



Pharmaceuticals

Submitted by: Joan Cappola BSN, MSA
Name: Teva Pharmaceuticals, Inc.
US Medical Information
41 Moores Road, Frazer, PA 19355
Phone: 610-727-6248
Email: Joan.cappola@tevapharm.com
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Hodgkin Lymphoma ; Multiple Myeloma; Small Cell Lung Cancer; Waldenstroms Lymphoma
Guidelines Panel:

On behalf of Teva Pharmaceuticals, Inc., I respectfully request the *NCCN CLL and NHL Panel* to review the enclosed BENDEKA™ (bendamustine hydrochloride) Injection full Prescribing Information and data for inclusion of BENDEKA for the treatment of chronic lymphocytic leukemia (CLL). Efficacy relative to first line therapies other than chlorambucil has not been established. Also, requested is the inclusion of BENDEKA for the treatment of indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

BENDEKA is a new, liquid formulation of bendamustine hydrochloride.. BENDEKA was approved by the US Food and Drug Administration (FDA) via the 505(b)(2) Regulatory Pathway for New Drug Products on December 7, 2015. Because of this application process, BENDEKA was able to rely on the clinical studies of efficacy and safety used for the FDA approval of TREANDA® (bendamustine hydrochloride). BENDEKA Injection is the only bendamustine hydrochloride injection formulated as a ready-to-dilute solution (25mg/mL) with an infusion time of 10 minutes, administered as a 50 mL admixture.

Rationale: In support of the proposed change, the FDA granted approval for BENDEKA™ (bendamustine hydrochloride) Injection, for intravenous use, to treat patients with CLL and indolent B-cell NHL in December, 2015.

The following items are submitted in support of this proposed change:

1. BENDEKA™ (bendamustine hydrochloride) Injection prescribing information. North Wales, PA: Teva Pharmaceuticals, Inc., 2015.
2. Edenfield WJ, Mattar B, Anthony SP, Mutch P, Chanas B, Smith M. Phase 1, Open-Label, Randomized, Bioequivalence Study of 2 Bendamustine Hydrochloride Formulations; a Ready-to-Dilute Low-Volume, Rapid Infusion Solution and a Lyophilized Powder Formulation. *Blood* 2015; 126:4857; published ahead of print December 4, 2015.

3. Mattar B, Anthony SP, Edenfield WJ, Smith M, Hepner A. Comparative Safety of Two Bendamustine Hydrochloride Formulations; a Ready-to-Dilute Low-Volume, Rapid Infusion Solution, and a Lyophilized Powder: Results from a Phase 1 Study. *Blood* 2015; 126:4861; published ahead of print December 4, 2015

Do not hesitate to reach out to me directly should you have any questions.

Sincerely,

Joan Cappola, BSN, MSA

