

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)	<input type="checkbox"/>
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 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

Tyrosine Kinase Inhibitors

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), and Value Formulary Chart (VFC).

Plan Design Summary

This program applies to the tyrosine kinase inhibitor products specified in this document. Coverage for targeted products 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 all members requesting treatment with the targeted product Gleevec. This program also applies to members who are new to treatment with the targeted products Iclusig, Scemblix and Tasigna for the first time.

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

Table. Tyrosine Kinase Inhibitors

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

	Products
Preferred	<ul style="list-style-type: none"> • Bosulif (bosutinib) • imatinib mesylate (generic) • Sprycel (dasatinib)
Target	<ul style="list-style-type: none"> • Gleevec (imatinib mesylate) • Iclusig (ponatinib) • Scemblix (asciminib) • Tasigna (nilotinib)

Exception Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Tasigna

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

- Member is currently receiving treatment with the 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, resistance, intolerable adverse event, or contraindication to prior therapy with all of the preferred products: Bosulif, imatinib, and Sprycel.
- Member has a documented inadequate response or resistance to primary treatment with Bosulif and has a documented intolerable adverse event or contraindication to Sprycel.
- Member has a documented inadequate response or resistance to primary treatment with Sprycel and has a documented intolerable adverse event or contraindication to Bosulif.

Gleevec

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

- Member has had a documented intolerable adverse event to generic imatinib that was NOT an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the brand and generic medication).
- Member has a documented intolerable adverse event or contraindication to prior therapy with the other preferred products: Bosulif and Sprycel.

Iclusig

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

- Member is currently receiving treatment with the 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, resistance, intolerable adverse event, or contraindication to prior therapy with all of the preferred products: Bosulif, imatinib, and Sprycel.
- For chronic myeloid leukemia (CML), member has any documented BCR::ABL1 mutation that predicts resistance to the preferred products.
- For CML, member has a documented resistance to primary treatment with a second generation TKI and has no identifiable BCR::ABL1 mutations.
- For Philadelphia chromosome positive (Ph-positive) acute lymphoblastic leukemia (ALL), member has any documented BCR::ABL1 mutation that predicts resistance to the preferred products.
- For Ph-positive ALL, member is requesting the targeted product for frontline treatment (without a trial of the preferred products).
- For relapsed/refractory Ph-positive ALL, member has a documented inadequate response, resistance or intolerable adverse event to prior therapy with two of the preferred products (i.e., imatinib and Sprycel)

Scemblix

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

- Member is currently receiving treatment with the 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, resistance, intolerable adverse event, or contraindication to prior therapy with all of the preferred products: Bosulif, imatinib, and Sprycel.
- For CML, member has any documented BCR::ABL1 mutation that predicts resistance to the preferred products.

References

1. Bosulif [package insert]. New York, NY: Pfizer Inc.; September 2023.
2. Gleevec [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp.; March 2024.
3. Iclusig [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; March 2024.

Reference number(s)
4930-D

4. Imatinib [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; September 2022.
5. Scemblix [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; August 2024.
6. Sprycel [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; July 2024.
7. Tasigna [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2024.
8. NCCN Clinical Practice Guidelines in Oncology® Chronic Myeloid Leukemia (Version 2.2024). © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed April 25, 2024.