ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Urgent**[1] ☐ **Non-Urgent**

Requested Drug Name: Xeljanz® (tofacitinib)

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit: ☐ New Request ☐ Reauthorization

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Xeljanz® (tofacitinib)

Diagnosis (documentation supportive of diagnosis is required)

☐ Moderate to Severe Rheumatoid Arthritis
☐ Other (please state):_____

Clinical Consideration (for approval, acknowledge and provide supporting documentation of the following):

☐ Documented inadequate response or intolerance to methotrexate is required
☐ Documented inadequate response or intolerance to 1 or more biologic DMARDs (e.g. Humira®, Enbrel®, Cimzia®, Simponi®, Orencia®) is required

Physician Specialty

☐ Rheumatologist
☐ Other (please state): _____

☐ For use in clinical trial? (If yes, provide trial name and registration number):			
Drug Name (Brand Name and Scientific Name)/Strength:			
Dose:	Route:	Frequency:	
Quantity:	Number of Refills:		
Product will be delivered to: ☐ Patient's Home ☐Physician Office		Other:	
Prescriber or Authorized Signature:		Date:	
Dispensing Pharmacy Name and Phone Number:			
☐ **Approved** ☐ **Denied**			
If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:			

1. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request

Xeljanz® (tofacitinib)

CLASSIFICATION

- Antirheumatic
- Janus kinase inhibitor

DESCRIPTION

- Tofacitinib inhibits Janus kinases (JAK), which are intracellular enzymes, and modulates a signaling pathway that influences the cellular processes of hematopoiesis and immune cell function. Signals in this pathway arise from cytokine or growth factor-receptor interactions on the cellular membrane. Inhibition of JAK prevents the phosphorylation and activation of Signal Transducers and Activators of Transcription (STATs), which modulate gene expression and other intracellular activity.
- Tofacitinib citrate is indicated *for monotherapy or in combination with methotrexate (MTX) or other nonbiologic disease-modifying antirheumatic drugs (DMARDs)* in adults with moderately to severely active rheumatoid arthritis who have had an *inadequate response or intolerance to methotrexate.*
- Tofacitinib citrate should not be used concurrently with biologic disease-modifying antirheumatic drugs (DMARDs) or with potent immunosuppressants (e.g., azathioprine, cyclosporine).
- Biologic DMARDs available to treat moderate to severe RA in patients with inadequate response to MTX include the TNF inhibitors Humira® (adalimumab), Enbrel® (etanercept), Cimzia® (certolizumab pegol), Remicade® (infliximab), and Simponi® (golimumab).
- Other biologic DMARDs that may be utilized in patients with inadequate response to MTX include Actemra® (tocilizumab), Orencia® (abatacept), Rituxan® (rituximab) and Kineret® (anakinra).
- Traditional non-biologic oral DMARDs include MTX, leflunomide, hydroxychloroquine, and sulfasalazine.
- REMS program to educate healthcare professionals and patients about serious risks associated with Xeljanz treatment including serious and other important infections, malignancies and other lymphoproliferative disorders, and changes in laboratory parameters, such as decreases in lymphocytes, neutrophils, and hemoglobin levels, and increases in lipids.
- In adults with active, moderate to severe rheumatoid arthritis who had an inadequate response to at least 1 previous tumor necrosis factor inhibitors (TNFi), tofacitinib plus methotrexate resulted in a significantly greater proportion of patients achieving improvement at month 3 compared with placebo, according to a 6-month, double-blind study (n=399). All patients continued stable doses of oral or parenteral methotrexate 7.5 to 25 mg/week. After 3 months of treatment, an American College of Rheumatology 20% (ACR20) response was significantly greater in the groups receiving tofacitinib 5 mg or 10 mg compared with placebo (41.7% and 48.1% vs 24.4%). For both tofacitinib groups, time to onset of ACR20 response was 2 weeks. Physical function, as change from baseline on HAQ-DI, was significantly improved by -0.43 and - 0.46 in the tofacitinib 5- and 10-mg groups compared with -0.18 in the placebo group. At 3 months, the Disease Activity Score for 28 joint counts based on the erythrocyte sedimentation rate (DAS28-4[ESR]) of less than 2.6 was significantly different between the tofacitinib 5-mg group (6.7%) and 10-mg group (8.8%) compared with placebo (1.7%). Tofacitinib was also associated with increased LDL cholesterol levels and decreased neutrophil counts. There were no reports of opportunistic infections or malignancies and no significant increase in hemoglobin concentrations in tofacitinib-treated patients.
- In the 12-month, randomized Oral Rheumatoid Arthritis Phase 3 Trials Standard (ORAL Standard) study, treatment with tofacitinib or adalimumab resulted in a significantly greater response compared with placebo, in adult patients (n=717) with active rheumatoid arthritis who received concomitant methotrexate therapy. Patients with an incomplete response to methotrexate who were not currently treated with other antirheumatic agents were randomized to receive either tofacitinib 5 mg orally twice daily, tofacitinib 10 mg

orally twice daily, adalimumab 40 mg subQ once every 2 weeks, or placebo. The ACR20 response was achieved by a significantly greater percentage of patients treated with tofacitinib 5 mg (51.5%), tofacitinib 10 mg (52.6%), or adalimumab 40 mg (47.2%), compared with 28.3% with placebo. Mean change from baseline in HAQ-DI score was significantly greater in all active treatment groups compared with placebo (-0.55, -0.61, -0.49, and -0.24 for tofacitinib 5 mg, tofacitinib 10 mg, adalimumab 40 mg, and placebo, respectively). Compared with 1.1% of patients treated with placebo, a significantly greater proportion of patients achieved a Disease Activity Score for 28 joint counts based on the erythrocyte sedimentation rate (DAS28-4[ESR]) score below 2.6 with active treatment (tofacitinib 5 mg, 6.2%; tofacitinib 10 mg, 12.5%; and adalimumab 40 mg, 6.7%). The magnitude of clinical response was sustained to the end of the study and remained numerically similar across the active treatment groups. An increase in cholesterol levels was seen in the tofacitinib-treated patients; at 3 months, LDL levels increased by 12.18% and 18.93% in the tofacitinib 5 mg and 10 mg groups, respectively, compared with 3.62% and 0.26% increases in the adalimumab and placebo groups. Increased LDL levels remained throughout the study.

