

ceritinib (ZYKADIA)

Diagnosis Considered for Coverage:

- Histiocytic Neoplasm – Erdheim-Chester Disease with ALK-fusion
- ALK+ Non-Small Cell Lung Cancer
- ROS1+ Non-Small Cell Lung Cancer
- Soft Tissue Sarcoma - Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation
- Uterine Sarcoma- Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation

Coverage Criteria:

For diagnosis of non-small cell lung cancer (NSCLC):

1. Tumor is positive for anaplastic lymphoma kinase (ALK) or ROS proto-oncogene 1 (ROS1) gene rearrangement, **and**
2. Being used as single agent therapy, **and**
3. Dose does not exceed 450 mg per day.

For diagnosis of histiocytic neoplasms of Erdheim-Chester Disease:

1. Presence of anaplastic lymphoma kinase (ALK)-fusion, **and**
2. Being used as a single agent **and**
3. Dose does not exceed 450 mg per day.

For diagnosis of soft tissue sarcoma (STS):

1. Being used for inflammatory myofibroblastic tumor (IMT), **and**
2. Patient has anaplastic lymphoma kinase (ALK) gene translocation, **and**
3. Being used as a single agent **and**
4. Dose does not exceed 450 mg per day

For diagnosis of uterine sarcoma:

1. Disease is advanced, recurrent/metastatic, or inoperable, **and**
2. Being used for inflammatory myofibroblastic tumor (IMT) with ALK translocation, **and**
4. Being used as single agent therapy **and**
3. Dose does not exceed 450 mg per day.

Coverage Duration: one year

Effective Date: 8/30/2023