

Keytruda[®] (pembrolizumab) – Expanded indication

- On May 10, 2017, Merck announced the FDA approval of Keytruda (pembrolizumab) in combination with Alimta[®] (pemetrexed) and carboplatin, as first-line treatment of patients with metastatic nonsquamous non-small cell lung cancer (NSCLC).
- Keytruda is also approved to treat the following:
 - Treatment of patients with unresectable or metastatic melanoma.
 - As a single agent for the first-line treatment of patients with metastatic NSCLC whose tumors have high PD-L1 expression [(Tumor Proportion Score (TPS) \geq 50%)] as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.
 - As a single agent for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 (TPS \geq 1%) as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda.
 - Treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma with disease progression on or after platinum-containing chemotherapy.
 - Treatment of adult and pediatric patients with refractory classical Hodgkin lymphoma, or who have relapsed after 3 or more prior lines of therapy.
- The expanded indication for Keytruda was approved based on the KEYNOTE-021, Cohort G1, study of 123 patients who were previously untreated with metastatic nonsquamous NSCLC with no EGFR or ALK genomic tumor aberrations and irrespective of PD-L1 expression. Patients received Keytruda and pemetrexed + carboplatin (pem/carbo) or pem/carbo alone. The major efficacy outcome was objective response rate (ORR). Additional efficacy outcome measures were progression-free survival (PFS) and duration of response.
 - The ORR was significantly improved in the Keytruda + pem/carbo group vs. the pem/carbo group (55% [95% CI: 42, 68] vs. 29% [95% CI: 18, 41]; $p = 0.0032$).
 - There was significantly greater improvement in PFS for Keytruda + pem/carbo patients (13.0 months [95% CI: 8.3, not estimable]) vs. pem/carbo patients (8.9 months [95% CI: 4.4, 10.3]) (HR 0.53 [95% CI: 0.31, 0.91]; $p = 0.0205$).
 - Duration of response for > 6 months was seen in 93% (range: 1.4+ – 13+ months) of Keytruda + pem/carbo patients vs. 81% (range: 1.4+ – 15.2+ months) of pem/carbo patients.

- The recommended dose of Keytruda for NSCLC is 200 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.
 - When administering Keytruda in combination with chemotherapy, Keytruda should be administered prior to chemotherapy when given on the same day.
 - Consult drug labels for pemetrexed and carboplatin dosing recommendations.
- Consult Keytruda's drug label for dosing recommendations for other indications.



OptumRx[®] specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum[®] company — a leading provider of integrated health services. Learn more at [optum.com](https://www.optum.com).

All Optum[®] trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews[®] is published by the OptumRx Clinical Services Department.

©2017 Optum, Inc. All rights reserved.