

Policy Name	Policy Number	Scope	
<b>Monoclonal Antibodies to Interlukin-6:</b> tocilizumab (Actemra) and biosimilars, sarilumab (Kevzara)	MP-RX-FP-59-23	<input checked="" type="checkbox"/> MMM MA	<input checked="" type="checkbox"/> MMM Multihealth
<b>Service Category</b> <input type="checkbox"/> Anesthesia <input type="checkbox"/> Surgery <input type="checkbox"/> Radiology Procedures <input type="checkbox"/> Pathology and Laboratory Procedures <input type="checkbox"/> Medicine Services and Procedures <input type="checkbox"/> Evaluation and Management Services <input type="checkbox"/> DME/Prosthetics or Supplies <input checked="" type="checkbox"/> Part B DRUG			
<b>Service Description</b> <p>This document addresses the use of <a href="#">Monoclonal Antibodies to Interlukin-6: tocilizumab (Actemra), sarilumab (Kevzara)</a> , a drug approved by the Food and Drug Administration (FDA) for the treatment of <a href="#">of rheumatoid arthritis, giant cell arteritis, polyarticular and systemic juvenile idiopathic arthritis, chimeric antigen receptor (CAR) T cell-induced severe or lifethreatening cytokine release syndrome, and other conditions as applicable.</a></p> <p>Agents addressed in this clinical guideline include:</p> <ul style="list-style-type: none"> <li>• Actemra (tocilizumab) and biosimilars</li> <li>• Kevzara (sarilumab)</li> </ul> <p><b>Background Information</b></p> <p>Rheumatoid Arthritis: The American College of Rheumatology (ACR) guidelines recommend disease-modifying antirheumatic drug (DMARD) monotherapy as first-line treatment in individuals with RA with moderate to high disease activity. Methotrexate (MTX) monotherapy, titrated to a dose of at least 15 mg, is recommended over hydroxychloroquine, sulfasalazine, and leflunomide. Methotrexate monotherapy is also recommended over monotherapy with biologics (tumor necrosis factor inhibitors [TNFi], IL-6 inhibitors, abatacept) or JAK inhibitors. For individuals taking maximally tolerated doses MTX who are not at target, the addition of a biologic or JAK inhibitor is recommended. Non-TNFi biologics or JAK inhibitors are conditionally recommended over TNFi in individuals with heart failure.</p> <p>Juvenile Idiopathic Arthritis: The American College of Rheumatology (ACR) guidelines provide recommendations for juvenile idiopathic arthritis, including systemic disease (SJIA) and JIA with polyarthritis (PJIA). SJIA is an autoinflammatory condition marked by intermittent fever, rash, and arthritis. PJIA is marked by the presence of more than four affected joints in the first six months of illness. For SJIA, NSAIDs or glucocorticoids are conditionally recommended as initial monotherapy, depending on whether macrophage activation syndrome (MAS) is present or not. IL-1 inhibitors (anakinra or canakinumab), or tocilizumab are also conditionally recommended as initial therapy or to achieve inactive disease, with no preferred agent. For SJIA without MAS, IL-1 inhibitors (anakinra or canakinumab) and tocilizumab are strongly recommended for</p>			

