Reference number(s)
2746-A

STANDARD MEDICARE PART B MANAGEMENT

TREANDA (bendamustine)
BENDEKA (bendamustine)
BELRAPZO (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. Multiple myeloma (MM)
3. Small lymphocytic lymphoma (SLL)
4. B-cell lymphomas:
   i. Acquired immune deficiency syndrome (AIDS)-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
      c. Nongastric MALT lymphoma
      d. Splenic marginal zone lymphoma
   v. Mantle cell lymphoma (MCL)
   vi. Post-transplant lymphoproliferative disorders
   vii. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma
   viii. Histologic transformation of follicular lymphoma to diffuse large B-cell lymphoma
   ix. High grade B-cell lymphoma
5. Primary cutaneous lymphomas:
   i. Primary cutaneous CD30+ T-cell lymphoproliferative disorder: cutaneous anaplastic large cell lymphoma (ALCL)
   ii. Mycosis fungoides (MF)/Sezary syndrome (SS)
6. T-cell lymphomas:
   i. Adult T-cell leukemia/lymphoma (ATLL)
   ii. Hepatosplenic gamma-delta T-Cell lymphoma
   iii. Peripheral T-cell lymphoma (PTCL)
7. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (WM/LL)
8. Small cell lung cancer
9. Metastatic breast cancer

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)
3. Acquired immune deficiency syndrome (AIDS)-related B-cell lymphoma
4. Marginal zone lymphoma
    i. Nodal marginal zone lymphoma
    ii. Gastric mucosa-associated lymphoid tissue (MALT) lymphoma
    iii. Nongastric MALT lymphoma
    iv. Splenic marginal zone lymphoma
5. Mantle cell lymphoma (MCL)
6. Post-transplant lymphoproliferative disorders
7. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma
8. Histologic transformation of follicular lymphoma to diffuse large B-cell lymphoma
9. High grade B-cell lymphoma

B. Primary cutaneous lymphoma

Authorization of 12 months may be granted for treatment of primary cutaneous lymphoma with any of the following subtypes:

1. Cutaneous anaplastic large cell lymphoma (ALCL)
2. Mycosis fungoides (MF)/Sezary syndrome (SS)

C. 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)
2. Hepatosplenic gamma-delta T-Cell lymphoma
3. Peripheral T-cell lymphoma (PTCL)

D. 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

E. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (WM/LL)

Authorization of 12 months may be granted for treatment of Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma.

F. Multiple myeloma (MM)

Authorization of 12 months may be granted for treatment of MM.

G. Classical Hodgkin lymphoma (CHL)

Authorization of 12 months may be granted for treatment of CHL.

H. Small cell lung cancer

Authorization of 12 months may be granted for the treatment of small cell lung cancer.

I. Metastatic breast cancer
Authorization of 12 months may be granted for the treatment of metastatic breast cancer.

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 medication.
B. The requested medication is being used to treat an indication enumerated in Section II.
C. The member is receiving benefit from therapy.

IV. REFERENCES

1. Treanda [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; December 2017.
2. Bendeka [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; October 2019.
3. Belrapzo [package insert]. Woodcliff, NJ; Eagle Pharmaceuticals, Inc; December 2018.
4. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 20, 2020.
5. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at https://www.micromedexsolutions.com Accessed April 20, 2020.
6. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Hematology-Oncology Clinical Programs. June 2018.