Drug Policy:

Imbruvica™ (ibrutinib)

POLICY NUMBER UM ONC_1262	**SUBJECT** Imbruvica™ (ibrutinib)	**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 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, 08/12/20	**APPROVAL DATE** August 12, 2020	**EFFECTIVE DATE** August 28, 2020	**COMMITTEE APPROVAL DATES** (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, 08/12/20
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
URAC STANDARDS HUM 1	**NCQA STANDARDS** UM 2	**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**	**APPLICABLE LINES OF BUSINESS** 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 Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. 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
2. 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

3. 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
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When available, generic alternatives are preferred over brand-name drugs.

B. Mantle Cell Lymphoma (MCL)

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

C. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)

1. Imbruvica (ibrutinib) use as a single agent is supported for initial and subsequent therapy for all prognostic categories of CLL/SLL.
2. Imbruvica (ibrutinib) use in combination with an anti-CD20 antibody [e.g. Rituxan (rituximab) or Gazyva (obinutuzumab)] is not supported per NCH policy/NCH Pathway. 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].

D. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma

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

E. Nodal & Extra-Nodal Marginal Zone Lymphoma & Splenic Marginal Zone Lymphoma

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

III. EXCLUSION CRITERIA

A. Disease progression while receiving Imbruvica/Imbruvica (ibrutinib) containing regimen or another BTK inhibitor/BTK inhibitor containing regimen, e.g. Calquence (acalabrutinib) or Brukinsa (zanubrutinib).

B. For the treatment of CLL: concurrent use with an anti-CD20 antibody including any rituximab products or Gazyva (obinutuzumab). Per NCH Policy and NCH Pathway single agent Imbruvica (ibrutinib) is as effective as Imbruvica (ibrutinib) + any anti CD-20 antibody ,e.g. Gazyva (obinutuzumab)& Rituxan (rituximab).

C. Dosing exceeds single dose limit of Imbruvica (ibrutinib) 560 mg.

D. Treatment exceeds the maximum limit of 120 (140 mg) capsules a month of 240 (70 mg) capsules

E. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Imbruvica prescribing information. Pharmacyclics, Inc. Sunnyvale, CA. 2020.

B. Clinical Pharmacology Elsevier Gold Standard. 2020.

C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.

D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.

E. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.

New Century Health