Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: N/A**
Policy Number: PHW.PDL.071	**Effective Date: 01/01/2020** **Revision Date: 07/2020**
Policy Name: Cytokine and CAM Antagonists	

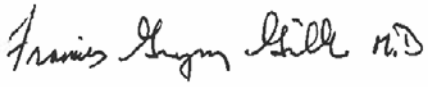
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ✓ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Q3 2020 annual review: no changes.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Cytokine and CAM Antagonists

Reference Number: PHW.PDL.071
Effective Date: 01/01/2020
Last Review Date: 07/2020

Revision Log

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 health plans affiliated with PA Health and 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 beneficiary:

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

4. Is not taking any other Cytokine and CAM Antagonist; **AND**

5. Had all potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary about the risks associated with the use of both medications when they interact); **AND**

6. Does not have a contraindication to the prescribed Cytokine and CAM Antagonist; **AND**

7. 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**

8. For a Cytokine and CAM Antagonist associated with an increased risk of infection according to the FDA-approved package labeling, **all** of the following:

    a. **One** of the following:

        i. Is up-to-date with immunizations in accordance with Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) recommendations
        ii. Has a plan for receiving CDC/ACIP recommended immunizations,

    b. Was evaluated for active or latent tuberculosis infection documented by results of a tuberculin skin test (purified protein derivative [PPD]) or blood test (interferon-gamma release assay),

    c. Does not have active, severe, and/or uncontrolled infection as recommended in the FDA-approved package labeling,

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

        i. Completion of the hepatitis B immunization series

        ii. **Both** of the following:
            a) Hepatitis B screening (sAb, sAg, and cAb)
            b) **One** of the following:
                (i) If screening results indicate a risk of hepatitis B virus reactivation, a follow- up plan to address this risk
                (ii) If negative for hepatitis B, a plan for vaccination against hepatitis B virus;

AND

9. 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), **both** of the following:

    a. Was evaluated for a history of prior suicide attempt, bipolar disorder, or major depressive disorder
    b. Will be monitored for behavioral and mood changes as recommended in the FDA- approved package labeling;

    AND

10. For treatment of Crohn's disease, **one** of the following:
    a. For a diagnosis of moderate-to-severe Crohn's disease, **one** of the following:
        i. Has Crohn's disease that has remained active despite treatment with at least **one** of the following:
            a) Corticosteroids
            b) Immunomodulators in accordance with current consensus guidelines[1]
        ii. Has a history of contraindication or intolerance to **both** of the following:
            a) Corticosteroids
            b) Immunomodulators in accordance with current consensus guidelines[1]
    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

11. 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) Has UC that has remained active despite treatment with at least **one** of the following:

                (i) Aminosalicylates,
                (ii) Corticosteroids,

[1] e.g., American College of Gastroenterology [ACG], American Gastroenterological Association [AGA], Canadian Association of Gastroenterology [CAG], European Crohn's and Colitis Organization [ECCO], World Gastroenterology Organization [WGO]
[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, perianal and/or severe rectal disease, deep ulcers on colonoscopy, prior surgical resection, stricturing and/or penetrating behavior (AGA, 2014), need for steroid therapy at initial diagnosis, extra-intestinal manifestations (e.g., arthropathy, metabolic bone disease, cardiopulmonary disease, hepatobiliary disease, erythema nodosum, pyoderma gangrenosum, Sweet's syndrome, venous thromboembolism) (ECCO, 2017), and laboratory markers such as low hemoglobin, low albumin, high C-reactive protein, and high fecal calprotectin levels (CAG, 2019).
[3] Poor prognostic factors include: initial diagnosis or clinical evidence supports the onset of symptoms at <40 years of age, extensive colitis, severe endoscopic disease (presence of deep ulcers), hospitalization for colitis, elevated inflammatory markers, low serum albumin (ACG, 2019), and extra-intestinal manifestations (AGA, 2019).

(iii) Immunomodulators in accordance with current consensus guidelines[4]

b) Has a history of contraindication or intolerance to **all** of the following:

(i) Aminosalicylates,
(ii) Corticosteroids,
(iii) Immunomodulators in accordance with current consensus guidelines[4]

b. **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

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

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

AND

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

a. Has a history of **one** of the following:
i. 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 high disease activity[7] or one or more poor prognostic feature(s),[8]
d. Has active sacroiliitis and/or enthesitis and a history of one of the following:

[4] e.g., American College of Gastroenterology [ACG], American Gastroenterological Association [AGA], Canadian Association of Gastroenterology [CAG], European Crohn's and Colitis Organization [ECCO], World Gastroenterology Organization [WGO]
[5] e.g., American College of Rheumatology [ACR], European League Against Rheumatism [EULAR]
[6] Active systemic features include the following: fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, and serositis (ACR, 2013).
[7] High-disease activity is defined as meeting at least 3 of the following elements: a minimum of 8 active joints, inflammatory markers greater than twice the upper limit of normal, physician global disease activity assessment of at least 7 (0 to 10 scale), and patient/parent overall well-being assessment of at least 5 (0 to 10 scale) (ACR, 2011).
[8] Examples of poor prognostic features include: cervical or hip arthritis, rheumatoid factor or cyclic citrullinated peptide positivity, and radiographic evidence of joint damage (erosions or joint space narrowing) (ACR, 2011).

i. Therapeutic failure of a 2-week trial of an oral non-steroidal anti-inflammatory drug (NSAID)
ii. Contraindication or intolerance to oral NSAIDs;

AND

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

a. 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[9] psoriatic arthritis, **one** of the following:

a. Has axial disease and/or enthesitis and a history of **one** of the following:

i. Therapeutic failure of a 2-week trial of continuous treatment with 2 different oral NSAIDs
ii. A contraindication or intolerance to oral NSAIDs,

b. Has peripheral disease and a history of **one** of the following:

i. Therapeutic failure of an 8-week trial of a conventional non-biologic DMARD
ii. A contraindication or intolerance to conventional non-biologic DMARDs,

c. Has severe disease as determined by the prescriber,[10]

d. Has concomitant moderate-to-severe nail disease;

AND

[9] Active disease 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).
[10] Examples of severe disease include the presence of ≥1 of the following: a poor prognostic factor (erosive disease, 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).

