Xeljanz® (tofacitinib), Xeljanz XR (tofacitinib) – New indication

- On December 14, 2021, Pfizer announced the FDA approval of Xeljanz/Xeljanz XR (tofacitinib), for the treatment of adult patients with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
    - The use of Xeljanz/Xeljanz XR in combination with biologic disease-modifying antirheumatic drugs (DMARDs) or potent immunosuppressants such as azathioprine and cyclosporine is not recommended.
- Xeljanz/Xeljanz XR are also approved for rheumatoid arthritis, psoriatic arthritis, and ulcerative colitis. Additionally, Xeljanz is also approved for polyarticular course juvenile idiopathic arthritis.
- The approval of Xeljanz/Xeljanz XR for the new indication was based on Study AS-I, a randomized, double-blind, placebo-controlled, study in 269 adult patients with AS who had an inadequate response (inadequate clinical response or intolerance) to at least 2 nonsteroidal anti-inflammatory drugs (NSAIDs). Patients were randomized and treated with Xeljanz or placebo for 16 weeks of blinded treatment and then all received treatment of Xeljanz for additional 32 weeks. The primary endpoint was the proportion of patients who achieved an Assessment in SpondyloArthritis International Society (ASAS)20 response at week 16.
    - ASAS20 response was achieved in 56% of patients treated with Xeljanz vs. 29% with placebo (treatment difference 27, 95% CI: 16, 38; $p < 0.0001$).
- Xeljanz/Xeljanz XR carry boxed warnings for serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis.
- The recommended dose of Xeljanz for the treatment of AS is 5 mg orally twice daily. The recommended dose of Xeljanz XR is 11 mg orally once daily.
    - Refer to the Xeljanz/Xeljanz XR drug label for dosing for their other indications.