Supplemental Approvals

Generic Name (Trade Name—Company)

May 24, 2017

Pembrolizumab

(Keytruda—Merck)

First cancer treatment approved for any solid tumor with a specific biomarker

Uses/Notes

FDA has granted accelerated approval to use of pembrolizumab for patients whose cancers have a genetic biomarker referred to as microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).

This is the first time the agency has approved a cancer treatment on the basis of a common biomarker rather than location in the body where the tumor originated.

Pembrolizumab is indicated for the treatment of adult and pediatric patients with unresectable or metastatic solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, as well as patients with colorectal cancer that has progressed following treatment with certain chemotherapy drugs.

MSI-H and dMMR tumors contain abnormalities that affect the proper repair of DNA. Tumors with these biomarkers are most commonly found in colorectal, endometrial, and gastrointestinal cancers, but also less commonly appear in cancers arising in the breast, prostate, bladder, thyroid gland, and other places. Approximately 5% of patients with metastatic colorectal cancer have MSI-H or dMMR tumors.

Pembrolizumab works by blocking the PD-1/PD-L1 cellular pathway, which helps the body’s immune system fight the cancer cells.

FDA previously approved pembrolizumab for treatment of certain patients with metastatic melanoma, metastatic non–small cell lung cancer, recurrent or metastatic head and neck cancer, refractory classical Hodgkin lymphoma, and urothelial carcinoma.

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