Reference number(s)
7130-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: Marketplace Formulary (MF).

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 Danziten, Gleevec, Phyrago, Tasigna, and Sprycel. This program also applies to members who are new to treatment with the targeted products Bosulif 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	• dasatinib (generic) • imatinib mesylate (generic) • nilotinib (generic) • Scemblix (asciminib)
Target	• Bosulif (bosutinib) • Danziten (nilotinib) • Gleevec (imatinib mesylate) • 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 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: dasatinib, imatinib, nilotinib, and Scemblix.
- Member has a documented inadequate response or resistance to primary treatment with dasatinib and has a documented intolerable adverse event or contraindication to therapy with nilotinib and Scemblix.
- Member has a documented inadequate response or resistance to primary treatment with Scemblix and has a documented intolerable adverse event or contraindication to therapy with dasatinib and nilotinib.
- Member has a documented inadequate response or resistance to primary treatment with nilotinib and has a documented intolerable adverse event or contraindication to therapy with dasatinib and Scemblix.

Danziten and Tasigna

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

- Member has had 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 the preferred products: imatinib, dasatinib, and Scemblix.
    - Member has a documented inadequate response or resistance to primary treatment with dasatinib and has a documented intolerable adverse event or contraindication to therapy with Scemblix.
    - Member has a documented inadequate response or resistance to primary treatment with Scemblix and has a documented intolerable adverse event or contraindication to therapy with dasatinib.
    - Member has a documented inadequate response or resistance to primary treatment with a second generation TKI and has a documented intolerable adverse event or contraindication to therapy with Scemblix and dasatinib.

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 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: dasatinib, nilotinib, and Scemblix.

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: dasatinib, nilotinib, and Scemblix.

Phyrago and Sprycel

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 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 the preferred products: 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 therapy with Scemblix.
    - Member has a documented inadequate response or resistance to primary treatment with Scemblix and has a documented intolerable adverse event or contraindication to therapy with nilotinib.
    - Member has a documented inadequate response or resistance to primary treatment with a second generation TKI and has a documented intolerable adverse event or contraindication to therapy with nilotinib and Scemblix.

References

1. Bosulif [package insert]. New York, NY: Pfizer Inc.; December 2024.
2. Danziten [package insert]. Woburn, MA: Azurity Pharmaceuticals, Inc.; November 2024.
3. dasatinib [package insert]. Weston, FL: Apotex Corp.; September 2024.
4. Gleevec [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp.; January 2026.
5. Imkeldi [package insert]. Cambridge, MA: Shorla Oncology Inc.; December 2024.
6. imatinib [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; September 2022.
7. nilotinib [package insert]. Weston, FL: Apotex Corp.; August 2025.
8. Phyrago [package insert]. San Jose, CA: Handa Therapeutics, LLC; August 2025.
9. Scemblix [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; November 2025.
10. Sprycel [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; July 2024.
11. Tasigna [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2024.