

Nivolumab IV (OPDIVO) and Nivolumab/hyaluronidase-nvhy SUBQ (OPDIVO QVANTIG) Criteria for Use June 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

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 www.pbm.va.gov or [PBM INTRANet](#) for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive either nivolumab product.

- Autoimmune disease
- Immunosuppression requiring a corticosteroid equivalent to >10 mg per day of prednisone
- Primary immunodeficiency
- History of allogeneic hematopoietic stem cell or solid organ transplant
- Known pregnancy
- Breastfeeding

Inclusion Criteria

One of the following must be fulfilled

- Indication is FDA-approved[^]
- Off-label use supported by high-level published data

[^] Nivolumab IV has approval in classical Hodgkin Lymphoma; nivolumab/hyaluronidase SUBQ does not and should not replace nivolumab IV in this setting; Nivolumab/hyaluronidase-nvhy should not replace nivolumab when given in combination with ipilimumab

Additional Inclusion Criteria

All of the following must be fulfilled

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

Additional Inclusion Criteria

If applicable

- For females who can become pregnant: Pregnancy must be excluded prior to receiving either nivolumab product.
- For females who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 5 months after stopping treatment

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