

Keytruda® (pembrolizumab) – New indication

- On June 13, 2025, Merck announced the FDA approval of Keytruda (pembrolizumab), for the treatment of adult patients with resectable locally advanced head and neck squamous cell cancer (HNSCC) whose tumors express PD-L1 (Combined Positive Score [CPS] ≥ 1) as determined by an FDA-approved test, as a single agent as neoadjuvant treatment, continued as adjuvant treatment in combination with radiotherapy with or without cisplatin and then as a single agent.
- Refer to the Keytruda drug label for a complete listing of all its other indications and usages.
- The approval of Keytruda for the new indication was based on KEYNOTE-689, a randomized, open-label, active-controlled study in 714 patients with resectable locally advanced HNSCC. Patients were randomized to one of the following treatment arms: (1) neoadjuvant Keytruda for 2 cycles prior to surgical resection; within 6 weeks following surgery, 3 cycles of adjuvant Keytruda every 3 weeks in combination with radiotherapy with or without 3 cycles of cisplatin every 3 weeks; this was followed by Keytruda every 3 weeks for up to 12 cycles; or (2) no neoadjuvant treatment prior to surgery; within 6 weeks following surgery, adjuvant radiotherapy with or without 3 cycles of concurrent cisplatin every 3 weeks. The major outcome measure was event-free survival (EFS).
 - Median EFS was 59.7 months in the Keytruda arm vs. 29.6 months in the radiotherapy with or without cisplatin arm (hazard ratio 0.70, 95% CI: 0.55, 0.89; p = 0.00140).
- The recommended intravenous dose of Keytruda for the treatment of adult patients with locally advanced HNSCC is 200 mg every 3 weeks or 400 mg every 6 weeks.
 - For neoadjuvant treatment, Keytruda should be administered for 6 weeks or until disease progression that precludes definitive surgery or unacceptable toxicity.
 - For adjuvant treatment, Keytruda should be administered in combination with radiotherapy with or without cisplatin. Keytruda as a single agent should be continued until disease recurrence or unacceptable toxicity or up to one year
- Refer to the Keytruda drug label for dosing for all its other uses and indications.



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