pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 24, 2020	January 5, 2021	*See below

SUBJECT

Prior Authorization of Cytokine and CAM Antagonists – Pharmacy Services

BY

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IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Cytokine and CAM Antagonists submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Cytokine and CAM Antagonists will be utilized in the MA fee-for-service delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of Cytokine and CAM Antagonists to the appropriate MCO.

BACKGROUND:

*01-20-47	09-20-46	27-20-42	33-20-43
02-20-40	11-20-40	30-20-39	
03-20-40	14-20-41	31-20-47	
08-20-50	24-20-41	32-20-39	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs Web site at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.

The Department of Human Services' (Department) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective Drug Use Review and Retrospective Drug Use Review programs.

DISCUSSION:

During the October 21, 2020, meeting, the DUR Board recommended the following revisions to the guidelines to determine medical necessity of Cytokine and CAM Antagonists:

- Removal of the guideline that the beneficiary does not have active, severe, and/or uncontrolled infection;
- Revisions to the step therapy requirements for the treatment of Crohn's disease in some patients based on current medical literature;
- Revisions to the step therapy requirements for the treatment of ulcerative colitis in some patients based on current medical literature;
- Addition of guidelines specific to the treatment of adult-onset Still's disease (AOSD) to address the recent U.S. Food and Drug Administration expanded approval of Ilaris (canakinumab) and the place in therapy of biologics (e.g., TNF inhibitors, IL-1 inhibitors, IL-6 inhibitors);
- Revision to the guidelines for multiple indications to clarify the number of drugs that should be tried prior to approval of a Cytokine and CAM Antagonist;
- Removal of the guideline specific to Cosentyx (secukinumab) based on changes to statuses of the drugs in this class on the Statewide PDL as recommended by the Department's P&T Committee; and
- Revision of the guideline specific to infliximab products to reflect the recent addition of Avsola (infliximab-axxq) to the list of available infliximab biosimilars.

The revisions to the guidelines to determine medical necessity of Cytokine and CAM Antagonists, as recommended by the DUR Board, were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Cytokine and CAM Antagonists are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Cytokine and CAM Antagonists) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx

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 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) or blood test (interferon-gamma release assay),

c. 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. 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 an immunomodulator in accordance with current consensus guidelines[1]
b) Has a contraindication or intolerance to immunomodulators in accordance with

[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]

current consensus guidelines,**Error! Bookmark not defined.**

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) 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 an immunomodulator in accordance with current consensus guidelines[4]
(ii) Has a contraindication or intolerance to immunomodulators in accordance with current consensus guidelines**Error! Bookmark not defined.**

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, 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).
[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]

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:

        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 adult-onset Still's disease, **one** of the following:

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

[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. 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 a history of **one** of the following:

i. Therapeutic failure of a conventional non-biologic DMARD
ii. Contraindication or intolerance to conventional non-biologic DMARDs;

AND

15. 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

16. 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,

[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).

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

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

AND

17. 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

18. 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:

[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).
[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

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

AND

19. 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 immunosuppressive,[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

20. 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

21. 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

[15] e.g., doxycycline, minocycline, or tetracycline; clindamycin; clindamycin + rifampin; rifampin + moxifloxacin + metronidazole; rifampin + levofloxacin + metronidazole; amoxicillin/clavulanate
[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.

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,[18]

    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

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 Avsola (infliximab-axxq), **one** of the following:

    a. Has a history of therapeutic failure, contraindication, or intolerance of Avsola (infliximab-axxq) 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

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

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

    See the Preferred Drug List (PDL) for the list of preferred Cytokine and CAM Antagonists at: https://papdl.com/preferred-drug-list;

    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 the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

    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 the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

   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

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Inflammatory Bowel Disease

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