

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

*FHK- Florida Healthy Kids

Kevzara (sarilumab)

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

Medications	Quantity Limit
Kevzara (sarilumab)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Kevzara (sarilumab) 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)] or a tumor necrosis factor (TNF) antagonist (ACR 2015)

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 Kevzara (sarilumab); **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 the Kevzara (sarilumab); **OR**
 - B. Individual's age; **OR**
 - C. Pregnant or planning on becoming pregnant; **OR**
 - D. Serious infections or concurrent sepsis;

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New Program Date 06/06/2017

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.

CRX-ALL-0339-19

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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OR

3. The individual has either concomitant clinical condition:
 - 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 the requested non-preferred agent 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.

Requests for Kevzara (sarilumab) may **not** be approved for the following:

- I. In combination with JAK inhibitors or other biologic drugs (such as anti-CD20 monoclonal antibodies, IL-1R antagonists, selective co-stimulation modulators, or TNF antagonists); **OR**
- II. At initiation of therapy, absolute neutrophil count less than 2000/mm³, platelet count less than 150,000/mm³, or alanine aminotransferase or aspartate aminotransferase greater than 1.5 times the upper limit of normal ; **OR**
- III. Tuberculosis, invasive fungal infection, or other active serious infections or a history of recurrent infections; **OR**
- IV. Individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC-) and Prevention-recommended equivalent to evaluate for latent tuberculosis prior to initiating Kevzara (sarilumab).

Note:

Kevzara (sarilumab) has a black box warning for risk of serious infections. Individuals treated with Kevzara are at increased risk for developing serious infections that may lead to hospitalization or death. Most individuals who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Kevzara should be discontinued if an individual develops a serious infection or sepsis. Individuals should be tested for latent tuberculosis (TB) before sarilumab use and during therapy. Treatment for latent TB should be initiated prior to use. Risks and benefits of treatment with sarilumab should be carefully considered prior to initiation of therapy in individuals with chronic or recurrent infection.

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

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

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. 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 on: September 14, 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.; 2018; Updated periodically.
5. NCCN Drugs & Biologics Compendium (NCCN Compendium®) 2016 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically. Accessed on: September 14, 2018.
6. 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.
7. Ringold S, Weiss PF, Beukelman T, et al. 2013 Update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. *Arthritis Rheum*. 2013; 65(10):2499-2512.
8. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. *Arthritis Care & Research*. 2011; 63(4):465-482.
9. Choi J, Aubert O, Vo A, et al. Assessment of tocilizumab (anti-interleukin-6 receptor monoclonal) as a potential treatment for chronic antibody-mediated rejection and transplant glomerulopathy in HLA-sensitized renal allograft recipients. *Am J Transplant*. 2017; 17(9):2381-2389.

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