UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Ayvakit

Program	Prior Authorization
Medication	Ayvakit™ (avapritinib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York CHIP, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	2/2020
Pharmacy and Therapeutics Approval Date	1/2021
Effective Date	3/2021

1. Background:

Ayvakit (avapritinib) is a kinase inhibitor indicated for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations.

The National Comprehensive Cancer Network (NCCN) also recommends use as single agent therapy as continued treatment for limited progression of GIST, for unresectable, recurrent, or metastatic disease after failure on approved therapies. Additionally, NCCN recommends use for treatment of GIST with PDGFRA exon 18 mutations, including the PDGFRA D842V mutation, for disease that is unresectable, recurrent, metastatic, persistent microscopic or gross residual disease, or as treatment for resectable disease with significant morbidity that is insensitive to imatinib.

The NCCN also recommends use of Ayvakit for treatment for myeloid/lymphoid neoplasms with eosinophilia and FIP1L1-PDGFRA rearrangement if PDGFRA D84V mutation is found which is resistant to imatinib.

2. Coverage Criteria:

A. <u>Gastrointestinal Stromal Tumor (GIST)</u>

1. <u>Initial Authorization</u>

a. Ayvakit will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of gastrointestinal stromal tumor (GIST)

-AND-

(2) **One** of the following:

(a) Treatment is used for **one** of the following:
i. Unresectable, recurrent, or metastatic disease after failure on approved therapies (e.g., imatinib [Gleevec] and Sutent® [sunitinib])
ii. Continuation of therapy for limited progression

-OR-

(b) **All** of the following:
i. Presence of platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation (including PDGFRA D842V mutations)

-AND-

ii. **One** of the following:
- Mutations are insensitive to imatinib (Gleevec) and used for treatment of resectable disease with significant morbidity
- Mutations are sensitive to imatinib (Gleevec) and used for treatment of one of the following:
  - Unresectable, recurrent, metastatic disease
  - Persistent residual disease

Authorization will be issued for 12 months.

2. Reauthorization

a. Ayvakit will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on **Ayvakit** therapy

Authorization will be issued for 12 months.

B. Myeloid/Lymphoid Neoplasms

1. Initial Authorization

a. Ayvakit will be approved based on **all** of the following criteria:

(1) Diagnosis of myeloid/lymphoid neoplasms with eosinophilia

-AND-

(2) Presence FIP1L1-PDGFRA rearrangement

-AND-

(3) PDGFRA D842V mutation is found to be resistant to imatinib (Gleevec)

Authorization will be issued for 12 months.

2. Reauthorization

a. Ayvakit will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on **Ayvakit** therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

1. Initial Authorization

a. **Ayvakit** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Ayvakit** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Ayvakit therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes

(ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Ayvakit [package insert]. Cambridge, MA: Blueprint Medicines Corporation; January 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on December 14, 2020.

Program	Prior Authorization
Change Control	
Date	Change
2/2020	New program
5/2020	Added step through imatinib for non-D842V PDGFRA exon 18 mutations. Updated references.
2/2021	Annual review. Updated criteria for GIST according to NCCN recommendations. Added criteria for Myeloid/Lymphoid neoplasms according to NCCN recommendations. Updated reference.