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

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Kevzara (sarilumab)

CG-DRUG-93

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

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

APPROVAL CRITERIA

I. Kevzara (sarilumab) may be approved for the treatment of an individual with moderately to severely active Rheumatoid Arthritis when **ALL** of the following criteria are met:
   A. Individual is 18 years of age or older; **AND**
   B. Agent is used for any of the following reasons:
      1. To reduce signs or symptoms; **OR**
      2. To induce or maintain clinical response; **OR**
      3. To inhibit the progression of structural damage; **OR**
      4. To improve physical function;

   AND
   C. Individual has had an inadequate response to a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of one or more disease modifying anti-rheumatic drugs (such as, methotrexate) or a tumor necrosis factor antagonist drug; **AND**
   D. May be used alone or in combination with methotrexate **or** with other nonbiologic disease modifying anti-rheumatic drugs;

   AND
   E. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response 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**

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

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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

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.

Kevzara (sarilumab) may **NOT** be approved for an individual with **any** of the following:

A. In combination with other biologic disease modifying anti-rheumatic drugs such as anti-CD20 monoclonal antibodies, IL-1R antagonists, , selective co-stimulation modulators, or tumor necrosis factor antagonists; **OR**
B. At initiation of therapy, absolute neutrophil count less than 2000/mm^3, platelet count less than 150,000/mm^3, or alanine aminotransferase or aspartate aminotransferase greater than 1.5 times the upper limit of normal ; **OR**
C. Tuberculosis, invasive fungal infection, or other active serious infections or a history of recurrent infections; **OR**
D. Individual has not had a tuberculin skin test or Centers for Disease Control and Prevention-recommended equivalent to evaluate for latent tuberculosis prior to initiating Kevzara (sarilumab).

Kevzara (sarilumab) may **not** be approved when the criteria above are not met and for all other indications, including but not limited to the treatment of:

A. Ankylosing spondylitis; **OR**
B. Non-infectious uveitis; **OR**
C. Polyarticular juvenile idiopathic arthritis; **OR**
D. Systemic juvenile idiopathic arthritis.

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. Opportunistic infections have also been reported in patients receiving sarilumab. Most patients who developed infections were taking concomitant

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

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immunosuppressants such as methotrexate or corticosteroids. Avoid use of Kevzara (sarilumab) in patients with an active infection. Reported infections include: Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients should be tested for latent tuberculosis before sarilumab use and during therapy. Treatment for latent infection should be initiated prior to sarilumab use; Invasive fungal infections, such as candidiasis, and pneumocystis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease; Bacterial, viral and other infections due to opportunistic pathogens. Closely monitor patients for signs and symptoms of infection during treatment with sarilumab. If a serious infection develops, interrupt sarilumab until the infection is controlled. Consider the risks and benefits of treatment with sarilumab prior to initiating therapy in patients with chronic or recurrent infection.

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

Key References:

1. Centers for Disease Control (CDC) and Prevention. Updated guidelines for using interferon gamma release assays to detect *Mycobacterium tuberculosis* infection - United States, 2010; 59(No. RR 5):1-28. Available at: http://www.cdc.gov/mmwr/pdf/rr/rr5905.pdf. Accessed on January 23, 2018.
2. Kevzara [Product Information], sanofi-aventis U.S., Bridgewater, NJ and Regeneron Pharmaceuticals, Inc., Tarrytown, NY; May 2017. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761037s000lbl.pdf. Accessed on January 23, 2018.
3. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. Arthritis Rheumatol. 2016; 68(1):1-26.
4. U.S. National Institutes of Health (NIH). ClinicalTrials.gov. Search: sarilumab. Available at: https://clinicaltrials.gov/ct2/results?term=sarilumab&Search=Search. Accessed on January 23, 2018.