Clinical Policy: Cytokine and CAM Antagonists

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Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Cytokine and CAM Antagonists is **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Cytokine and CAM Antagonists

A. <u>Prescriptions That Require Prior Authorization</u>

All prescriptions for Cytokine and CAM Antagonists must be prior authorized.

B. <u>Review of Documentation for Medical Necessity</u>

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 the member:

1. Is prescribed the Cytokine and CAM Antagonist for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

4. Is prescribed the Cytokine and CAM Antagonist by or in consultation with an appropriate specialist (e.g., gastroenterologist, dermatologist, rheumatologist, ophthalmologist, immunologist, genetic specialist, pulmonologist, oncologist, etc.); **AND**

5. Does not have a contraindication to the prescribed medication; AND

6. If currently using a different Cytokine and CAM Antagonist, **one** of the following:

    a. Will discontinue use of that Cytokine and CAM Antagonist prior to starting the requested Cytokine and CAM Antagonist,

b. **One** of the following:

i. Has a medical reason for concomitant use of both Cytokine and CAM Antagonists that is supported by peer-reviewed medical literature or national treatment guidelines,
ii. Is dependent on glucocorticoids in addition to a Cytokine and CAM Antagonist to prevent life-threatening complications,
iii. Has 2 or more autoimmune or autoinflammatory conditions for which a single Cytokine and CAM Antagonist is not sufficient;

AND

7. For a Cytokine and CAM Antagonist associated with an increased risk of infection according to the FDA-approved package labeling, was evaluated for **both** of the following if recommended in the FDA-approved package labeling:

a. Active or latent tuberculosis infection documented by results of a tuberculin skin test (purified protein derivative [PPD]) or blood test (interferon-gamma release assay),
b. Hepatitis B infection documented by results of anti-HBs, HBsAg, and anti-HBc;

AND

8. For a Cytokine and CAM Antagonist associated with behavioral and/or mood changes as stated in the FDA-approved package labeling (e.g., Otezla, Siliq), was evaluated for a history of prior suicide attempt, bipolar disorder, or major depressive disorder; **AND**

9. For treatment of Crohn's disease, **one** of the following:

a. Has a diagnosis of moderate-to-severe Crohn's disease and **one** of the following:

i. Failed to achieve remission with or has a contraindication or intolerance to an induction course of corticosteroids,

ii. **One** of the following:

a) Failed to maintain remission with a conventional immunomodulator in accordance with current consensus guidelines[1]
b) Has a contraindication or intolerance to conventional

[1] e.g., American College of Gastroenterology [ACG], American Gastroenterological Association [AGA], Canadian Association of Gastroenterology [CAG], European Crohn's and Colitis Organization [ECCO]

immunomodulators in accordance with current consensus guidelines,

b. Has a diagnosis of Crohn's disease that is associated with one or more high-risk or poor prognostic feature(s),[2]

c. **Both** of the following:

i. Has achieved remission with the requested Cytokine and CAM Antagonist,
ii. Will be using the requested medication as maintenance therapy to maintain remission;

AND

10. For treatment of ulcerative colitis (UC), **one** of the following:

a. **Both** of the following:

i. Has **one** of the following diagnoses:

a) Mild UC that is associated with multiple poor prognostic factors[3]
b) Moderate-to-severe UC

ii. **One** of the following:

a) Failed to achieve remission with or has a contraindication or intolerance to an induction course of corticosteroids

b) **One** of the following:

(i) Failed to maintain remission with a conventional immunomodulator in accordance with current consensus guidelines[4]
(ii) Has a contraindication or intolerance to conventional immunomodulators in accordance with current consensus guidelines

b. **Both** of the following:

[2] Examples of high-risk or poor prognostic features in patients with Crohn's disease include initial diagnosis or clinical evidence supports the onset of symptoms at <30 years of age, extensive anatomic involvement, presence of fistula, perianal and/or severe rectal disease, large or deep mucosal lesions on endoscopy or imaging, prior surgical resection, stricturing and/or penetrating behavior, need for steroid therapy at initial diagnosis, extra-intestinal manifestations, laboratory markers such as low hemoglobin, low albumin, high C-reactive protein, high fecal calprotectin levels, severe growth delay (AGA 2014; ECCO 2017; CAG 2019; ECCO-ESPGHAN 2021; AGA 2021).
[3] Examples of poor prognostic factors in patients with ulcerative colitisinclude initial diagnosis or clinical evidence supports the onset of symptoms at <40 years of age, extensive colitis, severe endoscopic disease (presence of large and/or deep ulcers), hospitalization for colitis, elevated inflammatory markers, low serum albumin, extra-intestinal manifestations, early need for corticosteroids (ACG 2019; AGA 2019; AGA 2020).
[4] e.g., American College of Gastroenterology [ACG], American Gastroenterological Association [AGA], Canadian Association of Gastroenterology [CAG], European Crohn's and Colitis Organization [ECCO]

i. Has achieved remission with the requested Cytokine and CAM Antagonist
ii. Will be using the requested medication as maintenance therapy to maintain remission;

