PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Ayvakit Prior Authorization Policy
- Ayvakit® (avapritinib tablets – Blueprint Medicines)

REVIEW DATE: 02/10/2021

OVERVIEW

Ayvakit, a kinase inhibitor, is indicated for the **treatment** of adults with **unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (*PDGFRA*) exon 18 mutation, including *PDGFRA D842V* mutations**.[1] Patients should be selected for treatment with Ayvakit based on the presence of a *PDGFRA* exon 18 mutation; an FDA-approved test for the detection of this mutation is not currently available.

Guidelines

- **Gastrointestinal stromal tumors (GISTs):** According to the National Comprehensive Cancer Network (NCCN) GISTs guidelines (version 1.2021 – October 30, 2020), Ayvakit is one of the primary treatment options (category 2A) for GIST with *PDGFRA* exon 18 mutation, including *PDGFRA* D842V mutations.[2,3] Imatinib is a category 1 recommended option for primary treatment. The guidelines note that most mutations in the *PDGFRA* gene are associated with a response to imatinib, with the notable exception of *PDGFRA* D842V mutation. Ayvakit is listed as one of the recommended therapies after disease progression on imatinib, Sutent, and Stivarga (regorafenib tablets). Ayvakit (for *PDGFRA* exon 18 mutations that are insensitive to imatinib, including the *D842V* mutation) is listed as a preferred regimen for neoadjuvant therapy for resectable GISTs with significant morbidity. Imatinib is also a preferred regimen for neoadjuvant and adjuvant therapy.
- **Myeloid/Lymphoid Neoplasms with Eosinophilia:** The NCCN guidelines for myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes (version 3.2021 – August 21, 2020) notes that since Ayvakit targets *PDGFRA* exon 18 mutation, it may have a role for use in patients with this condition.[3,4] Its use maybe be specific to *PDGFRA* D842V mutation, which is resistant to imatinib. If clinical trial of Ayvakit for this condition is available, then the clinical trial is preferred, rather than off-label use.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Ayvakit. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Gastrointestinal Stromal Tumor (GIST).** Approve for 3 years if the patient meets the following criteria (A and B):

A) Patient is ≥ 18 years of age; AND
B) The tumor is positive for platelet-derived growth factor receptor alpha (*PDGFRA*) exon 18 mutation.
Note: *PDGFRA* exon 18 mutation includes *PDGFRA D842V* mutations.

Other Uses with Supportive Evidence

2. Myeloid/Lymphoid Neoplasms with Eosinophilia. Approve for 3 years if the patient meets the following criteria (A and B):
A) Patient is ≥ 18 years of age; AND
B) The tumor is positive for platelet-derived growth factor receptor alpha (*PDGFRA*) *D842V* mutation.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Ayvakit is not recommended in the following situations:

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

REFERENCES

1. Ayvakit™ tablets [prescribing information]. Cambridge, MA: Blueprint Medicines Corporation; January 2020.
2. The NCCN Gastrointestinal Stromal Tumors (GISTs) Clinical Practice Guidelines in Oncology (version 1.2021 – October 30, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on January 18, 2021.
3. The NCCN Drugs & Biologics Compendium. © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on January 18, 2021. Search term: avapritinib.
4. The NCCN Myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes Clinical Practice Guidelines in Oncology (version 3.2021 – August 21, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on January 18, 2021.