


ISSUE DATE November 5, 2021	EFFECTIVE DATE January 3, 2022	NUMBER *See below
SUBJECT Prior Authorization of Cytokine and CAM Antagonists – Pharmacy Services		BY  Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs

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 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:

*01-21-28	09-21-27	27-21-19	33-21-27
02-21-15	11-21-17	30-21-22	
03-21-15	14-21-18	31-21-30	
08-21-30	24-21-25	32-21-25	

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 website at <https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>.

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 14, 2021, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Cytokine and CAM Antagonists:

- Addition of oncologist and pulmonologist to the list of examples of appropriate specialists;
- Revision of the guideline regarding concomitant use of more than one Cytokine and CAM Antagonist based on consultation with a board-certified rheumatologist;
- Removal of the guidelines regarding drug interactions, general immunization requirements, and hepatitis B testing and vaccination;
- Removal of the guideline regarding monitoring for behavioral and mood changes for Cytokine and CAM Antagonists associated with behavioral and/or mood changes;
- Revision of the lists of examples of high-risk or poor prognostic features in people with Crohn's disease and ulcerative colitis based on recent consensus treatment guidelines;
- Removal of the definition of high disease activity for juvenile idiopathic arthritis and revision of examples of high-risk features based on recent consensus treatment guidelines;
- Revision of the guidelines for treatment of psoriatic arthritis based on recent consensus treatment guidelines and consultation with a board-certified rheumatologist;
- Revision of the guidelines for treatment of psoriasis and hidradenitis suppurativa based on consultation with a board-certified dermatologist;
- Addition of guidelines for treatment of atopic dermatitis and sarcoidosis;
- Removal of the guidelines specific to Arcalyst (rilonacept), Ilaris (canakinumab), and infliximab products;
- Clarification of the guidelines for a non-preferred Cytokine and CAM Antagonist; and
- Addition of a guideline to the requests for renewal of the prior authorization section that the beneficiary is prescribed an increased dose or frequency of the requested medication if the beneficiary has not experienced improvement in disease activity and/or level of functioning.

The revisions to the guidelines to determine medical necessity of prescriptions for Cytokine and CAM Antagonists submitted for prior authorization, as recommended by the P&T Committee, 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>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Cytokine and CAM Antagonists

A. Prescriptions That Require Prior Authorization

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

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, pulmonologist, oncologist, etc.); **AND**
4. 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

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

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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:
- a. Active or latent tuberculosis infection documented by results of a tuberculin skin test (purified protein derivative) or blood test (interferon-gamma release assay)
 - b. Hepatitis B virus 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. 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 an 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 guidelines¹
 - b) Has a contraindication or an intolerance to 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

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

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).

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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 factors³
 - b) Moderate to severe UC
 - ii. **One** of the following:
 - a) Failed to achieve remission with or has a contraindication or an 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 guidelines⁴
 - (ii) Has a contraindication or an intolerance to immunomodulators in accordance with current consensus guidelines
 - 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

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 drug (DMARD) in accordance with current consensus guidelines⁵
 - b. A contraindication or an intolerance to conventional non-biologic DMARDs;

AND

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

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 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]

⁵ e.g., American College of Rheumatology [ACR], European League Against Rheumatism [EULAR]

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- 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 an 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 factors⁷ 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)
 - ii. A contraindication or an 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 of or a 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:

⁶ Active systemic features include the following: fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, and serositis (ACR 2013).

⁷ Risk factors include positive anti-cyclic citrullinated peptide antibodies, positive rheumatoid factor, presence of joint damage (ACR-AF 2019).

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- 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 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 active⁸ psoriatic arthritis, **one** of the following:
 - a. Has axial disease and/or enthesitis,
 - b. Has peripheral disease and **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,
 - c. Has severe disease as determined by the prescriber,⁹
 - d. Has concomitant moderate to severe nail disease;

AND

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,¹⁰
 - iii. Significant disability or impairment of physical or mental functioning,

⁸ 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).

⁹ 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).

¹⁰ Critical areas include, but are not restricted to, hands, feet, scalp, face, genitals, nails, and intertriginous areas (AAD-NPF 2018).

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- b. Has **one** of the following:
 - i. A history of therapeutic failure of topical corticosteroids OR other topical pharmacologic therapy,¹¹
 - ii. A contraindication or an intolerance to topical corticosteroids AND other topical pharmacologic therapy,
 - iii. Moderate to severe nail disease,
- c. Has a history of therapeutic failure of or a contraindication or an intolerance to at least **one** of the following:
 - i. A 3-month trial of oral systemic therapy¹²
 - ii. Ultraviolet light therapy;¹³

AND

- 17. For treatment of moderate to severe hidradenitis suppurativa (HS), **one** of the following:
 - a. **Both** of the following:
 - i. Has Hurley stage II or stage III disease
 - ii. 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 antibiotic¹⁴
 - b. **Both** of the following:
 - i. Has Hurley stage III disease
 - 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,

¹¹ e.g., anthralin, calcineurin inhibitors, tar, tazarotene, vitamin D analogs

¹² e.g., methotrexate, cyclosporine, acitretin

¹³ e.g., NB-UVB, BB-UVB, PUVA, excimer laser

¹⁴ e.g., doxycycline, minocycline, or tetracycline; clindamycin; clindamycin + rifampin; rifampin + moxifloxacin + metronidazole; rifampin + levofloxacin + metronidazole; amoxicillin/clavulanate

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- 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 immunosuppressive,¹⁵
- c. **Both** of the following:
 - i. Has corticosteroid-dependent uveitis¹⁶
 - 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 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

- 21. For treatment of Behçet's syndrome, **all** of the following:
 - a. Has a diagnosis of Behçet's syndrome according to current consensus guidelines,¹⁷
 - b. Has recurrent oral ulcers associated with Behçet's syndrome,

¹⁵ e.g., azathioprine, cyclophosphamide, cyclosporine, methotrexate, mycophenolate, tacrolimus

¹⁶ 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.

¹⁷ e.g., EULAR, International Study Group for Behçet's Disease

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- 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

- 22. For treatment of moderate to severe chronic atopic dermatitis, has a history of therapeutic failure of at least **two** of the following OR a contraindication or an intolerance to **all** of the following:
 - a. **One** of the following:
 - i. For treatment of the face, skin folds, or other critical areas, a low-potency topical corticosteroid
 - ii. For treatment of other areas, a medium-potency or higher topical corticosteroid,
 - b. A topical calcineurin inhibitor,
 - c. Phototherapy in accordance with current consensus guidelines,
 - d. Systemic immunosuppressives in accordance with current consensus guidelines (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil);

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. Has a history of therapeutic failure of or a contraindication or an intolerance to a conventional non-biologic DMARD;

AND

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

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- a. Has a history of therapeutic failure of or a contraindication or an intolerance to 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 (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred [NOTE: biosimilars are NOT therapeutically equivalent generics])

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

AND

25. 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. **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

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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. 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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