

Imbruvica® (ibrutinib) (Oral)

Document Number: IC-0187

Last Review Date: 10/26/2020

Date of Origin: 01/28/2014

Dates Reviewed: 01/2014, 08/2014, 02/2015, 01/2016, 03/2016, 01/2017, 08/2017, 01/2018, 04/2018, 09/2018, 02/2019, 11/2019, 05/2020, 11/2020

I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Imbruvica 140 mg capsule/tablet: 4 capsules/tablets per day
- Imbruvica 70 mg capsule: 1 capsules per day
- Imbruvica 280 mg tablet: 2 tablets per day
- Imbruvica 560 mg tablet: 1 tablet per day
- Imbruvica 420 mg tablet: 2 tablets per day

B. Max Units (per dose and over time) [HCPCS Unit]:

CLL/SLL, WM/LPL, Hairy Cell Leukemia

- 420 mg daily

DLBCL, MCL, MZL, MALT, & PTLID

- 560 mg daily

Primary CNS Lymphoma

- 840 mg daily

III. Initial Approval Criteria ¹

Coverage for is provided for treatment of the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria ¹

- Patient will avoid concomitant therapy with all of the following:
 - Coadministration with voriconazole, posaconazole, and moderate CYP3A inhibitors (e.g., aprepitant, ciprofloxacin, diltiazem, etc.), or if therapy is unavoidable, the patient

will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**

- Coadministration with other strong CYP3A inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, grapefruit, Seville oranges, etc.); **AND**
- Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient does not have severe hepatic impairment (Child-Pugh class C); **AND**

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) † Φ^{1,2}

- Used as a single agent; **OR**
- Used in combination with rituximab and bendamustine for relapsed or refractory disease; **OR**
- Used in combination with rituximab or obinutuzumab as initial therapy

Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL) † Φ^{1,2}

- Used as single agent or in combination with rituximab

Chronic Graft versus Host Disease (cGVHD) † Φ^{1,2}

- Used as a single agent or in conjunction with systemic steroids; **AND**
- Patient is post-allogeneic stem cell transplant (generally 3 or more months); **AND**
- Patient has failed one or more previous lines of systemic therapy for the treatment of cGVHD (e.g., corticosteroids or immunosuppressants such as cyclosporine)

B-Cell Lymphomas^{1,2}

- Used as a single agent for recurrent, refractory, or progressive disease as subsequent therapy for one of the following:
 - Marginal Zone Lymphoma (MZL) † Φ (including Nodal and Splenic)
 - Follicular Lymphoma (FL) ‡
 - Nongastric MALT Lymphoma ‡
 - Gastric MALT Lymphoma ‡
- AIDS-Related B-cell Lymphoma ‡
 - Patient has AIDS-related non-germinal center diffuse large B-cell lymphoma; **AND**
 - Used as single agent as subsequent therapy for relapsed disease; **AND**
 - Patient is not a candidate for transplant
- Diffuse Large B-Cell Lymphoma ‡
 - Used as a single agent in patients with histologic transformation of FL or MZL to non-germinal center Diffuse Large B-cell Lymphoma as subsequent therapy after multiple lines of chemoimmunotherapy for indolent or transformed disease ‡; **OR**

- Used as a single agent as subsequent therapy for partial response, no response, relapsed, progressive, or refractory non-germinal center disease in non-candidates for transplant
- High-Grade B-Cell Lymphoma ‡
 - Used as a single agent as subsequent therapy for partial response, no response, relapsed, progressive, or refractory disease in non-candidates for transplant
- Mantle Cell Lymphoma (MCL) † ◻
 - Used as subsequent therapy as a single agent or in combination with rituximab; **OR**
 - Used in combination with rituximab as pre-treatment to limit the number of aggressive induction therapy cycles with RHyperCVAD (rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone) regimen ‡
- Post-Transplant Lymphoproliferative Disorders (PTLD) ‡
 - Used as subsequent therapy; **AND**
 - Used as a single agent for patients with partial response, persistent or progressive disease after receiving first-line chemoimmunotherapy for monomorphic PTLD (non-germinal center B-cell type disease)

