




Medical Assistance BULLETIN

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SUBJECT Prior Authorization of Cytokine and CAM Antagonists – Pharmacy Services		BY  Sally 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.pa.gov/en/agencies/dhs/resources/for-providers/provider-enrollment-information/provider-enrollment-documents.html>.

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 and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Cytokine and CAM Antagonists to the appropriate managed care organization.

BACKGROUND:

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 and products in therapeutic classes already included on the Statewide Preferred Drug List (PDL).

*01-25-13	09-25-13	27-25-13	33-25-13
02-25-13	11-25-13	30-25-13	
03-25-13	14-25-13	31-25-13	
08-25-14	24-25-13	32-25-13	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Fee-for-Service Provider Service Center: 1-800-537-8862

Visit the Office of Medical Assistance Programs website at:

<https://www.pa.gov/en/agencies/dhs/departments-offices/omap-info.html>

- Changes to the statuses of drugs and products on the Statewide PDL from preferred to non-preferred and non-preferred to preferred.
- Therapeutic classes of drugs and products to be added to or deleted from the Statewide PDL.
- New quantity limits.
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 10, 2024, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Cytokine and CAM Antagonists:

- Revision to the guideline related to testing for tuberculosis and hepatitis B virus infection.
- Revision of the guideline for spesolimab for the treatment of generalized pustular psoriasis to address the additional formulation and indication approved by the U.S. Food and Drug Administration.
- Addition of guidelines related to requests for a non-preferred Cytokine and CAM Antagonist with a therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that is preferred on the PDL.

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 and products 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.pa.gov/en/agencies/dhs/resources/pharmacy-services/pharmacy-prior-authorization-general-requirements.html>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines

<https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/clinical-guidelines.html>

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 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 two or more autoimmune or autoinflammatory conditions for which a single Cytokine and CAM Antagonist is not sufficient;

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 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) 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. Has a diagnosis of moderate to severe Crohn's disease and **one** of the following:
 - i. Failed to achieve remission with or has a contraindication or an intolerance to an induction course of corticosteroids
 - ii. **One** of the following:
 - a) Failed to maintain remission with a conventional immunomodulator in accordance with current consensus guidelines¹
 - b) Has a contraindication or an intolerance to conventional 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 drug 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 a conventional immunomodulator in accordance with current consensus guidelines⁴
- (ii) Has a contraindication or an intolerance to conventional 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 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 three-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

³ 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).

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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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 three-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) 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 two-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 in patients with JIA include the following: fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, and serositis (ACR 2013).

⁷ Risk factors for disease severity in patients with JIA include positive anti-cyclic citrullinated peptide antibodies, positive rheumatoid factor, presence of joint damage (ACR-AF 2019).

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

AND

15. For treatment of active⁸ psoriatic arthritis (PsA), **one** of the following:
- a. Has **one** of the following:
 - i. A history of therapeutic failure of an eight-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,⁹
 - d. Has concomitant moderate to severe nail disease,
 - e. Has concomitant active inflammatory bowel disease;

AND

16. For treatment of chronic psoriasis, **both** of the following:
- a. Has psoriasis associated with at least **one** of the following:
 - i. A body surface area (BSA) of 3% or more that is affected,

⁸ Active PsA 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 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).

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- ii. A BSA of less than 3% that is affected with involvement of critical areas,¹⁰
- iii. Significant disability or impairment of physical, mental, or psychosocial functioning

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

- i. Moderate to severe nail disease
- ii. **One** of the following:
 - a) A history of therapeutic failure of a four-week trial of topical corticosteroids OR an 8-week trial of other topical pharmacologic therapy¹¹
 - b) A contraindication or an intolerance to topical corticosteroids AND other topical pharmacologic therapy;

AND

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

- a. For Hurley stage II disease, has a history of therapeutic failure of or a contraindication or an intolerance to **both** of the following:
 - a) A three-month trial of topical clindamycin
 - b) An adequate trial of a systemic antibiotic¹²
- 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

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

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

¹² e.g., doxycycline, minocycline, or tetracycline; clindamycin; clindamycin + rifampin; rifampin + moxifloxacin + metronidazole; rifampin + levofloxacin + metronidazole; amoxicillin/clavulanate

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- ii. A conventional systemic immunosuppressive,¹³
- c. **Both** of the following:
 - i. Has corticosteroid-dependent uveitis¹⁴
 - 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 three-month trial of colchicine at maximum tolerated doses

¹³ e.g., azathioprine, cyclophosphamide, cyclosporine, methotrexate, mycophenolate, tacrolimus

¹⁴ Corticosteroid-dependent uveitis is defined as requiring a daily systemic corticosteroid dose equivalent to 7.5 mg or greater of prednisone in adults for six weeks or longer.