AND

11. For treatment of moderately-to-severely active rheumatoid arthritis, has **one** of the following:

    a. A history of therapeutic failure of a 3-month trial of a conventional non-biologic disease- modifying antirheumatic medication (DMARD) in accordance with current consensus guidelines[5]
    b. A contraindication or intolerance to conventional non-biologic DMARDs;

AND

12. For treatment of juvenile idiopathic arthritis (JIA), **one** of the following:

    a. Has **one** of the following:

        i. A history of therapeutic failure of a 3-month trial of a conventional non-biologic DMARD
        ii. A contraindication or intolerance to non-biologic DMARDs,

    b. Has systemic JIA with active systemic features,[6]

    c. Has a diagnosis of JIA that is associated with **both** of the following:

        i. One or more risk factors[7] for disease severity,

        ii. At least **one** of the following:

            a) Involvement of high-risk joints (e.g., cervical spine, hip, wrist),
            b) High disease activity,
            c) Is at high risk of disabling joint damage as judged by the prescriber,

    d. Has active sacroiliitis and/or enthesitis and **one** of the following:

        i. A history of therapeutic failure of a 2-week trial of an oral non-steroidal anti-inflammatory drug (NSAID),

[5] e.g., American College of Rheumatology [ACR], European League Against Rheumatism [EULAR]
[6] Active systemic features in patients with JIA include the following: fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, and serositis (ACR 2013).
[7] Risk factors for disease severity in patients with JIA include positive anti-cyclic citrullinated peptide antibodies, positive rheumatoid factor, presence of joint damage (ACR-AF 2019).

ii. A contraindication or intolerance to oral NSAIDs;

AND

13. For treatment of adult-onset Still's disease, **one** of the following:

    a. Has predominantly systemic disease and **one** of the following:

        i. Has a history of therapeutic failure with or contraindication or intolerance to systemic glucocorticoids,

        ii. **Both** of the following:
            a) Has glucocorticoid-dependent Still's disease,
            b) Will be using the requested Cytokine and CAM Antagonist with the intent of discontinuing or decreasing the dose of the systemic glucocorticoid,

    b. Has predominantly joint disease and **one** of the following:

        i. A history of therapeutic failure of a conventional non-biologic DMARD,
        ii. A contraindication or intolerance to conventional non-biologic DMARDs;

AND

14. For treatment of ankylosing spondylitis or other axial spondyloarthritis, has **one** of the following:

    a. A history of therapeutic failure of a 2-week trial of continuous treatment with 2 different oral NSAIDs (i.e., an oral NSAID taken daily for 2 weeks and a different oral NSAID taken daily for 2 weeks)
    b. A contraindication or intolerance to oral NSAIDs;

AND

15. For treatment of active[8] psoriatic arthritis, **one** of the following:

    a. Has one of the following:
        i. A history of therapeutic failure of an 8-week trial of a conventional non-biologic DMARD,
        ii. A contraindication or an intolerance to conventional non-biologic DMARDs,
    b. Has axial disease, dactylitis, and/or enthesitis,

[8] Active psoriatic arthritis is defined as disease causing symptoms at an unacceptable bothersome level as reported by the patient and judged by the examining clinician to be due to PsA based on 1 or more of the following: swollen joints, tender joints, dactylitis, enthesitis, axial disease, active skin and/or nail involvement, and extraarticular inflammatory manifestations such as uveitis or IBD (ACR-NPF 2018; EULAR 2015).

c. Has severe disease as determined by the prescriber,[9]
d. Has concomitant moderate-to-severe nail disease;
e. Has concomitant active inflammatory bowel disease;

AND

16. For treatment of chronic psoriasis, **both** of the following:

    a. Has psoriasis associated with at least **one** of the following:

        i. A body surface area (BSA) of 3% or more that is affected,
        ii. A BSA of less than 3% that is affected with involvement of critical areas,[10]
        iii. Significant disability or impairment of physical mental, or psychosocial functioning,

    b. Has **one** of the following:

        i. Moderate to severe nail disease
        ii. **One** of the following:
            a) A history of therapeutic failure of a 4-week trial of topical corticosteroids OR an 8-week trial of other topical pharmacologic therapy[11],
            b) A contraindication or intolerance to topical corticosteroids AND other topical pharmacologic therapy,

