Generic Name:
Ibrutinib with rituximab
Trade Name:
Imbruvica with Rituxan
Company:
AbbVie, Johnson & Johnson
Notes:

AbbVie announced FDA approval of ibrutinib plus rituximab to treat adult patients with Waldenström's macroglobulinemia (WM), a rare and incurable type of non?Hodgkin lymphoma. WM typically affects older adults and is primarily found in the bone marrow, although lymph nodes and the spleen also may be affected.

With this approval, ibrutinib plus rituximab is the first and only chemotherapy-free combination treatment indicated specifically for the disease.

The first-in-class Bruton's tyrosine kinase inhibitor was first approved as a single-agent therapy for WM in January 2015.

FDA approval of the combination for treatment of WM was supported by data from the Phase III iNNOVATE trial evaluating ibrutinib in combination with rituximab, versus rituximab alone, in 150 patients with previously untreated and relapsed/refractory WM.

The most common adverse reactions (occurring in 20% or more of patients) in the iNNOVATE study were bruising, musculoskeletal pain, hemorrhage, diarrhea, rash, arthralgia, nausea, and hypertension.

In combination with rituximab or as a single agent, the recommended dose for adults with WM is 420 mg taken orally once daily until disease progression or unacceptable toxicity.

Medication Monitor Categories:
Supplemental Approvals