Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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Xeljanz (tofacitinib), Xeljanz XR (tofacitinib extended-release)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended-release)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib extended-release) may be approved for the following:

I. Rheumatoid arthritis (RA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe RA; **AND**
   B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, leflunomide, or hydroxychloroquine)];

   AND

   C. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – Enbrel (etanercept), Humira (adalimumab)] unless the following criteria are met:
      1. Individual has been receiving and is maintained on a stable dose of Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib extended-release); **OR**
      2. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
         a. Known hypersensitivity to any active or inactive component which is not also associated with Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib extended-release); **OR**
         b. Individual's age; **OR**
         c. Pregnant or planning on becoming pregnant; **OR**
         d. Serious infections or concurrent sepsis; **OR**
      3. The individual has either concomitant clinical condition:

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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a. Demyelinating disease; **OR**
b. Heart failure with documented left ventricular dysfunction; **OR**

4. The preferred agent(s) do not have activity against a concomitant clinical condition and Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib extended-release) does. An example includes but may not be limited to the following:
    a. Concomitant Crohn's disease: TNFi (agents FDA-approved for both indications) are preferred;

OR

II. Psoriatic arthritis (PsA) when each of the following criteria are met:
A. Individual is 18 years of age or older with moderate to severe PsA; **AND**
B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, leflunomide)];
AND
C. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – Enbrel (etanercept), Humira (adalimumab)] unless the following criteria are met:
    1. Individual has been receiving and is maintained on a stable dose of Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib extended-release); **OR**
    2. The preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib extended-release) does; **OR**
    3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
        a. Known hypersensitivity to any active or inactive component which is not also associated with Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib extended-release); **OR**
        b. Individual's age; **OR**
        c. Pregnant or planning on becoming pregnant; **OR**
        d. Serious infections or concurrent sepsis; **OR**
    4. The individual has either concomitant clinical condition:
        a. Demyelinating disease; **OR**
        b. Heart failure with documented left ventricular dysfunction; **OR**
    5. The preferred agent(s) do not have activity against a concomitant clinical condition and Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib extended-release) does. Examples include but may not be limited to the following:

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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a. Concomitant Crohn's Disease: TNFi (agents FDA-approved for both indications) or Stelara are preferred; **OR**
b. Concomitant Ulcerative Colitis: TNFi (agents FDA-approved for both indications) are preferred.

Requests for Xeljanz (tofacitinib) may be approved for the following:

I. Ulcerative colitis (UC) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severeUC; **AND**
   B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as 5-aminosalicylic acid products, systemic corticosteroids, or immunosuppressants);

   AND

   C. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to ONE (1) preferred biologic agents [Current preferred biologics include – Humira (adalimumab), Inflectra (infliximab-dyyb), or Renflexis (infliximab-abda)] unless the following criteria are met:
      1. Individual has been receiving and is maintained on a stable dose of Xeljanz (tofacitinib); **OR**
      2. The preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Xeljanz (tofacitinib) does; **OR**
      3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
         a. Known hypersensitivity to any active or inactive component which is not also associated with Xeljanz (tofacitinib); **OR**
         b. Individual's age; **OR**
         c. Pregnant or planning on becoming pregnant; **OR**
         d. Serious infections or concurrent sepsis; **OR**
      4. Individual has any of the following concomitant clinical conditions:
         a. Demyelinating disease; **OR**
         b. Heart failure with documented left ventricular dysfunction; **OR**
         c. Malignancy [such as but not limited to, solid or hematologic cancers and excluding superficial skin cancers (such as basal and squamous cell)]; **OR**
      5. The preferred agent(s) do not have activity against a concomitant clinical condition and Xeljanz (tofacitinib) does. Examples include but may not be limited to the following:

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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a. Concomitant Psoriasis: TNFi (agents FDA-approved for both indications) or Stelara are preferred; **OR**
b. Concomitant Rheumatoid Arthritis: TNFi (agents FDA-approved for both indications) or Xeljanz are preferred.

Xeljanz XR (tofacitinib extended-release) may **not** be approved for the following:

I. Individual has a diagnosis of moderate [30-59 mL/min/1.73 m2 (NKF 2002, KDIGO 2012)] or severe [less than 30 mL/min/1.73 m2 (NKF 2002, KDIGO 2012)] renal impairment; **OR**
II. Individual has a diagnosis of moderate hepatic impairment (Child Pugh Class B).

Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib extended-release) may **not** be approved for the following:

I. In combination with other JAK inhibitors (such as Olumiant), biologic drugs (such as but not limited to, TNF antagonists, anti-CD20 monoclonal antibodies, IL-1R antagonists, selective co-stimulation modulators) or potent immunosuppressants (such as azathioprine and cyclosporine); **OR**
II. At initiation of therapy, absolute neutrophil count (ANC) less than 1000 cells/mm^3, lymphocyte count less than 500 cells/mm^3, or hemoglobin less than 9 g/dL; **OR**
III. Tuberculosis or other active serious infections or a history of recurrent infections; **OR**
IV. Individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis prior to initiating tofacitinib; **OR**
V. Individual has severe hepatic impairment (Child Pugh class C).

Note: Xeljanz (tofacitinib), Xeljanz XR (tofacitinib extended-release) has black box warnings for serious infections and malignancy. The increased risk of developing serious infections can result in hospitalization or death. Most individuals that developed serious infections were taking concomitant immunosuppressants. Individuals should be closely monitored for the development of an infection during and after treatment with discontinuation of therapy if the individual develops a serious infection. Reported infections include: Active tuberculosis (pulmonary or extrapulmonary disease), invasive fungal infections (including cryptococcosis and pneumocystosis), and infections (bacterial, viral, or other) due to opportunistic pathogens.

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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Individuals should be tested for latent tuberculosis prior to and during therapy. Latent tuberculosis should be treated prior to initiation of therapy. The risks and benefits of treatment with Xeljanz should be considered prior to initiating in individuals with chronic or recurrent infection. Lymphoma and other malignancies have occurred with therapy. Epstein Barr virus-associated post-transplant lymphoproliferative disorder has been observed in renal transplant individuals taking concomitant immunosuppressants.

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

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5. Singh JA, Saag KG, Bridges SL et al. 2015 American College of Rheumatology Guideline for the treatment of rheumatoid arthritis. *Arthritis Rheum*. 2016;68:1-26.
6. American Gastroenterological Association. Identification, assessment and initial medical treatment of ulcerative colitis Clinical Care Pathway. Available at https://gastro.org/guidelines/ibd-and-bowel-disorders. Accessed on: August 24, 2018.
7. Menter A, Korman NJ, Elmets CA et al for the American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. *J Am Acad Dermatol*. 2011; 65: 137-174.
8. Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. *Kidney Int Suppl.*2013; 3:1–150. Available from http://kdigo.org/home/guidelines/ckd-evaluation-management/. Accessed on: August 24, 2018.