MEDICAL MUTUAL®

Drug Policy

Policy:	Ayvakit (avapritinib)	Annual Review Date: 02/18/2021 Last Revised Date: 02/18/2021

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. 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.

POLICY STATEMENT

This policy involves the use of Ayvakit. Prior authorization is recommended for pharmacy benefit coverage of Ayvakit. 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 Ayvakit as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Ayvakit be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, Ayvakit 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 Ayvakit is recommended in those who meet the following criteria:

1. <u>Gastrointestinal Stromal Tumors (GIST)</u>
Criteria. *Patient must meet the following criteria*

- **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 (includes PDGFRA D842V mutations); AND
- **C.** The patient is 18 years of age or older; AND
- **D.** The patient has an ECOG performance status of 0 to 2

2. <u>Myeloid/Lymphoid Neoplasms with Eosinophilia</u>

Criteria. *Approve if tumors are positive for FIP1L1-PDGFRA rearrangement and PDGFRA D842V mutation is found.*

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 Ayvakit**
   Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Ayvakit 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. Ayvakit tablets [prescribing information]. Cambridge, MA: Blueprint Medicines Corporation; January 2020.
2. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (Version 4.2019 – September 12, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on January 10, 2020.

3. Avapritinib. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 3 February 2020. Accessed on 13 February 2020.
4. The NCCN Drugs and Biologics Compendium. © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed 9 February 2021.