



Submitted by:
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Date of Request: August 7, 2018

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 previously untreated patients with follicular lymphoma. This data, recently published in the New England Journal of Medicine, is being sent for the panel's consideration as a follow-up to the REVLIMID submission made by Celgene Corporation on June 3, 2018.

Specific Changes:

As noted in the June 3, 2018 submission, we respectfully request updating the recommendation for the lenalidomide + rituximab combination treatment regimen to a Category 2A, preferred first-line therapy for follicular lymphoma (Grade 1-2).

FDA Status:

REVLIMID is not approved for the treatment of follicular lymphoma. Please see the enclosed full Prescribing Information.

Rationale:

The June 3, 2018 submission was based on the results of a phase III clinical study evaluating the efficacy and safety of lenalidomide plus rituximab compared to rituximab plus chemotherapy followed by rituximab maintenance in patients with previously untreated follicular 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, Lymphoma Scientific Collaborations

Reference List:

1. Morschhauser F, Fowler NH, Feugier P, et al. Rituximab plus Lenalidomide in Advanced Untreated Follicular Lymphoma. *N Engl J Med*. 2018; 379(10): 934-947.