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Date of request: May 9, 2018
NCCN Guidelines® Panel: Multiple Myeloma

Dear NCCN,

On behalf of Janssen Biotech, Inc., I respectfully request the NCCN Guidelines® - Multiple Myeloma Panel review the updated DARZALEX® (daratumumab) full Prescribing Information (PI) Version 05/2018 with the addition of the ALCYONE Study.

Specific Changes:

Update Guidelines to include DARZALEX® (daratumumab) for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for high-dose chemotherapy with autologous stem cell transplant with a Category 1 evidence level rating for the following treatment option: Combination therapy with bortezomib, melphalan, and prednisone.

FDA Clearance:

DARZALEX® (daratumumab) is a human CD38-directed cytolytic antibody indicated for the treatment of multiple myeloma (1) in combination with bortezomib, melphalan and prednisone for patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant, (2) in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone in patients who have received at least one prior therapy, (3) in combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor, and (4) as a monotherapy in patients who have received at least three prior lines of therapy including a proteasome inhibitor and an immunomodulatory agent or who are double-refractory to a proteasome inhibitor and an immunomodulatory agent.

Rationale:

The DARZALEX® (daratumumab) full Prescribing Information (PI) Version 05/2018 was updated with the addition of the ALCYONE Study. These study data were previously submitted to the panel for review on January 29, 2018. A summary of the detailed changes to the PI related to these study data are enclosed.

In addition to this label change notification, we are requesting the timing of action on the submission, in light of the upcoming Multiple Myeloma panel review.

We at Janssen Pharmaceuticals are confident that we share in the common goal of having the most current and accurate information of our products available in your monographs and database(s). Patient safety is paramount to us, and we want to ensure that clinicians have access to the latest product information so they can make the most informed prescribing decisions for their patients.

We look forward to hearing from you and our sincere thanks for your consideration of the above request.

Sincerely,
Pulkita Patel, PharmD, BCOP
Scientific Knowledge Lead, Oncology, Medical Information
Janssen Scientific Affairs, LLC