JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP064
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	Subject **Actemra IV**	*Revision Date*	04/20/2022
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Actemra, Actemra IV

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I. POLICY

A. Actemra IV (tocilizumab) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Actemra IV may be approved for patients who meet the following:
1. Rheumatoid arthritis (RA)
a. Documentation has been submitted showing the following:
I. Patient has a diagnosis of active moderate or severe RA, and one of the following:
- Patient has previously received a biologic or targeted synthetic DMARD (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active RA
- Patient meets all the following:
  - Patient meets one of the following:
    - Patient has been tested for either of the following biomarkers and the test was positive, supported with a laboratory report:
      - Rheumatoid factor (RF)
      - Anti-cyclic citrullinated peptide (anti-CCP)
    - Patient has been tested for ALL of the following biomarkers, supported with a laboratory report:
      - RF
      - Anti-CCP
      - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
  - Patient meets one of the following:
    - Patient has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week)
    - Patient has had an intolerance to methotrexate, or a contraindication to its use such as one of the following:

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
- Breastfeeding
- Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
- Elevated liver transaminases
- History of intolerance or adverse event
- Hypersensitivity
- Interstitial pneumonitis or clinically significant pulmonary fibrosis
- Myelodysplasia
- Pregnancy or currently planning pregnancy
- Renal impairment
- Significant drug interaction

2. Articular juvenile idiopathic arthritis
   a. Documentation has been submitted showing the following:
      I. Patient has a diagnosis of active articular juvenile idiopathic arthritis, and one of the following:
         - Patient has previously received a biologic or targeted synthetic DMARD indicated for active articular juvenile idiopathic arthritis
         - Patient meets all the following:
            - Patient has had an inadequate response to methotrexate or another non-biologic DMARD administered at an adequate dose and duration
            - Patient has the following risk factors:
               - Positive rheumatoid factor
               - Positive anti-cyclic citrullinated peptide antibodies
               - Pre-existing joint damage
            - Patient meets one of the following:
               - High-risk joints are involved (e.g., cervical spine, wrist, or hip).
               - High disease activity
               - Judged to be at high risk for disabling joint disease
3. Systemic Juvenile Idiopathic Arthritis (sJIA)
   a. Documentation has been submitted showing the following:
      I. Patient has a diagnosis of active sJIA, and one of the following:
         - Patient has previously received a biologic indicated for active systemic juvenile idiopathic arthritis
         - Patient meets one of the following:
            - Patient has an inadequate response to at least a 1-month trial of nonsteroidal anti-inflammatory drugs (NSAIDs)
            - Patient has an inadequate response to at least a 2-week trial of corticosteroids
            - Patient has an inadequate response to at least a 3-month trial of methotrexate or leflunomide
4. Giant Cell Arteritis
   a. Documentation has been submitted showing the patient has a diagnosis of giant cell arteritis that was confirmed by one of the following:
      I. Temporal artery biopsy or cross-sectional imaging
      II. Acute-phase reactant elevation (i.e., high erythrocyte sedimentation rate [ESR] and/or high serum Creactive protein [CRP])
5. Cytokine release syndrome

a. Documentation has been submitted showing Actemra IV will be used for one of the following:
   1. Treatment of chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS)
   2. Treatment of cytokine release syndrome in members with refractory CRS related to blinatumomab therapy

6. Unicentric Castleman's Disease
   a. Documentation has been submitted showing that the patient has a diagnosis of unicentric Castleman's disease and the following:
      I. Patient is HIV-negative
      II. Patient is human herpesvirus-8-negative
      III. Actemra IV will be used as monotherapy
      IV. Actemra IV will be used as second-line therapy for relapsed or refractory disease
7. Multicentric Castleman's Disease
   a. Documentation has been submitted showing that the patient has a diagnosis of multicentric Castleman's disease and the following: when both of
      I. Actemra IV will be used as monotherapy
      II. Actemra IV will be used as second-line therapy for relapsed, refractory, or progressive disease
8. Immunotherapy-related Inflammatory Arthritis
   a. Documentation has been submitted showing the following:
      I. Patient has a diagnosis of severe or refractory immunotherapy-related inflammatory arthritis
      II. Patient has had inadequate response to corticosteroids and anti-inflammatory agents
9. Graft versus Host disease
   a. Documentation has been submitted showing the following:
      I. Patient has a diagnosis of acute graft versus host disease
      II. Patient meets one of the following:
         - Patient has experienced an inadequate response to systemic corticosteroids
         - Patient has an intolerance or contraindication to corticosteroids

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months of therapy
   1. Caveat: Approval for Cytokine release syndrome will limited to one month of therapy
B. Continuation of therapy may be approved based on indication:
   1. Moderately to severely active RA:
      a. Continuation of therapy may be approved in 12-month intervals with documentation showing the patient has achieved or maintained a positive clinical response as evidenced by:
         I. disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability
   2. Active articular juvenile idiopathic arthritis:
      a. Continuation of therapy may be approved in 12-month intervals with documentation showing the patient has achieved or maintained a positive clinical response as evidenced by:
         I. low disease activity, or improvement in any of the following from baseline:
            - Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
            - Number of joints with limitation of movement
            - Functional ability
   3. Active Systemic Juvenile Idiopathic Arthritis (sJIA):

a. Continuation of therapy may be approved in 12-month intervals with documentation showing the patient has achieved or maintained a positive clinical response as evidenced by:
   I. low disease activity, or improvement in any of the following from baseline:
      - Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
      - Number of joints with limitation of movement
      - Functional ability
      - Systemic symptoms (e.g., fevers, evanescent skin rashes)

4. Giant Cell Arteritis (GCA):
   a. Continuation of therapy may be approved in 12-month intervals with documentation showing the patient has achieved or maintained a positive clinical response as evidenced by:
      I. low disease activity, or improvement in any of the following from baseline:
         1.
            - Headaches
            - Scalp tenderness
            - Tenderness and/or thickening of superficial temporal arteries
            - Constitutional symptoms (e.g., weight loss, fever, fatigue, night sweats)
            - Jaw and/or tongue claudication
            - Acute visual symptoms (e.g., amaurosis fugax, acute visual loss, diplopia)
            - Symptoms of polymyalgia rheumatica (e.g., shoulder and/or hip girdle pain)
            - Limb claudication
5. Cytokine release syndrome, immunotherapy-related inflammatory arthritis, and Graft versus Host Disease:
   a. Continuation of therapy may be approved for the same duration as the initial approval for patients still meeting the criteria noted above
6. Unicentric and Multicentric Castleman's Diseases
   a. Continuation of therapy may be approved in 12-month intervals with documentation showing the patient is continuing to tolerate the regimen and there has not been disease progression while on treatment

IV. EXCLUSIONS

A. Actemra IV will not be covered for the following:
   1. Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) as this indication is only FDA-approved for the subcutaneous formulation of Actemra
   2. Any uses or other indications that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSAGE

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/ HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, tocilizumab, 1 mg	J3262

VII. REFERENCES

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VIII. APPROVALS

Signature on file at JHHC

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