This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)	✓	ACSF Chart (ACSFC)		Medical Benefit		Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)	✓	SF Chart (SFC)		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		Medicare Part B: Add-on
			IVL						

Reference #
3222-D

EXCEPTIONS CRITERIA
TYROSINE KINASE INHIBITORS

PREFERRED PRODUCTS: BOSULIF, IMATINIB, AND SPRYCEL

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

I. PLAN DESIGN SUMMARY

This program applies to the tyrosine kinase inhibitors specified in this policy. 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 product Tasigna for the first time.

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

Table. Tyrosine kinase inhibitors

	Products
Preferred*	• **Bosulif** (bosutinib) • **imatinib mesylate** (generic) • **Sprycel** (dasatinib)
Targeted	• **Gleevec** (imatinib mesylate) • **Tasigna** (nilotinib)

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

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

A. Tasigna
Coverage for the targeted product is provided when any of the following criteria is met:
1. Member is currently receiving treatment with Tasigna, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
2. 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.
3. Member has a documented inadequate response or resistance to primary treatment with Bosulif and has a documented intolerable adverse event or contraindication to Sprycel.
4. Member has a documented inadequate response or resistance to primary treatment with Sprycel and has a documented intolerable adverse event or contraindication to Bosulif.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)	✓	ACSF Chart (ACSFC)		Medical Benefit		Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)	✓	SF Chart (SFC)		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		Medicare Part B: Add-on
			IVL						

Reference #
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B. Gleevec

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

1. 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).
2. Member has a documented intolerable adverse event or contraindication to prior therapy with the other preferred products: Bosulif and Sprycel.

REFERENCES

1. Bosulif [package insert]. New York, NY: Pfizer Inc.; October 2021.
2. Gleevec [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp.; August 2022.
3. Imatinib [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; July 2022.
4. Sprycel [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; June 2021.
5. Tasigna [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2021.