

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 the Preferred Drug List (PDL) for the list of preferred Cytokine and CAM Antagonists at:

[www.providersynergies.com/services/documents/PAM\\_PDL.pdf](http://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 following:

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. The prescribed dose of the Cytokine and CAM Antagonist is appropriate for the recipient's renal function in accordance with the package labeling

**AND**

4. The Cytokine and CAM Antagonist is prescribed by, or in consultation with, a specialist (i.e. gastroenterologist, dermatologist, rheumatologist, etc.)

**AND**

5. If under 21 years of age, the recipient 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. If 21 years of age or older, the recipient is up to date on immunizations prior to initiating therapy

**AND**

7. The recipient:

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

**AND**

- b. For a biologic DMARD:

- i. Was evaluated for active or latent tuberculosis infection documented by either test results (purified protein derivative [PPD] testing) or blood testing

**AND**

- ii. Does not have active, severe uncontrolled infection

**AND**

- iii. Has documented hepatitis B antibody titer  $\geq 10$  mIU/mL

**OR**

- iv. Has documented hepatitis B screening

**AND**

- v. Does not have acute hepatitis B

**AND**

- vi. Does not have chronic hepatitis B with Child-Pugh class B or C

**AND**

8. For an initial request for Actemra (tocilizumab), whether the recipient:

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

**AND**

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- b. Does not have an absolute neutrophil count (ANC) below 2000 per mm<sup>3</sup>

**AND**

- c. Does not have a platelet count below 100,000 per mm<sup>3</sup>

**AND**

- 9. For an initial request for Xeljanz (tofacitinib citrate), whether the recipient:

- a. Does not have severe hepatic impairment

**AND**

- b. Does not have a lymphocyte count less than 500 cells/mm<sup>3</sup>

**AND**

- c. Does not have a hemoglobin less than 9 g/dL

**AND**

- d. Does not have an absolute neutrophil count (ANC) below 1000 cells per mm<sup>3</sup>

**AND**

- e. Is not taking a potent CYP3A4 inducer

**AND**

- 10. For an initial request for Entyvio (vedolizumab), the recipient:

- a. Had baseline LFTs

**AND**

- b. Does not have jaundice or elevated transaminases and/or bilirubin

**AND**

- c. Has never taken Tysabri (natalizumab)

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**AND**

11. For an initial request for Otezla (apremilast), the recipient:

- a. Was evaluated by a psychiatrist if the recipient has a history of prior suicide attempt, bipolar disorder, or major depressive disorder

**OR**

- b. For all others, had a mental health evaluation performed by the prescriber

**AND**

- c. Is not taking a strong cytochrome P450 enzyme inducer

**AND**

- d. Is being regularly monitored for weight loss

**AND**

12. 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**

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

- a. 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**

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

**AND**

14. 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**

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

a. Has a body surface area (BSA):

- i. Of 10% or more that is affected; **OR**
- ii. Involvement of < 10% in critical areas (palms, soles, genitals or face) that interferes with daily activities

**AND**

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

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- b. 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**

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

**OR**

- 16. 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.

FOR RENEWALS OF PRESCRIPTIONS FOR CYTOKINE AND CAM ANTAGONISTS: The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Cytokine and CAM Antagonists that were previously approved will take into account the following:

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

**AND**

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

**AND**

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

**AND**

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- ii. Did not develop an absolute neutrophil count (ANC) below 500 per mm<sup>3</sup>

**AND**

- iii. Did not develop A platelet count below 50,000 per mm<sup>3</sup>

**AND**

- 3. For Xeljanz (tofacitinib citrate), whether the recipient:

- a. Is being prescribed a dose that is in accordance with the package labeling and adjusted for side effects (e.g. liver abnormalities), as necessary

**AND**

- b. Has documented lymphocyte counts every 3 months

**AND**

- c. Did not develop lymphocyte count below 500 cells per mm<sup>3</sup>

**AND**

- d. Has a documented neutrophil count after 4-8 weeks of therapy then every 3 months

**AND**

- e. Did not develop an absolute neutrophil count (ANC) below 500 cells per mm<sup>3</sup>

**AND**

- f. Has documented hemoglobin levels after 4-8 weeks of therapy then every 3 months

**AND**

- g. Did not develop hemoglobin less than 8.0 g/dL or have a decrease greater than 2 g/dL

**AND**

- h. Has documented routine monitoring of liver function tests (LFTs)

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**AND**

- i. Has a documented lipid panel following 4-8 weeks of therapy

**AND**

- j. Is not taking a potent CYP3A4 inducer

**AND**

- 4. For Otezla (apremilast), whether the recipient:

- a. Is not taking a strong cytochrome P450 enzyme inducer

**AND**

- b. Has documentation of regular weight monitoring

**AND**

- c. If positive for a history of prior suicide attempt, bipolar disorder, major depressive disorder, continues to receive treatment for that condition

**OR**

- 5. 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 Section B. to assess the medical necessity of the request for a prescription for a Cytokine and CAM Antagonist. If the guidelines in Section B. 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

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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.

**References:**

1. Anakinra [package insert]. Thousand Oaks, CA: Amgen; October 2002
2. Raptiva[package insert]. South San Francisco, CA: Genentech, Inc.; June 2005
3. 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
4. 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](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](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](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](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

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24. Saag KG et.al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis and Rheumatology*. 2008;59(6):762
25. UpToDate, Tumor necrosis factor-alpha inhibitors: Risk of bacterial, viral, and fungal infections; accessed October 17, 2012.
26. Actemra package insert. Genentech Inc. 2012
27. Lok A, Bonis P. Hepatitis B virus reactivation associated with immunosuppression, UpToDate. Accessed March 7, 2013.
28. Enbrel package insert. Immunex Corporation, Thousand Oaks, CA. December 2012.
29. Remicade package insert. Janssen Biotech, Inc., Horsham, PA. October 2011.
30. Humira package insert. Abbvie Inc., North Chicago, IL. February 2013.
31. Oencia package insert. Bristol-Myers Squibb, Princeton, NJ. December 2011.
32. Xeljanz package insert. Pfizer Inc, New York, NY. November 2012.
33. Entyvio prescribing information. Takeda Pharmaceuticals America, Inc. May 2014
34. Otezla prescribing information. Celgene Corporation, March 2014
35. Overview of the medical management of severe or refractory Crohn disease in adults. UpToDate, accessed July 10, 2014.
36. Approach to adults with steroid-refractory and steroid-dependent ulcerative colitis. UpToDate, accessed July 10, 2014.
37. Menter A, et al. American Academy of Dermatology, Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6. *Journal of the American Academy of Dermatology* 2011; 65:137-74.
38. Brown, T. FDA Oks Vedolizumab (Entyvio) for Ulcerative Colitis, Crohn's. *Medscape News*, May 20, 2014.