**
   B. In combination with venetoclax for first-line treatment in individuals with or without del(17p)/TP53 mutation (NCCN 2A); **OR**
   C. In combination with acalabrutinib for first-line treatment in individuals with or without del (17p) mutation; **OR**
   D. As a single agent for first-line treatment in individuals who are frail or with del(17p)/TP53 mutation (NCCN 2A); **OR**
   E. As a single agent for the treatment of relapsed/refractory disease without del(17p)/TP53 mutation (NCCN 2A).

OR

III. Individual has a diagnosis of follicular lymphoma; **AND**
IV. Individual is using in combination with one of the following regimens *and* as monotherapy, for up to 24 months or until disease progression, following the listed combination therapy regimens:
   A. Cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP regimen); **OR**
   B. Cyclophosphamide, vincristine, and prednisone (CVP regimen); **OR**
   C. Bendamustine.

Requests for Gazyva (obinutuzumab) may **not** be approved for the following:

I. All other indications not included above; **OR**
II. Treatment of diffuse large B-cell lymphoma and mantle-cell lymphoma.

Note:
Gazyva (obinutuzumab) has a black box warning for hepatitis B (HBV) reactivation which, in some cases, results in fulminant hepatitis, hepatic failure, and death. Gazyva and concomitant

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

medications should be discontinued in the event of HBV reactivation. Gazyva also has a black box warning for progressive multifocal leukoencephalopathy (PML), including fatal PML, which can occur in patients receiving Gazyva.

Key References:

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4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
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    a. B-Cell Lymphomas. V7.2019. Revised December 18, 2019.
    b. Chronic Lymphocytic Leukemia/small lymphocytic lymphoma. V4.2020. Revised December 20, 2019.
7. Sehn LH, Goy A, Offner FC, et al. Randomized phase II trial comparing obinutuzumab (GA101) with Rituximab in patients with relapsed CD20+ indolent B-cell non-Hodgkin lymphoma: final analysis of the GAUSS study. J Clin Oncol. 2015; 33(30):3467-3474.