Clinical Policy Title:	avapritinib
Policy Number:	RxA.626
Drug(s) Applied:	Ayvakit®
Original Policy Date:	05/21/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	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 PDGGFRA 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 ≥ 50 x 10^9/L (≥ 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-PDGFRA-positive myeloid/lymphoid neoplasms with eosinophilia;
2. Member has PDGFRA D842V mutation;
   revious 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

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. 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. 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. 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. 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: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	8/28/2024	9/13/2024