

# 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. Individual has gross residual disease, unresectable primary disease, tumor rupture, or recurrent/metastatic disease (Label, NCCN 2A); **OR**
- IV. Disease is resectable with significant morbidity and Ayvakit is used as neoadjuvant therapy (NCCN 2A);

### **OR**

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

### **OR**

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

### **OR**

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

### **OR**

- XII. Individual has a diagnosis of Myeloid/Lymphoid Neoplasms with Eosinophilia and FIP1L1::PDGFRA rearrangement; **AND**
- XIII. PDGFR D842V mutation is present which is resistant to imatinib; **AND**
- XIV. 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: September 6, 2024.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on September 6, 2024.
  - a. Gastrointestinal Stromal Tumors (GISTs). V2.2024. Revised July 31, 2024.
  - b. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes V2.2024, Revised June 19, 2024.
  - c. Systemic Mastocytosis. V3.2024. Revised April 24, 2024.

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.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.