



Actemra
Actemra (tocilizumab) J3262
Tofidence (tocilizumab-bavi) Q5133
Prior Authorization Request
Medicare Part B Form

Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

Form with checkboxes for Standard Request (72 Hours) and Urgent Request, and fields for Date Requested, Requestor, Clinic name, Phone, and Fax.

MEMBER INFORMATION

*Name: *ID#: *DOB:

PRESCRIBER INFORMATION

*Name: MD FNP DO NP PA *Phone:

*Address: *Fax:

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: Phone:

*Address: Fax:

PROCEDURE / PRODUCT INFORMATION

Table with 5 columns: HCPC Code, Name of Drug, Dose (Wt: kg Ht:), Frequency, End Date if known.

Self-administered Provider-administered Home Infusion

Chart notes attached. Other important information:

Diagnosis: ICD10: Description:

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)

- Rheumatoid arthritis, as indicated by 1 or more of the following:
Initial course, as indicated by ALL of the following:
Age 18 years or older
Inadequate response to treatment with disease-modifying antirheumatic drug
Moderate to severe active rheumatoid arthritis, as indicated by 1 or more of the following:
Clinical Disease Activity Index score greater than 10
Disease Activity Score of 3.2 or greater
Patient Activity Scale of 3.71 or greater
Patient Activity Scale-II of 3.71 or greater
Routine Assessment of Patient Index Data 3 score greater than 2
Simplified Disease Activity Index score greater than 11

- Juvenile idiopathic arthritis, as indicated by **1 or more** of the following:
 - Initial course, as indicated by **ALL** of the following:
 - Age 2 years or older
 - Treatment needed for disease severity, as indicated by **1 or more** of the following:
 - Polyarticular juvenile idiopathic arthritis, as indicated by **ALL** of the following:
 - Five or more joints involved
 - Intolerance or inadequate response to traditional disease-modifying antirheumatic drugs (eg, methotrexate)
 - Systemic juvenile idiopathic arthritis, as indicated by **ALL** of the following:
 - Active arthritis involving one or more joints
 - Fever for at least 2 weeks
 - Signs or symptoms, as indicated by **1 or more** of the following:
 - Evanescent erythematous rash
 - Generalized lymphadenopathy
 - Hepatomegaly or splenomegaly
 - Pericarditis, pleuritis, or peritonitis
- Systemic sclerosis-associated interstitial lung disease, as indicated by **ALL** of the following:
 - Age 18 years or older
 - Diagnosis of systemic sclerosis
 - Interstitial lung disease documented by high-resolution computed tomography
- Coronavirus disease 2019 (COVID-19), as indicated by **ALL** of the following:
 - Age 18 years or older
 - Hospitalized patient receiving systemic corticosteroids
 - Respiratory status as indicated by **1 or more** of the following:
 - Extracorporeal membrane oxygenation (ECMO) required
 - Mechanical ventilation, invasive or noninvasive, required
 - Supplemental oxygen required
- Cytokine release syndrome, as indicated by **ALL** of the following:
 - Age 2 years or older
 - Diagnosis of severe or life-threatening chimeric antigen receptor (CAR) T-cell-induced cytokine release syndrome
- Giant cell arteritis in patient age 18 years or older
 - **No active infection**
 - **No concurrent treatment with another biological disease-modifying antirheumatic drug**
 - **No evidence of gastrointestinal perforation, gastrointestinal bleeding, active peptic ulcer disease, or diverticulitis in prior 3 months**
 - **No untreated latent or active tuberculosis**
 - **No use of live vaccine during treatment**

If not, please provide **clinical rationale** for formulary exception: _____

Part B Prior Authorization Guidelines

Continuation Requests: (Clinical documentation required for all requests)

Rheumatoid arthritis

Subsequent course, as indicated by **ALL** of the following:

Age 18 years or older

Favorable response to prior administration of tocilizumab

Juvenile idiopathic arthritis

Subsequent course, as indicated by **ALL** of the following[Ⓜ]:

Age 2 years or older

Favorable response to prior administration of tocilizumab

Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Actemra PA

Drug Name(s):

ACTEMRA
TOFIDENCE

TOCILIZUMAB
TOCILIZUMAB-BAVI

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Initial approval will be for 6 months. Continuation may be approved for up to 12 months.

FDA Indications:

Actemra, Tofidence

- COVID-19, In hospitalized patients receiving systemic corticosteroids and require supplementation oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)
- Cytokine release syndrome, Chimeric antigen receptor T-cell induced, severe or life threatening disease (Actemra only)
- Juvenile idiopathic arthritis, Polyarticular
- Lung disease with systemic sclerosis (Actemra only)
- Rheumatoid arthritis (Moderate to Severe), In patients who had an inadequate response to disease modifying antirheumatic therapy
- Systemic onset juvenile chronic arthritis
- Temporal arteritis

Off-Label Uses:

- Renal transplant rejection, Chronic, active antibody-mediated rejection
- Rheumatoid arthritis (Moderate to Severe), With no previous treatment failure
- Thyroid eye disease (Moderate to Severe), Active

Age Restrictions:

2 years and older

Other Clinical Considerations:

Black Box Warning: (IV; powder for solution)

Patients treated with tocilizumab are at increased risk for infections, some progressing to serious infections leading to hospitalization or death. These infections have included bacterial infection, tuberculosis, invasive fungal, or other opportunistic infections. Evaluate for latent tuberculosis and treat if necessary prior to initiation of therapy. Monitor patients



Part B Prior Authorization Guidelines

receiving tocilizumab for signs and symptoms of infection, including tuberculosis, even if initial latent tuberculosis test is negative

Resources:

https://careweb.careguidelines.com/ed28/ac/ac04_107.htm#top

<https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidenceexpert.DoIntegratedSearch?navitem=headerLogout#>

Clinical / CMS
Only