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<p>inadequate response to or intolerance of NSAIDs and/or glucocorticoids (ACR 2021). For children with active polyarthritis, biologic therapy including TNFi, abatacept, or tocilizumab +/- DMARD is recommended following initial DMARD therapy (preferably methotrexate) (ACR 2019). Adult-onset Still’s Disease (AOSD) describes SJIA when the condition begins after the patient’s 16th birthday. Though only canakinumab has been specifically FDA approved for AOSD, other agents used for SJIA may be useful in clinical practice.</p>		
<p>Chronic Antibody-Mediated Renal Transplant Rejection: Antibody-mediated rejection is caused by anti-donor-specific antibodies, mostly anti-HLA antibodies. Treatment for acute antibody-mediated rejection (AMR) generally consists of IVIG and rituximab, with or without plasma exchange. Although success has been reported with these therapies, chronic AMR (cAMR) and transplant glomerulopathy remain significant problems that are often unresponsive to current therapies. There is literature (Choi 2017) to support tocilizumab as a treatment option for cAMR and transplant glomerulopathy in human leucocyte antigen (HLA)-sensitive renal allograft recipients. Given limited alternative treatment options and supporting literature, tocilizumab may be an option for cAMR and transplant glomerulopathy who have failed standard therapy.</p>		
<p>Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD): Interstitial lung disease (ILD) is a common pulmonary manifestation of systemic sclerosis (SSc) and is a leading cause of systemic sclerosis-related death. SSc-ILD presents with fatigue, shortness of breath and dry cough. Diagnosis is based on the presence of characteristic findings of ILD on chest high resolution computed tomography (HRCT) in an individual with SSc and exclusion of other causes of ILD. The optimal treatment of SSc-ILD is unknown. Immunosuppressants, including mycophenolate and cyclophosphamide, are used off-label but the benefits are modest and the toxicities significant. Actemra was approved for preventing the decline of pulmonary function in adult patients with SSc-ILD. Approval was based on a post-hoc analysis of a randomized, double-blind, placebo-controlled trial of patients with SSc (Khanna 2020). Although primary efficacy endpoint in difference in change from baseline in skin fibrosis was not met, patients in the Actemra arm with ILD at baseline were observed to have less decline in baseline forced vital capacity (FVC) compared to placebo (-255 mL vs -14mL in 2 observed FVC; -6.40% vs 0.07% in percent predicted FVC). The subgroup with ILD had early, mild disease confirmed by HRCT with ppFVC greater than 55% (mean baseline 82%).</p>		
<p>Giant Cell Arteritis (GCA) and Polymyalgia Rheumatica (PMR): GCA is an inflammatory disease marked by vasculitis of large- and medium-sized vessels with common systemic symptoms including fatigue, fever, and weight loss. It is associated with PMR, a more common inflammatory condition characterized by aching and morning stiffness around the shoulders, hip, and neck. Both conditions occur in individuals over the age of 50 and are primarily treated with corticosteroids. Approximately half of individuals with GCA have PMR. Actemra is approved for GCA while Kevzara is approved for PMR; both are initiated with a tapering course of corticosteroids and then continued as monotherapy.</p>		

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<p>Other uses: The National Comprehensive Cancer Network® (NCCN) provides recommendations for off-label use of Actemra with a category 2A level of evidence. These include the use in steroid-refractory graft-versus-host-disease (Ganetsky 2019), immune checkpoint Inhibitor-related inflammatory arthritis, unicentric castleman’s disease, and Cytokine Release Syndrome (CRS) related to blinatumomab therapy. High-quality evidence supporting its safety and efficacy in these conditions has not been reported.</p>		
<p>IL-6 inhibitors have a black box warning for serious infections. Individuals treated with IL-6 inhibitors 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. IL-6 inhibitors should be discontinued if an individual develops a serious infection or sepsis. Individuals should be tested for latent tuberculosis (TB) before IL-6 inhibitor use and during therapy. Treatment for latent TB should be initiated prior to use. Risks and benefits of IL-6 inhibitors should be carefully considered prior to initiation of therapy in individuals with chronic or recurrent infection</p>		

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J3262	Injection, tocilizumab, 1 mg [Actemra]
C9399	Unclassified drugs or biologicals Hospital Outpatient Use ONLY) [when specified as sarilumab (Kevzara)]
J3490	Unclassified drug [when specified as sarilumab (Kevzara)]
J3590	Unclassified biologics [when specified as sarilumab (Kevzara)]

ICD-10	Description
C90.00-C95.92	Leukemias
D47.Z2	Castleman disease
M05.00-M05.9 R	Rheumatoid arthritis with rheumatoid factor
M06.00-M06.09	Rheumatoid arthritis without rheumatoid factor
M06.4	Inflammatory polyarthropathy
M06.80-M06.89	Other specified rheumatoid arthritis
M06.9	Rheumatoid arthritis, unspecified
M08.20-M08.29	Juvenile rheumatoid arthritis with systemic onset
M08.80-M08.89	Other juvenile arthritis
M08.3	Juvenile rheumatoid polyarthritis (seronegative)
M31.5	Giant cell arteritis with polymyalgia rheumatica
M31.6	Other giant cell arteritis
M34.81	Systemic sclerosis with lung involvement
M35.3	Polymyalgia rheumatica
R65.10-R65.11	Systemic inflammatory response syndrome (SIRS) of non-infectious origin [cytokine release syndrome]
T86.11	Kidney transplant rejection
T86.12	Kidney transplant failure
T86.19	Other complication of kidney transplant
U07.1	COVID-19
Z94.0	Kidney transplant status

## Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

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*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

