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) capsule, tablet, or suspension may be approved if the following criteria are met:

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

OR

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

OR

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

OR

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

OR

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

OR

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

OR

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

OR

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

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

Requests for Imbruvica (ibrutinib) suspension must also meet the following:

I. Individual is unable to swallow the oral tablet and capsule dose form due to a clinical condition including but not limited to the following:
   A. Dysphagia; **OR**
   B. Individual's age;

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. 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. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on June 21, 2023.
   a. B-Cell Lymphomas. V4.2023. Revised June 2, 2023.
   b. Central Nervous System Cancers. V2.2022. Revised September 29, 2022.
   c. Chronic Lymphocytic Lymphoma/Small Lymphocytic Lymphoma. V1.2023. Revised August 20, 2022.
   d. Hairy Cell Leukemia. V1.2023. Revised August 30, 2022.
   e. Hematopoietic Cell Transplantation. V2.2022. Revised September 28, 2022.
   f. Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma. V1.2023. Revised July 7, 2022.
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