Provider Bulletin

News and Information

June 22, 2022

FDA Approval of Ukoniq Withdrawn Due to Safety Concerns

Due to safety concerns, the U.S. Food and Drug Administration (FDA) announced on June 1, 2022, it has withdrawn approval for the cancer medicine Ukoniq (umbralisib). Ukoniq was approved to treat two specific types of lymphoma: marginal zone lymphoma (MZL) and follicular lymphoma (FL).

Updated findings from the UNITY-CLL clinical trial continued to show a possible increased risk of death in patients receiving Ukoniq.

What should patients who are taking the product do?

Patients should talk to their health care provider about alternative treatments and stop taking Ukoniq.

What should prescribers do?

Health care professionals should stop prescribing Ukoniq and switch patients to alternative treatments. Inform patients who currently take Ukoniq of the increased risk of death seen in the clinical trial and advise them to stop taking the medicine.

Where can I find additional information?

The FDA provides information on their website for health care professionals and patients.

FDA approval of lymphoma medicine Ukoniq (umbralisib) is withdrawn due to safety concerns | FDA

What is UCare doing?

We are removing Ukoniq from our formularies and will send letters to any impacted members. The letters will include information on alternative formulary drugs and direct members to contact their provider.

Questions:
If you have further questions, please call UCare's Provider Assistance Center at 612-676-3300 or 1-888-531-1493 toll-free, or visit ucare.org/providers.