



Submitted by: Colleen Barker, PharmD
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Teva Pharmaceuticals USA, Inc.
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NCCN Guidelines Panel: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)

On behalf of Teva Pharmaceuticals USA, Inc., I respectfully request the NCCN CLL/SLL Guidelines Panel review the enclosed and recently updated full Prescribing Information for TRUXIMA™ (rituximab-abbs), for inclusion of TRUXIMA for treatment of patients with previously treated or untreated CD20-positive Chronic Lymphocytic Leukemia (CLL).

Specific Changes:

Teva requests that TRUXIMA (rituximab-abbs) be included within the NCCN guidelines as equivalent to rituximab for the treatment of patients with CLL where rituximab is currently recognized.

FDA Clearance:

TRUXIMA is a CD20- directed cytolytic antibody, which initially received FDA approval as a Biosimilar to Rituxan® (rituximab) on Nov. 29, 2018 for the following indications:

- Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent.
- Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy.
- Non-progressing (including stable disease), low-grade, CD20 positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy.

Subsequently, on May 23, 2019, the FDA approved two Supplemental Biologics License Applications (sBLAs) for TRUXIMA (rituximab-abbs) for the following indications:

- Treatment of adult patients with previously untreated diffuse Large B-cell, CD20-positive non-Hodgkin's lymphoma (NHL) in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens.
- Treatment of adult patients with previously untreated and previously treated CD20-positive chronic lymphocytic leukemia (CLL) in combination with fludarabine and cyclophosphamide (FC).

Rationale: In support of the proposed change, based on the totality of evidence, the FDA has granted approval to TRUXIMA™ (rituximab-abbs) injection as a biosimilar to rituximab, for intravenous use, for the initiation of treatment for patients with previously untreated or treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC).

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

¹ TRUXIMA® (rituximab-abbs) injection, [current approved prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.

Respectfully submitted,

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US Medical Information
Teva Pharmaceuticals USA, Inc.