

<b>POLICY NUMBER</b> UM ONC_1262	<b>SUBJECT</b> Imbruvica™ (ibrutinib)	<b>DEPT/PROGRAM</b> UM Dept	<b>PAGE 1 OF 2</b>
<b>DATES COMMITTEE REVIEWED</b> 11/12/14, 12/18/15, 04/13/16, 02/08/17, 02/14/18, 02/13/19, 10/09/19, 12/11/19, 05/13/20	<b>APPROVAL DATE</b> May 13, 2020	<b>EFFECTIVE DATE</b> May 29, 2020	<b>COMMITTEE APPROVAL DATES</b> (latest version listed last) 11/12/14, 12/18/15, 04/13/16, 02/08/17, 02/14/18, 02/13/19, 10/09/19, 12/11/19, 05/13/20
<b>PRIMARY BUSINESS OWNER: UM</b> <b>APPROVED BY:</b> Dr. Andrew Hertler		<b>COMMITTEE/BOARD APPROVAL</b> Utilization Management Committee	
<b>URAC STANDARDS</b> HUM 1		<b>NCQA STANDARDS</b> UM 2	<b>ADDITIONAL AREAS OF IMPACT</b>
<b>CMS REQUIREMENTS</b>	<b>STATE/FEDERAL REQUIREMENTS</b>		<b>APPLICABLE LINES OF BUSINESS</b> All

## I. PURPOSE

To define and describe the accepted indications for Imbruvica (ibrutinib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

## II. INDICATIONS FOR USE/INCLUSION CRITERIA

### 1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

- When health plan Medicaid coverage provisions- including any applicable PDLs ( Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- When health plan Exchange coverage provisions- including any applicable PDLs ( Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies **AND**
- Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
- When available, generic alternatives are preferred over brand-name drugs.

### 2. Mantle Cell Lymphoma (MCL)

- The member has a diagnosis of relapsed or refractory MCL that has failed or has progressed on first line chemo-immunotherapy **AND**
- Imbruvica (ibrutinib) will be used as a single agent or in combination with rituximab.

### 3. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)



# New Century Health

**POLICY #UM ONC\_1262  
PROPRIETARY & CONFIDENTIAL**

- a. Imbruvica (ibrutinib) use as a single agent is supported for initial and subsequent therapy for all prognostic categories of CLL/SLL.
- b. Imbruvica (ibrutinib) use in combination with an anti-CD20 antibody (e.g. Rituximab or Obinutuzumab) is not supported per NCH policy. Per NCH Policy and NCH Pathway, single agent Imbruvica (ibrutinib) is considered as effective as Imbruvica(ibrutinib) + an anti-CD20 antibody e.g. Rituximab or Obinutuzumab.

#### **4. Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma**

- a. The member has a diagnosis Waldenström's macroglobulinemia/Lymphoplasmacytic Lymphoma **AND**
- b. Imbruvica (ibrutinib) will be used as a single agent or in combination with rituximab as initial therapy or therapy for relapsed disease.

#### **5. Nodal & Extra-Nodal Marginal Zone Lymphoma & Splenic Marginal Zone Lymphoma**

- a. The member has relapsed, or refractory nodal/extra-nodal/splenic marginal zone lymphoma **AND**
- b. Imbruvica (ibrutinib) will be used as a single agent as second-line or subsequent therapy.

### **III. EXCLUSION CRITERIA**

1. Disease progression while receiving Imbruvica/Imbruvica containing regimen or another BTK inhibitor/BTK inhibitor containing regimen, e.g. Acabrutinib or Zanubrutinib.
2. Dosing exceeds single dose limit of Imbruvica (ibrutinib) 560 mg.
3. Treatment exceeds the maximum limit of 120 (140 mg) capsules a month of 240 (70 mg) capsules
4. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

### **IV. MEDICATION MANAGEMENT**

Please refer to the FDA label/package insert for details regarding these topics.

### **V. APPROVAL AUTHORITY**

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

### **VI. ATTACHMENTS**

None

### **VII. REFERENCES**

1. Imbruvica prescribing information. Pharmacoclics, Inc. Sunnyvale, CA. 2020.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.