`I. Requirements for Prior Authorization of Cytokine and CAM Antagonists

A. Prescriptions That Require Prior Authorization

All prescriptions for Cytokine and CAM Antagonists must be prior authorized. See Preferred Drug List (PDL) for the list of preferred Cytokine and CAM Antagonists at: www.providersynergies.com/services/documents/PAM_PDL.pdf

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Cytokine and CAM Antagonist, the determination of whether the requested prescription is medically necessary will take into account the guidelines listed in Attachments 1-10:

1. Attachment 1: Amevive
2. Attachment 2: Enbrel
3. Attachment 3: Humira
4. Attachment 4: Kineret
5. Attachment 5: Orencia
6. Attachment 6: Remicade
7. Attachment 7: Cimzia
8. Attachment 8: Actemra
9. Attachment 9: Simponi
10. Attachment 10: Stelara

C . Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in the corresponding Section B. Attachment, to assess the medical necessity of the request for a prescription for a Cytokine and CAM Antagonist. If the guidelines in the corresponding Section B. Attachment are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

D. Dose and Duration of Therapy

The Department will limit authorization to the U.S. Food and Drug Administration (FDA) maximum recommended therapeutic dose for specific indications for each Cytokine and CAM Antagonist.

References:

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2. Anakinra [package insert]. Thousand Oaks, CA: Amgen; October 2002
3. Enbrel[package insert]. Thousand Oaks, CA: Immunex Corp.; March 2008
4. Humira[package insert]. North Chicago, IL: Abbott Laboratories; February 2007.
5. Orencia[package insert]. Princeton, NJ:Bristol-Myers Squibb; April 2008
6. Raptiva[package insert]. South San Franciso, CA: Genetech, Inc.; June 2005
7. Remicade[package insert]. Malvern, PA: Centocor, Inc.; October 2006
8. Recommendations for the Use of Nonbiologic and Biologic Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis; American College of Rheumatology 2008 Arthritis & Rheumatism 2008; 59(6): 762-784
9. Braun J, Davis J, Dougados M, et.al. First Update of the International ASAS Consensus Statement for the Use of Anti-Tumor Necrosis Factor Agents in Patients with Ankylosing Spondylitis; Ann Rheum Dis 2006; 65: 316-320
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11. Mease PJ, Goffe BS, Diagnosis and Treatment of Psoriatic Arthritis; J AM Acad Dermatol 2005; 52(1): 1-19
12. Hashkes PJ, Laxer RM, Medical Treatment of Juvenile Idiopathic Arthritis; JAMA 2005; 294(13): 1671-1684
13. Cimzia[package insert]. Smyrna, GA: UCB, Inc; April 2008
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18. FDA Alert: Information for Healthcare Professionals: http://www.fda.gov/cder/drug/InfoSheets/HCP/TNF_blockersHCP.htm
19. Menter A, et al. American Academy of Dermatology, Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 1. 2008.02.039; and Section 4. 2009.03.027
20.
21. Simponi [package insert]. Horsham, PA; Centocor Ortho Biotech Inc.; July 2010
22. Stelara [package insert]. Horsham, PA; Centocor Ortho Biotech Inc.; December 2009
23. Actemra Prescribing information. Genentech Inc. San Francisco, CA. April 2011
24. Beukelman et.al. 2011 American College of Rheumatology Recommendations For The Treatment Of Juvenile Idiopathic Arthritis: Initiation And Safety Monitoring of Therapeutic Agents For The Treatment Of Arthritis And Systemic Features: Arthritis Care & Research; 63 (4), 465–482

***DMARDs include: Cyclosporine, Leflunomide, Sulfasalazine, Methotrexate, Azathioprine**

Requirements for Prior Authorization of Cytokine and CAM Antagonists

Attachment 8: Actemra - In evaluating a request for prior authorization of Actemra, the determination of whether the requested prescription is medically necessary will take into account the following:

1. Whether the recipient:

a. Has a diagnosis of moderate to severe active Rheumatoid Arthritis
AND
b. Is 18 years of age or older

OR

c. Has a diagnosis of active Systemic Juvenile Idiopathic Arthritis (SJIA)
AND
d. Is 2 years of age or older but less than 18 year of age

AND

e. Was prescribed the medication by a specialist (i.e. dermatologist, gastroenterologist, rheumatologist, etc.)

AND

f. Is not taking a Cytokine and CAM Antagonist in combination with any other biologic disease Modifying Anti-Rheumatic Drug (DMARD)

AND

g. Was evaluated for active or latent tuberculosis infection by documented test results (PPD testing) or blood testing

AND

h. If under 21 years of age, is up to date on immunizations in accordance with current Early and Periodic Screening Diagnosis and Treatment (EPSDT) immunization guidelines prior to initiating therapy with Actemra

AND

i. Has a documented history of therapeutic failure of the preferred Cytokine and CAM Antagonists approved for this indication

***DMARDs include: Cyclosporine, Leflunomide, Sulfasalazine, Methotrexate, Azathioprine**

AND

j. For a diagnosis of severe active Rheumatoid Arthritis, has a documented history of therapeutic failure of a three (3) or more month trial of or documented contraindication or intolerance to:

i. Methotrexate

OR

ii. An alternate disease-modifying anti-rheumatic drug (DMARD*)

2. For an initial request:

a. Does not have transaminases ALT or AST greater than 1.5 times the upper limit of normal

AND

b. Does not have an absolute neutrophil count (ANC) below 2000 per mm^3

AND

c. Does not have a platelet count below 100,000 per mm^3

3. For a renewal of a prescription that was previously approved, whether:

a. The recipient had an improvement in disease activity and/or level of functioning

AND

b. The medication was well tolerated

AND

c. The requested medication was dosed according to package labeling and adjusted if needed for side effects (such as liver abnormalities)

d. The recipient did not develop:

i. An elevated ALT or AST greater than 5 times the upper limit of normal during previous treatment cycle(s).

OR

***DMARDs include: Cyclosporine, Leflunomide, Sulfasalazine, Methotrexate, Azathioprine**

ii. An absolute neutrophil count (ANC) below 500 per mm^3

OR

iii. A platelet count below 50,000 per mm^3

OR

4. The recipient does not meet the clinical review guidelines listed above, but in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

***DMARDs include: Cyclosporine, Leflunomide, Sulfasalazine, Methotrexate, Azathioprine**