Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 76.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Actemra IV (tocilizumab), Tolfidence IV (tocilizumab-bavi), Tyenne IV (tocilizumab-aazg)

Applicable line of business:

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Actemra IV (tocilizumab), Tolfidence IV (tocilizumab-bavi), Tyenne IV (tocilizumab-aazg)

II. Purpose/Objective:
To provide a policy of coverage regarding Actemra IV (tocilizumab), Tolfidence IV (tocilizumab-bavi), or Tyenne IV (tocilizumab-aazg)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

DESCRIPTION:
Tocilizumab is a humanized interleukin-6 receptor–inhibiting monoclonal antibody. It competes for both membrane-bound and soluble forms of the human interleukin-6 receptor, thus inhibiting the binding of interleukin to its receptors and leading to the blockade of interleukin-6 signaling through the soluble and membrane-bound interleukin-6 receptors. Interleukin-6 is a pro-inflammatory cytokine commonly expressed in patients with rheumatoid arthritis.

Indications which Do Not Require Prior Authorization for use:

Claims submitted with the following diagnosis for use do not require prior authorization for use:

- Chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS)

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

Actemra IV (tocilizumab), Tofidence IV (tocilizumab-bavi), or Tyenne IV (tocilizumab-aazg) will be considered medically necessary for commercial, exchange, and CHIP lines of business when all of the following criteria are met:

1. Adults with moderate to severe rheumatoid arthritis
   - Medical record documentation that member is 18 years of age or greater **AND**
   - Prescription written by a rheumatologist **AND**
   - Physician provided documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification of Diagnosis of Rheumatoid Arthritis) **AND**
   - Medical record documentation that Actemra or tocilizumab biosimilars are <u>not</u> being used concurrently with a TNF blocker or other biologic agent **AND**
   - Medical record documentation of a therapeutic failure on, contraindication to or intolerance to 12 weeks of Humira*, Rinvoq*, OR Xeljanz* **AND**
   - For tocilizumab reference product requests (i.e. Actemra IV), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to tocilizumab-bavi (Tolfidence*) and tocilizumab-aazg (Tyenne*).

     *Requires prior authorization

2. Active systemic juvenile idiopathic arthritis (SJIA)
   - Prescription written by a rheumatologist **AND**
   - Patient is 2 years of age or older **AND**
   - Medical record documentation of a diagnosis of systemic juvenile idiopathic arthritis **AND**
   - Medical record documentation that Actemra or tocilizumab biosimilars are <u>not</u> being used concurrently with a TNF blocker or other biologic agent **AND**
   - For tocilizumab reference product requests (i.e. Actemra IV), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to tocilizumab-bavi (Tolfidence*) and tocilizumab-aazg (Tyenne*).

     *Requires prior authorization

3. Active polyarticular juvenile idiopathic arthritis (PJIA)
   - Medical record documentation that member is 2 years of age or greater **AND**
   - Prescription is written by a rheumatologist **AND**
   - Medical record documentation of a diagnosis active polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND**
   - Medical record documentation that Actemra or tocilizumab biosimilars are <u>not</u> being used concurrently with a TNF blocker or other biologic agent **AND**
   - Physician provided documentation of a therapeutic failure on, contraindication to or intolerance to a minimum 4 month trial of Humira* **AND**
   - For tocilizumab reference product requests (i.e. Actemra IV), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to tocilizumab-bavi (Tolfidence*) and tocilizumab-aazg (Tyenne*).

     *Requires prior authorization

4. Giant Cell Arteritis
   - Medical record documentation of a diagnosis of Giant Cell Arteritis **AND**
   - Prescription written by a rheumatologist **AND**
   - Patient is 18 years of age or older **AND**
   - Medical record documentation that Actemra or tocilizumab biosimilars are not being used concurrently with a TNF blocker or other biologic agent **AND**
   - For tocilizumab reference product requests (i.e. Actemra IV), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to tocilizumab-bavi (Tolfidence*) and tocilizumab-aazg (Tyenne*).

