Harvard Pilgrim Health Care – Pharmacy Prior Authorization Guideline

Guideline Name	Actemra (tocilizumab)

1 . Criteria

Product Name: Actemra subcutaneous injection*	
Diagnosis	Rheumatoid Arthritis (RA)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe rheumatoid arthritis (RA)

AND

2 - Patient is 18 years of age or older

AND

3 - Prescribed by (or in consultation with) a rheumatologist

AND

4 - ONE of the following:

- Trial with at least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine; OR
- Patient has been treated with a biologic agent approved for RA

AND

5 - Previous trial with TWO of the following:

- Enbrel
- Humira
- Xeljanz/Xeljanz XR
- Rinvoq

Notes	*Approval Duration: 12 months for up to 13 fills.

Product Name: Actemra subcutaneous injection*	
Diagnosis	Juvenile Idiopathic Arthritis (JIA)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of polyarticular or systemic juvenile idiopathic arthritis (PJIA or SJIA)

AND

2 - Patient is 2 years of age or older

AND

3 - Prescribed by (or in consultation with) a rheumatologist

AND

4 - ONE of the following:

- Trial with at least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine; OR
- Patient has been treated with a biologic agent approved for JIA

AND

5 - Previous trial with Enbrel AND Humira

Notes	*Approval Duration: 12 months for up to 13 fills.

Product Name: Actemra subcutaneous injection*	
Diagnosis	Giant Cell Arteritis (GCA)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of giant cell arteritis (GCA)

AND

2 - Patient is 18 years of age or older

AND

3 - Prescribed by (or in consultation with) a rheumatologist **AND** **4** - Previous trial with ONE of the following: • Corticosteroid therapy such as: prednisone; OR • Actemra

Notes	*Approval Duration: 12 months for up to 13 fills.

Product Name: Actemra subcutaneous injection*	
Diagnosis	All indications
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribed for one of the following diagnoses:
- rheumatoid arthritis
- giant cell arteritis
- systemic juvenile idiopathic arthritis
- polyarticular juvenile idiopathic arthritis

AND

2 - Prescribed by (or in consultation with) a rheumatologist

AND

3 - Documentation that the patient experienced improvement while on therapy

Notes	*Approval Duration: 12 months for up to 13 fills.

2 . Background

Benefit/Coverage/Program Information

RATIONALE
Ensure appropriate utilization criteria are met for the management of requests for tocilizumab for use as monotherapy or in combination with methotrexate or other non-biologic DMARD and promote use of preferred agents.

FDA APPROVED INDICATIONS
Actemra (tocilizumab) is an interleukin-6 (IL-6) receptor antagonist. The subcutaneous route of administration is indicated for the treatment of:

- Rheumatoid Arthritis (RA) in adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs)
- Giant Cell Arteritis (GCA) in adult patients
- Polyarticular Juvenile Idiopathic Arthritis (PJIA) in patients 2 years of age and older
- Systemic Juvenile Idiopathic Arthritis (SJIA) in patients 2 years of age and older

The IV formulation is also indicated for the treatment of the following conditions; however, the IV infused product would only be covered on the medical benefit:

- Rheumatoid Arthritis (RA) in adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs)
- Polyarticular Juvenile Idiopathic Arthritis (PJIA) in patients 2 years of age and older
- Systemic Juvenile Idiopathic Arthritis (SJIA) in patients 2 years of age and older
- Cytokine Release Syndrome (CRS) in adults and pediatric patients 2 years of age and older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome

REFERENCES

- Actemra (tocilizumab) [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; June 2019.

Created: 09/14
P&T Approval: 12/02/19
Effective: 1/1/20