



## Prior Authorization Approval Criteria

### *Actemra (Tocilizumab)*

<b>Generic name:</b>	Tocilizumab
<b>Brand name:</b>	Actemra
<b>Medication class:</b>	Immunomodulator- interleukin-6 (IL-6) receptor inhibitor
<b>FDA-approved uses:</b>	Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to 1 or more tumor necrosis factor (TNF) antagonist therapies.
<b>Available dosage forms:</b>	Single use vials of 20mg/mL: 80mg/4ml 200mg/10ml 400mg/20ml
<b>Usual dose:</b>	IV infusion every 4 weeks, starting dose is 4mg/kg followed by an increase to 8mg/kg based on clinical response. Not recommended to exceed 800mg per dose.
<b>Approximate yearly cost:</b> (based on AWP 2010)	\$31,075.00/year
<b>Duration of therapy:</b>	Indefinite

**Criteria for use** (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Must be clinically diagnosed with moderately to severely active rheumatoid arthritis
- Must have tried and failed or intolerant to at least one DMARD
- Must have tried and failed or intolerant to methotrexate
- Must have tried and failed or intolerant to Enbrel and Humira.
- Must be 18 years of age or older.
- Must have a negative tuberculosis test or received treatment if tested positive.
- Absolute neutrophil count (ANC) must be  $> 2000/\text{mm}^3$
- Platelet count must be  $> 100,000/\text{mm}^3$
- ALT and AST must not be 1.5 times the upper limit of normal.
- Must not be used in combination with TNF antagonists, IL-1R antagonists, anti-CD20 monoclonal antibodies and selective co-stimulation modulators.
- May be used with methotrexate or other DMARDS (except for biological DMARDS).

**Caution:**

- Increased risk of serious infections.

**Monitoring:**

- Signs and symptoms of infections.

- Neutrophils, platelets and ALT and AST should be monitored every 4-8 weeks.
- Lipid parameters should be monitored 4-8 after initiation and every 6 months thereafter.

**Contraindication:**

- None known at this time.

**Not approved if:**

- Patient does not meet the above stated criteria.
- Absolute neutrophil count (ANC) < 2000/mm<sup>3</sup>
- Platelet count < 100,000/ mm<sup>3</sup>
- ALT and AST is 1.5 times the upper limit of normal.

**Special considerations:**

**Dose Modifications:**

<b>Liver Enzyme Abnormalities</b>	
<b>Lab Value</b>	<b>Recommendation</b>
> 1-3x ULN	Dose modify concomitant DMARDs if appropriate. For persistent increases in this range, reduce Actemra dose to 4 mg/kg or interrupt Actemra until ALT/AST have normalized
> 3-5x ULN	Interrupt Actemra dosing until, 3x ULN and follow recommendations above for >1-3x ULN. For persistent increases >3x ULN, discontinue Actemra
> 5x ULN	Discontinue Actemra

<b>Low Absolute Neutrophil Count (ANC)</b>	
<b>Lab Value (cells/mm<sup>3</sup>)</b>	<b>Recommendation</b>
ANC > 1000	Maintain dose
ANC 500-1000	Interrupt Actemra dosing. When ANC >1000 cells/mm <sup>3</sup> resume Actemra at 4mg/kg and increase to 8 mg/kg as clinically appropriate.
ANC <500	Discontinue Actemra

<b>Low Platelet Count</b>	
<b>Lab Value (cells/mm<sup>3</sup>)</b>	<b>Recommendation</b>
50,000-100,000	Interrupt Actemra dosing. When platelet count is > 100,000 cells/mm <sup>3</sup> resume Actemra at 4mg/kg and increase to 8mg/kg as clinically appropriate.
< 50,000	Discontinue Actemra

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 06/09/10

Revised: 03/14/12