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- b. A contraindication or an intolerance to colchicine;

AND

- 22. For treatment of Behçet's syndrome, **all** of the following:
 - a. Has a diagnosis of Behçet's syndrome according to current consensus guidelines,¹⁵
 - b. Has recurrent oral ulcers associated with Behçet's syndrome,
 - c. Has a history of therapeutic failure 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 maximum 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

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

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

AND

- 25. For spesolimab for treatment of generalized pustular psoriasis (GPP), **one** of the following:
 - a. For intravenous spesolimab, **both** of the following:
 - i. Is using intravenous spesolimab for the treatment of a GPP flare
 - ii. **One** of the following:
 - a) For a beneficiary 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 beneficiary 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;

AND

- 26. For treatment of gout flares, **all** of the following:
 - a. Has a history of therapeutic failure of maximum tolerated doses of or a contraindication or an intolerance to NSAIDs,
 - b. Has a history of therapeutic failure of maximum tolerated doses of or a contraindication or an intolerance to colchicine,
 - c. **One** of the following:
 - i. Has a history of therapeutic failure of maximum tolerated doses of or a contraindication or an intolerance to corticosteroids
 - ii. Has a medical reason why repeated courses of corticosteroids are not appropriate;

AND

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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 beneficiary'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 beneficiary'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;

AND

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 to the preferred Cytokine and CAM Antagonists approved or medically accepted for the beneficiary's diagnosis
 - ii. For a non-preferred Cytokine and CAM Antagonist with a therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that is preferred on the Preferred Drug List (PDL), has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that would not be expected to occur with the requested 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 brands when the therapeutically equivalent generic, interchangeable biosimilar, or unbranded biologic is preferred or to non-preferred generics, interchangeable biosimilars, or unbranded biologics when the therapeutically equivalent brand, interchangeable brand, or brand biologic is preferred).

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

AND

30. If a prescription for a Cytokine and CAM Antagonist is for a quantity that exceeds the

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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.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

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 a dose and duration of therapy that are consistent with 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 equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that would not be expected to occur with the requested drug.

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

AND

6. If a prescription for a Cytokine and CAM Antagonist is for 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.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

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. References

1. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; February 2022.
2. Arcalyst [package insert]. London, UK: Kiniksa Pharmaceuticals (UK), Ltd. March 2021.
3. Bimzelx [package insert]. Smyrna, GA: UCB, Inc. October 2023.
4. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; September 2019.
5. Cosentyx [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2021.
6. Enbrel [package insert]. Thousand Oaks, CA: Immunex Corporation; August 2020.
7. Entyvio [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.: April 2024.
8. Humira [package insert]. North Chicago, IL: AbbVie Inc.; February 2021.
9. Ilaris [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2023.
10. Ilaris: EPAR – Product Information. Dublin, Ireland: Novartis Europharm Limited; June 2019.
https://www.ema.europa.eu/en/documents/product-information/ilaris-epar-product-information_en.pdf. Accessed July 18, 2019.
11. Ilumya [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; March 2018.
12. Kevzara [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC: February 2023.
13. Kineret [package insert]. Stockholm, Sweden: Swedish Orphan Biovitrum AB; December 2020.
14. Kineret: EPAR – Product Information. Stockholm, Sweden: Swedish Orphan Biovitrum AB; May 2020.
https://www.ema.europa.eu/en/documents/product-information/kineret-epar-product-information_en.pdf. Accessed July 8, 2020.
15. Leqselvi [package insert]. Whippany, NJ: Halo Pharmaceutical, Inc. July 2024.
16. Litfulo [package insert]. New York, NY: Pfizer Inc. June 2023.
17. Olumiant [package insert]. Indianapolis, IN: Lilly USA, LLC; May 2022.

