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ONCOLOGY

April 11, 2016

Submission Request
National Comprehensive Cancer Network

RE: HEOR Evidence in Support of Farydak® (panobinostat) in Relapsed/Refractory Multiple Myeloma

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Date of request:	April 11, 2016
NCCN Guidelines Panel:	Multiple Myeloma

To Whom It May Concern:

As the NCCN Multiple Myeloma Panel reviews the Multiple Myeloma NCCN Evidence Blocks™, please find data relating to the value of panobinostat as a treatment option for patients with relapsed/refractory multiple myeloma enclosed for your consideration.

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Panobinostat in the treatment of relapsed/refractory multiple myeloma
This request is for the Panel to consider the submitted data when assessing the overall affordability of the regimen of panobinostat/bortezomib/dexamethasone in patients with relapsed/refractory multiple myeloma within the NCCN Evidence Blocks™.

The model framework provides an annual estimate of the total costs per patient for the treatment of patients with relapsed and/or refractory multiple myeloma using seven common treatment regimens, including panobinostat/bortezomib/dexamethasone. Total pharmacy and medical costs were assessed over the duration of therapy and include cost of drug (based on wholesale acquisition cost) and administration, as well as adverse event prophylaxis and monitoring and treatment of Grade 3/4 events. The total duration of therapy to achieve 12 months of progression-free survival was used to calculate the total costs of therapy per patient. [1]

The model framework assessed the following drug regimens[1]:

- Panobinostat/bortezomib/dexamethasone
- Bortezomib/dexamethasone
- Lenalidomide/dexamethasone
- Lenalidomide/bortezomib/dexamethasone
- Carfilzomib/lenalidomide/dexamethasone
- Carfilzomib
- Pomalidomide/dexamethasone

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Specific changes recommended for the Evidence Blocks
Please consider the data contained within the peer-reviewed publication when rating the affordability of the regimen of panobinostat/bortezomib/dexamethasone in the treatment of relapsed/refractory multiple myeloma.

FDA Status
FARYDAK, a histone deacetylase inhibitor, in combination with bortezomib and dexamethasone, is indicated for the treatment of patients with multiple myeloma who have received at least 2 prior regimens, including bortezomib and an immunomodulatory agent. This indication is approved under accelerated approval based on progression free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Rationale for recommended change
The estimated cost of therapy for panobinostat/bortezomib/dexamethasone has been estimated using a model framework and should be taken into consideration when assessing the overall affordability of the regimen within the Multiple Myeloma NCCN Evidence Blocks™.

Literature support
1. Roy A, Kish J, Bloudek L et al. Estimating the costs of therapy in patients with relapsed and/or refractory multiple myeloma: a model framework. Am Health Drug Benefits. 2015; 8(4):204-15.

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We appreciate the opportunity to provide this additional information for consideration by the NCCN Multiple Myeloma Panel. If you have any questions or require additional information, please do not hesitate to contact me at 1-862-778-5494 or via e-mail at Neilda.baron@novartis.com. Thank you for your time and consideration.

Sincerely,

Neilda Baron, MD
Executive Director, Medical Information Oncology
Novartis Pharmaceuticals Corporation

Enclosures: Copy of referenced primary literature