

The Medical Letter[®]

on Drugs and Therapeutics

Volume 67

Published online November 10, 2025

Online
Article

IN THIS ISSUE

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

Important Copyright Message

FORWARDING OR COPYING IS A VIOLATION OF U.S. AND INTERNATIONAL COPYRIGHT LAWS

The Medical Letter, Inc. publications are protected by U.S. and international copyright laws. Forwarding, copying, or any distribution of this material without permission to a nonsubscriber is prohibited.

Sharing a password with a nonsubscriber or otherwise making the contents of this site available to third parties is prohibited.

By accessing and reading the attached content I agree to comply with U.S. and international copyright laws and these terms and conditions of The Medical Letter, Inc.

For further information click: [Subscriptions](#), [Site Licenses](#), [Reprints](#)
or call customer service at: 800-211-2769

The Medical Letter®

on Drugs and Therapeutics

Volume 67

Published online November 10, 2025

Online
Article

IN THIS ISSUE

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 discontinue 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.

PRESIDENT: Mark Abramowicz, M.D.; **VICE PRESIDENT:** Gianna Zuccotti, M.D., M.P.H., F.A.C.P., Harvard Medical School; **VICE PRESIDENT, EDITOR IN CHIEF:** Jean-Marie Pflomm, Pharm.D.; **ASSOCIATE EDITORS:** Susan M. Daron, Pharm.D., Amy Faucard, MLS, Corinne Z. Morrison, Pharm.D., Michael P. Viscusi, Pharm.D. **CONSULTING EDITORS:** Joanna Esterow, PA-C, Mordechai Sacks, DMSc, PA-C, Brinda M. Shah, Pharm.D., F. Peter Swanson, M.D.

CONTRIBUTING EDITORS: Carl W. Bazil, M.D., Ph.D., Columbia University College of Physicians and Surgeons; Ericka L. Crouse, Pharm.D., B.C.P.P., C.G.P., F.A.S.H.P., F.A.S.C.P., Virginia Commonwealth University; Vanessa K. Dalton, M.D., M.P.H., University of Michigan Medical School; Eric J. Epstein, M.D., Dartmouth Hitchcock Medical Center; David N. Juurlink, BPhm, M.D., Ph.D., Sunnybrook Health Sciences Centre; Richard B. Kim, M.D., University of Western Ontario; Sandip K. Mukherjee, M.D., F.A.C.C., Yale School of Medicine; Dan M. Roden, M.D., Vanderbilt University School of Medicine; Esperance A.K. Schaefer, M.D., M.P.H., Harvard Medical School; Arthur M. F. Yee, M.D., Ph.D., F.A.C.R., Weill Medical College of Cornell University

MANAGING EDITOR AND DIRECTOR OF CONTENT OPERATIONS: Susie Wong; **EDITORIAL ASSISTANT:** Karrie Ferrara

FULFILLMENT AND SYSTEMS MANAGER: Cristine Romatowski; **EXECUTIVE DIRECTOR OF SALES:** Elaine Reaney-Tomaselli

EXECUTIVE DIRECTOR OF MARKETING AND COMMUNICATIONS: Joanne F. Valentino; **INTERIM PUBLISHER:** Jean-Marie Pflomm, Pharm.D.

Founded in 1959 by Arthur Kallet and Harold Aaron, M.D.

Copyright and Disclaimer: The Medical Letter, Inc. is an independent nonprofit organization that provides healthcare professionals with unbiased drug prescribing recommendations. The editorial process used for its publications relies on a review of published and unpublished literature, with an emphasis on controlled clinical trials, and on the opinions of its consultants. The Medical Letter, Inc. does not sell advertising or receive any commercial support. No part of the material may be reproduced or transmitted by any process in whole or in part without prior permission in writing. The Medical Letter, Inc. does not warrant that all the material in this publication is accurate and complete in every respect. The Medical Letter, Inc. and its editors shall not be held responsible for any damage resulting from any error, inaccuracy, or omission.

Subscription Services

Address:

The Medical Letter, Inc.
2 Madison Ave, Ste 211
Larchmont, NY 10538
www.medicalletter.org

Customer Service:

Call: 800-211-2769 or 914-235-0500
Fax: 914-632-1733
E-mail: custserv@medicalletter.org

Permissions:

To reproduce any portion of this issue,
please e-mail your request to:
permissions@medicalletter.org

Subscriptions (US):

1 year – \$179; \$65 per year
for students, interns, residents,
and fellows in the US and Canada.
Reprints – \$45 per issue or article

Site License Inquiries:

E-mail: SubQuote@medicalletter.org
Call: 800-211-2769
Special rates available for bulk
subscriptions.

Get Connected:



Copyright 2025. ISSN 0025-732X

The
Medical
Letter