

This policy applies to the following:

Standard Control (SF)	Managed Medicaid Template (MMT)	ACSF Chart (ACSFC)	Medical Benefit	✓	Medicare Part B	Reference #
Preferred Drug Plan Design (PDPD)	Marketplace (MF)	SF Chart (SFC)	Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First	5861-D
Advanced Control Specialty (ACSF)	New to Market (NTM)	VF Chart (VFC)	Medical Benefit: Add-on			
Value (VF)	Aetna Health Exchange (AHE)		Medical Benefit: Managed Medicaid			
	IVL					

## EXCEPTIONS CRITERIA MULTIPLE MYELOMA

### PREFERRED PRODUCTS: BORTEZOMIB (J9046, J9048 AND J9049)

#### 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 multiple myeloma products 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 members who are new to treatment with a targeted product for the first time.

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

Table. Multiple Myeloma

	Product(s)
Preferred*	<ul style="list-style-type: none"> <li>• <b>Bortezomib</b> (generic) J9046, NDC 43598-0865-60</li> <li>• <b>Bortezomib</b> (generic) J9048, NDC 63323-0721-10</li> <li>• <b>Bortezomib</b> (generic) J9049, NDC 00409-1703-01</li> </ul>
Targeted	<ul style="list-style-type: none"> <li>• <b>Empliciti</b> (elotuzumab)</li> <li>• <b>Kyprolis</b> (carfilzomib)</li> <li>• <b>Sarclisa</b> (isatuximab)</li> <li>• <b>Velcade (J9041)</b> (bortezomib)</li> </ul>

\*: 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.

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

- Member has received treatment with the targeted product in the past 365 days.
- The request is for Empliciti, Kyprolis or Sarclisa and the member has a documented inadequate response or intolerable adverse event with a preferred product.

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	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid			
			IVL							

- C. The request is for Velcade and the member has had a documented intolerable adverse event to a preferred product, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

## REFERENCES

1. bortezomib [package insert]. Lake Zurich, IL: Fresenius Kabi; April 2022.
2. Empliciti [package insert]. Princeton, NJ: Bristol-Myers Squibb; March 2022.
3. Kyprolis [package insert]. Thousand Oaks, CA: Onyx Pharmaceuticals, Inc.; June 2022.
4. Sarclisa [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; November 2023.
5. Velcade [package insert]. Lexington, MA: Takeda Pharmaceuticals America; August 2022.