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

Merck announced FDA approval of pembrolizumab to treat adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma (PMBCL) or relapsed PMBCL after two or more prior lines of therapy. With this indication, pembrolizumab becomes the first anti-PD-1 therapy to be approved for treatment of PMBCL, a type of non-Hodgkin lymphoma. It is the second indication for the agent for treatment of a hematologic malignancy.

This indication was approved under the FDA?s accelerated approval regulations based on tumor response rate and durability of response.

The agent is not recommended for treatment of patients with PMBCL who require urgent cytoreductive therapy.

Immune-mediated adverse reactions include pneumonitis, colitis, hepatitis, endocrinopathies, nephritis, severe skin reactions and solid organ transplant rejection. Because of the severity of the adverse reaction, pembrolizumab should be withheld or discontinued and corticosteroids administered if appropriate. Immune-mediated complications, including fatal events, occurred in patients with classical Hodgkin lymphoma who underwent allogeneic hematopoietic stem cell transplantation after treatment with pembrolizumab.

Medication Monitor Categories:
Supplemental Approvals