

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](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 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

**AND**

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6. The recipient:

a. Is not taking any other Cytokine and CAM Antagonist

**AND**

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

**AND**

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

**OR**

d. Has documented hepatitis B screening

**AND**

e. Does not have acute hepatitis B

**AND**

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

7. 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**

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**

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

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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

9. 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**

10. 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**
- ii. An alternate disease-modifying anti-rheumatic drug (DMARD\*)

**AND**

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

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11. 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**

12. 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**

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:

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

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- 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**

13. 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.

14. 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 (tocilizumab):

- 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)

**AND**

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

**AND**

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

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**AND**

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

- i. 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**

- ii. Has documented lymphocyte counts every 3 months

**AND**

- iii. Did not develop lymphocyte count below 500 cells per  $\text{mm}^3$

**AND**

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

**AND**

- v. Did not develop an absolute neutrophil count (ANC) below 500 cells per  $\text{mm}^3$

**AND**

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

**AND**

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

**AND**

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

**AND**

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

**AND**

- x. Is not taking a potent CYP3A4 inducer

**OR**

15. 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

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.

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