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18. Omvoh [package insert]. Indianapolis, IN: Eli Lilly and Company. April 2024.
 19. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; December 2021.
 20. Otezla [package insert]. Thousand Oaks, CA: Amgen Inc.; December 2021.
 21. Remicade [package insert]. Horsham, PA: Janssen Biotech, Inc.; October 2021.
 22. Rinvoq [package insert]. North Chicago, IL: AbbVie Inc.; April 2022.
 23. Siliq [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; February 2017.
 24. Simponi [package insert]. Horsham, PA: Janssen Biotech, Inc; September 2019.
 25. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2021.
 26. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc.; June 2022.
 27. Sotyktu [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; September 2022.
 28. Spevigo [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc. March 2024.
 29. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; July 2022.
 30. Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; March 2021.
 31. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; July 2020.
 32. Xeljanz [package insert]. New York, NY: Pfizer Inc.; December 2021.
- Crohn's Disease
33. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: Management of Crohn's disease in adults. *Am J Gastroenterol.* 2018;113(4):481-517.
 34. Steinhart AH, Panaccione R, Targownik, L, et al. Clinical practice guideline for the medical management of perianal fistulizing Crohn's disease: The Toronto Consensus. *Inflamm Bowel Dis.* 2019;25(1):1-13.
 35. Torres J, Bonovas S, Doherty G, et al. ECCO guidelines on therapeutics in Crohn's disease: Medical treatment. *J Crohns Colitis.* 2020;14(1):4-22.
 36. van Rheenen PF, Aloï M, Assa A, et al. The medical management of paediatric Crohn's disease: An ECCO-ESPGHAN guideline update. *J Crohns Colitis.* 2021;15(2):171-194.
 37. Feuerstein JD, Ho EY, Shmidt E, et al. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. *Gastroenterology.* 2021;160:2496-2508.
 38. Al Hashash J, Regueiro M. Overview of medical management of high-risk, adult patients with moderate to severe Crohn disease. In: *UpToDate [internet database].* Kane SV, Robson KM, eds. Waltham, MA: UpToDate Inc. Updated March 3, 2021. Accessed July 23, 2021.
- Ulcerative Colitis
39. Bressler B, Marshall JK, Bernstein CN, et al. Clinical practice guidelines for the medical management of nonhospitalized ulcerative colitis: The Toronto Consensus. *Gastroenterology.* 2015;148:1035-58.
 40. Harbord M, Eliakim R, Bettenworth D, et al. Third European evidence-based consensus on diagnosis and management of ulcerative colitis. Part 2: Current management. *J Crohns Colitis;* 2017;11(7):769-784.
 41. Turner D, Ruemmele FM, Orlanski-Meyer E, et al. Management of paediatric ulcerative colitis, part 1: Ambulatory care – an evidence-based guideline from European Crohn's and Colitis Organization and European Society of Paediatric Gastroenterology, Hepatology and Nutrition. *J Pediatr Gastroenterol Nutr;* 2018;67(2):257-291.
 42. Turner D, Ruemmele FM, Orlanski-Meyer E, et al. Management of paediatric ulcerative colitis, part 2: Acute severe colitis – an evidence-based guideline from European Crohn's and Colitis Organization and European Society of Paediatric Gastroenterology, Hepatology and Nutrition. *J Pediatr Gastroenterol Nutr.* 2018;67(2):292-310.
 43. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG clinical guideline: Ulcerative colitis in adults. *Am J Gastroenterol.* 2019;114:384-413.
 44. Ko CW, Singh S, Feuerstein JD, Falck-Ytter C, Falck-Ytter Y, Cross RK. AGA clinical practice guidelines on the management of mild-to-moderate ulcerative colitis. *Gastroenterology.* 2019;156:748-764.
 45. Feuerstein JD, Isaacs KL, Schneider Y, Siddique SM, Falck-Ytter Y, Singh S. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterology.* 2020;158:1450-1461.
 46. Cohen RD, Stein AC. Management of moderate to severe ulcerative colitis in adults. In: *UpToDate [internet database].* Lamont JT, Robson KM, eds. Waltham, MA: UpToDate Inc. Updated August 23, 2021. Accessed August 26, 2021.
- Rheumatoid Arthritis
47. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care Res (Hoboken).* 2016;68(1):1-25.
 48. Smolen JS, Landewé R, Bijlsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis.* 2020;79:685-699.
- Juvenile Idiopathic Arthritis
49. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: Initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. *Arthritis Care Res (Hoboken).* 2011;63(4):465-482.
 50. Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: Recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. *Arthritis Care Res (Hoboken).* 2013;65(10):1551-63.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

51. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: Therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. *Arthritis Care Res (Hoboken)*. 2019;71(6):717-734.
52. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: Therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol*. 2022;74(4):553-569.
53. Weiss PF. Polyarticular juvenile idiopathic arthritis: Treatment. In: UpToDate [internet database]. Klein-Gitelman M, TePas E, eds. Waltham, MA: UpToDate Inc. Updated January 19, 2022. Accessed June 7, 2022.
54. Kimura Y. Systemic juvenile idiopathic arthritis: Treatment. In: UpToDate [internet database]. Klein-Gitelman M, TePas E, eds. Waltham, MA: UpToDate Inc. Updated December 30, 2020. Accessed July 27, 2021.
55. Weiss PF. Oligoarticular juvenile idiopathic arthritis. In: UpToDate [internet database]. Klein-Gitelman M, TePas E, eds. Waltham, MA: UpToDate Inc. Updated August 13, 2021. Accessed June 7, 2022.

Still's Disease

56. Mimura T, Kondo Y, Ohta A, et al. Evidence-based clinical practice guideline for adult Still's disease. *Mod Rheumatol*. 2018;28(5):736-757.
57. Mandl LA. Treatment of adult Still's disease. In: UpToDate [internet database]. O'Dell JR, Romain PL, eds. Waltham, MA: UpToDate Inc. Updated December 21, 2020. Accessed July 22, 2021.

Ankylosing Spondylitis

58. van der Heijde D, Ramiro S, Landewé R, et al. 2016 update of the ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis*. 2017;76:978-991.
59. Hamilton L, Barkham N, Bhalla A, et al. BSR and BHPR guideline for the treatment of axial spondyloarthritis (including ankylosing spondylitis) with biologics. *Rheumatology (Oxford)*. 2017;56(2):313-316.
60. Ward MM, Deodhar A, Gensler LS, et al. 2019 update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol*. 2019;71(10):1599-1613.
61. Yu DT, van Tubergen A. Treatment of axial spondyloarthritis (ankylosing spondylitis and nonradiographic axial spondyloarthritis) in adults. In: UpToDate [internet database]. Siper J, Romain PL, eds. Waltham, MA: UpToDate Inc. Updated November 20, 2020. Accessed July 22, 2021.

Psoriatic Arthritis

62. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. *Arthritis Care Res (Hoboken)*. 2019;71(1):2-29.
63. Gossec L, Baraliakos X, Kerschbaumer A, et al. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. *Ann Rheum Dis*. 2020;79:700-712.
64. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): Updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol*. 2022;18:465-479.
65. Gladman DD, Ritchlin C. Treatment of psoriatic arthritis. In: UpToDate [internet database]. Sieper J, Romain PL, eds. Waltham, MA: UpToDate Inc. Updated November 20, 2020. Accessed July 28, 2021.

Psoriasis

66. Crowley JJ, Weinberg JM, Wu JJ, et al. Treatment of nail psoriasis: Best practice recommendations from the Medical Board of the National Psoriasis Foundation. *JAMA Dermatol*. 2015;151(1):87-94.
67. Gelfand JM, Wan J, Zhang H, et al. Risk of liver disease in patients with psoriasis, psoriatic arthritis, and rheumatoid arthritis receiving methotrexate: A population-based study. *J Invest Dermatol*. 2018;138(4):760-767.
68. Ogdie A, Grewal SK, Noe MH, et al. Risk of incident liver disease in patients with psoriasis, psoriatic arthritis, and rheumatoid arthritis: A population-based study. *J Invest Dermatol*. 2018;138(4):760-767.
69. Rigopoulos D, Baran R, Chiheb S, et al. Recommendations for the definition, evaluation, and treatment of nail psoriasis in adult patients with no or mild skin psoriasis: A dermatologist and nail expert group consensus. *J Am Acad Dermatol*. 2019;81(1):228-240.
70. Elmets CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology – National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy. *Am J Acad Dermatol*. 2019;81:775-804.
71. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80:1029-1072.
72. Nast A, Smith C, Spuls PI, et al. EuroGuiDerm guideline on the systemic treatment of psoriasis vulgaris – part 1: Treatment and monitoring recommendations. *J Eur Acad Dermatol Venereol*. 2020;34:2461-2498.
73. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology – National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol*. 2020;82(6):1445-1486.
74. Menter A, Cordoro KM, Davis DMR, et al. Joint American Academy of Dermatology – National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients. *J Am Acad Dermatol*. 2020;82(1):161-201.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

75. Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. *J Am Acad Dermatol.* 2021;84:432-470.
76. Armstrong AW. Nail psoriasis. In: UpToDate [internet database]. Duffin KC, Ofori AO, eds. Waltham, MA: UpToDate Inc. Updated February 14, 2022. Accessed June 6, 2022.
77. Paller AS, Lund BE. Psoriasis in children: Management of chronic plaque psoriasis. In: UpToDate [internet database]. Duffin KC, Levy ML, Ofori AO, eds. Waltham, MA: UpToDate Inc. Updated October 30, 2020. Accessed July 29, 2021.
78. Feldman SR. Treatment of psoriasis in adults. In: UpToDate [internet database]. Dellavalle RP, Duffin KC, Ofori AO, eds. Waltham, MA: UpToDate Inc. Updated May 24, 2022. Accessed June 7, 2022.
79. Kalb RE. Pustular psoriasis: Management. In: UpToDate [internet database]. Duffin KC, Ofori AO, eds. Waltham, MA: UpToDate Inc. Updated February 23, 2022. Accessed September 2, 2022.

Hidradenitis Suppurativa

80. Mikkelsen PR, Jemec GBE. Hidradenitis suppurativa in children and adolescents: A review of treatment options. *Pediatr Drugs.* 2014;16(6):483-489.
81. Zouboulis CC, Desai N, Emtestam L, et al. European S1 guideline for the treatment of hidradenitis suppurativa/acne inversa. *J Eur Acad Dermatol Venereol.* 2015;29(4):619-644.
82. Liy-Wong C, Pope E, Lara-Corrales I. Hidradenitis suppurativa in the pediatric population. *J Am Acad Dermatol.* 2015;33(1):18-27.
83. Gulliver W, Zouboulis CC, Prens E, Jemec GBE, Tzellos T. Evidence-based approach to the treatment of hidradenitis suppurativa/acne inversa, based on the European guidelines for hidradenitis suppurativa. *Rev Endocr Metab Disord.* 2016;17:343-351.
84. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations. Part II: Topical, intralesional, and systemic medical management. *J Am Acad Dermatol.* 2019;81:91-101.
85. Ingram JR. Hidradenitis suppurativa: Management. In: UpToDate [internet database]. Dellavalle RP, Owen C, Ofori AO, eds. Waltham, MA: UpToDate Inc. Updated January 22, 2021. Accessed July 23, 2021.

Non-Infectious Uveitis

86. Levy-Clarke G, Jabs DA, Read RW, Rosenbaum JT, Vitale AB, Van Gelder RN. Expert panel recommendations for the use of anti-tumor necrosis factor biologic agents in patients with ocular inflammatory disorders. *Ophthalmology.* 2014;121(3):785-796.
87. Constantin T, Foeldvari I, Anton J, et al. Consensus-based recommendations for the management of uveitis associated with juvenile idiopathic arthritis: The SHARE initiative. *Ann Rheum Dis.* 2018;77:1107-1117.
88. Dick AD, Rosenbaum JT, Al-Dhibi HA, et al. Guidance on noncorticosteroid systemic immunomodulatory therapy in noninfectious uveitis: Fundamentals of Care for Uveitis (FOCUS) initiative. *Ophthalmology.* 2018;125(5):757-773.
89. Angeles-Han ST, Lo MS, Henderson LA, et al. Childhood Arthritis and Rheumatology Research Alliance consensus treatment plans for juvenile idiopathic arthritis-associated and idiopathic chronic anterior uveitis. *Arthritis Care Res (Hoboken).* 2019;71(4):482-491. doi:10.1002/acr.23610.
90. Rosenbaum JT. Uveitis: Treatment. In: UpToDate [internet database]. Thorne JE, Romain PL, eds. Waltham, MA: UpToDate Inc. Updated March 22, 2021. Accessed July 30, 2021.

