U.S. FOOD & DRUG ADMINISTRATION

Frequently Asked Questions on Olumiant (Baricitinib) for the Treatment of COVID-19

Q. Is Olumiant (baricitinib) approved by FDA to treat COVID-19?
A. On May 10, 2022, FDA approved Olumiant (baricitinib) for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Q. Is Olumiant available for use under an emergency use authorization for pediatric patients?
A. Olumiant is authorized under an emergency use authorization (EUA) for the treatment of COVID-19 in hospitalized patients 2 to less than 18 years of age who require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). The EUA for hospitalized adults for the same indication was revoked following FDA approval for this population on May 10, 2022.

For additional information on the authorized use of Olumiant under the EUA, refer to the Fact Sheet for Healthcare Providers.

Clinical trials assessing the safe and effective use of Olumiant in pediatric populations remain ongoing.

Q. What is the difference between an Emergency Use Authorization (EUA) and an FDA approval?
A. Under section 564 of the Federal Food, Drug & Cosmetic Act (FD&C Act), after a declaration by the HHS Secretary based on one of four types of determinations, FDA may authorize an unapproved product or unapproved uses of an approved product for emergency use. In issuing an EUA, the FDA must determine, among other things, that based on the totality of scientific evidence available to the agency, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition caused by a chemical, biological, radiological, or nuclear agent; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such diseases or conditions, outweigh the known and potential risks for the product; and that there are no adequate, approved, and available alternatives. Emergency use authorization is NOT the same as FDA approval or licensure.

Q. Can Olumiant be used outside the hospital (i.e., for non-hospitalized patients with COVID-19)?
A. No, Olumiant is approved by FDA to treat certain hospitalized adults. Under the EUA, Olumiant is authorized for emergency use to treat certain hospitalized pediatric patients with COVID-19. The Letter of Authorization clarifies that individuals determined as being appropriate for acute inpatient hospitalization and who are admitted or transferred to an alternate care site (ACS) that can provide acute care that is comparable to general inpatient hospital care are within the terms and conditions of the EUA. An ACS is intended to provide additional hospital surge capacity and capability for communities overwhelmed by patients with COVID-19.

Q. What data support FDA's determination that Olumiant is safe and effective for use in hospitalized adults for the treatment of COVID-19?

A. The approval of Olumiant for adults on May 10, 2022, was supported by data from two phase 3, randomized, double-blind, placebo-controlled clinical trials (COVID I and COVID II). Approval was also supported by a substudy in mechanically ventilated patients and top-line results from an open-label pragmatic study, Randomised Evaluation of COVID-19 Therapy (RECOVERY).

In the COVID I trial, 1,033 hospitalized adults were randomized to receive Olumiant plus remdesivir (n=515) or placebo plus remdesivir (n=518). In this trial, the primary endpoint was time to recovery (defined as discharged from hospital or hospitalized but not requiring supplemental oxygen or ongoing medical care) within 29 days after randomization. Data from this study demonstrated an improvement in time to recovery, and the median time to recovery was 7 days for Olumiant and remdesivir compared to 8 days for placebo and remdesivir. The proportion of patients who died by Day 29 was 4.7% (24/515) for Olumiant and remdesivir compared to 7.1% (37/518) for placebo and remdesivir.

In the COVID II trial, 1,525 hospitalized adults were randomized to receive Olumiant (n=764) or placebo (n=761). In this trial, the primary endpoint was the proportion of patients who died or progressed to non-invasive ventilation/high-flow oxygen or invasive mechanical ventilation within the first 28-days of the study. The estimated proportion of patients who died or progressed to non-invasive ventilation/high-flow oxygen or invasive mechanical ventilation was lower in patients treated with Olumiant (27.8%) compared to placebo (30.5%), but this effect was not statistically significant. The proportion of patients who died by Day 28 was 8.1% (62/764) for Olumiant compared to 13.3% (101/761) for placebo.

In a separate group of patients requiring invasive mechanical ventilation or ECMO at baseline and enrolled in a substudy of COVID II, a total of 101 patients were randomized to Olumiant (n=51) or placebo (n=50). The proportion who died by Day 28 was 39.2% (20/51) for Olumiant compared to 58.0% (29/50) for placebo.

RECOVERY was a randomized, controlled, open-label, platform trial that evaluated the efficacy of Olumiant in patients with COVID-19 pneumonia. A total of 8,156 hospitalized patients were reported to be randomized, with 4,008 patients randomized to the usual care group and 4,148 patients randomly allocated to the Olumiant group. The primary endpoint evaluated death through 28 days of follow-up. Treatment with Olumiant was reported to reduce deaths, with 513 deaths (12%) reported in patients treated with Olumiant and 546 deaths (14%) in patients treated with usual care group at Day 28.

Q. Are side effects possible with Olumiant?

A. Yes. Possible side effects of Olumiant are:

- Serious venous thrombosis, including pulmonary embolism, and serious infections have been observed in COVID-19 patients treated with Olumiant and are known adverse drug reactions of Olumiant. Olumiant is not recommended for patients with known active tuberculosis infections, who are on dialysis, have end-stage renal disease, or have acute kidney injury.
- See Warnings and Precautions in the FDA-approved full prescribing information for additional information on risks associated with longer-term treatment with Olumiant.

Q: Is Olumiant approved to treat health conditions other than COVID-19?
A: In 2018, FDA approved Olumiant for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor blockers.

Q. How can Olumiant for use under the EUA be obtained?
A. Eli Lilly and Company and its authorized distributors distribute Olumiant to hospitals and health care facilities for its authorized use under the EUA. Licensed health care providers interested in administering Olumiant should contact Lilly.

Q. Is there a requirement for providers to report side effects as part of the EUA?
A. Yes. As part of the EUA for the pediatric population, FDA is requiring health care providers who prescribe Olumiant to treat COVID-19 to report all serious adverse events and medication errors that are considered to be potentially related to Olumiant through FDA's MedWatch Adverse Event Reporting program. Providers can complete and submit the report online; or download and complete the form, then submit it via fax at 1-800-FDA-0178. This requirement is outlined in the EUA's health care provider Fact Sheet. FDA MedWatch forms should also be provided to Lilly.

Q. Are there post-marketing safety reporting requirements for the approved Olumiant?
A. Applicants of NDAs and other responsible parties are subject to regulatory requirements regarding post-marketing safety reporting. For further information, see 21 CFR 314.80 (Postmarketing reporting of adverse drug experiences) or FDA's March 2001 guidance for industry, "Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines."

Q. Do patient outcomes need to be reported under the EUA?
A. No, reporting of patient outcomes is not required under the EUA. However, reporting of all medication errors and adverse events considered to be potentially related to the emergency use of Olumiant occurring during treatment is required under the authorization.

Q. Does the EUA authorize Olumiant to be used to prevent COVID-19?
A. No. The EUA for Olumiant does not authorize the emergency use of Olumiant for the prevention of COVID-19.

Q. Can health care providers share the patient/caregiver Fact Sheet electronically?
A. The letter of authorization for Olumiant requires that Fact Sheets be made available to healthcare providers and to patients/caregivers, "through appropriate means." Electronic delivery of the Fact Sheet is an appropriate means. For example, when the patient requests the Fact Sheet electronically, it can be delivered as a PDF prior to medication administration. Health care providers should confirm receipt of the Fact Sheet with the patient.