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May 12, 2020

Kristina Gregory  
3025 Chemical Road  
Plymouth Meeting, PA 19462  
USA

Dear Ms. Gregory,

Please consider the following information.

**Response(s):**

- DARZALEX - NCCN Compendium Communication – Use in Combination with RVd – May 2020

I look forward to working with you as you consider the enclosed information. The information provided is not intended as an endorsement of any usage not contained in the Prescribing Information. For complete information, please refer to the full Prescribing Information, including the following sections: INDICATIONS AND USAGE, DOSAGE AND ADMINISTRATION, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS.

If you require further information, please feel free to contact me via the Janssen Medical Information Center at 1-800-JANSSEN (1-800-526-7736).

Sincerely,

Cynthia Toso, PharmD

Associate Director  
Medical Information

Inquiry #:01736267

Enclosure(s)/Electronic Link(s):

- DARZALEX® (daratumumab) Prescribing Information at [https://imedicalknowledge.veevavault.com/ui/approved\\_viewer?token=7994-dc33e1e3-dde0-4c18-b1e3-a3a79c07d600](https://imedicalknowledge.veevavault.com/ui/approved_viewer?token=7994-dc33e1e3-dde0-4c18-b1e3-a3a79c07d600)
- Daratumumab, lenalidomide, bortezomib, & dexamethasone for transplant-eligible newly diagnosed multiple myeloma: GRIFFIN.
- DARZALEX Prescribing Information

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**Need Help?** If you have any additional questions, please contact us via:



**1-800-JANSSEN**

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To report a possible adverse event or product quality complaint, please call the Medical Information Center immediately, at 1-800-JANSSEN (1-800-526-7736).

**DARZALEX® (daratumumab)**  
**NCCN Compendium Communication – Use in Combination with Lenalidomide,  
Bortezomib, and Dexamethasone – May 2020**

Name: Cindy Toso, PharmD  
Company/Organization: Janssen Biotech, Inc.  
Address: 850 Ridgeview Drive Horsham, PA 19044  
Phone: 215.325.4244  
E-mail: ctoso@its.jnj.com  
Date of request: May 12, 2020  
NCCN Guidelines® Panel: Multiple Myeloma

Dear NCCN,

As a follow-up to our Janssen Biotech, Inc. submissions on September 24, 2019, December 20, 2019, and April 14, 2020, we would like to inform the NCCN Guidelines® Multiple Myeloma Panel that the results from the ongoing phase 2 GRIFFIN study of intravenous (IV) daratumumab in combination with lenalidomide, bortezomib, and dexamethasone (RVd) for the treatment of transplant-eligible newly diagnosed (ND) multiple myeloma (MM) patients have been published in *Blood*.<sup>1</sup>

**Specific Changes:** Request an update to the Guidelines to include daratumumab in combination with RVd for primary therapy of transplant candidates (MYEL-F 1 of 3; Version 3.2020) with a Category 2a evidence level rating.

**FDA Clearance:** The FDA has approved DARZALEX® (daratumumab) use for the treatment of adult patients with MM (1) in combination with lenalidomide and dexamethasone in ND patients who are ineligible for autologous stem cell transplant (ASCT) and in patients with relapsed or refractory MM who have received at least one prior therapy, (2) in combination with bortezomib, melphalan and prednisone in ND patients who are ineligible for ASCT, (3) in combination with bortezomib, thalidomide, and dexamethasone in ND patients who are eligible for ASCT, (4) in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy, (5) in combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor (PI), and (6) as monotherapy, in patients who have received at least three prior lines of therapy including a PI and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.<sup>2</sup>

The data referred to in this communication are considered off-label data.

**Rationale:** Results from an ongoing, phase 2, randomized, open-label study (GRIFFIN) of daratumumab IV + RVd (D-RVd) in patients with NDMM eligible for high-dose therapy and ASCT have been published in *Blood*.<sup>1</sup> The publication includes results for the primary endpoint analysis presented at the 17<sup>th</sup> International Myeloma Workshop<sup>3</sup> which were included with our submission on September 24<sup>th</sup>, 2019 and follow-up results presented at the 2019 American Society of Hematology Annual Meeting<sup>4</sup> which were included in our submission on December 20, 2019.

The following publication is submitted with the Full Prescribing Information. Please note that the pdf of the online publication accessed from <https://ashpublications.org/blood> includes highlighting, which reflects edits between a previous version and the final accepted manuscript.

Voorhees PM, Kaufman JL, Laubach J, et al. Daratumumab, lenalidomide, bortezomib, & dexamethasone for transplant-eligible newly diagnosed multiple myeloma: GRIFFIN [published online ahead of print April 23, 2020]. *Blood*. doi: 10.1182/blood.2020005288.

We would like to acknowledge the contributions of NCCN Panel members who are co-authors or co-contributors to this study.

Sincerely,

Cindy Toso, PharmD

Associate Director, Payer & Health Systems, Medical Information & Knowledge Integration  
Janssen Scientific Affairs, LLC

## REFERENCES

1. Voorhees PM, Kaufman JL, Laubach JP, et al. Daratumumab, lenalidomide, bortezomib, & dexamethasone for transplant-eligible newly diagnosed multiple myeloma: GRIFFIN. [published online ahead of print April 23, 2020]. *Blood*. 2020;doi: 10.1182/blood.2020005288.
2. DARZALEX (daratumumab) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; [https://imedicalknowledge.veevavault.com/ui/approved\\_viewer?token=7994-dc33e1e3-dde0-4c18-b1e3-a3a79c07d600](https://imedicalknowledge.veevavault.com/ui/approved_viewer?token=7994-dc33e1e3-dde0-4c18-b1e3-a3a79c07d600).
3. Voorhees PM, Kaufman JL, Laubach J, et al. Daratumumab + lenalidomide, bortezomib & dexamethasone improves depth of response in transplant-eligible newly diagnosed multiple myeloma: GRIFFIN. Oral presentation presented at: 17th International Myeloma Workshop (IMW); September 12-15, 2019; Boston, MA.
4. Voorhees PM, Kaufman JL, Laubach J, et al. Depth of response to daratumumab (DARA), lenalidomide, bortezomib, and dexamethasone (RVd) improves over time in patients (pts) with transplant-eligible newly diagnosed multiple myeloma (NDMM): GRIFFIN study update. Oral presentation presented at: 61st American Society of Hematology (ASH) Annual Meeting & Exposition; December 7-10, 2019; Orlando, FL.