TOFACITINIB (XELJANZ ®)

UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS: Janus kinases (JAKs) inhibitors

BRAND (generic) NAMES: Xeljanz (tofacitinib)

5 mg tablet

FDA APPROVED INDICATIONS:

Xeljanz is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs).

COVERAGE AUTHORIZATION CRITERIA

Xeljanz (tofacitinib) is covered when the following criteria are met:

1. The patient is 18 years of age or older; **AND**
2. The patient is diagnosed with moderately or severely active rheumatoid arthritis; **AND**
3. The patient will not be using tofacitinib in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine, tacrolimus or cyclosporine); **AND**
4. The patient is using no more than two 5 mg tablets per day; **AND**
5. The patient has experienced a therapeutic failure or has had an inadequate response to methotrexate; **OR**
6. The patient is unable to receive methotrexate (e.g., use of methotrexate is contraindicated)

BLACK BOX WARNING

WARNING: SERIOUS INFECTIONS AND MALIGNANCY

SERIOUS INFECTIONS

Patients treated with Xeljanz are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

If a serious infection develops, interrupt Xeljanz until the infection is controlled.

Reported infections include:

Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients should be tested for latent tuberculosis before Xeljanz use and during therapy. Treatment for latent infection should

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be initiated prior to Xeljanz use.

Invasive fungal infections, including cryptococcosis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.

Bacterial, viral, and other infections due to opportunistic pathogens.

The risks and benefits of treatment with Xeljanz should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.

Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with Xeljanz, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

MALIGNANCIES

Lymphoma and other malignancies have been observed in patients treated with Xeljanz. Epstein Barr Virus- associated post-transplant lymphoproliferative disorder has been observed at an increased rate in renal transplant patients treated with Xeljanz and concomitant immunosuppressive medications.

WARNINGS AND PRECAUTIONS

- Serious Infections – Do not administer Xeljanz during an active infection, including localized infections. If a serious infection develops, interrupt Xeljanz until the infection is controlled.
- Lymphomas and other malignancies have been reported in patients treated with Xeljanz.
- Gastrointestinal Perforations – Use with caution in patients that may be at increased risk.
- Laboratory monitoring – Recommended due to potential changes in lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids.
- Immunizations – Live vaccines should not be given concurrently with Xeljanz.
- Severe hepatic impairment – Not recommended.

DOSAGE AND ADMINISTRATION

Xeljanz is given 5mg orally twice daily with or without food.

Xeljanz dosage should be reduced to 5 mg once daily in patients:
- with moderate or severe renal insufficiency
- with moderate hepatic impairment
- receiving potent inhibitors of Cytochrome P450 3A4 (CYP3A4) (e.g., ketoconazole)
- receiving one or more concomitant medications that result in both moderate inhibition of CYP3A4 and potent inhibition of CYP2C19 (e.g., fluconazole).

REFERENCES