



**Chemotherapy: PD-1 Inhibitor
Opdivo (nivolumab) J9299
Prior Authorization Request
Medicare Part B Form**

Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

<input type="checkbox"/>	Standard Request– (72 Hours)	<input type="checkbox"/>	Urgent Request (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

MEMBER INFORMATION

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ MD FNP DO NP PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

Self-administered Provider-administered Home Infusion

Chart notes attached. **Other important information:** _____

Diagnosis: ICD10: _____ **Description:** _____

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)
 Provider has reviewed the attached “Criteria for Approval” and attests the member meets ALL required PA criteria.
 If not, please provide **clinical rationale** for formulary exception: _____

Continuation Requests: (Clinical documentation required for all requests)
 Patient had an adequate response or significant improvement while on this medication.
 If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Oncology: PD-1 Inhibitors PA

Drug Name(s):

OPDIVO

NIVOLUMAB

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Prescribed by, or in consultation with an oncologist or other cancer specialist related to the diagnosis.
3. Drug is being used appropriately per MCG GUIDELINES, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

Cannot be prescribed for experimental or investigational use.

Prescriber Restrictions:

Oncologist or other cancer specialist

Coverage Duration:

New Start: Approval will be for 6 months

Continuation: Approval will be for 12 months

FDA Indications:

Opdivo

- Esophageal cancer, Adenocarcinoma, advanced or metastatic, in combination with fluoropyrimidine- and platinum-containing chemotherapy
- Esophageal cancer, Adjuvant, completely resected with residual pathologic disease in patients who have received neoadjuvant chemoradiotherapy
- Esophageal cancer, Squamous cell carcinoma, unresectable advanced, recurrent or metastatic, after prior fluoropyrimidine- and platinum-based chemotherapy
- Esophagogastric cancer, Adjuvant, completely resected with residual pathologic disease in patients who have received neoadjuvant chemoradiotherapy
- Esophagogastric cancer, Advanced or metastatic, in combination with fluoropyrimidine- and platinum-containing chemotherapy
- Gastric cancer, Advanced or metastatic, in combination with fluoropyrimidine- and platinum-containing chemotherapy
- Hodgkin's disease, Classical, relapsed or progressed disease after autologous hematopoietic stem cell transplantation (auto-HSCT) and brentuximab vedotin, or 3 or more lines of systemic therapy that includes auto-HSCT
- Liver carcinoma, In patients previously treated with sorafenib
- Malignant melanoma, Adjuvant, following complete resection of lymph node involvement or metastatic disease
- Malignant melanoma, Unresectable or metastatic disease, as monotherapy
- Malignant melanoma, Unresectable or metastatic disease, in combination with ipilimumab
- Malignant mesothelioma of pleura, Unresectable disease, first-line treatment

- Metastatic colorectal cancer, In combination with ipilimumab, after progression following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan - Microsatellite instability-high, Or mismatch repair deficient
- Metastatic colorectal cancer, Progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan - Microsatellite instability-high, Or mismatch repair deficient
- Metastatic urothelial carcinoma, Or locally advanced, with progression during or after platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy
- Non-small cell lung cancer, Metastatic, PD-L1 expression with no EGFR or ALK tumor aberrations, first-line treatment, in combination with ipilimumab
- Non-small cell lung cancer, Metastatic disease, with progression on or after platinum-based chemotherapy; patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving nivolumab
- Non-small cell lung cancer, Metastatic or recurrent, no EGFR or ALK tumor aberrations, first-line treatment, in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy
- Renal cell carcinoma, In combination with cabozantinib, advanced disease
- Renal cell carcinoma, In combination with ipilimumab, first-line treatment of advanced disease in patients with intermediate or poor risk
- Renal cell carcinoma, Monotherapy, advanced disease in patients who have received prior antiangiogenic therapy
- Squamous cell carcinoma of head and neck, Recurrent or metastatic disease, after progression on or after platinum-based chemotherapy
- Urothelial carcinoma, Adjuvant treatment in those at high risk for recurrence
- Non-small cell lung cancer, Neoadjuvant treatment in combination with platinum-doublet chemotherapy

Off-Label Uses:

N/A

Age Restrictions:

N/A

Other Clinical Considerations:

Criteria as per NCCN or other FDA-approved cancer related guidelines.

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/2A51FB/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYN/C/93F3E7/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=931326&contentSetId=100&title=Nivolumab&servicesTitle=Nivolumab&brandName=Opdivo&UserMdxSearchTerm=Opdivo&=null#