SmartHealth

Ascension

Nivolumab and Relatlimab-rmbw

(Opdualag®) J9299

Covered with prior authorization

Nivolumab and relatlimab-rmbw (Opdualag®) may be authorized when the following criteria are met:

- Individual is ≥ 12 years of age; **AND**
- Individual weight ≥ 40 kg; **AND**
- Individual has a diagnosis of metastatic or unresectable melanoma (stage III or IV); **AND**
- If individual has had previous treatment (containing a PD-1, CTLA-4, BRAF, or MEK inhibitor) then therapy was complete 6 months or more before the date of disease recurrence; **AND**
- Prescriber is an oncology practitioner; **AND**
- Individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-1; **OR**
- Lansky performance score ≥ 80% for minors (12 to 17 years of age).

Exclusion criteria:

Requests may not be approved for the following:

- Opdualag® (nivolumab and relatlimab-rmbw) may not be approved when the above criteria are not met and for all other indications;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk;
- Individual has uveal melanoma;
- Individual has active, untreated brain metastasis or leptomeningeal metastasis.

Initial authorization is up to 12 months.

Continuation requests may be approved if there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:

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This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Nivolumab and relatlimab-rmbw is a combination of two IgG4 kappa monoclonal antibodies (mAbs), nivolumab which is a programmed death receptor-1 (PD-1) blocking antibody and relatlimab which is a lymphocyte activation gene-3 (LAG-3) blocking antibody. Opdualag is indicated for the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma.

References:

Nivolumab and relatlimab-rmbw (Opdualag®). (2020-2022). National Comprehensive Cancer Network, Inc. (Copyright © National Comprehensive Cancer Network, Inc). *NCCN Guidelines: Treatment by Cancer Type*. NCCN Clinical Practice Guidelines in Oncology. Retrieved May 11, 2023, from https://www.nccn.org/guidelines/guidelines-process/transparency-process-and-recommendations/GetFileFromFileManagerGuid?FileManagerGuidId=31878bfc-8d17-4d6f-8092-c11f76e9311f

OPDUALAG® (nivolumab and relatlimab-rmbw) Label. (2022, March). Accessdata.fda.gov. Retrieved May 11,2023, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761234s000lbl.pdf

NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on May 11, 2023. a. Melanoma: Cutaneous V.3.2022. Revised March 23, 2022

Criteria History/ Revision Information:

Date	Summary of Changes
April 2023	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
May 2023	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
June 2023	Criteria for use summary approved by the Hematology/Oncology Expert Review Panel (ERP)
July 2023	Criteria for use summary approved by the Ambulatory Care Leadership Council..
August 2023	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.