Harvard Pilgrim Health Care – Pharmacy Prior Authorization Guideline

Guideline Name	Actemra (tocilizumab)

1 . Criteria

Product Name: Actemra subcutaneous injection	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 months for up to 13 fills
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 - ONE of the following:

5.1 - Trial and failure with TWO of the following (please specify drug names):

- Cimzia
- Humira
- Simponi
- Xeljanz/Xeljanz XR
- Rinvoq

OR

5.2 - Contraindication to ALL of the following: Cimzia, Humira, Simponi, Xeljanz/Xeljanz XR, and Rinvoq

Product Name: Actemra subcutaneous injection	
Diagnosis	Juvenile Idiopathic Arthritis (JIA)
Approval Length	12 months for up to 13 fills
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 - Trial and failure with or contraindication to Humira

Product Name: Actemra subcutaneous injection	
Diagnosis	Giant Cell Arteritis (GCA)
Approval Length	12 months for up to 13 fills
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

Product Name: Actemra subcutaneous injection	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
Approval Length	12 months for up to 13 fills
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)

AND

2 - Patient is 18 years of age or older

AND

3 - Prescribed by (or in consultation with) an appropriate specialist (e.g., rheumatologist or pulmonologist)

Product Name: Actemra subcutaneous injection	
Diagnosis	All indications
Approval Length	12 months for up to 13 fills
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribed for one of the following diagnoses:
- rheumatoid arthritis (RA)
- giant cell arteritis (GCA)
- systemic juvenile idiopathic arthritis (SJIA)
- polyarticular juvenile idiopathic arthritis (PJIA)

- systemic sclerosis-associated interstitial lung disease (SSc-ILD)

AND

2 - Prescribed by (or in consultation with) an appropriate specialist (e.g., rheumatologist or pulmonologist)

AND

3 - Documentation that the patient experienced improvement while on therapy

2 . Background

Benefit/Coverage/Program Information

RATIONALE

To ensure appropriate utilization criteria are met for the management of requests for Actemra (tocilizumab) for use as monotherapy or in combination with methotrexate or other non-biologic DMARD and to promote use of preferred agents where appropriate.

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
- Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) in adults (Systemic Sclerosis [SSc] is also known as scleroderma)
- 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.; March 2021.
- Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.

- Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. 2013;65(10):2499-512.
- 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 Rheumatol. 2019;71(6):846-863.
- Docken, WP. Treatment of giant cell arteritis. In: Curtis, MR, ed. UpToDate [database online]. Waltham, MA: UpToDate, 2020. https://www.uptodate.com. Accessed October 7, 2020.
- Varga J, Montesi S. Treatment and prognosis of interstitial lung disease in systemic sclerosis (scleroderma) In: Hollingsworth, H, ed. UpToDate [database online]. Waltham, MA: UpToDate, 2021. https://www.uptodate.com. Accessed April 7, 2021.

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Revised: • Annual review (effective: 1/1/20) • 10/7/20 - Annual review: background updates; criteria updates to account for new preferred agents (effective: 1/1/21) • 4/8/21 - Updated criteria to include new indication for Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
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