Opdualag (nivolumab and relatlimab-rmbw)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	
Opdualag (nivolumab and relatlimab-rmbw) intravenous solution	

APPROVAL CRITERIA

Requests for Opdualag may be approved if the following criteria are met:

- I. Individual is 12 years of age or older and weighing at least 40 kg (Label; Tawbi HA et.al. 2022, NCCN 1):**AND**
- II. Individual has a diagnosis of unresectable or metastatic (Stage III or IV) melanoma;
- III. Individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-1 or a Lansky performance score ≥ 80% for minors (12 to 17 years of age).

Requests for Opdualag may not be approved for the following criteria:

- I. If individual had uveal melanoma; **OR**
- II. If individual has active brain metastases or leptomeningeal metastases; **OR**
- III. When the above criteria are not met, and for all other indications.

Key References:

- Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
- 2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 8, 2023
- 3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- 4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
- 5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on July 8, 2023.
 - a. Melanoma: Cutaneious V2.2023. Revised March 10, 2023.
- 6. Tawbi HA, Schadendorf D, Lipson EJ, et al. Relatlimab and Nivolumab versus Nivolumab in Untreated Advanced Melanoma. N. Engl J Med.2022;386(1):24-34. Accessed July 8, 2023

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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