Indian Health Service
National Pharmacy and Therapeutics Committee

Pharmacovigilance Drug Safety Communication

July 26, 2019

Increased risk of blood clots and death with tofacitinib (Xeljanz, Xeljanz XR)

The U.S. Food and Drug Administration has approved a new Boxed Warning about an increased risk of blood clots and of death with the 10 mg twice daily dose of tofacitinib (Xeljanz, Xeljanz XR), which is used in patients with ulcerative colitis.

Tofacitinib 10 mg twice daily is not approved or recommended for the treatment of rheumatoid arthritis or psoriatic arthritis.

For the treatment of ulcerative colitis, reserve tofacitinib as second-line therapy for use in patients who have failed or cannot tolerate TNF blockers.

- For ulcerative colitis, use tofacitinib at the lowest effective dose and for the shortest duration needed to achieve/maintain therapeutic response.

- The induction dose is 10 mg twice daily for 8 weeks. Evaluate patients and transition to maintenance therapy depending on therapeutic response. If needed, continue 10 mg twice daily for an additional 8 tofacitinib (Xeljanz, Xeljanz XR), weeks or a maximum of 16 weeks. Discontinue 10 mg twice daily after 16 weeks if adequate therapeutic response is not achieved.

- The maintenance dose is 5 mg twice daily. Use of 10 mg twice daily beyond induction should be limited to those with loss of response and used for the shortest duration, with careful consideration of the benefits and risks for the individual patient. Use the lowest effective dose needed to maintain response. Discontinue tofacitinib and promptly evaluate patients with symptoms of thrombosis.

Avoid tofacitinib in patients who may be at increased risk of thrombosis.

Counsel patients to seek medical attention immediately if they experience unusual symptoms, including those of thrombosis.

Encourage patients to read the Medication Guide they receive with each tofacitinib prescription, which explains the safety risks and provides other important information.

To help FDA track safety issues with medicines, report adverse events involving tofacitinib or other medicines to the FDA MedWatch program.