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In Brief: *Keytruda Qlex* – A Subcutaneous Formulation of Pembrolizumab

IN BRIEF

Keytruda Qlex – A Subcutaneous Formulation of Pembrolizumab

The programmed death receptor-1 (PD-1) blocking antibody pembrolizumab (*Keytruda* – Merck), which has been available in an IV formulation since 2014 for treatment of various malignancies, has now been approved in a subcutaneous formulation as *Keytruda Qlex*. *Keytruda Qlex* is the first immune checkpoint inhibitor to become available in the US that can be administered subcutaneously. It has been approved for 38 of the 41 solid tumor indications that *Keytruda* is approved for. *Keytruda's* patent exclusivity expires in 2028.

Pronunciation Key
Pembrolizumab: pem" broe liz' ue mab
***Keytruda Qlex*:** key true duh cue lex

MECHANISM OF ACTION — Binding of programmed death ligand-1 (PD-L1) and PD-L2 to PD-1 on T cells suppresses T-cell proliferation and cytokine production. Pembrolizumab binds to PD-1 on T cells, blocking its interaction with PD-L1 and PD-L2 and restoring T-cell antitumor immune responses. *Keytruda Qlex* contains berahyaluronidase alfa, an endoglycosidase, which increases permeability of subcutaneous tissue and the absorption of pembrolizumab.

CLINICAL STUDIES — FDA approval of *Keytruda Qlex* was based on the results of an open-label trial in 377 patients ≥18 years old with newly-diagnosed metastatic non-small cell lung cancer (NSCLC) and no EGFR, ALK, or ROS1 alterations. Patients were randomized to receive SC pembrolizumab 790 mg or IV pembrolizumab 400 mg once every 6 weeks, each in addition to platinum-based chemotherapy. Overall exposure and trough pembrolizumab serum concentrations with SC administration were noninferior to those with IV administration. The overall response rate was 45.4% with SC pembrolizumab and 42.1% with IV pembrolizumab. Progression-free survival and overall survival were also similar in both groups.[1]

ADVERSE EFFECTS — Common adverse effects in patients treated with subcutaneous pembrolizumab and chemotherapy in the clinical trial included nausea, fatigue, and musculoskeletal pain. Injection-site reactions occurred in 2.4% of patients. Patients who received SC pembrolizumab were less likely than those who received IV pembrolizumab to dicontinue treatment due to adverse effects (8.4% vs 15.1%).[1]

DOSAGE, ADMINISTRATION, AND COST — *Keytruda Qlex* is supplied in 395 mg/2.4 mL and 790 mg/4.8 mL single-dose vials. It is given subcutaneously over 1-2 minutes once every 3 or 6 weeks by a healthcare provider. IV pembrolizumab is generally given over 30 minutes once every 3 or 6 weeks. The wholesale acquisition cost (WAC) for one 395-mg vial of *Keytruda Qlex* is $12,031; *Keytruda* costs about $12,000 for a 3-week treatment cycle (200 mg every 3 weeks).[2]

CONCLUSION — *Keytruda Qlex*, the new subcutaneous formulation of pembrolizumab, appears to be similar in efficacy to IV pembrolizumab *(Keytruda)*. It offers a shorter administration time and could be a more convenient option for treatment of adults with various solid tumor cancers. ■

1. E Felip et al. Subcutaneous versus intravenous pembrolizumab, in combination with chemotherapy, for treatment of metastatic non-small-cell lung cancer: the phase III 3475A-D77 trial. Ann Oncol 2025; 36:775.
2. Approximate WAC. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. October 5, 2025. Reprinted with permission by First Databank, Inc. All rights reserved. ©2025. www.fdbhealth.com/policies/drug-pricing-policy.

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