

Commercial/Healthcare Exchange PA Criteria
Effective: July 7, 2017

Prior Authorization: Alunbrig

Products Affected: Alunbrig (brigatinib) oral tablets

Medication Description: Alunbrig (Brigatinib) is a tyrosine kinase inhibitor with in vitro activity at clinically achievable concentrations against multiple kinases including ALK, ROS1, insulin-like growth factor-1 receptor (IGF-1R), and FLT-3 as well as EGFR deletion and point mutations. Brigatinib inhibited autophosphorylation of ALK and ALK-mediated phosphorylation of the downstream signaling proteins STAT3, AKT, ERK1/2, and S6 in in vitro and in vivo assays. Brigatinib also inhibited the in vitro proliferation of cell lines expressing EML4-ALK and NPM-ALK fusion proteins and demonstrated dose-dependent inhibition of EML4-ALK-positive NSCLC xenograft growth in mice.

Covered Uses: Treatment of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC).

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. Anaplastic lymphoma kinase (ALK)-positive NSCLC status confirmed by an FDA-approved test [documentation required]

Age Restrictions: 18 years of age or older

Prescriber Restriction: Prescribed by, or in consultation with, an oncologist.

Coverage Duration: 3 years

Other Criteria:

Anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC)

- A. Patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC); AND
- B. Patient's disease is anaplastic lymphoma kinase (ALK)-positive as detected by FDA-approved test.

References:

1. Alunbrig [package insert]. Cambridge, MA; Ariad; April 2017.

Policy Revision history

| Rev # | Type of Change | Summary of Change | Sections Affected | Date |
|-------|----------------|--|-------------------|---------|
| 1 | New Policy | Adopted EH policy EH revision history: 7/2019, 6/2020 | All | 6/10/20 |