



Submitted by:

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Dear NCCN Multiple Myeloma Guidelines Panel:

On behalf of Celgene Corporation, we respectfully request that the NCCN Guidelines Panel for Multiple Myeloma review three recent publications on the continuous or maintenance use of REVLIMID[®] (lenalidomide) in patients with multiple myeloma.

Specific Changes: Recommend the use of lenalidomide as a preferred regimen for myeloma therapy in the maintenance setting with a *Category 1* recommendation. In addition, we respectfully request an update to the discussion surrounding the use of lenalidomide as maintenance therapy on pages MS-13, MS-19, and MS-20 of the Multiple Myeloma Clinical Practice Guidelines to reflect the results presented in these publications.

FDA Clearance: Lenalidomide in combination with dexamethasone is indicated for the treatment of multiple myeloma patients who have received at least one prior therapy.

Rationale:

Three Phase III studies recently published in the *New England Journal of Medicine* evaluated the use of lenalidomide continuous treatment in newly diagnosed multiple myeloma or maintenance treatment with lenalidomide following autologous stem cell transplant. Results from the three studies consistently demonstrated improved outcomes with the use of continuous or maintenance lenalidomide in patients with multiple myeloma.

1. Attal M, Lauwers-Cances V, Marit G, et al. Lenalidomide maintenance after stem-cell transplantation for multiple myeloma. *New England Journal of Medicine* 2012; 366(19): 1782-91.
2. McCarthy P, Owzar K, Hofmeister C, et al. Lenalidomide after stem-cell transplantation for multiple myeloma. *New England Journal of Medicine* 2012; 366(19): 1770-81.
3. Palumbo A, Hajek R, Delforge M, et al. Continuous lenalidomide treatment for newly diagnosed multiple myeloma. *New England Journal of Medicine* 2012; 366(19): 1759-69.

Your consideration of this submission is greatly appreciated.

Sincerely,



Eulena Horne, PharmD

Sr. Manager, Global Medical Information



Ali Nourbakhsh, MD

Senior Director, Global Medical Affairs Disease Lead – Multiple Myeloma

Cited References:

1. Attal M, Iauwiers-Cances V, Marit G, et al. Lenalidomide maintenance after stem-cell transplantation for multiple myeloma. New England Journal of Medicine 2012; 366(19): 1782-91.
2. McCarthy P, Owzar K, Hofmeister C, et al. Lenalidomide after stem-cell transplantation for multiple myeloma. New England Journal of Medicine 2012; 366(19): 1770-81.
3. Palumbo A, Hajek R, Delforge M, et al. Continuous lenalidomide treatment for newly diagnosed multiple myeloma. New England Journal of Medicine 2012; 366(19): 1759-69.