## *Tocilizumab (Actemra)*

### **A. Criteria For Initial Approval**

- 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. Actemra (tocilizumab) is used in combination with a tapering course of corticosteroids (such as prednisone); OR
  - c. Actemra (tocilizumab) is used as a single agent following discontinuation of corticosteroids;

OR
- 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 methotrexate titrated to maximally tolerated dose (ACR 2021); OR
  - c. If methotrexate is not tolerated or contraindicated, individual has had an inadequate response to, is intolerant of, or has a contraindication to other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine);

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 DMARDs (such as methotrexate)];

OR
- iv. Still's disease (Adult-onset Still's Disease [AOSD] or Systemic juvenile idiopathic arthritis (SJIA) when the following is met:
  - a. Individual is 2 years of age or older with Still's Disease as either AOSD or SJIA;

OR
- v. Multicentric Castleman Disease when each of the following criteria are met (NCCN 2A):
  - a. Individual with a diagnosis of relapsed/refractory or progressive multicentric Castleman disease; AND
  - b. Used as a single agent; AND
  - c. Human immunodeficiency virus negative; AND
  - d. Human herpes-8 negative; AND

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<p>e. No concurrent clinically significant infection (for example, Hepatitis B or C); AND</p> <p>f. No concurrent lymphoma;</p> <p>OR</p> <p>vi. Cytokine Release Syndrome when the following criteria are met:</p> <p>a. Individual is 2 years of age or older with chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (Label, NCCN 2A);</p> <p>OR</p> <p>vii. Chronic Antibody-Mediated Renal Transplant Rejection when the following criteria are met (Choi 2017):</p> <p>a. Individual has chronic active antibody-mediated rejection plus donor-specific antibodies and transplant glomerulopathy; AND</p> <p>b. Individual has failed to respond to intravenous immune globulin (IVIG) plus rituximab therapy (with or without plasma exchange);</p> <p>OR</p> <p>viii. Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) when each of the following criteria is met:</p> <p>a. Individual has a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD); AND</p> <p>b. Diagnosis has been confirmed through chest high resolution computed tomography (HRCT) scan showing ground glass opacification or fibrosis; AND</p> <p>c. Documentation is provided that individual has confirmed pulmonary function tests showing Forced Vital Capacity (% FVC) greater than 55% of predicted (Khanna 2020);</p> <p>OR</p> <p>ix. Coronavirus Disease 2019 (COVID-19) when each of the following criteria are met:</p> <p>a. Individual is 18 years of age or older; AND</p> <p>b. Individual is currently hospitalized with COVID-19; AND Individual is currently receiving systemic corticosteroids and requires supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)</p> <p><b>B. Criteria For Continuation of Therapy</b></p> <p>i. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.</p> <p><b>C. Conditions Not Covered</b></p>		

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*Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):*

- i. In combination with topical or oral JAK inhibitors, ozanimod, deucravacitinib, nintedanib, pirfenidone, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, other IL-6 inhibitors, rituximab, or natalizumab; OR
- ii. If initiating therapy for a diagnosis other than COVID-19 or CRS, individual has an absolute neutrophil count less than 2000/mm<sup>3</sup>, platelet count less than 100,000/mm<sup>3</sup>, or alanine aminotransferase or aspartate aminotransferase greater than 1.5 times the upper limit of normal; OR
- iii. Tuberculosis, other active serious infections or a history of recurrent infections; OR
- iv. If initiating therapy for a diagnosis other than COVID-19 or CRS, 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 (unless switching therapy from another targeted immune modulator and no new risk factors); OR
- v. Individual with SSc-ILD and concomitant class II or higher pulmonary arterial hypertension (Khanna 2020); OR
- vi. When the above criteria are not met and for all other indications.

## *Sarilumab (Kevzara)*

### **A. Criteria For Initial Approval**

- i. Rheumatoid arthritis (RA) when each of the following criteria are met:
  - a. Individual is 18 years of age or older with moderately to severe RA; AND
  - b. Individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021); OR
  - c. If methotrexate is not tolerated or contraindicated, individual has had an inadequate response to, is intolerant of, or has a contraindication to other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine)

OR
- ii. Polymyalgia Rheumatica (PMR) when each of the following criteria are met:
  - a. Individual is 18 years of age or older with PMR; AND
  - b. Individual has had an inadequate response to corticosteroids or cannot tolerate corticosteroid taper; AND
  - c. Individual has had at least one episode of unequivocal PMR flare (unequivocal symptoms include shoulder and/or hip girdle pain associated with inflammatory stiffness) while on corticosteroid therapy (NCT03600818); AND

