VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Ayvakit® (avapritinib tablets – Blueprint Medicines)

DATE REVIEWED: 01/15/2020

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. 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

According to the National Comprehensive Cancer Network (NCCN) soft tissue sarcoma guidelines (version 6.2019 – February 10, 2020), Ayvakit is one of the primary treatment options (category 2A) for GIST with *PDGFRA* exon 18 mutation, including *PDGFRA* D842V mutations.[2] 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. Upon disease progression on imatinib, Sutent® (sunitinib tablets) is a category 1 recommended option. The guidelines note that there are no appropriate treatment options for GIST progressing on Ayvakit. For disease progression on Sutent, Stivarga is the recommended option (category 1). Ayvakit is listed as one of the recommended therapies after disease progression on imatinib, Sutent, and Stivarga. Based on limited data, the guidelines recommend other small molecule inhibitors such as Nexavar® (sorafenib tablets), Votrient® (pazopanib tablets), Tasigna® (nilotinib tablets), and everolimus + TKI (all category 2A). Sprycel® (dasatinib tablets) is also recommended, based on limited data, for patients with *PDGFRA* D842V mutation (category 2A).

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)** The patient has unresectable or metastatic disease; 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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Ayvakit has not been shown to be effective or there are limited or preliminary data that are not supportive of general approval for the following conditions.

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 Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (Version 6.2019 – February 10, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 3, 2020.