SmartHealth Ascension

Bendamustine

(Treanda®) J9033 (1mg), (Bendeka®) J9034 (1mg), (Belrapzo®) J9036 (1mg)

Covered with prior authorization

Bendamustine may be authorized when the following criteria are met:

- Individual has a diagnosis of one of the following:
  - Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL); **OR**
  - Relapsed or refractory classical Hodgkin lymphoma; **OR**
  - Non-Hodgkin lymphoma (NHL); **OR**
  - Relapsed or progressive multiple myeloma; **OR**
  - Relapsed or refractory systemic light chain amyloidosis; **OR**
  - Waldenstrom's macroglobulinemia

Exclusion criteria:

- Treatment of metastatic breast cancer.
- Treatment of small cell lung cancer (SCLC).
- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.
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Ascension considers bendamustine experimental and investigational for all other indications including the following (not an all-inclusive list):

- Acute myeloid leukemia
- Anaplastic glioma
- Blastic plasmacytoid dendritic cell leukemia
- Breast cancer
- Colorectal cancer
- Hairy cell leukemia
- Head and neck cancer
- Immune thrombocytopenic purpura
- Langerhans cell sarcoma
- Melanoma
- Myelodysplastic syndrome

- Non-small cell lung cancer
- Primary central nervous system (CNS) lymphoma
- Small cell lung cancer (SCLC)
- Systemic light-chain (AL) amyloidosis

Initial authorization approval is up to 12 months.

Reauthorization approval is up to 12 months.

Reauthorization Criteria:
Bendamustine is considered medically necessary for continued use when initial criteria are met; **AND** the patient has experienced clinical benefit to therapy; **AND** has not experienced an unacceptable toxicity.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Bendamustine is an alkylating drug indicated for treatment of:
- Chronic lymphocytic leukemia (CLL)
- 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. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
2. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022
3. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp.

Criteria History/ Revision Information:

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review

Date	Summary of Changes
	Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.