JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP065
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	Subject **Bendeka, Treanda, and Belrapzo**	*Revision Date*	04/20/2022
		Page	1 of 4

This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Belrapzo, Bendeka, Treanda

Table of Contents		Page Number
I.	POLICY	1
II.	POLICY CRITERIA	1
III.	AUTHORIZATION PERIOD/LIMITATIONS	3
IV.	EXCLUSIONS	4
V.	RECOMMENDED DOSAGE	4
VI.	CODES	4
VII.	REFERENCES	4
VIII.	APPROVALS	4

I. POLICY

A. Bendeka, Treanda, and Belrapzo (bendamustine) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Bendeka, Treanda, or Belrapzo may be approved for patients who meet the following:
1. B-cell lymphoma
   a. Documentation has been submitted showing one of the following:
      I. Patient has a diagnosis of AIDS-related B-cell lymphoma and the following:
         - The requested benamustine product will be used as subsequent therapy
         - Patient is not a candidate for transplant
      II. Patient has a diagnosis of Diffuse large B-cell lymphoma (DLBCL) and the following:
         - The requested benamustine product will be used as subsequent therapy
         - The requested benamustine product is used in combination with polatuzumab vedotin-piiq with or without rituximab
         - Patient is not a candidate for transplant
      III. Patient has a diagnosis of Follicular lymphoma
      IV. Patient has a diagnosis of High-grade B-cell lymphoma and the following:
         - The requested benamustine product will be used as subsequent therapy
         - Patient is not a candidate for transplant
      V. Patient has had a histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma and the following:
         - Patient has received at least two lines of chemoimmunotherapy
         - The requested benamustine product will be used as one of the following:
            - Monotherapy
            - Combination with rituximab
            - Combination with polatuzumab vedotin-piiq with or without rituximab

VI. Patient has had a histologic transformation of follicular lymphoma to diffuse large B-cell lymphoma without translocations of MYC and BCL2 and/or BCL6 and the following:
- The requested benamustine product will be used as one of the following:
  - Monotherapy
  - Combination with polatuzumab vedotin-piiq with or without rituximab
- The requested benamustine product will be used as subsequent therapy

VII. Patient has a diagnosis of Mantle cell lymphoma (MCL), and one of the following:
- The requested benamustine product will be used in combination with rituximab
- The requested benamustine product will be used as a component of RBAC500 (rituximab, bendamustine, and cytarabine)

VIII. Marginal zone lymphoma
- Patient will be using the requested benamustine product in combination with rituximab or obinutuzumab for one of the following diagnosis:
  - Nodal marginal zone lymphoma
  - Gastric MALT lymphoma
  - Nongastric MALT lymphoma
  - Splenic marginal zone lymphoma

IX. Patient has a diagnosis of a post-transplant lymphoproliferative disorder, and the following:
- The requested benamustine product will be used as subsequent therapy
- The requested benamustine product will be used as one of the following:
  - Monotherapy
  - Combination with rituximab
  - Combination with polatuzumab vedotin-piiq with or without rituximab

2. Primary cutaneous lymphoma
   a. Documentation has been submitted showing one of the following:
      I. Patient has a diagnosis of cutaneous anaplastic large cell lymphoma (ALCL), and the following:
      - The requested benamustine product will be used as monotherapy
      - The requested benamustine product will be used for relapsed or refractory disease

      II. Patient has a diagnosis of Mycosis fungoides (MF) or Sezary syndrome (SS)
3. T-cell lymphoma
   a. Documentation has been submitted showing one of the following:
      I. Patient has a diagnosis of Adult T-cell leukemia/lymphoma (ATLL) and the following:
      - The requested benamustine product will be used as monotherapy
      - The requested benamustine product will be used as subsequent therapy

      II. Patient has a diagnosis of Hepatosplenic T-Cell lymphoma and the following:
      - The requested benamustine product will be used as monotherapy
      - The requested benamustine product will be for refractory disease

      III. Patient has a diagnosis of Peripheral T-cell lymphoma (PTCL) and the following:
      - Patient has a diagnosis of one of 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
- follicular T-cell lymphoma] when all of the following criteria
- The requested benamustine product will be used as monotherapy for palliative or subsequent therapy

IV. Patient has a diagnosis of breast implant associated anaplastic large cell lymphoma (ALCL), and the following:
- The requested benamustine product will be used as monotherapy
- The requested benamustine product will be used as subsequent therapy

4. Chronic lymphocytic leukemia/small lymphocytic leukemia (CLL/SLL)
   a. Documentation has been submitted showing the patient has a diagnosis of CLL/SLL without chromosome 17p deletion or TP53 mutation
5. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma
   a. Documentation has been submitted showing the following:
      I. Patient has a diagnosis of Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma
      II. The requested benamustine product will be used as one of the following:
         1. Monotherapy
         2. Combination with rituximab
6. Multiple myeloma (MM)
   a. Documentation has been submitted showing the following:
      1. Patient has a diagnosis of relapsed or progressive MM
      2. The requested benamustine product will be used as one of the following:
         - Monotherapy
         - Combination with lenalidomide and dexamethasone
         - Combination with bortezomib and dexamethasone
7. Classical Hodgkin lymphoma (CHL)
   a. Documentation has been submitted showing the following:
      I. Patient has a diagnosis of CHL
      II. The requested benamustine product will be used for subsequent or palliative therapy
      III. The requested benamustine product will be used as one of the following:
         - Combination with brentuximab vedotin
         - Combination with gemcitabine and vinorelbine
         - Combination with carboplatin and etoposide
         - Monotherapy
8. Nodular Lymphocyte Predominant Hodgkin Lymphoma (NLPHL)
   a. Documentation has been submitted showing the following:
      I. The requested benamustine product will be used for subsequent or palliative treatment of NLPHL
      II. The requested benamustine product will be used in combination with rituximab

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months of therapy
B. Continuation of therapy may be approved in 12-month intervals with documentation showing the patient is continuing to tolerate the regimen and there has not been disease progression while on treatment

IV. EXCLUSIONS

A. Bendeka, Treanda, and Belrapzo will not be covered for the following:
   1. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSAGE

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/ HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS.CPT Code
Injection, bendamustine hcl (bendeka), 1 mg	J9034
Injection, bendamustine HCL (treanda), 1 mg	J9033
Injection, bendamustine hydrochloride, (belrapzo/ bendamustine), 1 mg	J9036

VII. REFERENCES

1. Bendeka [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; October 2021.
2. Treanda [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2019.
3. Belrapzo [prescribing information]. Woodcliff Lake, NJ; Eagle Pharmaceuticals, Inc; November 2020.
4. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. https:// www.nccn.org. Accessed March 28, 2022.

VIII. APPROVALS

Signature on file at JHHC

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