

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

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 Primary relapsed or refractory Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma (label, NCCN 2A);

OR

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

OR

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

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.

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XII. Individual has received multiple lines of chemoimmunotherapy for indolent or transformed disease (NCCN 2A);

OR

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

OR

XIV. Individual has a diagnosis of B-cell lymphomas including, Diffuse large B-Cell, AIDS-related, or Post-transplant lymphoproliferative disorders (NCCN 2A);

OR

XV. Individual has a diagnosis of Progressive Hairy Cell Lymphoma (NCCN 2A);

OR

XVI. Individual has a diagnosis of Relapsed or refractory chronic Graft versus Host Disease (cGVHD); **AND**

XVII. Individual has failed one or more lines of systemic therapy.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018.
URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: 4/2018

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

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