Bendamustine Products (Treanda®, Belrapzo®, Bendeka®, Vivimusta™, Bendamustine)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Chronic lymphocytic leukemia (CLL)
2. Indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen

B. Compendial Uses
1. Classical Hodgkin lymphoma (CHL)
2. Nodular lymphocyte predominant Hodgkin lymphoma (NLPHL)
3. Multiple myeloma (MM)
4. CLL/small lymphocytic lymphoma (SLL)
5. B-cell lymphomas:
   a. Human immunodeficiency virus (HIV)-related B-cell lymphoma
   b. Diffuse large B-cell lymphoma (DLBCL)
   c. Follicular lymphoma
   d. High grade B-cell lymphoma
   e. Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
   f. Marginal zone lymphoma
      i. Nodal marginal zone lymphoma
      ii. Gastric mucosa associated lymphoid tissue (MALT) lymphoma (extranodal marginal zone lymphoma of the stomach)
      iii. Nongastric MALT lymphoma (nongastric extranodal marginal zone lymphoma)
      iv. Splenic marginal zone lymphoma
   g. Mantle cell lymphoma (MCL)
   h. Post-transplant lymphoproliferative disorders
6. T-cell lymphomas:
   a. Adult T-cell leukemia/lymphoma (ATLL)
   b. Hepatosplenic T-Cell lymphoma
   c. Peripheral T-cell lymphoma (PTCL)
   d. Breast implant associated anaplastic large cell lymphoma (ALCL)
7. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma/Bing-Neel syndrome
8. Systemic light chain amyloidosis
9. Hematopoietic cell transplantation

10. Cold agglutinin disease

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. B-cell lymphoma

Authorization of 12 months may be granted for treatment of B-cell lymphomas with any of the following subtypes:

1. HIV-related B-cell lymphoma (HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma, plasmablastic lymphoma) when all of the following criteria are met:
   i. The requested drug is used as subsequent therapy
   ii. The requested drug is used in combination with polatuzumab vedotin-piiq with or without rituximab
   iii. The member is not a candidate for transplant or the requested drug will be used as a bridging option until CAR T-cell product is available
2. Diffuse large B-cell lymphoma (DLBCL) when all of the following criteria are met:
   i. The requested drug is used as subsequent therapy
   ii. The requested drug is used in combination with polatuzumab vedotin-piiq with or without rituximab
   iii. The member is not a candidate for transplant or the requested drug will be used as a bridging option until CAR T-cell product is available
3. Follicular lymphoma
4. High-grade B-cell lymphoma when all of the following criteria are met:
   i. The requested drug is used as subsequent therapy
   ii. The requested drug will be used in combination with polatuzumab vedotin-piiq with or without rituximab
   iii. The member is not a candidate for transplant or the requested drug will be used as a bridging option until CAR T-cell product is available.
5. Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma when all of the following criteria are met:
   i. The requested drug is used in combination with polatuzumab vedotin-piiq with or without rituximab.
   ii. The requested drug is used as subsequent therapy.
   iii. The member is not a candidate for transplant.
6. Mantle cell lymphoma (MCL) when either of the following criteria are met:
   i. The requested drug is used in combination with rituximab, or
   ii. The requested drug as a component of RBAC500 (rituximab, bendamustine, and cytarabine).
7. Marginal zone lymphoma
   i. Nodal marginal zone lymphoma when used in combination with rituximab or obinutuzumab.
   ii. Gastric MALT lymphoma (extranodal marginal zone lymphoma of the stomach) when used in combination with rituximab or obinutuzumab.
   iii. Nongastric MALT lymphoma (nongastric extranodal marginal zone lymphoma) when used in combination with rituximab or obinutuzumab.
   iv. Splenic marginal zone lymphoma when used in combination with rituximab or obinutuzumab.
8. Post-transplant lymphoproliferative disorders when all of the following criteria are met:
   i. The requested drug is used as subsequent therapy
   ii. The member is not a candidate for transplant or the requested drug will be used as a bridging option until CAR T-cell product is available

iii. The requested drug will be used in combination with polatuzumab vedotin-piiq with or without rituximab

B. T-cell lymphoma

Authorization of 12 months may be granted for treatment of T-cell lymphomas with any of the following subtypes:

1. Adult T-cell leukemia/lymphoma (ATLL) when all of the following criteria are met:
   i. The requested drug is used as a single agent
   ii. The requested drug is used as subsequent therapy
2. Hepatosplenic T-Cell lymphoma when all of the following criteria are met:
   i. The requested drug is used as a single agent
   ii. The requested drug is used for refractory disease after 2 first-line therapy regimens
3. Peripheral T-cell lymphoma (PTCL) [including the following subtypes: anaplastic large cell lymphoma, peripheral T-cell lymphoma not otherwise specified, angioimmunoblastic T-cell lymphoma, enteropathy associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, nodal peripheral T-cell lymphoma with TFH phenotype, or follicular T-cell lymphoma] when all of the following criteria are met:
   i. The requested drug is used as a single agent
   ii. The requested drug is used as palliative or subsequent therapy
4. Breast implant associated anaplastic large cell lymphoma (ALCL) when all of the following are met:
   i. The requested drug is used as a single agent
   ii. The requested drug is used as subsequent therapy

C. Chronic lymphocytic leukemia/small lymphocytic leukemia (CLL/SLL)

Authorization of 12 months may be granted for treatment of CLL/SLL without chromosome 17p deletion or TP53 mutation

D. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma/Bing-Neel syndrome

Authorization of 12 months may be granted for treatment of Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma or Bing-Neel syndrome when either of the following criteria are met:

1. The requested drug will be used in combination with rituximab, or
2. The requested drug will be used as a single agent.

E. Multiple myeloma (MM)

Authorization of 12 months may be granted for treatment of MM when all of the following criteria are met:

1. The disease is relapsed or progressive, and the member has tried more than 3 prior therapies, and
2. The requested drug will be used in any of the following regimens:
   i. In combination with lenalidomide and dexamethasone, or
   ii. In combination with bortezomib and dexamethasone, or
   iii. In combination with carfilzomib and dexamethasone, or
   iv. As a single agent.

F. Classical Hodgkin lymphoma (cHL)

Authorization of 12 months may be granted for treatment of cHL when all of the following criteria are met:

1. The requested drug will be used as subsequent therapy or palliative therapy, and
2. The requested drug will be used in any of the following regimens:
   i. In combination with brentuximab vedotin, or
   ii. In combination with gemcitabine and vinorelbine, or

iii. In combination with carboplatin and etoposide
iv. As a single agent.

G. Nodular lymphocyte predominant Hodgkin lymphoma (NLPHL)
Authorization of 12 months may be granted for treatment of nodular lymphocyte predominant Hodgkin lymphoma when all of the following criteria are met:
1. The requested drug will be used as subsequent therapy
2. The requested drug will be used in combination with rituximab

H. Systemic light chain amyloidosis
Authorization of 12 months may be granted for treatment of systemic light chain amyloidosis when all of the following criteria are met:
1. The requested drug will be used in combination with dexamethasone
2. The requested drug will be used to treat relapsed or refractory disease

I. Hematopoietic Cell Transplantation
Authorization of 12 months may be granted for use in hematopoietic cell transplantation when all of the following criteria are met:
1. The requested drug will be used as conditioning for autologous transplant
2. The requested drug will be used in combination with etoposide, cytarabine and melphalan

J. Cold agglutinin disease
Authorization of 12 months may be granted for treatment of cold agglutinin disease when used in combination with rituximab.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Treanda [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; October 2022.
2. Bendeka [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; October 2021.
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4. Vivimusta [package insert]. Princeton, NJ; Slayback Pharma LLC; December 2022.
5. Bendamustine [package insert]. Durham, NC; Accord Healthcare Inc; February 2018.
6. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 5, 2023.
7. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at https://www.micromedexsolutions.com Accessed April 8, 2023.

EFFECTIVE DATE 8/30/2024

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