Reference number(s)
2746-A

STANDARD MEDICARE PART B MANAGEMENT

TREANDA (bendamustine)
BENDEKA (bendamustine)
BELRAPZO (bendamustine)
VIVIMUSTA (bendamustine)
bendamustine

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 Use
1. Classical Hodgkin lymphoma (CHL)
2. Nodular lymphocyte predominant Hodgkin lymphoma (NLPHL)
3. Multiple myeloma (MM)
4. Small lymphocytic lymphoma (SLL)
5. B-cell lymphomas:
   i. Human immunodeficiency virus (HIV)-related B-cell lymphoma
   ii. Diffuse large B-cell lymphoma (DLBCL)
   iii. Follicular lymphoma (FL)
   iv. Marginal zone lymphoma
      a. Nodal marginal zone lymphoma
      b. Gastric mucosa associated lymphoid tissue (MALT) lymphoma (extranodal marginal zone lymphoma of the stomach)
      c. Nongastric MALT lymphoma (nongastric extranodal marginal zone lymphoma)
      d. Splenic marginal zone lymphoma
   v. Mantle cell lymphoma (MCL)
   vi. Post-transplant lymphoproliferative disorders
   vii. Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
   viii. High grade B-cell lymphoma
6. T-cell lymphomas:
   i. Adult T-cell leukemia/lymphoma (ATLL)
   ii. Hepatosplenic T-Cell lymphoma
   iii. Peripheral T-cell lymphoma (PTCL)
   iv. Breast implant associated anaplastic large cell lymphoma (ALCL)
7. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (WM/LL)/Bing-Neel syndrome
8. Small cell lung cancer

9. Metastatic breast cancer
10. Systemic light chain amyloidosis
11. Hematopoietic cell transplantation
12. Cold agglutinin disease

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. B-cell lymphoma

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

1. Follicular lymphoma
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. Human immunodeficiency virus (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
4. Marginal zone lymphoma
   i. Nodal marginal zone lymphoma when used in combination with rituximab or obinutuzumab
   ii. Gastric mucosa-associated lymphoid tissue (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
5. 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).
6. 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
7. 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.

8. 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

B. T-cell lymphoma

Authorization of 12 months may be granted for treatment of T-cell lymphoma 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 criteria 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 (WM/LL)/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 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. Small cell lung cancer

Authorization of 12 months may be granted for the subsequent treatment of small cell lung cancer when used as a single agent.

H. Metastatic breast cancer

Authorization of 12 months may be granted for the treatment of metastatic breast cancer when used as a single agent or in combination with chemotherapy.

I. Nodular lymphocyte predominant Hodgkin lymphoma (NLPHL)

Authorization of 12 months may be granted for the treatment of nodular lymphocyte predominant Hodgkin lymphoma (NLPHL) 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

J. Systemic light chain amyloidosis

Authorization of 12 months may be granted for the 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

K. 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

L. 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

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with the requested drug.
B. The requested drug is being used to treat an indication enumerated in Section II.
C. The member is receiving benefit from therapy. Benefit is defined as:
   i. No evidence of unacceptable toxicity while on the current regimen AND
   ii. No evidence of disease progression while on the current regimen.

IV. 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.
3. Belrapzo [package insert]. Woodcliff Lake, NJ; Eagle Pharmaceuticals, Inc; June 2022.
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.