POLICY NUMBER UM ONC_1277	SUBJECT Alecensa™ (Alectinib)		DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 03/23/16, 01/05/17, 01/10/18, 02/13/19, 12/11/19, 02/12/20	APPROVAL DATE February 12, 2020	EFFECTIVE DATE March 01, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 03/23/16, 01/05/17, 01/10/18, 02/13/19, 12/11/19, 02/12/20	
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 Alecensa (Alectinib) 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: http://pathways.newcenturyhealth.com **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. **Non-Small Cell Lung Cancer (NSCLC)**
    a. **NOTE:** The preferred agent, per NCH Policies, for first line therapy of metastatic , ALK+ NSCLC is ALECTINIB.
    b. The member has recurrent or metastatic NSCLC and Alecensa (Alectinib) is being used as a single agent for **ALL** of the following:
        i. The tumor is ALK positive **AND**
        ii. Alecensa (Alectinib) is being use as first line therapy **OR**
        iii. As subsequent therapy following disease progression on first-line therapy **OR**

iv. Continuation of therapy if used first line.

III. EXCLUSION CRITERIA

1. Concurrent use with chemotherapy.
2. Dosing exceeds single dose limit of Alecensa (Alectinib) 600 mg.
3. Treatment exceeds the maximum limit of 240 (150 mg) capsules/month.
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 – UM Department
2. Final Approval – UM Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Alecensa Prescribing Information. Genentech, Inc. South San Francisco, CA 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.