Generic Name:
Pembrolizumab
Trade Name:
Keytruda
Company:
Merck
Notes:

FDA approved a new indication for pembrolizumab, an anti-PD-1 therapy, for treatment of hepatocellular carcinoma (HCC) in patients who have been previously treated with sorafenib. HCC is the most common type of liver cancer in adults.

The recommended dosage for HCC is 200 mg every 3 weeks until disease progression or unacceptable toxicity.

The humanized monoclonal antibody works by blocking the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T lymphocytes, which may affect both tumor cells and healthy cells.

Approval was based on data from a single-arm, open-label, multicenter trial evaluating pembrolizumab in 104 patients with HCC who had disease progression on or after sorafenib or who were intolerant to sorafenib.

Immune-mediated adverse reactions, which may be severe or fatal, can occur with use, including pneumonitis, colitis, hepatitis, endocrinopathies, nephritis, severe skin reactions, solid organ transplant rejection, and complications of allogeneic hematopoietic stem cell transplantation.

Depending on the severity of the adverse reaction, the drug should be withheld or discontinued and corticosteroids administered if appropriate.

Pembrolizumab can also cause severe or life-threatening infusion-related reactions, as well as fetal harm when administered to a pregnant woman.

Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials, stated Merck in a news release.

Medication Monitor Categories:
Supplemental Approvals

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