

Submitted by:
Eulena Horne, PharmD
Celgene Corporation
86 Morris Avenue
Summit, NJ 07901
Ph: 908-673-1652
Email: ehorne@celgene.com
Date of Request: April 8, 2016

Dear NCCN Multiple Myeloma Guidelines Panel Members:

On behalf of Celgene Corporation, we respectfully request that the NCCN Guidelines Panel for Multiple Myeloma review recently presented data on the use of POMALYST® (pomalidomide) in combination with dexamethasone and pembrolizumab in patients with previously treated multiple myeloma (MM).

Specific Changes: Recommend an update of the guidelines regarding previously treated MM to reflect results of the Phase II study of the triplet combination of pomalidomide/dexamethasone/pembrolizumab described herein.

FDA Clearance: POMALYST is a thalidomide analogue indicated, in combination with dexamethasone, for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy (Celgene Corporation, 2015).

Rationale for Proposed Change:

The addition of triplet combinations to the treatment landscape for multiple myeloma has expanded the therapy options for patients with RRMM in later lines of treatment. Despite tremendous progress, there continues to be an unmet medical need in the treatment of RRMM.

The combination of pomalidomide, dexamethasone and pembrolizumab has been evaluated in a Phase II study in 33 patients with relapsed/refractory multiple myeloma (RRMM) who had received ≥ 2 prior therapies including an immunomodulatory agent and proteasome inhibitor (median age, 65 years; median of 3 prior lines of treatment; 42% high risk; 70% double refractory) (Badros et al., 2015). Pomalidomide 4 mg on Days 1-21, pembrolizumab 200 mg on Days 1 and 14 and dexamethasone 40 mg (20 mg if >70 years) on Days 1, 7, 14 and 21 were administered in 28-day cycles. Response was achieved in more than half of the patients (overall response rate [ORR], 59%), with early achievement of best response (median time to best response, 2 months). Response rates among double refractory patients (ORR, 55%) and high risk cytogenetics patients (ORR, 50%) were similar to the overall study population. Grade 3/4 adverse events (AEs) included hematologic (anemia, neutropenia, thrombocytopenia) toxicities. Grade 3/4 immune-related AEs included pneumonitis and hepatitis. Due to a high infection rate, all patients received prophylactic antibiotics.

A copy of this study recently presented at the American Society of Hematology Annual Meeting is enclosed for your review.

Your consideration of this submission is greatly appreciated.

Sincerely,



Eulena Horne, PharmD
Assoc Director, Global Medical Information



Peg Squier
Vice President, US Medical Affairs

Cited References:

1. Badros AZ, Kocoglu MH, Ma N, et al. A Phase II Study of Anti PD-1 Antibody Pembrolizumab Pomalidomide and Dexamethasone in Patients with Relapsed/Refractory Multiple Myeloma [Oral]. Oral presented at: 57th Annual Meeting and Exposition of the American Society of Hematology (ASH); December 5-8, 2015; Orlando, FL, USA.
2. Celgene Corporation. Pomalyst (pomalidomide) [Package Insert]. Summit, NJ: Celgene Corporation. <http://www.pomalyst.com/>.