| Reference number(s) |
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| 1705-A |

# SPECIALTY GUIDELINE 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 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. Acquired immune deficiency syndrome (AIDS)-related B-cell lymphoma
    b. Diffuse large B-cell lymphoma (DLBCL)
    c. Follicular lymphoma
    d. High grade B-cell lymphoma
    e. Histologic transformation of follicular lymphoma to diffuse large B-cell lymphoma without translocations of MYC and BCL2 and/or BCL6
    f. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell
    g. 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
    h. Mantle cell lymphoma (MCL)
    i. Post-transplant lymphoproliferative disorders
6. Primary cutaneous lymphomas:
    a. Cutaneous anaplastic large cell lymphoma (ALCL)
    b. Mycosis fungoides (MF)/Sezary syndrome (SS)
7. 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)
8. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma

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. AIDS-related B-cell lymphoma 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
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.
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 member is not a candidate for transplant.
5. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma all of the following criteria are met:
   i. The requested drug is used as a single agent, in combination with rituximab, or in combination with polatuzumab vedotin-piiq with or without rituximab
   ii. The member has received at least two lines of chemoimmunotherapy.
6. Histologic transformation of follicular lymphoma to diffuse large B-cell lymphoma without translocations of MYC and BCL2 and/or BCL6 when all of the following criteria are met:
   i. The requested drug is used as a single agent or in combination with polatuzumab vedotin-piiq with or without rituximab
   ii. The requested drug is used as subsequent therapy.
7. 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).
8. Marginal zone lymphoma
   i. Nodal marginal zone lymphoma when used in combination with rituximab or obinutuzumab.
   ii. Gastric MALT lymphoma when used in combination with rituximab or obinutuzumab.
   iii. Nongastric MALT lymphoma when used in combination with rituximab or obinutuzumab.
   iv. Splenic marginal zone lymphoma when used in combination with rituximab or obinutuzumab.
9. Post-transplant lymphoproliferative disorders 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 any of the following regimens:
      a. As a single agent
      b. In combination with rituximab
      c. In combination with polatuzumab vedotin-piiq with or without rituximab

### B. Primary cutaneous lymphoma

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

1. Cutaneous 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 for relapsed or refractory disease.
2. Mycosis fungoides (MF)/Sezary syndrome (SS)

**C. 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
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

**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**

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

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

**F. 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
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. As a single agent.

**G. 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.

**H. 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

## 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.

## IV. REFERENCES

1. Treanda [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2019.
2. Bendeka [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; November 2020.
3. Belrapzo [package insert]. Woodcliff Lake, NJ; Eagle Pharmaceuticals, Inc; November 2020.
4. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 14, 2021.