Primary CNS Lymphoma ‡^{2,16}

- Used for relapsed or refractory disease; **AND**
 - Used as a single agent; **AND**
 - Patient has received previous whole brain radiation therapy; **OR**
 - Used in combination with radiation therapy in patients who had either no response or a short response (< 12 month duration) to a high-dose methotrexate based regimen without previous radiation therapy; **OR**
 - Patient had a long response (\geq 12 months) to prior high-dose methotrexate-based regimen without prior radiation therapy **OR** to prior high-dose chemotherapy with stem cell rescue; **OR**
 - Used in combination with high-dose methotrexate and rituximab; **AND**
 - Patient has received previous whole brain radiation therapy; **OR**
 - Patient had a long response (\geq 12 months) to prior high-dose methotrexate-based regimen without prior radiation therapy; **OR**
- Used as induction therapy as a single agent; **AND**
 - Patient is unsuitable for or intolerant to high-dose methotrexate

Hairy Cell Leukemia ‡^{2,24}

- Used as a single agent as subsequent therapy for relapsed/refractory or progressive disease

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); ◻ Orphan Drug

IV. Renewal Criteria ¹

Authorizations can be renewed based on the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hemorrhage, severe infections, myelosuppression (neutropenia, thrombocytopenia, anemia), ventricular tachyarrhythmia, atrial fibrillation/flutter, tumor lysis syndrome, hypertension, second primary malignancies, etc.; **AND**

Oncology indications:

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

cGVHD:

- Response to therapy with an improvement in one or more of the following:
 - Clinician assessments (e.g., NIH Skin Score, Upper GI Response Score, NIH Lung Symptom Score, etc.)
 - Patient-reported symptoms (e.g., Lee Symptom Scale, etc.)

V. Dosage/Administration ^{1,3,7,21-23,25}

Indication	Dose
DLBCL, MCL, MZL, MALT, & PTLD	560 mg orally once daily until disease progression or unacceptable toxicity
CLL/SLL (single agent or in combination with rituximab and bendamustine or with rituximab or obinutuzumab)	420 mg orally once daily until disease progression or unacceptable toxicity <i>*When used in combination with rituximab or obinutuzumab, consider administering Imbruvica prior to therapy, when given on the same day.</i>
WM/LPL (single agent or in combination with rituximab)	420 mg orally once daily until disease progression or unacceptable toxicity
cGVHD	420 mg orally once daily until progression, recurrence of an underlying malignancy, or unacceptable toxicity
Primary CNS Lymphoma	560 or 840 mg orally once daily until disease progression or unacceptable toxicity
Hairy Cell Leukemia	420 mg once daily until disease progression or unacceptable toxicity

VI. Billing Code/Availability Information

HCPCS Code:

- J8999 - Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

NDC:

- Imbruvica 140 mg capsule: 57962-0140-xx
- Imbruvica 70 mg capsule: 57962-0070-xx
- Imbruvica 560 mg tablet: 57962-0560-xx
- Imbruvica 420 mg tablet: 57962-0420-xx
- Imbruvica 280 mg tablet: 57962-0280-xx
- Imbruvica 140 mg tablet: 57962-0014-xx

VII. References

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2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for ibrutinib. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed October 2020.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for B-Cell Lymphomas Version 4.2020. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed October 2020.
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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C83.00	Small cell B-cell lymphoma, unspecified site
C83.01	Small cell B-cell lymphoma, lymph nodes of head, face, and neck
C83.02	Small cell B-cell lymphoma, intrathoracic lymph nodes
C83.03	Small cell B-cell lymphoma, intra-abdominal lymph nodes

ICD-10	ICD-10 Description
C83.04	Small cell B-cell lymphoma, lymph nodes of axilla and upper limb
C83.05	Small cell B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.06	Small cell B-cell lymphoma, intrapelvic lymph nodes
C83.07	Small cell B-cell lymphoma, spleen
C83.08	Small cell B-cell lymphoma, lymph nodes of multiple sites
C83.09	Small cell B-cell lymphoma, extranodal and solid organ sites
C83.10	Mantle cell lymphoma, unspecified site
C83.11	Mantle cell lymphoma, lymph nodes of head, face, and neck
C83.12	Mantle cell lymphoma, intrathoracic lymph nodes
C83.13	Mantle cell lymphoma, intra-abdominal lymph nodes
C83.14	Mantle cell lymphoma, lymph nodes of axilla and upper limb
C83.15	Mantle cell lymphoma, lymph nodes of inguinal region and lower limb
C83.16	Mantle cell lymphoma, intrapelvic lymph nodes
C83.17	Mantle cell lymphoma, spleen
C83.18	Mantle cell lymphoma, lymph nodes of multiple sites
C83.19	Mantle cell lymphoma, extranodal and solid organ sites
C83.30	Diffuse large B-cell lymphoma, unspecified site
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites
C83.80	Other non-follicular lymphoma, unspecified site
C83.81	Other non-follicular lymphoma, lymph nodes of head, face and neck
C83.82	Other non-follicular lymphoma, intrathoracic lymph nodes
C83.83	Other non-follicular lymphoma, intra-abdominal lymph nodes
C83.84	Other non-follicular lymphoma, lymph nodes of axilla and upper limb
C83.85	Other non-follicular lymphoma, lymph nodes of inguinal region and lower limb
C83.86	Other non-follicular lymphoma, intrapelvic lymph nodes
C83.87	Other non-follicular lymphoma, spleen
C83.88	Other non-follicular lymphoma, lymph nodes of multiple sites

