Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

Rinvoq (upadacitinib)

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

Medications	Quantity Limit
Rinvoq (upadacitinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Rinvoq (upadacitinib) 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 Rinvoq (upadacitinib 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 Rinvoq (upadacitinib extended-release); **OR**
         b. Pregnant or planning on becoming pregnant; **OR**
         c. Serious infections or concurrent sepsis.
      3. The individual has either concomitant clinical condition:
         a. Demyelinating disease; **OR**
         b. Heart failure with documented left ventricular dysfunction; **OR**

Rinvoq (upadacitinib) may **not** be approved for the following:

I. In combination with other JAK inhibitors (such as Xeljanz), biologic drugs (such as but not limited to, TNF antagonists, anti-CD20 monoclonal antibodies, IL-1R antagonists,

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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/mm3, lymphocyte count less than 500 cells/mm3, or hemoglobin less than 8 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 upadacitinib; **OR**

V. Individual has severe hepatic impairment (Child Pugh class C); OR

VI. Individual has end stage renal disease [less than 15 mL/min/1.73 m2 (KDIGO 2012)].

Note:
Rinvoq (upadacitinib) has black box warnings for serious infections and 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 cryptococcosis and pneumocystosis), and infections (bacterial, viral, or other) due to opportunistic pathogens. 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 Rinvoq 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 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, pulmonary embolism, and arterial thrombosis have occurred in patients treated with JAK-inhibitors used to treat inflammatory conditions. Many of these adverse events were serious and some resulted in death. Consider the risks and benefits prior to treating patients who may be at increased risk. Patients with symptoms of thrombosis should be promptly evaluated and treated appropriately.

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

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 18, 2018
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
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. 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.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.