Reference number(s)
5861-D

This document applies to the following:

Product	Applies
Medicare Part B	☑
Medicare Part B: Advanced Biosimilars First	☑

Medicare Part B Step Therapy Multiple Myeloma

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.

These criteria were developed to align with the following: Medicare Part B and Medicare Part B Advanced Biosimilars First.

Plan Design Summary

This program applies to the multiple myeloma products specified in this document. Coverage for non-preferred 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 non-preferred product.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Multiple Myeloma

Medications considered preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	• bortezomib (generic) J9046, NDC 43598-0865-60 • bortezomib (generic) J9048, NDC 63323-0721-10 • bortezomib (generic) J9049, NDC 00409-1703-01

	Product(s)
Non-preferred	• Empliciti (elotuzumab) • Kyprolis (carfilzomib) • Sarclisa (isatuximab) • Velcade (J9041) (bortezomib)

Step Therapy Criteria

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

Coverage for a non-preferred product is provided when any of the following criteria are met:

- Member has received treatment with the non-preferred 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.
- 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; October 2024.
5. Velcade [package insert]. Lexington, MA: Takeda Pharmaceuticals America; August 2022.