     *Requires prior authorization

   Note to Reviewer: If Actemra or Tofidence IV are being prescribed for COVID-19, see the FDA website for Emergency Use Authorizations at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs for current FDA authorized use. At this time, Actemra is authorized for inpatient use only for COVID-19 and would not be covered for outpatient use.

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or a lack of progression in the signs and symptoms of the targeted disease state at six (6) months of therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of the targeted disease while on therapy.

Actemra IV (tocilizumab), Tofidence IV (tocilizumab-bavi), or Tyenne IV (tocilizumab-aazg) will be considered medically necessary for Medicare line of business when all of the following criteria are met:

1. Adults with moderate to severe rheumatoid arthritis
   - Medical record documentation that member is 18 years of age or greater **AND**
   - Prescription written by a rheumatologist **AND**
   - Physician provided documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification of Diagnosis of Rheumatoid Arthritis); **AND**
   - Medical record documentation that Actemra or tocilizumab biosimilars are not being used concurrently with a TNF blocker or other biologic agent **AND**
   - Medical record documentation of a therapeutic failure on, contraindication to or intolerance to at least one Disease-Modifying Anti-Rheumatic Drug (DMARD)

2. Active systemic juvenile idiopathic arthritis (SJIA)
   - Prescription written by a rheumatologist **AND**
   - Patient is 2 years of age or older **AND**
   - Medical record documentation of a diagnosis of systemic juvenile idiopathic arthritis **AND**
   - Medical record documentation that Actemra or tocilizumab biosimilars are not being used concurrently with a TNF blocker or other biologic agent

3. Active polyarticular juvenile idiopathic arthritis (PJIA)
   - Medical record documentation that member is 2 years of age or greater **AND**
   - Prescription is written by a rheumatologist; **AND**
   - Medical record documentation of a diagnosis active polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND**
   - Medical record documentation that Actemra or tocilizumab biosimilars are not being used concurrently with a TNF blocker or other biologic agent

4. Giant Cell Arteritis
   - Medical record documentation of a diagnosis of Giant Cell Arteritis **AND**
   - Prescription written by a rheumatologist **AND**
   - Patient is 18 years of age or older **AND**
   - Medical record documentation that Actemra or tocilizumab biosimilars are not being used concurrently with a TNF blocker or other biologic agent

Note to Reviewer: If Actemra or Tofidence IV are being prescribed for COVID-19, see the FDA website for Emergency Use Authorizations at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs for current FDA authorized use. At this time, Actemra is authorized for inpatient use only for COVID-19 and would not be covered for outpatient use.

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or a lack of progression in the signs and symptoms of the targeted disease state at six (6) months of therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of the targeted disease while on therapy.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Actemra [prescribing information]. South San Francisco, CA: Genentech Inc; December 2022.
2. Tofidence [Prescribing Information]. Cambridge MA. Biogen MA Inc. July 2024.
3. Tyenne [Prescribing Information]. Lake Zurich, IL. Fresenius Kabi USA, LLC. March 2024.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 3/10/10

Revised: 11/11 (added indication); 7/13 (indication added); 9/13; 2/14 (update auth period), 8/14, 11/18/14 (P&T); 12/31/14 (formulary alts updated for PJIA and RA), 9/15/15 (removed joint counts), 9/19/17 (CAR, CRS added), 9/18/18 (formulary alts updated), 1/21/20 (RA form alt), 2/28/22 (COVID-19 Note), 8/25/22 (Giant Cell Arteritis, formatting), 2/20/23 (LOB carve out, Medicaid business segment), 12/31/23 (references added), 9/17/24 (added biosimilars alts, deleted Medicaid business segment, LOB table, taglines)

Reviewed: 11/18/14, 9/28/16, 7/31/17, 8/30/18, 1/19/21, 1/18/22, 2/14/24

MA UM Committee approval: 12/31/23