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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Olumiant (baricitinib)

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

Washington Medicaid – See State Specific Mandates

Medications	Quantity Limit
Olumiant (baricitinib) 2 mg tablets	May be subject to quantity limit

APPROVAL CRITERIA

Olumiant (baricitinib) may be approved based on the following criteria:

I. Rheumatoid Arthritis (RA) when the following criteria are met:
   A. Individual is 18 years of age or older with moderately to severely active RA; **AND**
   B. Individual has had an inadequate response to one or more tumor necrosis factor (TNF) antagonist agents; **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 is met:
      1. Individual has been receiving and is maintained on a stable dose of Olumiant (baricitinib); **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 Olumiant (baricitinib) ; **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:
         a. Demyelinating disease; **OR**
         b. Heart failure with documented left ventricular dysfunction; **OR**

Market Applicability														
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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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4. The preferred agent(s) do not have activity against a concomitant clinical condition and Olumiant (baricitinib) 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.

Olumiant (baricitinib) may **not** be approved for the following:

I. In combination with other JAK inhibitors (such as Xeljanz), biologic disease-modifying antirheumatic drugs (DMARDs) (such as but not limited to, TNF agents, 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 8 g/dL; **OR**
III. Tuberculosis or other active serious infections or a history of recurrent infection; **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 Olumiant; **OR**
V. Individual has severe hepatic impairment (Child Pugh class C); **OR**
VI. Individual has a diagnosis of moderate [30-59 mL/min/1.73 m^2 (KDIGO 2012)] or severe [less than 30 mL/min/1.73 m^2 (KDIGO 2012)] renal impairment.

Note: Olumiant (baricitinib) has black box warnings for serious infections, malignancy, and thrombosis. 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 candidiasis and pneumocystosis), and infections (bacterial, viral, or other) due to opportunistic pathogens. Individuals should be tested for latent tuberculosis prior to administration of Olumiant. Latent tuberculosis should be treated prior to initiation of therapy. The risks and benefits of treatment with Olumiant should be considered prior to initiating in individuals with chronic or recurrent infection. Lymphoma and other malignancies have occurred with therapy. The risks and benefits of treatment with Olumiant should be considered prior to initiating in individuals with a known malignancy other than a successfully treated non-melanoma skin cancer. Thrombosis, including deep venous thrombosis and pulmonary embolism, has been observed at an

Market Applicability														
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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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increased incidence in individuals treated with Olumiant. In addition, there were cases of arterial thrombosis. Many of these adverse events were serious and some resulted in death. Olumiant should be used with caution in individuals at an increased risk for thrombosis. Individuals with symptoms of thrombosis should be promptly evaluated.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
Washington	1/1/2018	Washington State PDL prefers Enbrel and Humira; all other clinical criteria apply

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: http://www.clinicalpharmacology.com. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.