### Overview

Ayvakit is indicated for unresectable or metastatic gastrointestinal stromal tumor harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations in adults and advanced systemic mastocytosis (AdvSM) in adults, including aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm, and mast cell leukemia.

### Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with Ayvakit excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

**OR**

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

#### Unresectable or metastatic GIST

Prescriber provides documentation of ALL of the following:

1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Member has disease harboring a PDGFRA exon 18 mutation (including PDGFRA D842V mutations)
5. Quantity requested is \( \leq 1 \) tablet/day
Advanced systemic mastocytosis (AdvSM), systemic mastocytosis (SM) with associated hematological neoplasm, mast cell leukemia

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is an oncologist or hematologist
3. Appropriate dosing
4. **ONE** of the following:
   a. Member meets **ALL** of the following:
      i. Member has aggressive SM without the D816V c-Kit mutation (as determined by an FDA-approved test) or with c-Kit mutation status unknown
      ii. Physician documentation of inadequate response, adverse reaction, or contraindication to imatinib
   b. D816V c-Kit mutation positive (as determined by an FDA-approved test)
5. Quantity requested is ≤1 tablet/day

**Continuation of Therapy**

Reauthorization will be granted when physician provides attestation of positive response to therapy.

**Limitations**

1. Initial approvals and reauthorizations will be granted for 12 months
2. The following quantity limits apply:

| Ayvakit tablets | 30 tablets per 30 days |

**Appendix**

**Appendix A: Exceeding Quantity Limitations**

Requests exceeding the quantity limit should be evaluated on a case-by-case basis. If there is compelling rationale for exceeding the quantity limit, please forward to clinical review for case-by-case evaluation (e.g., stability, past approvals at a dose exceeding the quantity limit, specific clinical rationale for dose is documented).

In addition to criteria in the procedure table above, requests exceeding the quantity limit must have **ALL** of the following:

1. Dose is appropriate
2. Dose is consolidated
3. Appropriate clinical rationale for exceeding the quantity limit

**References**


**Review History**

11/17/2021 – Created and Reviewed for Nov P&T. Matched with MH UPPL. Effective 01/01/2022

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