Generic Name:
Nivolumab
Trade Name:
Opdivo
Company:
Bristol-Myers Squibb
Notes:

FDA expanded the indication of nivolumab to treat patients with metastatic renal cell carcinoma, the most common form of kidney cancer, and have received prior anti-angiogenic therapy.

Nivolumab was previously approved for melanoma and non?small cell lung cancer.

The agent works by targeting the cellular pathway known as PD-1/PD-L1. By blocking this pathway, nivolumab may help the body?s immune system fight cancer cells.

Safety and efficacy of nivolumab for this use were demonstrated in an open-label, randomized study of 821 patients with advanced renal cell carcinoma whose disease worsened during or after treatment with an anti-angiogenic agent.

Patients were treated with nivolumab or another type of kidney cancer treatment called everolimus (Afinitor?Novartis). Those treated with nivolumab lived an average of 25 months after starting treatment compared with 19.6 months in those treated with everolimus. This effect was observed regardless of the PD-L1 expression level of patients? renal cell tumors. In addition, 21.5% of those treated with nivolumab experienced a complete or partial shrinkage of their tumors, which lasted an average of 23 months, compared with 3.9% of those taking everolimus, lasting an average of 13.7 months.

The most common adverse effects of nivolumab for this use are conditions relating to abnormal weakness or lack of energy, cough, nausea, rash, difficulty breathing, diarrhea, constipation, decreased appetite, back pain, and joint pain.

The agent may also cause serious adverse effects that result from its immune system effect. These severe immune-mediated adverse effects involve healthy organs, including the lung, colon, liver, kidneys, hormone-producing glands, and the brain.

FDA granted the nivolumab application a breakthrough therapy designation, fast track designation, and priority review status.

Medication Monitor Categories:
Supplemental Approvals