BlueCross BlueShield
Federal Employee Program

OPDIVO QVANTIG
(nivolumab and hyaluronidase-nvhy)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Opdivo Qvantig (nivolumab and hyaluronidase-nvhy) is a monoclonal antibody formulated with an endoglycosidase to allow for subcutaneous administration. Nivolumab is a programmed death receptor-1 (PD-1) blocking antibody which is indicated to treat many categories of cancer. Nivolumab can bind to the PD-1 receptor and block its interaction with programmed death receptor ligands such as PD-L1 and PD-L2 and decrease tumor growth (1).

Regulatory Status

FDA-approved indications: Opdivo Qvantig is a combination of nivolumab, a programmed death receptor-1 (PD-1)-blocking antibody, and hyaluronidase, an endoglycosidase, indicated for the treatment of: (1)

1. Renal Cell Carcinoma (RCC)
    a. Adult patients with intermediate or poor risk advanced RCC, as a first-line treatment following combination treatment with intravenous nivolumab and ipilimumab.
        i. Limitations of Use: Opdivo Qvantig is not indicated in combination ipilimumab for the treatment of renal cell carcinoma.
    b. Adult patients with advanced RCC, as first-line treatment in combination with cabozantinib.
    c. Adult patients with advanced RCC who have received prior anti-angiogenic therapy.
2. Melanoma
    a. Adult patients with unresectable or metastatic melanoma.
    b. Adult patients with unresectable or metastatic melanoma following combination treatment with intravenous nivolumab and ipilimumab.
        i. Limitations of Use: Opdivo Qvantig is not indicated in combination with ipilimumab for the treatment of unresectable or metastatic melanoma.
    c. For the adjuvant treatment of adult patients with completely resected Stage IIB, Stage IIC, Stage III, or Stage IV melanoma.
3. Non-Small Cell Lung Cancer (NSCLC)
    a. Adult patients with resectable (tumors ≥4 cm or node positive) NSCLC in the neoadjuvant setting, in combination with platinum-doublet chemotherapy.

b. Adult patients with resectable (tumors ≥4 cm or node positive) NSCLC and no known EGFR mutations or ALK rearrangements, for neoadjuvant treatment, in combination with platinum-doublet chemotherapy, followed by Opdivo Qvantig monotherapy as adjuvant treatment after surgery.

c. Adult patients with metastatic NSCLC and progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on an FDA-approved therapy for these aberrations prior to receiving Opdivo Qvantig.

i. Limitations of Use: Opdivo Qvantig is not indicated in combination with ipilimumab for the treatment of metastatic NSCLC.

4. Squamous Cell Carcinoma of the Head and Neck (SCCHN)
   a. Adult patients with recurrent or metastatic SCCHN with disease progression on or after a platinum-based therapy.
5. Urothelial Carcinoma (UC)
   a. Adjuvant treatment of adult patients with UC who are at high risk of recurrence after undergoing radical resection of UC.
   b. Adult patients with unresectable or metastatic UC, as first-line treatment in combination with cisplatin and gemcitabine.
   c. Adult patients with locally advanced or metastatic UC who:
      i. Have disease progression during or following platinum-containing chemotherapy.
      ii. Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
6. Colorectal Cancer (CRC)
   a. Adult patients with Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic CRC that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, as monotherapy or as monotherapy following combination treatment with intravenous nivolumab and ipilimumab.
      i. Limitations of Use: Opdivo Qvantig is not indicated in combination ipilimumab for the treatment of MSI-H or dMMR metastatic CRC.
7. Hepatocellular Carcinoma (HCC)

a. Adult patients with HCC previously treated with sorafenib and following combination treatment with intravenous nivolumab and ipilimumab.
    i. Limitations of Use: Opdivo Qvantig is not indicated in combination ipilimumab for the treatment of HCC.

8. Esophageal Cancer
    a. Adult patients with completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease, who have received neoadjuvant chemoradiotherapy (CRT).
    b. Adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) as first-line treatment in combination with fluoropyrimidine- and platinum-containing chemotherapy whose tumors express PD-L1 (≥1).
        i. Limitations of Use: Opdivo Qvantig is not indicated in combination ipilimumab for the treatment of patients with unresectable advanced or metastatic ESCC.
    c. Adult patients with unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC) after prior fluoropyrimidine- and platinum-based chemotherapy.
9. Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma
    a. Adult patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma whose tumors express PD-L1 (≥1) in combination with fluoropyrimidine- and platinum-containing chemotherapy.

Opdivo Qvantig carries warnings for immune-mediated adverse reactions, complications of allogeneic hematopoietic stem cell transplantation (HSCT), and embryo-fetal toxicity. Clinically significant immune-mediated adverse reactions may occur with Opdivo Qvantig therapy including pneumonitis, colitis, hepatitis, nephritis, renal dysfunction, hyperthyroidism, and hypothyroidism. Patients should be monitored for signs and symptoms of adverse reactions and based on the severity, Opdivo Qvantig should be withheld or discontinued, and corticosteroids administered. Opdivo Qvantig may cause fetal harm when administered to a pregnant woman. Female patients of reproductive potential should be advised of the potential hazard to a fetus (1).

The safety and effectiveness of Opdivo Qvantig have not been established in pediatric patients

less than 18 years of age (1).

Summary

Opdivo Qvantig (nivolumab and hyaluronidase-nvhy) is a combination of a monoclonal antibody and an endoglycosidase for subcutaneous administration. Opdivo Qvantig works by binding to the programmed cell death-1 (PD-1) receptor, and blocking its interaction with PD-1 ligands, PD-L1 and PD-L2. This interaction releases the inhibitory effects of PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response, resulting in decreased tumor growth. Opdivo Qvantig carries warnings for immune-mediated adverse reactions, infusion-related reactions, complications of allogeneic HSCT and embryo-fetal toxicity. The safety and effectiveness of Opdivo Qvantig have not been established in pediatric patients less than 18 years of age (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Opdivo Qvantig while maintaining optimal therapeutic outcomes.

References

1. Opdivo Qvantig [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; May 2025.
2. NCCN Drugs & Biologics Compendium® Nivolumab and hyaluronidase-nvhy 2025. National Comprehensive Cancer Network, Inc. Accessed on April 22, 2025.