Xeljanz® (tofacitinib) – New indication

- On May 30, 2018, the FDA announced the approval of Pfizer's Xeljanz (tofacitinib), for the treatment of adult patients with moderately to severely active ulcerative colitis (UC).
    - Use of Xeljanz in combination with biological therapies for UC or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.
- Xeljanz is also indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate and for the treatment of adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs.
- UC is a chronic, inflammatory bowel disease affecting the colon. Patients experience recurrent flares of abdominal pain and bloody diarrhea. Other symptoms include fatigue, weight loss and fever. More than 900,000 patients are affected in the U.S.
- Tofacitinib is also available as Xeljanz XR.
    - Xeljanz XR is indicated for RA and PsA.
- The approval of Xeljanz for UC was based on 2 placebo-controlled induction studies enrolling 1,139 adults with moderately to severely active UC and one maintenance study enrolling 593 patients from the first two studies and re-randomized them for 52 weeks. The primary endpoint of the first two studies was the proportion of patients in remission at week 8. The primary endpoint of the maintenance study was the proportion of patients in remission at week 52.
    - In the first study, 18% of the Xeljanz patients vs. 8% of the placebo patients were in remission at week 8 (treatment difference: 10% [95% CI: 4.3, 16.3; $p < 0.01$]).
    - In the second study, 17% of the Xeljanz patients vs. 4% of the placebo patients were in remission at week 8 (treatment difference: 13% [95% CI: 8.1, 17.9; $p < 0.001$]).
    - In the maintenance study, 41% of the Xeljanz 10 mg patients, 34% of the Xeljanz 5 mg patients vs. 11% of the placebo patients were in remission at week 52 (treatment difference vs. placebo: 30% for Xeljanz 10 mg [95% CI: 21.4, 37.6; $p < 0.0001$] and 23% for the Xeljanz 5 mg [95% CI: 15.3, 31.2; $p < 0.0001$]).
- Xeljanz carries a boxed warning for serious infections and malignancy.
- The most common adverse reactions (≥ 5% and ≥ 1% than placebo) with Xeljanz use in UC were nasopharyngitis, elevated cholesterol levels, headache, upper respiratory tract infection, increased blood creatine phosphokinase, rash, diarrhea, and herpes zoster.
- The recommended dosage of Xeljanz for adults with UC is 10 mg orally twice daily for at least 8 weeks; followed by 5 or 10 mg twice daily, depending on therapeutic response.

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- Use the lowest effective dose to maintain response.
- Discontinue Xeljanz after 16 weeks of treatment with 10 mg twice daily, if adequate therapeutic benefit is not achieved.
- Consult the Xeljanz drug label for recommended dosage for other indications.