

<b>Clinical Policy Title:</b>	avapritinib
<b>Policy Number:</b>	RxA.626
<b>Drug(s) Applied:</b>	Ayvakit®
<b>Original Policy Date:</b>	05/21/2020
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Gastrointestinal Stromal Tumor (GIST) (must meet all):

1. Diagnosis of unresectable or metastatic GIST;
2. Member has one of the following (a or b):
  - a. PDGFR exon 18 mutations indicating the PDGFRA D842V mutation;
  - b. PDGFR exon 18 mutation other than D842V and member is insensitive to imatinib\* unless contraindicated or clinically significant adverse effects are experienced;
- \*Prior authorization may be required for imatinib
3. Prescribed as monotherapy.

#### Approval Duration

**All Lines of Business (except Medicare):** 6 months

#### B. Systemic Mastocytosis (SM) (must meet all):

1. Diagnosis of one of the following (a or b):
  - a. Advanced systemic mastocytosis and one of the following: (i, ii or iii):
    - i. Aggressive systemic mastocytosis;
    - ii. Systemic mastocytosis with an associated hematological neoplasm;
    - iii. Mast cell leukemia;
  - b. Indolent systemic mastocytosis;
2. Documentation of platelet count  $\geq 50 \times 10^9/L$  ( $\geq 50,000/mcL$ ).

#### Approval Duration

**All Lines of Business (except Medicare):** 6 months

#### C. Myeloid/Lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes (Off-label) (must meet all):

1. Diagnosis of FIP1L1-PDGFR-positive myeloid/lymphoid neoplasms with eosinophilia;
2. Member has PDGFRA D842V mutation; previous failure of imatinib\* therapy, unless contraindicated or clinically significant adverse effects are experienced.\*Prior authorization may be required for imatinib

#### Approval Duration

**All Lines of Business (except Medicare):** 6 months

### II. Continued Therapy Approval

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

**A. All indications listed in Section I (must meet all):**

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

**Approval Duration**

**All Lines of Business (except Medicare): 12 months**

**References**

1. National Comprehensive Cancer Network Guidelines. Soft Tissue Sarcoma Version 2.2024. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/sarcoma.pdf](https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf). Accessed August 28, 2024.
2. National Comprehensive Cancer Network Guidelines. Gastrointestinal tumors (GIST) Version 2.2024. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/gist.pdf](https://www.nccn.org/professionals/physician_gls/pdf/gist.pdf). Accessed August 28, 2024.
3. National Comprehensive Cancer Network Guidelines. Systemic Mastocytosis Version 3.2024. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/mastocytosis.pdf](https://www.nccn.org/professionals/physician_gls/pdf/mastocytosis.pdf). Accessed August 28, 2024.
4. National Comprehensive Cancer Network Guidelines. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes. Version 2.2024. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/mlne.pdf](https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf). Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	05/21/2020	05/21/2020
Policy was reviewed: 1. Continuation therapy criteria II.A.1. added listed in this policy;" 2. References were updated 3. Added initial therapy approval criteria for myeloid/lymphoid neoplasms and updated continued therapy criteria to reflect the same.	02/15/2021	03/09/2021
Policy was reviewed: 1. Initial Approval Criteria, 1.B: Updated to include approval criteria for indication AdvSM. 2. References were reviewed and updated.	12/08/2021	01/17/2021
Policy was reviewed: 1. Initial Approval Criteria, I.B.4: Updated prescriber criteria to include allergist, or immunologist. 2. References were reviewed and updated.	10/19/2022	01/17/2023
Policy was reviewed: 1. Initial Approval Criteria, I.B.1.a: Updated Diagnosis criteria from Individual has one of the following subtypes of Advanced systemic mastocytosis (a, b or c) to Advanced systemic mastocytosis (AdvSM) and one of the following: (i, ii or iii). 2. Initial Approval Criteria, I.B.1.b: Updated to include new diagnosis criteria for indication ISM. 3. References were reviewed and updated.	06/27/2023	07/13/2023

Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Removed age restrictions.</li> <li>2. Removed prescriber restrictions.</li> <li>3. Removed dose restrictions.</li> <li>4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days.</li> <li>5. Removed reauthorization requirement for positive response to therapy.</li> <li>6. Updated approval duration verbiage.</li> <li>7. References were reviewed and updated.</li> </ol>	8/28/2024	9/13/2024
Policy was reviewed.	12/05/2024	N/A
Policy reviewed.	12/11/2025	12/11/2025