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

Imbruvica (ibrutinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Imbruvica (ibrutinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Imbruvica (ibrutinib) may be approved if the following criteria are met:

I. Individual has a diagnosis of Mantle cell lymphoma (MCL); **AND**
II. Individual is using in the treatment for relapsed, refractory or progressive disease; **AND**
III. Individual has received at least one prior therapy;
OR
IV. Individual is using in combination with rituximab (NCCN 2A);

OR
V. Individual has a diagnosis of Chronic lymphocytic leukemia/Small Lymphocytic Lymphoma (CLL/SLL); **AND**
VI. Individual is using for relapsed or refractory disease (NCCN 2A);
OR
VII. Individual is using for CLL or SLL with or without 17p deletion (label, NCCN 1);

OR
VIII. Individual has a diagnosis of relapsed/refractory Central Nervous System (CNS) cancer; **AND**
IX. Individual is using for recurrent disease for brain metastases if active against the primary tumor (CNS lymphoma) (NCCN 2A);

OR
X. Individual has a diagnosis of Primary relapsed or refractory Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma (label, NCCN 2A); **AND**
XI. Individual is using as a single agent or in combination with rituximab (NCCN 2A);

OR

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

XII. Individual has a diagnosis of Splenic or nodal Marginal Zone Lymphoma (MZL) (label, NCCN 2A); **AND**
XIII. Individual has received at least one prior anti-CD20-based therapy (e.g. rituximab);

OR

XIV. Individual has a diagnosis of Follicular lymphoma (grade 1-2) (NCCN 2A); **AND**

OR

XV. Individual has a diagnosis of recurrent/refractory or progressive gastric or nongastric mucosa-associated lymphoid tissue (MALT) lymphomas (NCCN 2A);

OR

XVI. Individual has a diagnosis of B-cell lymphomas including, Diffuse large B-Cell, AIDS-related, or Post-transplant lymphoproliferative disorders (NCCN 2A); **AND**
XVII. Individual is using as subsequent therapy (e.g. partial response, persistent or progressive disease);

OR

XVIII. Individual has a diagnosis of relapsed/refractory Progressive Hairy Cell Lymphoma (NCCN 2A);

OR

XIX. Individual has a diagnosis of relapsed or refractory chronic Graft versus Host Disease (cGVHD); **AND**
XX. Individual has failed one or more lines of systemic therapy.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 14, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on October 13, 2019.
    a. B-Cell Lymphomas. V5.2019. Revised September 23, 2019.
    b. Central Nervous System Cancers. V2.2019. Revised September 16, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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

c. Chronic Lymphocytic Lymphoma/Small Lymphocytic Lymphoma. V2.2020. Revised October 8, 2019.
d. Hairy Cell Leukemia. V1.2020. Revised August 23, 2019.
e. Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma. V2.2019. Revised September 14, 2018.