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<p>d. Kevzara (sarilumab) is used in combination with a tapering course of corticosteroids; OR</p> <p>e. Kevzara (sarilumab) is used in combination with a tapering course of corticosteroids.</p> <p><b>B. Criteria For Continuation of Therapy</b></p> <p>i. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.</p> <p><b>C. Conditions Not Covered</b>  <i>Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):</i></p> <p>i. In combination with topical or oral JAK inhibitors, ozanimod, deucravacitinib, nintedanib, pirfenidone, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, other IL-6 inhibitors, rituximab, or natalizumab; OR</p> <p>ii. If initiating therapy, individual has an absolute neutrophil count less than 2000/mm<sup>3</sup>, platelet count less than 150,000/mm<sup>3</sup>, or alanine aminotransferase or aspartate aminotransferase greater than 1.5 times the upper limits of normal; OR</p> <p>iii. Tuberculosis, other active serious infections or a history of recurrent infections; OR</p> <p>iv. If initiating therapy, 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 (unless switching therapy from another targeted immune modulator and no new risk factors); OR</p> <p>v. When the above criteria are not met and for all other indication</p>		



## Limits or Restrictions

### A. Therapeutic Alternatives

This medical policy may be subject to Step Therapy. Please refer to the document published on the MMM Website: <https://www.mmm-pr.com/planes-medicos/formulario-medicamentos>

### B. Quantity Limitations

*Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.*

Drug	Limit
Actemra (tocilizumab) 80 mg, 200 mg, & 400 mg vial for intravenous infusion	8 mg/kg* as frequently as every 4 weeks
Exceptions	
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;
IV.	For Coronavirus Disease 2019 (COVID-19), may approve a total of up to two intravenous doses at least 8 hours apart; each dose up to 8 mg/kg*.
*For rheumatoid arthritis, CRS, and COVID-19, each dose should not exceed 800mg total; For giant cell arteritis, each dose should not exceed 600 mg total.	

Drug	Limit
Actemra (tocilizumab) 162 mg/0.9 mL ACTPen prefilled autoinjector	4 autoinjectors per 28 days
Actemra (tocilizumab) 162 mg/0.9 mL prefilled syringe	4 syringes per 28 days

Drug	Limit
Kevzara (sarilumab) 150 mg, 200 mg prefilled pen/syringe	2 pens/syringes per 28 days

## Reference Information

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

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<ol style="list-style-type: none"> <li>2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <a href="http://dailymed.nlm.nih.gov/dailymed/about.cfm">http://dailymed.nlm.nih.gov/dailymed/about.cfm</a>. Accessed on: March 10, 2022.</li> <li>3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.</li> <li>4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.</li> <li>5. NCCN Drugs &amp; Biologics Compendium (NCCN Compendium®) 2022 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically. Accessed on: October 4, 2022.</li> <li>6. Fraenkel L, Bathon JM, England BR et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care &amp; Research. 2021;73(7):924-939. 6</li> <li>7. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis Rheum. 2022; 74(4):553-569.</li> <li>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.</li> <li>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.</li> <li>10. Ganetsky A, Frey NV, Hexner EO, et al. Tocilizumab for the treatment of severe steroid-refractory acute graft-versus-host-disease: analysis of a single-center experience. Leuk Lymphoma 2019:2223-2229.</li> <li>11. Varga J, Montesi S. Treatment and prognosis of interstitial lung disease in systemic sclerosis (scleroderma). Last updated: Jul 26, 2022. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: October 4, 2022.</li> <li>12. Centers for Disease Control and Prevention (CDC). Tuberculosis (TB). Available at: <a href="https://www.cdc.gov/tb/topic/basics/risk.htm">https://www.cdc.gov/tb/topic/basics/risk.htm</a>. Last updated: March 18, 2016. Accessed October 4, 2022.</li> <li>13. Khanna D, Lin CJF, Furst DE, et al; focuSSced investigators. Tocilizumab in systemic sclerosis: a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet Respir Med. 2020 Oct;8(10):963-974. Erratum in: Lancet Respir Med. 2020 Oct;8(10):e75. Erratum in: Lancet Respir Med. 2021 Mar;9(3):e29</li> </ol>		

# Medical Policy

Healthcare Services Department

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**Policy History**

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Policy Inception	Elevance Health’s Medical Policy adoption.	N/A	11/30/2023

Revised: 3/13/2023