

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Bendeka (bendamustine hydrochloride)

CG-DRUG-98

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Bendeka (bendamustine hydrochloride)

APPROVAL CRITERIA

Bendeka (bendamustine HCL) may be approved for the following indications:

- I. Chronic lymphocytic leukemia (CLL); **OR**
- II. Relapsed or refractory classical Hodgkin lymphoma; **OR**
- III. Non-Hodgkin lymphoma (NHL) (for example, adult T-cell leukemia, AIDS-related B-cell lymphoma, diffuse-large B-cell lymphoma, follicular lymphoma, gastric MALT lymphoma, mantle cell lymphoma, mycosis fungoides/Sézary syndrome, nodal marginal zone lymphoma, non-gastric MALT lymphoma, primary cutaneous B-cell lymphoma, primary cutaneous CD30+ T-cell lymphoproliferative disorders, peripheral T-cell lymphoma, small lymphocytic lymphoma, splenic marginal zone lymphoma); **OR**
- IV. Multiple myeloma for disease relapse or refractory disease; **OR**
- V. Waldenström's macroglobulinemia.

Bendeka (bendamustine HCL) may **not** be approved when the criteria above are not met and for all other indications, including, but not limited to **any** of the following:

- I. Metastatic breast cancer;
- II. Small cell lung cancer (SCLC).

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Bauer K, Rancea M, Roloff V, et al. Rituximab, ofatumumab and other monoclonal anti-CD20 antibodies for chronic lymphocytic leukaemia. Cochrane Database Syst Rev. 2012;(11):CD008079.
2. BENDEKA [Product information]. North Wales, PA. Teva Pharmaceuticals USA, Inc.; Revised February 2017. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208194s005lbl.pdf . Accessed on April 2, 2018.
3. NCCN Clinical Practice Guidelines in Oncology® . © 2018 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 3, 2018.
 - B-Cell Lymphoma (V.2.2018). Revised February 26, 2018.
 - Breast Cancer (V.1.2018). Revised March 20, 2018.
 - Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (V.5.2018). Revised March 26, 2018.
 - Hodgkin Lymphoma (V.1.2018). Revised December 20, 2017.
 - Multiple Myeloma (V.4.2018). Revised February 12, 2018.
 - Small Cell Lung Cancer (V.2.2018). Revised January 17, 2018.
 - T-Cell Lymphomas (V.3.2018). Revised February 22, 2018.
 - Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma (V.1 2018). Revised March 7, 2018.
4. Siegel R, Ma J, Zou A, Jemal A. Cancer Statistics 2015. CA Cancer J Clin. 2015; 65:5-29.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.