

This document applies to the following:

Formulary	Applies
Standard Control (SF)	<input checked="" type="checkbox"/>
Standard Control – Choice (SCCF)	<input checked="" type="checkbox"/>
Preferred Drug Plan Design (PDPD)	<input type="checkbox"/>
Advanced Control Specialty (ACSF)	<input checked="" type="checkbox"/>
Advanced Control Specialty – Choice (ACSCF)	<input checked="" type="checkbox"/>
Managed Medicaid Template (MMT)	<input type="checkbox"/>
Marketplace (MF)	<input type="checkbox"/>
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	<input type="checkbox"/>
Aetna Individual Lives (IVL)	<input type="checkbox"/>
Value (VF)	<input checked="" type="checkbox"/>

Formulary	Applies
New to Market (NTM)	<input checked="" type="checkbox"/>
Standard Formulary Chart (SFC)	<input checked="" type="checkbox"/>
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	<input type="checkbox"/>
Advanced Control Specialty Formulary Chart (ACSFC)	<input checked="" type="checkbox"/>
Value Formulary Chart (VFC)	<input checked="" type="checkbox"/>
Medical Benefit	<input type="checkbox"/>
Medical Benefit: Advanced Biosimilars First	<input type="checkbox"/>
Medical Benefit: Managed Medicaid (MMMB)	<input type="checkbox"/>
Medicare Part B	<input type="checkbox"/>
Medicare Part B: Advanced Biosimilars First	<input type="checkbox"/>

# Exceptions Criteria

## Ayvakit

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF), Value Formulary (VF), Advanced Control Specialty Formulary Chart (ACSFC), Standard Control Formulary Chart (SFC), Value Formulary Chart (VFC), and New to Market.

## Plan Design Summary

This program applies to the oncology product(s) specified in this document. Coverage for targeted product(s) is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

## Table. Oncology Agents

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	<ul style="list-style-type: none"> <li>• Rydapt (midostaurin)</li> <li>• Stivarga (regorafenib)</li> <li>• sunitinib (generic)</li> </ul>
Target	<ul style="list-style-type: none"> <li>• Ayvakit (avapritinib)</li> </ul>

## Exception Criteria

This program applies to members requesting treatment for gastrointestinal stromal tumor (GIST) and advanced systemic mastocytosis.

Coverage for the targeted product is provided when any of the following criteria is met:

### Gastrointestinal Stromal Tumor (GIST)

- Member is currently receiving treatment with a targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
- Member has a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including the PDGFRA D842V mutation.
- Member has a documented inadequate response or intolerable adverse event with Stivarga and sunitinib.

### Advanced Systemic Mastocytosis

- Member is currently receiving treatment with a targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented inadequate response or intolerable adverse event with Rydapt.

## References

1. Ayvakit [package insert]. Cambridge, MA: Blueprint Medicines Corporation.; May 2023.
2. Rydapt [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2023.
3. Stivarga [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; December 2020.
4. Sunitinib [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; September 2021.