

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 whether:

1. The prescribed Cytokine and CAM Antagonist is for treatment of a condition that is a **U.S.** Food and Drug Administration (FDA) approved, or a medically accepted, indication

AND

2. If the request is for a non-preferred Cytokine and CAM antagonist, the recipient has a documented history of therapeutic failure, contraindication or intolerance to the preferred Cytokine and CAM Antagonists approved for the recipient's indication

AND

3. If the request is for Amevive, the recipient:
 - a. Does not have a history of receiving Amevive therapy for a duration of 12 months

AND

- b. Has CD4 positive T lymphocyte counts \geq 250 cells/mcL

OR

4. If the request is for Actemra:
 - a. For an initial request, the recipient:
 - i. Does not have transaminases ALT or AST greater than 1.5 times the upper limit of normal.

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AND

- ii. Does not have an absolute neutrophil count (ANC) below 2000 per mm³

AND

- iii. Does not have a platelet count below 100,000 per mm³

AND

- 5. For treatment of Crohn's Disease or moderate to severe Ulcerative Colitis, the recipient:
 - a. Has a diagnosis of Crohn's Disease or Ulcerative Colitis which has remained active despite treatment with one or more of the following therapies:
 - i. Aminosalicylates OR
 - ii. Corticosteroids OR
 - iii. Immunomodulators

AND

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

AND

- c. Is not taking any other Cytokine and CAM Antagonist

AND

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

AND

- e. 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

OR

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6. For treatment of moderate to severe active Rheumatoid Arthritis OR Juvenile Idiopathic Arthritis (JIA), the recipient:

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

AND

b. Is not taking any other Cytokine and CAM Antagonist

AND

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

AND

d. 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

AND

e. Has a documented history of therapeutic failure of a three (3) or more month trial of or a documented contraindication or intolerance to:

i. Methotrexate OR

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

OR

7. For treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) the recipient:

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

AND

b. Is not taking any other Cytokine and CAM Antagonist

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

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AND

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

AND

- d. 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

OR

- 8. For treatment of Ankylosing Spondylitis, or other Spondyloarthropathies, OR a diagnosis of active Psoriatic Arthritis the recipient:

- a. Has Axial Disease **AND:**

- i. A documented history of therapeutic failure of a six (6) week trial of two (2) Non-Steroidal Anti-Inflammatory drugs (NSAIDs) **OR**
- ii. A documented contraindication or intolerance to NSAIDs

OR

- b. Has Peripheral Disease **AND:**

- i. A documented history of therapeutic failure of a six (6) week trial of two (2) NSAIDs **AND**
- ii. A documented history of therapeutic failure of a three (3) or more month trial of methotrexate OR an alternate DMARD* **OR**
- iii. A documented contraindication or intolerance to NSAIDs, methotrexate, or an alternate DMARD*

AND

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

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

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AND

- d. Is not taking any other Cytokine and CAM Antagonist

AND

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

AND

- f. 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

OR

- 9. For treatment of chronic moderate to severe Plaque Psoriasis, whether the recipient:

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

AND

- b. Is not taking any other Cytokine and CAM Antagonist

AND

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

AND

- d. 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

AND

- e. Has a body surface area (BSA)
 - i. Of 10% or more that is affected; **OR**

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- ii. Involvement of < 10% in critical areas (palms, soles, genitals or face) that interferes with daily activities

AND

- f. Has a history of therapeutic failure of a three (3) or more month trial of one of the following photochemotherapies OR a documented history of intolerance or contraindication to:
 - i. Psoralens (methoxsalen, trioxsalen) with UVA light (PUVA) **OR**
 - ii. UVB light with coal tar or dithranol

AND

- g. History of therapeutic failure, contraindication or intolerance of a trial of oral systemic therapy (Methotrexate, Cyclosporine, Soriatane)

OR

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

11. For a renewal of a prescription that was previously approved:

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

AND

- b. For Actemra:
 - i. The requested medication was dosed according to package labeling and adjusted if needed for side effects (such as liver abnormalities)

AND

- ii. The recipient:
 - a) Did not develop Elevated ALT or AST greater than 5 times the upper limit of normal during previous treatment cycle(s)

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AND

- b) Did not develop An absolute neutrophil count (ANC) below 500 per mm³

AND

- c) Did not develop A platelet count below 50,000 per mm³

OR

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

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 as follows:

1. The U.S. Food and Drug Administration (FDA) maximum recommended therapeutic dose for specific indications for each Cytokine and CAM Antagonist.
2. For Amevive when prescribed for the treatment of plaque psoriasis, no more than 2 treatment cycles per year.

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References:

1. Amevive [package insert]. Cambridge, MA: Biogen Idec Inc.; May 2010
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 Francisco, 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
10. Kyle S, Chandler D, Griffiths CEM, et. al. Guidelines for Anti-Tumor Necrosis Factor in Psoriatic Arthritis; Rheumatology 2005; 44(3): 390-397
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
14. FDA MedWatch Report:
http://www.fda.gov/cder/drug/early_comm/TNF_blockers.htm
Accessed on January 26, 2009.
15. FDA Alert: Information for Healthcare Professionals:
http://www.fda.gov/cder/drug/InfoSheets/HCP/TNF_blockersHCP.htm
Accessed on January 26, 2009.
16. Cimzia[package insert]. Smyrna, GA: [UCB, Inc](#); Nov 2008
17. FDA MedWatch Report:
http://www.fda.gov/cder/drug/early_comm/TNF_blockers.htm
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. Simponi [package insert]. Horsham, PA; Centocor Ortho Biotech Inc.; July 2010
21. Stelara [package insert]. Horsham, PA; Centocor Ortho Biotech Inc.; December 2009
22. Actemra Prescribing information. Genentech Inc. San Francisco, CA. April 2011
23. 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