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

Actemra (tocilizumab)

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

Medications	Line of Business	Dosing/Quantity Limit
Actemra (tocilizumab) 80 mg, 200 mg, 400 mg vial for intravenous infusion	VA MCD and All L-AGP	8 mg/kg* as frequently as every 4 weeks
Actemra (tocilizumab) ACTPen prefilled autoinjector, prefilled syringe 162 mg/0.9 mL	All MCD	4 autoinjectors/syringes per 28 days

Dosing Override Criteria

I. For polyarticular juvenile idiopathic arthritis (PJIA), may approve up to 10 mg/kg every 4 weeks for individuals weighing less than 30 kg.
II. For systemic juvenile idiopathic arthritis (SJIA), may approve up to 12 mg/kg every 2 weeks for patients weighing less than 30 kg and up to 8 mg/kg every 2 weeks for patients at or above 30 kg.
III. For cytokine release syndrome (CRS), may approve a total of up to four intravenous doses at least 8 hours apart; each dose up to 8 mg/kg for individuals weighing at or above 30 kg and up to 12 mg/kg in individuals weighing less than 30 kg.

*For rheumatoid arthritis and CRS, Each dose should not exceed 800mg total

APPROVAL CRITERIA

Requests for Actemra (tocilizumab) may be approved for the following:

I. Giant cell arteritis (GCA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with GCA; **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

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

II. 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 b**i**ologics 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, including 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. Pregnant or planning on becoming pregnant; **OR**
         c. 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

III. Polyarticular juvenile idiopathic arthritis (PJIA) when each of the following criteria are met:
   A. Individual is 2 years of age or older with moderate to severe PJIA;

   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)]; **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 b**i**ologics 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 acceptable due to concomitant clinical

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

conditions, including 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. Pregnant or planning on becoming pregnant; **OR**
   c. 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

IV. Systemic juvenile idiopathic arthritis (SJIA) when each of the following criteria are met:
   A. Individual is 2 years of age or older with SJIA; **AND**
   B. Individual has failed to respond to, is intolerant of, or has a contraindication to corticosteroids or nonsteroidal anti-inflammatory drugs (NSAIDs);

OR

V. Multicentric Castleman Disease when each of the following criteria are met (NCCN 2A):
   A. Individual with a diagnosis of relapsed/refractory of progressive multicentric Castleman disease; **AND**
   B. Used as a single agent; **AND**
   C. Human immunodeficiency virus (HIV)-negative; **AND**
   D. Human herpes-8 negative; **AND**
   E. No concurrent clinically significant infection (for example, Hepatitis B or C); **AND**
   F. No concurrent lymphoma;

OR

VI. Cytokine Release Syndrome when the following criteria are met:
   A. Individual 2 years of age or older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome;

OR

VII. Chronic Antibody-Mediated Renal Transplant Rejection when each of the following criteria are met (Choi 2017):
   A. Individual has chronic active antibody-mediated rejection plus donor-specific antibodies and transplant glomerulopathy; **AND**
   B. Individual 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 the following:

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

I. All other indications not included above; **OR**
II. In combination with JAK inhibitors, apremilast, or other biologic (such as anti-CD20 monoclonal antibodies, IL-1R antagonists, selective co-stimulation modulators, or tumor necrosis factor (TNF) antagonists; **OR**
III. 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**
IV. Tuberculosis, or other active serious infections or a history of recurrent infections; **OR**
V. 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 Actemra (tocilizumab) (in a setting of non-emergent use only).

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 such as methotrexate or corticosteroids. Actemra should be discontinued if an individual develops serious infection or sepsis. Individuals should be tested for latent tuberculosis (TB) before tocilizumab use and during therapy. Treatment for latent TB should be initiated prior to use. Risks and benefits of tocilizumab should be carefully considered prior to initiation of therapy in individuals with chronic or recurrent infection.

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) 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: November 28, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.

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.

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

4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. NCCN Drugs & Biologics Compendium (NCCN Compendium®) 2019 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically. Accessed on: September 14, 2019.
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. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Rheum. 2019; 71(6):846-863.
9. 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.
10. 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.

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.