POLICY NUMBER UM ONC_1331	SUBJECT Calquence™ (acalabrutinib)		DEPT/PROGRAM UM Department	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 12/14/17, 11/14/18, 11/13/19, 12/11/19, 05/13/20	APPROVAL DATE May 13, 2020	EFFECTIVE DATE May 29, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 12/14/17, 11/14/18, 11/13/19, 12/11/19, 05/13/20	
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 Calquence (acalabrutinib) 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:**
    a. 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**
    b. 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**
    c. 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**
    d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
    e. When available, generic alternatives are preferred over brand-name drugs.
2. **Mantle Cell Lymphoma (MCL)**
    a. NOTE: The preferred Bruton tyrosine kinase (BTK) inhibitor regimen, per NCH policy & NCH Pathway, for Mantle Cell Lymphoma, is IBRUTINIB over Acalabrutinib or Zanubrutinib.
    b. Acalabrutinib may be used in relapsed/refractory Mantle Cell Lymphoma if the member has intolerance/contraindication to Ibrutinib.
3. **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma**

a. **NOTE: The preferred Bruton tyrosine kinase (BTK) inhibitor agent per NCH policy and NCH Pathway, is IBRUTINIB over Acalabrutinib, except when the member is intolerant to or has a contraindication to Ibrutinib.**

b. Acalabrutinib may be used, as a single agent, for first line or subsequent line therapy of CLL/SLL in members who are intolerant to or have a contraindication to Ibrutinib.

c. Acalabrutinib use in combination with Gazyva (obinutuzumab) is not supported by NCH policy. Per NCH Policy and NCH Pathway single agent Acalabrutinib is as effective as [Acalabrutinib + Gazyva/other anti-CD 20 antibody].

III. EXCLUSION CRITERIA

1. Disease progression while receiving Acalabrutinib/Acalabrutinib-containing regimen or while receiving another BTK inhibitor/regimen containing another BTK inhibitor (e.g. Ibrutinib or Zanubrutinib).
2. Concurrent use with an anti-CD20 antibody including Rituximab/Rituximab Hycela/Rituximab Biosimilars/Gazyva. Per NCH Policy and NCH Pathway single agent Acalabrutinib is as effective as Acalabrutinib + Gazyva/other anti-CD 20 antibody.
3. Dosing exceeds single dose limit of Calquence (acalabrutinib) 100 mg.
4. Treatment exceeds the maximum limit of 60 (100 mg) capsules/month.
5. 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. Calquence PI prescribing information. AstraZeneca Pharmaceuticals LP Wilmington, DE 2019.
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.