MEDICAL MUTUAL®

Drug Policy

Policy:	Alunbrig (brigatinib)	Annual Review Date: 05/21/2020 Last Revised Date: 05/21/2020

OVERVIEW

Alunbrig, a kinase inhibitor, is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to Xalkori® (crizotinib capsules). Alunbrig targets ALK, c-ros oncogene 1 (ROS1), insulin-like growth factor-1 receptor (IGF-1R), FLT-3, epidermal growth factor receptor (EGFR) deletion and point mutations. The whole-body efficacy and the intracranial efficacy of Alunbrig were established in one pivotal study (ALTA).

POLICY STATEMENT

This policy involves the use of Alunbrig. Prior authorization is recommended for pharmacy benefit coverage of Alunbrig. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Alunbrig as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Alunbrig be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, Alunbrig must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Alunbrig is recommended in those who meet the following criteria:

1. **Non-Small Cell Lung Cancer (NSCLC)**
   Criteria. *Patient must meet the following criteria (A and B):*
   - A. The patient has advanced, metastatic, or recurrent NSCLC that is anaplastic lymphoma kinase (ALK)-positive; AND
   - B. The patient meets ONE of the following criteria (a, b, or c):
     - a. Alunbrig will be used as first-line therapy
     - b. The patient has progressed on first-line therapy with Xalkori (crizotinib) and has not had symptomatic systemic disease with an isolated lesion; OR
     - **c.** The patient is intolerant to Xalkori (crizotinib).

2. **Recurrent Brain Metastases**
   Criteria. *Approve if Alunbrig is active against primary cancer and patient has stable systemic disease.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days
B) *Extended Approval:* 365 days

OTHER USES WITH SUPPORTIVE EVIDENCE

3. **Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
   Criteria. *Prescriber will provide specific diagnosis for documentation. Approve.*

4. **Patient has been started on Alunbrig**
   Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days
B) *Extended Approval:* 365 days

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Alunbrig has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or

performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Alunbrig™ tablets [prescribing information]. Cambridge, MA: ARIAD/Takeda Pharmaceuticals; April 2017.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 4.2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed 8 May 2019.
3. Brigatinib. In: DRUGDEX (online database). Truven Health Analytics; Greenwood Village, CO. Last updated 31 December 2018. Accessed on 8 May 2019.