Reference number(s)
4931-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)	☑
Aetna Individual Lives (IVL)	☑
Value (VF)	☐
New to Market (NTM)	☐

Formulary	Applies
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 Medical (CBM)	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

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), Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE) Formulary, and Aetna Individual Lives (IVL) Formulary.

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, and Sprycel. This program also applies to members who are new to treatment with the targeted products Bosulif, Imkeldi 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	• dasatinib (generic) • imatinib mesylate (generic)
Target	• Bosulif (bosutinib) • Danziten (nilotinib) • Gleevec (imatinib mesylate) • Imkeldi (imatinib) • 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 and Tasigna

Coverage for the targeted products 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 both of the preferred products: imatinib and dasatinib.
- Member has a documented inadequate response or resistance to primary treatment with dasatinib.
- 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 therapy with dasatinib.

Danziten

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

- Member has a documented inadequate response, resistance, intolerable adverse event, or contraindication to prior therapy with both of the preferred products: imatinib and dasatinib.
- Member has a documented inadequate response or resistance to primary treatment with dasatinib.
- 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 therapy with 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 product, dasatinib.

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 product, dasatinib.

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).
- Either of the following criteria are met:
    - Member has a documented inadequate response, resistance, intolerable adverse event, or contraindication to prior therapy with the preferred product: imatinib, or
    - Member has a documented inadequate response or resistance to primary treatment with a second generation TKI or Scemblix.

Reference number(s)
4931-D

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.; March 2024.
5. Imkeldi [package insert]. Cambridge, MA: Shorla Oncology Inc.; December 2024.
6. imatinib [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; September 2022.
7. Sprycel [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; July 2024.
8. Tasigna [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2024.