

## Corporate Medical Policy

### Tocilizumab (Actemra)

<b>File Name:</b>	tocilizumab_actemra
<b>Origination:</b>	02/2010
<b>Last CAP Review:</b>	2/2011
<b>Next CAP Review:</b>	02/2012
<b>Last Review:</b>	6/2011

#### Description of Procedure or Service

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Rheumatoid arthritis is a chronic condition where the person's own immune system causes inflammation of the joints and the tissue around the joints. The body is equipped with a defense mechanism called the immune system which protects you from disease and infection. When a person has an autoimmune condition, the immune system creates antibodies that attack its own tissues by mistake. Rheumatoid arthritis usually starts between the age of 25 and 55 and the cause is unknown. Symptoms of rheumatoid arthritis (RA) are described as painful inflammation of the synovial tissue lining the joints. These patients have elevated levels of tumor necrosis factor alpha (TNF-a) in their joints. Chronic joint inflammation leads to tissue break down, cell damage to the bone, edema, warmth, redness, joint stiffness, and pain. These patients are also fatigued, weak, have a low-grade fever, and loss of appetite.

Tocilizumab (Actemra®) is a recombinant humanized anti-human interleukin 6 (IL-6) receptor monoclonal antibody of the immunoglobulin IgG1κ subclass with a typical H<sub>2</sub>L<sub>2</sub> polypeptide structure. Tocilizumab binds specifically to both soluble and membrane-bound IL-6 receptors, and has been shown to inhibit IL-6-mediated signaling through these receptors. IL-6 has been shown to be involved in diverse physiological processes such as T-cell activation, induction of immunoglobulin secretion, initiation of hepatic acute phase protein synthesis, and stimulation of hematopoietic precursor cell proliferation and differentiation. IL-6 is also produced by synovial and endothelial cells leading to local production of IL-6 in joints affected by inflammatory processes such as rheumatoid arthritis.

Tocilizumab is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more Tumor Necrosis Factor (TNF) antagonist therapies.

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

#### Policy

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**BCBSNC will provide coverage for Tocilizumab (Actemra®) for the treatment of rheumatoid arthritis when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.**

#### Benefits Application

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Please refer to the Member's Benefit Booklet for availability of benefits. This policy relates only to the services or supplies described herein. Member's benefits may vary according to benefit design, therefore Member benefit language should be reviewed before applying the terms of this medical policy.

Coverage for Tocilizumab (Actemra®) requires prior review.

# Tocilizumab (Actemra)

## When Tocilizumab (Actemra®) is covered

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Tocilizumab (Actemra®) may be medically necessary for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.

## When Tocilizumab (Actemra®) is not covered

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Tocilizumab (Actemra®) is not covered for use in patients with an absolute neutrophil count (ANC) below 2000/mm<sup>3</sup>, platelet count below 100,000/mm<sup>3</sup>, or who have ALT or AST above 1.5 times the upper limit of normal.

Tocilizumab (Actemra®) should not be administered in patients with an active infection, including localized infections. The risks and benefits of treatment should be considered prior to initiation of Tocilizumab (Actemra®) in patients:

- with chronic or recurrent infection;
- who have been exposed to tuberculosis;
- with a history of serious or opportunistic infection;
- who have resided or traveled in areas of endemic tuberculosis or endemic mycoses; or with underlying conditions that may predispose them to these infections.

Tocilizumab (Actemra®) should not be used in combination with biological DMARDs such as TNF antagonists, anakinra (Kineret®), rituximab (Rituxan®), and abatacept (Orencia®).

## Policy Guidelines

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Serious and sometimes fatal infections due to bacterial, mycobacterial, invasive fungal, viral, protozoal, or other opportunistic pathogens have been reported in patients receiving immunosuppressive agents including Tocilizumab for rheumatoid arthritis. Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment, as signs and symptoms of acute inflammation may be lessened due to suppression of the acute phase reactants.

Tocilizumab may be used alone or in combination with methotrexate or other DMARDs.

The safety and effectiveness of Tocilizumab in pediatric patients and pregnant or nursing women has not been established.

According to the Food and Drug Administration (FDA) approved labeling for Tocilizumab, the dose should not exceed 800 mg every 28 days.

The approved labeling does not describe circumstances in which dosages above this maximum would be considered safe and effective.

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

# Tocilizumab (Actemra)

*Applicable codes: J3262*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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U.S. Food and Drug Administration. BLA Approval letter dated January 8, 2010. BL 1215276.

U.S. Food and Drug Administration. Actemra® Prescribing Information. Retrieved 2/1/10 from [http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label\\_ApprovalHistory#aphist](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#aphist)

Actemra® Medication Guide. Retrieved 2/1/10 from [http://www.actemra.com/pdf/medication\\_guide.pdf](http://www.actemra.com/pdf/medication_guide.pdf)

Specialty Matched Consultant Advisory Panel Review 2/2011

U.S. Food and Drug Administration. Prescribing information. Retrieved 6/23/11 from <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM197463.pdf>

FDA website. Retrieved 6/23/11 from <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM197463.pdf>

## Policy Implementation/Update Information

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- 3/2/10 New medical policy issued. Tocilizumab (Actemra®) may be medically necessary for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies. Notification date 3/02/10 for effective date of 6/08/10. (adn)
- 1/4/11 Added new HCPCS code J3262 to Billing/Coding section. Removed J3590. (lpr)
- 3/15/11 Specialty Matched Consultant Advisory Panel Review 2/2011. Added “these infections” to end of last bullet statement which reads “who have resided or traveled in areas of endemic tuberculosis or endemic mycoses; or with underlying conditions that may predispose them to these infections.” (lpr)
- 7/1/11 Added quantity limitations to Policy Guidelines. Medical director review 6/2011. Notification date 7/1/11 for effective date of 10/1/11. (lpr)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.