AND

17. For treatment of moderate-to-severe hidradenitis suppurativa (HS), **one** of the following:

    a. For Hurley stage II disease, has a history of therapeutic failure of or a contraindication, or an intolerance to **both** of the following:

        a) A 3-month trial of topical clindamycin
        b) An adequate trial of a systemic antibiotic;[12]

    b. For Hurley stage III disease, **one** of the following:

[9] Examples of severe PsA include the presence of ≥1 of the following: a poor prognostic factor (erosive disease, dactylitis, elevated levels of inflammation markers such as C-reactive protein or erythrocyte sedimentation rate attributable to PsA), long-term damage that interferes with function (e.g., joint deformities, vision loss), highly active disease that causes major impairment in quality of life (i.e., active psoriatic inflammatory disease at many sites [including dactylitis, enthesitis] or function-limiting inflammatory disease at a few sites), and rapidly progressive disease (ACR-NPF 2018; EULAR 2015).
[10] Critical areas in patients with psoriasis include, but are not restricted to, hands, feet, scalp, face, genitals, nails, and intertriginous areas (AAD-NPF 2018).
[11] e.g., anthralin, calcineurin inhibitors, tar, tazarotene, vitamin D analogs
[12] e.g., doxycycline, minocycline, or tetracycline; clindamycin; clindamycin + rifampin; rifampin + moxifloxacin + metronidazole; rifampin + levofloxacin + metronidazole; amoxicillin/clavulanate

i. Has a history of therapeutic failure of or a contraindication or intolerance to an adequate trial of a systemic antibiotic,
ii. Is a candidate for or has a history of surgical intervention for HS;

AND

18. For treatment of non-infectious uveitis, **one** of the following:

a. Has a diagnosis of uveitis associated with JIA or Behçet's syndrome,

b. Has a history of therapeutic failure, contraindication, or intolerance to **one** of the following:

i. A systemic, topical, intraocular, or periocular corticosteroid,
ii. A conventional systemic immunosuppressant[13],

c. **Both** of the following:

i. Has corticosteroid-dependent uveitis[14],
ii. Will be using the requested Cytokine and CAM Antagonist with the intent of discontinuing or decreasing the dose of the systemic corticosteroid;

AND

19. For treatment of giant cell arteritis, **one** of the following:

a. Has a history of therapeutic failure, contraindication, or intolerance to systemic glucocorticoids,

b. Is at high-risk for glucocorticoid-related complications,

c. **Both** of the following:
i. Has glucocorticoid-dependent disease,
ii. Will be using the requested Cytokine and CAM Antagonist with the intent of discontinuing or decreasing the dose of the systemic glucocorticoid;

AND

20. For treatment of polymyalgia rheumatica, **one** of the following:

a. Has a history of therapeutic failure of or a contraindication or an intolerance to

[13] e.g., azathioprine, cyclophosphamide, cyclosporine, methotrexate, mycophenolate, tacrolimus
[14] Corticosteroid-dependent uveitis is defined as requiring a daily systemic corticosteroid dose equivalent to 7.5 mg or greater of prednisone in adults for six weeks or longer.

systemic glucocorticoids

b. **Both** of the following:

i. Has glucocorticoid-dependent disease
ii. Will be using the requested Cytokine and CAM Antagonist with the intent of discontinuing or decreasing the dose of the systemic glucocorticoid;

21. For treatment of familial Mediterranean fever, has **one** of the following:

a. A history of therapeutic failure of at least a 3-month trial of colchicine at maximally tolerated doses,
b. A contraindication or intolerance to colchicine;

AND

22. For treatment of Behçet's syndrome, **all** of the following:

a. Has a diagnosis of Behçet's syndrome according to current consensus guidelines,[15]

b. Has recurrent oral ulcers associated with Behçet's syndrome,

c. Has a history of therapeutic failure, contraindication, or intolerance of a topical corticosteroid (e.g., triamcinolone dental paste),

d. Has **one** of the following:

i. A history of therapeutic failure of an adequate trial of colchicine at maximally tolerated doses,
ii. A contraindication or intolerance to colchicine;

AND

23. For treatment of sarcoidosis, **both** of the following:

a. **One** of the following:

i. Has a history of therapeutic failure of a contraindication or an intolerance to systemic glucocorticoids,
ii. Has glucocorticoid-dependent sarcoidosis

b. **One** of the following:
i. Has a history of therapeutic failure of a conventional non-biologic DMARD
ii. Has a contraindication or an intolerance to conventional non-biologic

[15] e.g., EULAR, International Study Group for Behçet's Disease

DMARDs;