16. For treatment of moderate-to-severe chronic psoriasis, **all** 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,[11]
        iii. Significant disability or impairment of physical or mental functioning,

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

        i. Therapeutic failure of a trial of topical corticosteroids OR other topical pharmacologic therapy[12]
        ii. A contraindication or intolerance to topical corticosteroids AND other topical pharmacologic therapy,

    c. Has a history of **one or more** of the following:

        i. Therapeutic failure of a 3-month trial of oral systemic therapy,[13]
        ii. Therapeutic failure of ultraviolet light therapy,[14]
        iii. A contraindication or intolerance to oral systemic therapies AND ultraviolet light therapy;

    AND

17. For treatment of moderate-to-severe hidradenitis suppurativa, **both** of the following:

    a. Has Hurley stage II or stage III disease

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

        i. A 3-month trial of topical clindamycin
        ii. An adequate trial of systemic antibiotics;[15]

    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,

[11] Critical areas include, but are not restricted to, hands, feet, scalp, face, genitals, nails, and intertriginous areas (AAD-NPF, 2018) (ACR-NPF, 2018).
[12] e.g., anthralin, calcineurin inhibitors, tar, tazarotene, vitamin D analogs
[13] e.g., methotrexate, cyclosporine, acitretin
[14] e.g., NB-UVB, BB-UVB, PUVA, excimer laser
[15] e.g., doxycycline, minocycline, or tetracycline; clindamycin; clindamycin + rifampin; rifampin + moxifloxacin + metronidazole; rifampin + levofloxacin + metronidazole; amoxicillin/clavulanate

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

   i. Systemic, topical, intraocular, or periocular corticosteroids
   ii. Conventional systemic immunosuppressives[16]

c. **Both** of the following:

   i. Has corticosteroid-dependent uveitis[17]
   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 familial Mediterranean fever, has a history of **one** of the following:
a. Therapeutic failure of at least a 3-month trial of colchicine at maximally tolerated doses
b. A contraindication or intolerance to colchicine;

AND

21. For treatment of Behçet's syndrome, **all** of the following:
a. Has a diagnosis of Behçet's syndrome according to current consensus guidelines,[18]

[16] e.g., azathioprine, cyclophosphamide, cyclosporine, methotrexate, mycophenolate, tacrolimus
[17] 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.
[18] e.g., EULAR, International Study Group for Behçet's Disease

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 a history of one of the following:
    i. Therapeutic failure of an adequate trial of colchicine at maximally tolerated doses
    ii. A contraindication or intolerance to colchicine;

AND

22. For Cosentyx (secukinumab), **one** of the following:

    a. Has a history of therapeutic failure, contraindication, or intolerance of Humira (adalimumab) if approved or medically accepted for the beneficiary's diagnosis
    b. Has a current history (within the past 90 days) of being prescribed Cosentyx (secukinumab);

    AND

23. For Arcalyst (rilonacept), **one** of the following:

    a. Has a history of therapeutic failure, contraindication, or intolerance of Kineret (anakinra) if approved or medically accepted for the beneficiary's diagnosis
    b. Has a current history (within the past 90 days) of being prescribed Arcalyst (rilonacept);

    AND

24. For Ilaris (canakinumab), **one** of the following:
    a. Has a history of therapeutic failure, contraindication, or intolerance of Kineret (anakinra) if approved or medically accepted for the beneficiary's diagnosis
    b. Has a current history (within the past 90 days) of being prescribed Ilaris (canakinumab);

    AND

25. For an infliximab product other than Renflexis (infliximab-abda), **one** of the following:
    a. Has a history of therapeutic failure, contraindication, or intolerance of Renflexis (infliximab-abda) if approved or medically accepted for the beneficiary's diagnosis
    b. Has a current history (within the past 90 days) of being prescribed the requested infliximab product;

AND

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

    a. Has a history of therapeutic failure, contraindication, or intolerance of the preferred Cytokine and CAM Antagonists approved or medically accepted for the beneficiary's diagnosis
    b. Has a current history (within the past 90 days) of being prescribed the same non- preferred Cytokine and CAM Antagonist

AND

27. 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 beneficiary 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 beneficiary, 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 beneficiary:

1. Experienced improvement in disease activity and/or level of functioning since initiating therapy with the requested Cytokine and CAM Antagonist; **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, 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. Had all potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary about the risks associated with the use of both medications when they interact); **AND**

5. Is not taking any other Cytokine and CAM Antagonist; **AND**

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

7. 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 beneficiary 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 beneficiary, 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 beneficiary

D. Approval Duration:
- **New Request: 6 months**
- **Renewal Request: 12 months**

E. References

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23. Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; May 2018.
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Rheumatoid Arthritis

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children receiving biologic medications. Arthritis Care Res (Hoboken). 2013;65(10):1551-63.
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