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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Actemra (tocilizumab)

CG-DRUG-81

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Line of Business	Quantity Limit
Actemra (tocilizumab) vials	VA MCD and All L-AGP	May be subject to quantity limit
Actemra (tocilizumab) syringes	All MCD	

APPROVAL CRITERIA

I. Actemra (tocilizumab) may be approved for the treatment of an individual with giant cell arteritis when the following criteria are met:
   A. Individual is 18 years of age or older; **AND**
   B. Agent is used in combination with a tapering course of corticosteroids (such as, prednisone);
      OR
   C. Agent is used as a single agent following discontinuation of corticosteroids;

OR

II. Actemra (tocilizumab) may be approved for the treatment of an individual with moderately to severely active rheumatoid arthritis when 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 (for example, 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**

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-0276-18

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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E. 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 Actemra (tocilizumab); **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 Actemra (tocilizumab); **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

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

III. Actemra (tocilizumab) may be approved for the treatment of an individual with active polyarticular juvenile idiopathic arthritis when the following criteria are met:
A. Individual is 2 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;

AND

C. Individual has failed to respond to, is intolerant of, or has a medical contraindication to one or more nonbiologic disease modifying anti-rheumatic drugs (such as methotrexate); **AND**

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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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D. 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) and Humira (adalimumab)] unless the following criteria are met:
    1. Individual has been receiving and is maintained on a stable dose of Actemra (tocilizumab); **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 Actemra (tocilizumab) 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 Actemra (tocilizumab); **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

IV. Actemra (tocilizumab) may be approved for the treatment of an individual with active systemic juvenile idiopathic arthritis when the following criteria are met:
    A. Individual is 2 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;

    AND

    C. Individual has failed to respond to, is intolerant of, or has a medical contraindication to 1 or more corticosteroids or nonsteroidal anti-inflammatory drugs;

OR

V. Actemra (tocilizumab) may be approved as subsequent therapy for the treatment of an individual with relapsed/refractory or progressive multicentric Castleman disease when all of the following criteria are met:
    A. Used as a single agent; **AND**
    B. Human immunodeficiency virus (HIV)-negative; **AND**

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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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C. Human herpes-8 negative; **AND**
D. No concurrent clinically significant infection (for example, Hepatitis B or C); **AND**
E. No concurrent lymphoma;

OR

VI. Actemra (tocilizumab) may be approved for the treatment of cytokine release syndrome when all of the following criteria are met:
   A. Individual 2 years of age or older; **AND**
   B. Individual has chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome;

OR

VII. Actemra (tocilizumab) may be approved for the treatment of an individual with chronic active antibody-mediated rejection plus donor-specific antibodies and transplant glomerulopathy who has failed to respond to intravenous immune globulin (IVIg) plus rituximab therapy (with or without plasma exchange).

Requests for Actemra (tocilizumab) may **not** be approved for an individual with any of the following:

I. In combination with other biologic disease modifying anti-rheumatic drugs such as anti-CD20 monoclonal antibodies, IL-1R antagonists, Janus kinase inhibitors (for example, tofacitinib citrate), selective co-stimulation modulators, or TNF antagonists; **OR**
II. At initiation of therapy, absolute neutrophil count less than 2000/mm^3, platelet count less than 100,000/mm^3, 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 or Centers for Disease Control and Prevention (CDC)-recommended equivalent to evaluate for latent tuberculosis prior to initiating tocilizumab (in a setting of non-emergent use only).

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

I. Adult onset Still's disease; **OR**
II. Ankylosing spondylitis; **OR**
III. Crohn's disease; **OR**

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

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IV. Takayasu arteritis; **OR**
V. Systemic lupus erythematosus; **OR**
VI. Tumor necrosis factor receptor-associated periodic syndrome; **OR**
VII. Unicentric Castleman disease.

Note: Actemra (tocilizumab) has a black box warning for risk of serious infections. Individuals treated with Actemra 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. Reported infections include: Tuberculosis, invasive fungal infections (including candidiasis, aspergillosis, and pneumocystosis), and infections (bacterial, viral, or other) due to opportunistic pathogens. The risks and benefits of treatment with Actemra should be considered prior to initiating in individuals with chronic or recurrent infection. If a serious infection develops, Actemra therapy should be interrupted until the infection is controlled. Individuals should be closely monitored for the development of signs and symptoms of infection during and after treatment with Actemra, including the possible development of tuberculosis in individuals who tested negative for latent tuberculosis infection prior to initiating therapy.

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

Key References:

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3. National Comprehensive Cancer Network®. NCCN Drugs & Biologic Compendium® (electronic version). For additional information visit the NCCN website: http://www.nccn.org. Accessed on June 8, 2018.

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

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4. NCCN Clinical Practice Guidelines in Oncology®. © 2018 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on June 8, 2018.
   - B-cell Lymphomas (V4.20187). Revised May 15, 2018.
   - Management of Immunotherapy-Related Toxicities (Immune-Checkpoint Inhibitor-Related Toxicities) (V1.2018). Revised February 14, 2018.
5. 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.
6. 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.
7. Tocilizumab. In: DrugPoints System (electronic). Truven Health Analytics, Greenwood Village, CO. Updated May 15, 2018. Available at: http://www.micromedexsolutions.com. Accessed on June 8, 2018.

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