AND

24. For treatment of alopecia areata, **both** of the following:

    a. Has alopecia associated with at least **one** of the following:
        i. Alopecia universalis,
        ii. Alopecia totalis,
        iii. Greater than 50% scalp involvement,
        iv. Significant disability or impairment of physical, mental, or psychosocial functioning

    b. Has a current episode of alopecia areata of greater than 6 months' duration;

25. For spesolimab for treatment of generalized pustular psoriasis (GPP), **one** of the following:

    a. For intravenous spesolimab, both of the following:
        i. Is using intravenous spesolimab for the treatment of a GPP flare
        ii. One of the following:
            a) For a member who has received a single dose of spesolimab for the current GPP flare, continues to experience moderate to severe GPP flare symptoms since the previous dose of spesolimab

            b) For a member who has not received a dose of spesolimab for the current GPP flare, is experiencing a moderate to severe GPP flare that warrants rapid stabilization or improvement in the opinion of the prescriber;

    b. For subcutaneous spesolimab, both of the following:
        i. Has a history of at least one GPP flare
        ii. Is using subcutaneous spesolimab for the prevention of GPP flares;

26. For treatment of gout flares, **all** of the following:

    a. Has a history of therapeutic failure of maximally tolerated doses of or a contraindication or an intolerance to NSAIDs,

    b. Has a history of therapeutic failure of maximally tolerated doses of or a contraindication or an intolerance to colchicine,

    c. **One** of the following:

        i. Has a history of therapeutic failure of maximally tolerated doses of or a contraindication or an intolerance to corticosteroids

ii. Has a medical reason why repeated courses of corticosteroids are not appropriate;

27. For all other diagnoses, has a history of therapeutic failure of or a contraindication or an intolerance to first line therapy(ies) if applicable according to consensus treatment guidelines; AND

28. For an oral Janus kinase (JAK) inhibitor, **one** of the following:
    a. Has a history of therapeutic failure of at least one tumor necrosis factor (TNF) blocker or another biologic if recommended for the member's diagnosis in the FDA-approved package labeling for the requested oral JAK inhibitor,
    b. Has a contraindication or an intolerance to TNF blockers or other biologics if recommended for the member's diagnosis in the FDA-approved package labeling for the requested oral JAK inhibitor,
    c. Has a current history (within the past 90 days) of being prescribed an oral JAK inhibitor;

29. For a non-preferred Cytokine and CAM Antagonist, **one** of the following:

    a. Both of the following:
        i. Has a history of therapeutic failure, contraindication, or intolerance of the preferred Cytokine and CAM Antagonists approved or medically accepted for the member's diagnosis,
        ii. For a non-preferred Cytokine and CAM Antagonist with a therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that is preferred on the Preferred Drug List (PDL), has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that would not be expected to occur with the requested medication
    b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Cytokine and CAM Antagonist (does not apply to non-preferred brands when the therapeutically equivalent generic, interchangeable biosimilar, or unbranded biologic is preferred or to non-preferred generics, interchangeable biosimilars, or unbranded biologics when the therapeutically equivalent brand, interchangeable brand, or brand biologic product is preferred),

AND

30. If a prescription for a Cytokine and CAM Antagonist is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the member does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR CYTOKINE AND CAM ANTAGONISTS: The determination of medical necessity of a request for renewal of a prior authorization for a Cytokine and CAM Antagonist that was previously approved will take into account whether the member:

1. **One** of the following:

   a. Experienced improvement in disease activity and/or level of functioning since initiating therapy with the requested Cytokine and CAM Antagonist,
   b. Is prescribed an increased dose or more frequent administration of the requested Cytokine and CAM Antagonist that is supported by peer-reviewed medical literature or national treatment guidelines;

   AND

2. Is prescribed the Cytokine and CAM Antagonist by or in consultation with an appropriate specialist (e.g., gastroenterologist, dermatologist, rheumatologist, ophthalmologist, immunologist, genetic specialist, pulmonologist, oncologist, etc.); **AND**

3. Is prescribed a dose and duration of therapy that is consistent with the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. For a Cytokine and CAM Antagonist associated with behavioral and/or mood changes as stated in the FDA-approved package labeling, was recently reevaluated for behavioral and mood changes as recommended in the FDA-approved package labeling; **AND**

5. For a non-preferred Cytokine and CAM Antagonist with a therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that would not be expected to occur with the requested medication.

6. If a prescription for a Cytokine and CAM Antagonist is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the member does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of 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 member

D. Approval Duration:

- **New Request: 6 months**
- **Renewal Request: 12 months**

E. References

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Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021: policy revised according to DHS revisions effective 01/05/2021.	11/2020
Q1 2022: policy revised according to DHS revisions effective 01/03/2022.	10/2021
Q1 2023: policy revised according to DHS revisions effective 01/09/2023.	10/2022
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