Submitted by:
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Date of Request: March 22, 2019

Dear NCCN B-Cell Lymphoma Guidelines Panel:

On behalf of Celgene Corporation, we respectfully request that the NCCN Guidelines Panel for B-Cell Lymphoma review the enclosed data regarding the use of REVLIMID® (lenalidomide) in combination with rituximab in patients with relapsed/refractory follicular or marginal zone lymphoma. This data, recently published in the Journal of Clinical Oncology, is being sent for the panel's consideration as a follow-up to the REVLIMID submission made by Celgene Corporation on December 3, 2018.

Specific Changes:
We respectfully request updating the recommendation for the lenalidomide + rituximab combination to a Category 1, preferred regimen for second-line and subsequent therapy in follicular lymphoma.

FDA Status:
REVLIMID is not approved for the treatment of follicular or marginal zone lymphoma. Please see the enclosed full Prescribing Information.

Rationale:
The December 3, 2018 submission was based on the results of a phase III clinical study evaluating the efficacy and safety of lenalidomide plus rituximab (R^2) compared to rituximab-placebo (control) in patients with relapsed/refractory follicular or marginal zone lymphoma and included the oral presentation of data from that study. The attached full publication and supplementary appendix include additional safety and efficacy endpoint results from the phase III study that were not included in the previously submitted oral presentation.

Your consideration of this submission is greatly appreciated.

Sincerely,

Arpit Shah, PharmD
Sr. Manager, Global Medical Information

Kenneth Foon, MD
Vice President, Global Medical Affairs, Lymphoma

Reference List:

1. Leonard JP, Trneny M, Izutsu K, et al. AUGMENT: A Phase III Study of Lenalidomide Plus Rituximab Versus Placebo Plus Rituximab in Relapsed or Refractory Indolent Lymphoma [epub ahead of print]. *J Clin Oncol*. 2019: JCO1900010.