ICD-10	ICD-10 Description
C83.89	Other non-follicular lymphoma, extranodal and solid organ sites
C83.90	Non-follicular (diffuse) lymphoma, unspecified, unspecified site
C83.91	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of head, face, and neck
C83.92	Non-follicular (diffuse) lymphoma, unspecified, intrathoracic lymph nodes
C83.93	Non-follicular (diffuse) lymphoma, unspecified, intra-abdominal lymph nodes
C83.94	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of axilla and upper limb
C83.95	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of inguinal region and lower limb
C83.96	Non-follicular (diffuse) lymphoma, unspecified, intrapelvic lymph nodes
C83.97	Non-follicular (diffuse) lymphoma, unspecified, spleen
C83.98	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of multiple sites
C83.99	Non-follicular (diffuse) lymphoma, unspecified, extranodal and solid organ sites
C85.10	Unspecified B-cell lymphoma, unspecified site
C85.11	Unspecified B-cell lymphoma, lymph nodes of head, face, and neck
C85.12	Unspecified B-cell lymphoma, intrathoracic lymph nodes
C85.13	Unspecified B-cell lymphoma, intra-abdominal lymph nodes
C85.14	Unspecified B-cell lymphoma, lymph nodes of axilla and upper limb
C85.15	Unspecified B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.16	Unspecified B-cell lymphoma, intrapelvic lymph nodes
C85.17	Unspecified B-cell lymphoma, spleen
C85.18	Unspecified B-cell lymphoma, lymph nodes of multiple sites
C85.19	Unspecified B-cell lymphoma, extranodal and solid organ sites
C85.20	Mediastinal (thymic) large B-cell lymphoma, unspecified site
C85.21	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of head, face, and neck
C85.22	Mediastinal (thymic) large B-cell lymphoma, intrathoracic lymph nodes
C85.23	Mediastinal (thymic) large B-cell lymphoma, intra-abdominal lymph nodes
C85.24	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of axilla and upper limb
C85.25	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.26	Mediastinal (thymic) large B-cell lymphoma, intrapelvic lymph nodes
C85.27	Mediastinal (thymic) large B-cell lymphoma, spleen
C85.28	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of multiple sites
C85.29	Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites
C85.80	Other specified types of non-Hodgkin lymphoma, unspecified site
C85.81	Other specified types of non-Hodgkin lymphoma, lymph nodes of head, face and neck
C85.82	Other specified types of non-Hodgkin lymphoma, intrathoracic lymph nodes
C85.83	Other specified types of non-Hodgkin lymphoma, intra-abdominal lymph nodes

ICD-10	ICD-10 Description
C85.84	Other specified types of non-Hodgkin lymphoma, lymph nodes of axilla and upper limb
C85.85	Other specified types of non-Hodgkin lymphoma, lymph nodes of inguinal region of lower limb
C85.86	Other specified types of non-Hodgkin lymphoma, intrapelvic lymph nodes
C85.87	Other specified types of non-Hodgkin lymphoma, spleen
C85.88	Other specified types of non-Hodgkin lymphoma, lymph nodes of multiple sites
C85.89	Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites
C88.0	Waldenström macroglobulinemia
C88.4	Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue (MALT-lymphoma)
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
C91.40	Hairy cell leukemia not having achieved remission
C91.42	Hairy cell leukemia, in relapse
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)
D89.811	Chronic graft-versus-host disease
D89.812	Acute on chronic graft-versus-host disease
D89.813	Graft-versus-host disease, unspecified
T86.09	Other complications of bone marrow transplant
Z94.81	Bone marrow transplant status

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Article (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC