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

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.

FDA-Approved Indications

- 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.

Compendial Uses

- CLL/small lymphocytic lymphoma (SLL)
- B-cell lymphomas
  - Diffuse large B-cell lymphoma (DLBCL)
  - Follicular lymphoma
  - High grade B-cell lymphoma (HGBL)
  - Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
  - Human immunodeficiency virus (HIV)-related B-cell lymphoma
  - Mantle cell lymphoma (MCL)
  - Marginal zone lymphoma
    - Nodal marginal zone lymphoma
    - Extranodal marginal zone lymphoma of the stomach (gastric mucosa associated lymphoid tissue (MALT) lymphoma)
    - Extranodal marginal zone lymphoma of nongastric sites (nongastric MALT lymphoma)
    - Splenic marginal zone lymphoma
  - Post-transplant lymphoproliferative disorders (PTLD)
- Classic Hodgkin lymphoma (cHL)
- Cold agglutinin disease
- Hematopoietic cell transplantation
- Multiple myeloma (MM)
- Nodular lymphocyte predominant Hodgkin lymphoma (NLPHL)
- POEMS (Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal Protein, Skin Changes) Syndrome
- Plasma cell-related Monoclonal Immunoglobulin Deposition Disease (MIDD)
- Plasma cell-related Monoclonal Gammopathy of Renal Significance (MGRS)

This document has been classified as public information

- Systemic light chain amyloidosis
- T-cell lymphomas:
  - Adult T-cell leukemia/lymphoma (ATLL)
  - Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)
  - Hepatosplenic T-cell lymphoma (HSTCL)
  - Peripheral T-cell lymphoma (PTCL)
  - T-cell prolymphocytic leukemia
- Waldenström macroglobulinemia/lymphoplasmacytic lymphoma/Bing-Neel syndrome

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

COVERAGE CRITERIA

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.

B-Cell Lymphomas

Authorization of 12 months may be granted for treatment of B-cell lymphomas when any of the following criteria are met:

- The member has diffuse large B-cell lymphoma (DLBCL) and all of the following criteria are met:
  - The requested medication will be used as subsequent therapy.
  - The requested medication will be used in combination with polatuzumab vedotin-piiq with or without a rituximab product.
- The member has follicular lymphoma.
- The member has high-grade B-cell lymphoma (HGBL) and all of the following criteria are met:
  - The requested medication will be used as subsequent therapy.
  - The requested medication will be used in combination with polatuzumab vedotin-piiq with or without a rituximab product.
- The member has histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma and all of the following criteria are met:
  - The requested medication will be used in combination with polatuzumab vedotin-piiq with or without a rituximab product.
  - The member has received treatment with an anthracycline-based regimen (e.g., doxorubicin).
- The member is not a candidate for transplant.
- The member has HIV-related B-cell lymphoma (HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma, and plasmablastic lymphoma) and all of the following criteria are met:
  - The requested medication will be used as subsequent therapy.
  - The requested medication will be used in combination with polatuzumab vedotin-piiq with or without a rituximab product.
- The member has mantle cell lymphoma (MCL) and any of the following criteria are met:
  - The requested medication will be used in combination with a rituximab product.
  - The requested medication will be used as a component of RBAC500 (rituximab, bendamustine, and cytarabine).
  - The requested medication will be used in combination with acalabrutinib and a rituximab product.
- The member has marginal zone lymphoma and all of the following criteria are met:

- The requested medication will be used in combination with a rituximab product or obinutuzumab.
- The requested medication will be used for treatment of nodal marginal zone lymphoma, extranodal marginal zone lymphoma of the stomach (gastric MALT lymphoma), extranodal marginal zone lymphoma of nongastric sites (nongastric MALT lymphoma), or splenic marginal zone lymphoma.

- The member has monomorphic post-transplant lymphoproliferative disorders (PTLD) (B-cell type) and all of the following criteria are met:
  - The requested medication will be used as subsequent therapy.
  - The requested medication will be used in combination with polatuzumab vedotin-piiq with or without a rituximab product.

T-Cell Lymphomas

Authorization of 12 months may be granted for treatment of T-cell lymphomas when any of the following criteria are met:

- The member has adult T-cell leukemia/lymphoma (ATLL) and all of the following criteria are met:
  - The requested medication will be used as a single agent.
  - The requested medication will be used as subsequent therapy.
- The member has breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) and all of the following criteria are met:
  - The requested medication will be used as a single agent.
  - The requested medication will be used as subsequent therapy.
- The member has hepatosplenic T-cell lymphoma (HSTCL) and all of the following criteria are met:
  - The requested medication will be used as a single agent.
  - The requested medication will be used for refractory disease after 2 first-line therapy regimens.
- The member has 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] and all of the following criteria are met:
  - The requested medication will be used as a single agent
  - The requested medication will be used as palliative or subsequent therapy
- The member has T-cell prolymphocytic leukemia and the requested medication will be used as a single agent for symptomatic disease.

Multiple Myeloma (MM)

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

- The disease is relapsed or refractory and the member has tried more than 3 prior therapies.
- The requested medication will be used in any of the following regimens:
  - In combination with lenalidomide and dexamethasone.
  - In combination with bortezomib and dexamethasone.
  - In combination with carfilzomib and dexamethasone.
  - As a single agent.

Authorization of 12 months may be granted for treatment of MM with CNS disease when used in combination with systemic chemotherapy.

POEMS (Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal Protein, Skin Changes) Syndrome, plasma cell-related Monoclonal Immunoglobulin Deposition Disease (MIDD), plasma cell-related Monoclonal Gammopathy of Renal Significance (MGRS)

Authorization of 12 months may be granted for treatment of POEMS syndrome, plasma cell-related MIDD, or plasma cell-related MGRS when all of the following criteria are met:

- The disease is relapsed or refractory and the member has tried more than 3 prior therapies.
- The requested medication will be used in any of the following regimens:
  - In combination with lenalidomide and dexamethasone.
  - In combination with bortezomib and dexamethasone.
  - In combination with carfilzomib and dexamethasone.
  - As a single agent.

Classic Hodgkin Lymphoma (cHL)

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

- The requested medication will be used as re-induction, subsequent therapy, or palliative therapy.
- The requested medication will be used in any of the following regimens:
  - In combination with brentuximab vedotin, with or without nivolumab.
  - In combination with gemcitabine and vinorelbine.
  - In combination with carboplatin and etoposide.
  - As a single agent.

Nodular Lymphocyte Predominant Hodgkin Lymphoma (NLPHL)

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

- The requested medication will be used as subsequent therapy.
- The requested medication will be used in combination with a rituximab product.

Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma/Bing-Neel Syndrome

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

- The requested medication will be used as a single agent.
- The requested medication will be used in combination with a rituximab product.

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:

- The requested medication will be used in combination with dexamethasone.
- The requested medication will be used for relapsed or refractory disease.

Hematopoietic Cell Transplantation

Authorization of 12 months may be granted for use in hematopoietic cell transplantation when all of the following criteria are met:

- The requested medication will be used as conditioning for autologous transplant.
- The requested medication will be used in combination with etoposide, cytarabine and melphalan.

Cold Agglutinin Disease

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

CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section 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.
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EFFECTIVE DATE 1/30/2027

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