Reference number(s)
7538-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Value (VF)	☑

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☑
Medical Benefit	☐
Medical Benefit: Advanced Biosimilars First	☐
Combined Benefit Management (CBM)	☐
Combined Benefit Management Pharmacy (CBMP)	☐
Medical Benefit Managed Medicaid (MMMB)	☐

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: Value Formulary (VF) 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 products Bosulif, Danziten, Gleevec, Phyrago, Sprycel, and Tasigna. This program also applies to members who are new to treatment with the targeted products Iclusig and Imkeldi 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	• bosutinib (generic) • dasatinib (generic) • imatinib mesylate (generic) • nilotinib (generic) • Scemblix (asciminib)
Target	• Bosulif (bosutinib) • Danziten (nilotinib) • Gleevec (imatinib mesylate) • Iclusig (ponatinib) • Imkeldi (imatinib) • Phyrago (dasatinib) • Sprycel (dasatinib) • Tasigna (nilotinib)

Exception Criteria

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

Bosulif

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

- Member has a documented intolerable adverse event to generic bosutinib 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).
- Any of the following criteria are met:
    - Member has a documented inadequate response, resistance, intolerable adverse event, or contraindication to prior therapy with at least three of the preferred products: dasatinib, imatinib, nilotinib, and Scemblix.
    - Member has a documented inadequate response or resistance to primary treatment with a second generation TKI or Scemblix and has a documented intolerable adverse event or contraindication to two of the preferred products.

Danziten and Tasigna

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

- Member has a documented intolerable adverse event to generic nilotinib 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).
- Any of the following criteria are met:
    - Member has a documented inadequate response, resistance, intolerable adverse event, or contraindication to prior therapy with at least three of the preferred products: bosutinib, imatinib, dasatinib, and Scemblix or
    - Member has a documented inadequate response or resistance to primary treatment with a second generation TKI or Scemblix and has a documented intolerable adverse event or contraindication to two of the preferred products.

Gleevec

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

- Member has 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 at least three of the preferred products: bosutinib, dasatinib, nilotinib, and Scemblix.

Imkeldi

Coverage for the targeted product is provided when any of the following criteria are 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.
- The requested product is Imkeldi oral solution and the member is unable to swallow generic imatinib tablets.
- Member meets both of the following criteria:
    - Member has 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 at least three of the preferred products: bosutinib, dasatinib, nilotinib, and Scemblix.

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 at least three of the preferred products: bosutinib, dasatinib, imatinib, nilotinib, and Scemblix.
- 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 or Scemblix 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 dasatinib).

Phyrago and Sprycel

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

- Member has a documented intolerable adverse event to generic dasatinib 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).
- Any of the following criteria are met:
    - Member has a documented inadequate response, resistance, intolerable adverse event, or contraindication to prior therapy with at least three of the preferred products: bosutinib, imatinib, nilotinib, and Scemblix.
    - Member has a documented inadequate response or resistance to primary treatment with nilotinib and has a documented intolerable adverse event or contraindication to bosutinib and Scemblix.
    - Member has a documented inadequate response or resistance to primary treatment with bosutinib and has a documented intolerable adverse event or contraindication to Scemblix and nilotinib.
    - Member has a documented inadequate response or resistance to primary treatment with Scemblix and has a documented intolerable adverse event or contraindication to bosutinib and nilotinib.

References

1. Bosulif [package insert]. New York, NY: Pfizer Inc.; March 2026.
2. bosutinib [package insert]. Bedminster, NJ: Alembic Pharmaceuticals, Inc.; May 2026.
3. Danziten [package insert]. Woburn, MA: Azurity Pharmaceuticals, Inc.; November 2024.
4. dasatinib [package insert]. Weston, FL: Apotex Corp.; September 2024.
5. Gleevec [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp.; January 2026.
6. Iclusig [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; October 2025.
7. imatinib [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; September 2022.
8. Imkeldi [package insert]. Cambridge, MA: Shorla Oncology Inc.; December 2024.
9. nilotinib [package insert]. Weston, FL: Apotex Corp.; August 2025.
10. Phyrago [package insert]. San Jose, CA: Handa Therapeutics, LLC; August 2025.
11. Scemblix [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; November 2025.
12. Sprycel [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; July 2024.
13. Tasigna [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2025.
14. NCCN Clinical Practice Guidelines in Oncology® Chronic Myeloid Leukemia (Version 1.2027). © 2026 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed July 9, 2026.