

- b. First-line treatment (no prior chemotherapy treatment for metastatic NSCLC) in a patient whose tumor has high PD-L1 expression (TPS $\geq 50\%$) as determined by an FDA-approved test, with no EGFR- or ALK-mutated disease
 - c. First-line treatment in a patient with *non-squamous* NSCLC in combination with pemetrexed and carboplatin, with no EGFR- or ALK-mutated disease
 - d. First-line treatment in patient with *squamous* NSCLC in combination with carboplatin and either paclitaxel or nab-paclitaxel
3. Recurrent or metastatic squamous cell head and neck cancer (non-nasopharyngeal) with disease progression on or after platinum-containing chemotherapy
 4. Classical Hodgkin's lymphoma in patients with refractory disease or who have relapsed after 3 or more prior lines of therapy
 5. Refractory Primary Mediastinal Large B-Cell Lymphoma (PMBCL), who have relapsed after 2 or more prior lines of therapy (not recommended for treatment of PMBCL who require urgent cytoreductive therapy).
 6. Unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair-deficient (dMMR):
 - a. Solid tumors that have progressed following prior treatment and with no satisfactory alternative treatment options
 - b. Colorectal cancer that has progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan
 7. Advanced gastric or gastroesophageal junction adenocarcinoma with tumors expressing PD-L1 (combined positive score ≥ 1) as determined by an FDA-approved test, with disease progression on or after ≥ 2 prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy, and if appropriate, HER2/neu-targeted therapy
 8. Locally advanced or metastatic urothelial carcinoma in patients not eligible for cisplatin-containing chemotherapy or with progression during or after platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy
 9. Recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (combined positive score ≥ 1) as determined by an FDA-approved test.
 10. Liver carcinoma, previously treated with sorafenib.

Note: Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

Priority Health Precertification Documentation

A. What condition is this drug being requested for?

- Unresectable or metastatic melanoma
- Metastatic non-small cell lung cancer (NSCLC)
 - Squamous
 - Non-squamous
- Metastatic squamous cell head and neck cancer (non-nasopharyngeal)
- Classical Hodgkin's lymphoma
- Refractory Primary Mediastinal Large B-cell Lymphoma
- Unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer
 - Solid tumor
 - Colorectal cancer
- Advanced gastric or gastroesophageal junction cancer
- Advanced urothelial cancer
- Recurrent or metastatic cervical cancer
- Liver carcinoma, previously treated with sorafenib
- Other – rationale for use: _____

Metastatic NSCLC:

A. Does the patient have EGFR- or ALK-positive disease?

- Yes
- No
- Unknown/Not tested. *Rationale:* _____

B. Does the patient's tumor express the programmed cell-death-1 ligand (PD-L1)?

- Yes (send test result to Priority Health)
Please list the tumor proportion score: _____
- No

C. What therapies has the patient tried?

- None; this is the first treatment for metastatic NSCLC
- Platinum-containing chemotherapy (e.g., carboplatin, cisplatin, oxaliplatin)

Drug/Regimen: _____ Dates: _____ Outcome: _____

EGFR- or ALK-targeted therapy

- | | | |
|------------------------------------------------|--------------|----------------|
| <input type="checkbox"/> erlotinib (Tarceva) | Dates: _____ | Outcome: _____ |
| <input type="checkbox"/> afatinib (Gilotrif) | Dates: _____ | Outcome: _____ |
| <input type="checkbox"/> gefitinib (Iressa) | Dates: _____ | Outcome: _____ |
| <input type="checkbox"/> crizotinib (Xalkori) | Dates: _____ | Outcome: _____ |
| <input type="checkbox"/> ceritinib (Zykadia) | Dates: _____ | Outcome: _____ |
| <input type="checkbox"/> alectinib (Alecensa) | Dates: _____ | Outcome: _____ |
| <input type="checkbox"/> brigatinib (Alunbrig) | Dates: _____ | Outcome: _____ |

D. For non-squamous and squamous NSCLC, will Keytruda be used in combination with pemetrexed (Alimta) and carboplatin?

- Yes No

Metastatic squamous cell head and neck cancer:

A. Does the patient have nasopharyngeal cancer?

- Yes No

B. Please provide which therapies have been tried:

Drug: _____ Dates: _____ Outcome: _____
 Drug: _____ Dates: _____ Outcome: _____

C. Is patient a candidate for surgery?

- Yes
- No

Classical Hodgkin's lymphoma:

A. Please provide which therapies have been tried:

Drug: _____ Dates: _____ Outcome: _____
 Drug: _____ Dates: _____ Outcome: _____
 Drug: _____ Dates: _____ Outcome: _____
 Drug: _____ Dates: _____ Outcome: _____

Refractory Primary Mediastinal Large B-Cell Lymphoma (PMBCL)

A. Please provide which therapies have been tried:

Drug: _____ Dates: _____ Outcome: _____
 Drug: _____ Dates: _____ Outcome: _____
 Drug: _____ Dates: _____ Outcome: _____
 Drug: _____ Dates: _____ Outcome: _____

Advanced microsatellite instability-high (MSI-H) or mismatch repair-deficient (dMMR) cancer

A. Please provide which therapies have been tried:

Drug: _____ Dates: _____ Outcome: _____
 Drug: _____ Dates: _____ Outcome: _____
 Drug: _____ Dates: _____ Outcome: _____
 Drug: _____ Dates: _____ Outcome: _____

B. Are there other satisfactory alternative treatment options available?

Yes
 No. *Please explain:* _____

Advanced gastric or gastroesophageal junction adenocarcinoma

A. Does the patient's tumor express the programmed cell-death-1 ligand (PD-L1)?

Yes (send test result to Priority Health)
 Please list the tumor proportion score: _____
 No

B. Please provide which therapies have been tried:

Drug: _____ Dates: _____ Outcome: _____
 Drug: _____ Dates: _____ Outcome: _____
 Drug: _____ Dates: _____ Outcome: _____
 Drug: _____ Dates: _____ Outcome: _____

Advanced urothelial carcinoma

A. Please indicate which of the following best describe the patient's disease type:

Patient is not eligible for cisplatin-containing chemotherapy. *Please explain:* _____
 Patient has progressed during or after platinum-containing chemotherapy
 Patient has progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy

B. Please provide which therapies have been tried:

Drug: _____ Dates: _____ Outcome: _____
 Drug: _____ Dates: _____ Outcome: _____

Recurrent or metastatic cervical cancer

A. Does the patient's tumor express the programmed cell-death-1 ligand (PD-L1)?

Yes (send test result to Priority Health)
 Please list the tumor proportion score: _____
 No

B. Please provide which therapies have been tried:

Drug: _____ Dates: _____ Outcome: _____
 Drug: _____ Dates: _____ Outcome: _____
 Drug: _____ Dates: _____ Outcome: _____
 Drug: _____ Dates: _____ Outcome: _____