- Most common adverse reactions during the first 3 months in controlled clinical trials were upper respiratory tract infection, headache, diarrhea, and nasopharyngitis.
- Most common serious adverse effect was infection including pneumonia, cellulitis, herpes zoster, and urinary tract infections.
- In the 7 RCTs during 0 to 3 month exposure, 2 malignancies were reported; in the 7 RCTs during the 0 to 12 months exposure, 12 malignancies occurred (11 solid; 1 lymphoma). It is unknown if increasing exposure to Xeljanz increases the risk of malignancy.
- Most common types of malignancy were lung and breast cancer, followed by gastric, colorectal, renal cell, prostate, lymphoma, and malignant melanoma.

FORMULARY COVERAGE

Prior authorization: Required
Good Health Formulary: Tier 5
Commercial Formulary: Tier 4
Medicare Part D coverage: Tier 5

COVERAGE CRITERIA

Xeljanz® (tofacitanib) meets the definition of **medical necessity** for the following:

- Documented diagnosis of moderate to severe rheumatoid arthritis WITH documented intolerance or inadequate response to:
    - Methotrexate
      -AND-
    - One or more biologic DMARDs for RA
        - TNF Inhibitor Examples: Humira® (adalimumab), Enbrel® (etanercept), Cimzia® (certolizumab pegol), Remicade® (infliximab), and Simponi® (golimumab).
        - Non-TNF Inhibitor Examples: Actemra® (tocilizumab), Orencia® (abatacept), Rituxan® (rituximab) and Kineret® (anakinra).
- Documentation of prior therapies is required for approval of Xeljanz®.

Xeljanz® (tofacitanib) is considered **experimental** for the following:

- Any condition or diagnosis not FDA approved or Compendia supported

Required Provider Specialty:

- Approval is limited to Rheumatologist

DOSAGE/ADMINISTRATION

Adult Dosing (safety and efficacy has not been determined for pediatric patients):
Moderate to severe Rheumatoid arthritis in patients who had an inadequate response or intolerance to MTX:
Do not initiate in patients with an absolute neutrophil count < 1000 cells/mm^3, a lymphocyte count < 500 cells/mm^3, or a hemoglobin level < 9 g/Dl

- Normal Dosing: 5 mg orally twice daily, as monotherapy or in combination with methotrexate or other DMARDs.
- Dosage in Renal Failure: if moderate or severe impairment, reduce dose to 5 mg orally once daily.
- Dosage in Hepatic Insufficiency: if moderate impairment, reduce dose to 5 mg orally once daily; if severe impairment, use is not recommended.
- **See complete prescribing information for dose modifications.**

PRECAUTIONS

- Black Box Warnings:
  - **Serious Infections:** Patients treated with tofacitinib are at increased risk of 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 tofacitinib 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 tofacitinib use and during therapy. Treatment for latent infection should be initiated prior to tofacitinib 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 tofacitinib should be carefully monitored 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 tofacitinib, 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 tofacitinib. Epstein Barr Virus-associated post-transplant lymphoproliferative disorder has been observed at an increased rate in renal transplant patients treated with tofacitinib and concomitant immunosuppressive medications
- Precautions:
  - Do not initiate treatment if active infection, including localized infections.
  - Coadministration with biologic disease-modifying antirheumatic drugs, potent CYP3A4 inducers, or potent immunosuppressants (e.g., cyclosporine, azathioprine) is not recommended.
  - Gastrointestinal perforation has occurred. Use cautiously in patients with associated risk (e.g., history of diverticulitis).
  - Lipid increases may occur. Monitoring is recommended and dose interruption may be required.
  - Liver enzyme elevations may occur. Monitoring is recommended and dose interruption may be required.
  - Myelosuppression (lymphocytopenia, neutropenia, and anemia) may occur. Monitoring is recommended and dose adjustment, interruption, and initiation deferment may be needed.
  - Dose adjustment required in moderate hepatic impairment.
  - Use is not recommended if severe hepatic impairment.
  - Dose adjustment required in moderate or severe renal impairment.
  - Do not administer live vaccines during therapy.
  - Viral reactivation, including cases of herpes virus reactivation, has occurred.
  - Geriatric patients have increased risk of serious infection.
  - Non-melanoma skin cancers (NMSC) have been reported. Monitoring is recommended in patients with increased risk.

- Viral reactivation, including cases of herpes virus reactivation, has occurred. Screen for viral hepatitis prior to initiation.

Billing/Coding information

HCPCS Coding:

J8499	Prescription drug, oral, non-chemotherapeutic, Not Otherwise Specified

COST

- AWP (January 2013): Xeljanz 5mg tablet PO (60): $2,466
- AWP (January 2014): Xeljanz 5mg tablet PO (60): $2,636.40

COMMITTEE APPROVAL

- January 2013

GUIDELINE UPDATE INFORMATION

January 2013	Prior Authorization and Coverage Policy created
May 2014	Coverage Policy updated

REFERENCES

- DRUGDEX®, accessed 1/12/2013, 5/7/2014
- Product Information: Xeljanz® (tofacitinib) tablets, for oral use. Pfizer Labs, NY, NY. 11/2012, 4/2014.