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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Retired Effective Date: 02/02/2023

Bendamustine Products

Belrapzo [™] (bendamustine hydrochloride) Bendeka[®] (bendamustine hydrochloride) Treanda[®] (bendamustine hydrochloride)

HCPCS: Belrapzo J9036; Bendeka J9034; Treanda J9033

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - Diagnosis of chronic lymphocytic leukemia made by or in consultation with an oncologist or hematologist OR
 - b. Diagnosis of indolent B-cell non-Hodgkin lymphoma, Mantle Cell lymphoma, or Waldenstroms Macroglobulinemia made by or in consultation with an oncologist or hematologist
 - i. Prior treatment with rituximab or a rituximab-containing regimen
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limits: Align with FDA recommended dosing
 - Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for up to 6 months at a time
 - c. Renewal Criteria: Treatment continued until unacceptable toxicity, disease progression, or treatment failure occurs

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

Bendamustine is an alkylating agent indicated for the treatment of chronic lymphocytic leukemia (CLL) and indolent
 B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

References:

- 1. Bendeka [package insert]. North Wales, PA: Teva Pharmaceuticals. November 2020.
- 2. Treanda [package insert]. North Wales, PA: Teva Pharmaceuticals. December 2017.
- 3. Belrapzo [package insert]. Woodcliff Lake, NJ: Eagle Pharmaceuticals, Inc. November 2020.
- 4. Knauf WU, Lissichkov T, Aldaoud A, et al. Phase III randomized study of bendamustine compared with chlorambucil in previously untreated patients with chronic lymphocytic leukemia. J Clin Oncol 2009;27:4378-4384.
- 5. Knauf WU, Lissichkov T, Aldaoud A, et al. Bendamustine compared with chlorambucil in previously untreated patients with chronic lymphocytic leukemia: updated results of a randomized phase III trial. Br J Haematol 2012:159:67-77.
- 6. Kahl BS, Bartlett NL, Leonard JP, et al. Bendamustine is effective therapy in patients with rituximvaialbleab-refractory, indolent B-cell non-Hodgkin lymphoma: results from a multicenter study. Cancer 2010;116:106-114.
- 7. National Comprehensive Cancer Network. Chronic lymphocytic leukemia/small lymphocytic lymphoma (Version 3.2022). 2022 June 3. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed on: June 14, 2022.

#	Date	Change Description	
1.6	Effective Date: 02/02/2023	Retiring policy as drug will no longer be part of the prior authorization program	
1.5	Effective Date: 08/04/2022	Updated approval length to allow for FDA recommended dosing or up to 6 months at a time	
1.4	Effective Date: 08/12/2021	Annual review of medical policy	
1.3	Effective Date: 08/13/2020	Annual review of medical policy	
1.2	Effective Date: 03/16/2020	PA added to Belrapzo for MAPPO and BCNA	
1.1	Effective Date: 08/15/2019	Added Belrapzo	
1.0	Effective Date: 05/09/2019	New coverage criteria	
		Line of Business	PA Required in Medical Management System (Yes/No)
		BCBS	No
		BCN	No
		MAPPO	No
		BCNA	No

^{*} The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.