

Submitted by:

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NCCN Guidelines® Panel: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

On behalf of AbbVie and Genentech, I respectfully request the NCCN Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Guideline Panel to consider the enclosed published data on total cost of care for Venclexta® (venetoclax) with and without Rituxan® (rituximab) in relapsed/refractory (R/R) CLL.

Specific Changes: Consider an update to the CLL/SLL NCCN Affordability Evidence Block rating for venetoclax in combination with rituximab.

FDA Clearance:

- **Venclexta® (venetoclax)** is approved for the treatment of adult patients with CLL/SLL.¹
 - Please refer to Venclexta® (venetoclax) prescribing information for full FDA-approved indications and safety information, available at:
<https://www.rxabbvie.com/pdf/venclexta.pdf>.
- **Rituxan® (rituximab)** is approved for the treatment of patients with CLL.²
 - Please refer to Rituxan® (rituximab) prescribing information for full FDA-approved indications and safety information available at:
https://www.gene.com/download/pdf/rituxan_prescribing.pdf

Rationale: Although treat to progression (TTP) CLL therapies demonstrated improved efficacy vs. immunotherapy or chemoimmunotherapy approaches, they are associated with a significant economic burden to the health system and the patients.³

Included in this submission is the total cost of care (TCC) and budget impact analysis in R/R CLL. This health economic analysis compared the TCC to the US healthcare system across commonly used CLL novel targeted therapies. The model compared the TCC and incremental budget impact for venetoclax plus rituximab, ibrutinib, idelalisib plus rituximab and venetoclax monotherapy over the 3-year time horizon.⁴

The TCC per treated patient was estimated for each regimen and included drug costs, wastage, drug administration, adverse events, monitoring, and routine costs of care in CLL.

Average annual per patient TCC in R/R CLL is estimated to be lower over a 3-year period for venetoclax plus rituximab fixed treatment duration compared to targeted CLL therapies administered to progression. The top two categories contributing to the TCC are treatment costs and routine cost of care in CLL.

In the year 3, the TCC per patient was lower for venetoclax plus rituximab at \$100,870 compared to \$235,644 for ibrutinib, \$211,822 for idelalisib plus rituximab and \$223,154 for venetoclax monotherapy. Reduction in the TCC with venetoclax plus rituximab is driven by the reduction in the treatment costs in year 3, due to the 24 months fixed treatment duration with venetoclax plus rituximab (after completion of a 5-week ramp up period) vs. other targeted therapies.

In the year 3, treatment costs were \$13,009 with venetoclax plus rituximab, \$147,783 for ibrutinib, \$123,961 for idelalisib plus rituximab, and \$135,293 for venetoclax monotherapy.

Over the 3-year time horizon, the cumulative TCC was lower for venetoclax plus rituximab fixed duration regimen compared with treat-to-progression therapies resulting in the healthcare system savings. The per patient TCC savings with venetoclax plus rituximab compared with idelalisib plus rituximab, ibrutinib, and venetoclax monotherapy are -\$107,238, -\$98,518, and -\$67,942, respectively.

References:

1. Venclexta® [package insert]. Chicago, IL: AbbVie, Inc, 2019.
2. Rituxan® [package insert]. South San Francisco, CA: Genentech, IL: AbbVie, Inc, 2019.
3. Chen Q, Jain N, Ayer T, et al. Economic burden of chronic lymphocytic leukemia in the era of oral targeted therapies in the United States. *J Clin Oncol*. 2017;35(2):166-174.
4. Cho SK, Samp J, Keim H, et al. Total cost of care and budget impact of treatment with 24 months fixed duration of venetoclax + rituximab in patients with CLL. Poster presented at the ISPOR Europe Annual Meeting; November 10–14, 2018; Barcelona, Spain. Poster PCN84.

Respectfully submitted,

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