Clinical Policy: Cytokine and CAM Antagonists

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Effective Date: 01/01/2020
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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. Prescriptions That Require Prior Authorization

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

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 the member:

1. Is prescribed the Cytokine and CAM Antagonist for the treatment of a diagnosis that is consistent with the U.S. Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **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 drug; 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 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;
b. Has a diagnosis of Crohn's disease that is associated with one or more high-risk or poor prognostic feature(s), [1]

[1] 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

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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).

c. **Both** of the following:

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

AND

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

a. Has a diagnosis of moderate to severe UC,
b. Has a diagnosis of mild UC that is associated with multiple poor prognostic factors,[2]

c. **Both** of the following:

i. Has achieved remission with the requested Cytokine and CAM Antagonist
ii. Will be using the requested drug 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[3]
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,

[2] Examples of poor prognostic factors in patients with ulcerative colitis include 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).
[3] e.g., American College of Rheumatology [ACR], European League Against Rheumatism [EULAR]

b. Has systemic JIA with active systemic features,[4]

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

i. One or more risk factors[5] 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) 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),
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 an 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 an intolerance to conventional non-biologic DMARDs;

AND

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

[4] Active systemic features in patients with JIA include the following: fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, and serositis (ACR 2013).
[5] 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).

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 an intolerance to oral NSAIDs;

AND

15. For treatment of active[6] psoriatic arthritis (PsA), **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,
c. Has severe disease as determined by the prescriber,[7]
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,[8]
   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:

[6] 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).
[7] 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).
[8] Critical areas in patients with psoriasis include, but are not restricted to, hands, feet, scalp, face, genitals, nails, and intertriginous areas (AAD-NPF 2018).

a) A history of therapeutic failure of an 8-week trial of medium potency topical corticosteroid,
b) A history of therapeutic failure of **both** of the following:
   (i) A four-week trial of a medium potency topical corticosteroid,
   (ii) A four-week trial of a high potency topical corticosteroid,
c) A history of therapeutic failure of an eight-week trial of a non-steroidal topical pharmacologic therapy approved or medically accepted for the treatment of the beneficiary's diagnosis (e.g., anthralin, topical calcineurin inhibitors, tar, tazarotene, vitamin D analogs),
d) Both of the following:
   (i) A contraindication or an intolerance to medium potency and high potency topical corticosteroids,
   (ii) A contraindication or an intolerance to all other non-steroidal topical pharmacologic therapies approved or medically accepted for the treatment of the beneficiary's diagnosis;

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;[9]

    b. For Hurley stage III disease, **one** of the following:
        i. Has a history of therapeutic failure of or a contraindication or an 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 of or a contraindication or an intolerance to **one** of the following:

        i. A systemic, topical, intraocular, or periocular corticosteroid,
        ii. A conventional systemic immunosuppressant[10],

[9] e.g., doxycycline, minocycline, or tetracycline; clindamycin; clindamycin + rifampin; rifampin + moxifloxacin + metronidazole; rifampin + levofloxacin + metronidazole; amoxicillin/clavulanate
[10] e.g., azathioprine, cyclophosphamide, cyclosporine, methotrexate, mycophenolate, tacrolimus

c. **Both** of the following:

i. Has corticosteroid-dependent uveitis[11],
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 of or a contraindication or an 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 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;

AND

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 an intolerance to colchicine;

AND

[11] 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.

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

    a. Has a diagnosis of Behçet's syndrome according to current consensus guidelines, [13][12]

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

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

AND

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

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

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 of or a contraindication or an 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/generic or corresponding biosimilar/brand biologic/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/generic or corresponding biosimilar/brand biologic/unbranded biologic that would not be expected to occur with the requested drug
    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 Cytokine and CAM Antagonists when a therapeutically equivalent brand/generic or corresponding biosimilar/brand biologic/unbranded biologic 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 a dose and duration of therapy that is consistent with the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. 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**

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 brand/generic or corresponding biosimilar/brand biologic/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/generic or corresponding biosimilar/brand biologic/unbranded biologic that would not be expected to occur with the requested drug.

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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Crohn's Disease

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Q1 2021: policy revised according to DHS revisions effective 01/05/2021.	11/2020
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