

Nivolumab and Relatlimab-rmbw (OPDUALAG)

Criteria for Use

December 2022

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information. See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTERnet](#) or [PBM INTRANet](#) site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive nivolumab and relatlimab-rmbw.

- Autoimmune disease
- Immunosuppression including corticosteroid equivalent to >10 mg per day of prednisone
- Primary immunodeficiency
- History of allogeneic hematopoietic stem cell or solid organ transplant
- Pregnancy (i.e. known pregnancy or positive pregnancy test)
- Breastfeeding

Inclusion Criteria

The answers to both of the following must be fulfilled to meet criteria.

- Untreated unresectable or metastatic melanoma
- Patient is not expected to tolerate treatment with nivolumab and ipilimumab, the preferred first-line immunotherapy combination due to comorbidities or performance status (see Metastatic Cutaneous Melanoma Drug Sequencing Document in Clinical Recommendations) [^]

[^]Consider ipilimumab 1mg/nivolumab 3mg dosing if patient unlikely to tolerate ipilimumab 3mg/nivolumab 1 mg

Additional Inclusion Criteria

All of the following criteria must be met:

- Care provided by a VA/VA Community Care oncology or hematology provider
- Goals of care and role of Palliative Care consult have been discussed and documented
- Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2

Additional Inclusion Criteria-Select if applicable

- For patients who can become pregnant and patients with partners who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for at least 5 months after stopping treatment

Other Justification

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