

Ayvakit (avapritinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Ayvakit (avapritinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Ayvakit (avapritinib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of gastrointestinal stromal tumor (GIST); **AND**
- II. Tumor has a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including D842V mutation; **AND**
- III. Disease is unresectable or metastatic (Label); **OR**
- IV. Disease is resectable with significant morbidity and Ayvakit is used as neoadjuvant therapy (NCCN 2A);

OR

- V. Individual has a diagnosis of unresectable, recurrent, or metastatic gastrointestinal stromal tumor (GIST); **AND**
- VI. Disease has progressed on approved therapies, including imatinib, sunitinib, regorafenib, and ripretinib (NCCN 2A);

OR

- VII. Individual has a diagnosis of advanced systemic mastocytosis (AdvSM), including aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm, and mast cell leukemia; **AND**
- VIII. Individual has a platelet count of $\geq 50 \times 10^9 /L$;

OR

- IX. Individual has a diagnosis of non-advanced, indolent systemic mastocytosis (ISM); **AND**
- X. Individual has a platelet count of $\geq 50 \times 10^9 /L$;

OR

- XI. Individual has a diagnosis of Myeloid/Lymphoid Neoplasms with Eosinophilia and FIP1L1::PDGFRA rearrangement; **AND**
- XII. PDGFR D842V mutation is present which is resistant to imatinib; **AND**
- XIII. A clinical trial is not available or appropriate.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 4, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 3, 2024.
 - a. Gastrointestinal Stromal Tumors (GISTs). V1.2023. Revised March 13, 2023.
 - b. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes V1.2024. Revised December 21, 2023.
 - c. Systemic Mastocytosis. V1.2024. Revised December 21, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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