Giant Cell Arteritis

91. Yates M, Loke YK, Watts RA, MacGregor AJ. Prednisolone combined with adjunctive immunosuppression is not superior to prednisolone alone in terms of efficacy and safety in giant cell arteritis: A meta-analysis. *Clin Rheumatol.* 2014;33:227-236.
92. Biennvenu B, Ly KH, Lambert M, et al. Management of giant cell arteritis: Recommendations of the French Study Group for Large Vessel Vasculitis (GEFA). *Rev Med Interne.* 2016;37(3):154-65.
93. Stone JH, Tuckwell K, Dimonaco S, et al. Trial of tocilizumab in giant-cell arteritis. *N Engl J Med.* 2017;377(4):317-28.
94. Roberts J, Clifford A. Update on the management of giant cell arteritis. *Ther Adv Chronic Dis.* 2017;8(4-5):69-79.
95. Koster MJ, Warrington KJ. Tocilizumab – a new frontier for GCA therapy. *Nature Reviews Rheumatology.* 2017;13:700-701.
96. Koster MJ, Matteson EL, Warrington KJ. Large-vessel giant cell arteritis: Diagnosis, monitoring and management. *Rheumatology.* 2018;57:ii32-ii42.
97. González-Gay MA, Pina T, Prieto-Peña D, Calderon-Goercke M, Blanco R, Castañeda S. Current and emerging diagnosis tools and therapeutics for giant cell arteritis. *Expert Rev Clin Immunol.* 2018;14(7):593-605.
98. Pfeil A, Oelzner P, Hellmann P. The treatment of giant cell arteritis in different clinical settings. *Front Immunol.* 2019;9:1-8.
99. Turesson C, Börjesson O, Larsson K, Mohammad AJ, Knight A. Swedish Society of Rheumatology 2018 guidelines for investigation, treatment, and follow-up of giant cell arteritis. *Scand J Rheumatol.* 2019;48:259-265.
100. Koster MJ, Yeruva K, Crowson CS, Muratore F, Labarca C, Warrington KJ. Efficacy of methotrexate in real-world management of giant cell arteritis: A case-control study [published online ahead of print January 15, 2019]. *J Rheumatol.* doi: 10.3899/jrheum.180429.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

101. Low C, Conway R. Current advances in the treatment of giant cell arteritis: The role of biologics. *Ther Adv Musculoskel Dis.* 2019;11:1-11.
102. Mackie SL, Dejaco C, Appenzeller S, et al. British Society for Rheumatology guideline on diagnosis and treatment of giant cell arteritis. *Rheumatology.* 2020;59:e1-e23.
103. Maz M, Chung SA, Abril A, et al. 2021 American College of Rheumatology/Vasculitis Foundation guideline for the management of giant cell arteritis and Takayasu arteritis. *Arthritis Rheumatol.* 2021;73(8):1349-1365.
104. Docken WP. Treatment of giant cell arteritis. In: UpToDate [internet database]. Trobe J, Matteson EL, Curtis MR, eds. Waltham, MA: UpToDate Inc. Updated January 2, 2020. Accessed July 23, 2021.

Polymyalgia Rheumatica

105. Dejaco C, Singh YP, Perel P, et al. 2015 recommendations for the management of polymyalgia rheumatica: a European League Against Rheumatism/American College of Rheumatology collaborative initiative. *Ann Rheum Dis.* 2015;74:1799-1807.
106. Buttgerit F, Dejaco C, Matteson E, Dasgupta B. Polymyalgia rheumatic and giant cell arteritis: a systematic review. *JAMA.* 2016;315(22):2442-2458.
107. Salvarani C, Muratore F. Treatment of polymyalgia rheumatica. In: UpToDate [internet database]. Warrington KJ, Seo P, eds. Waltham, MA: UpToDate Inc. Updated April 3, 2023. Accessed August 31, 2023.

Autoinflammatory Syndromes

108. ter Haar NM, Oswald M, Jeyaratnam J, et al. Recommendations for the management of autoinflammatory diseases. *Ann Rheum Dis.* 2015;0:1-9.
109. Ozen S, Demirkaya E, Erer B, et al. EULAR recommendations for the management of familial Mediterranean fever. *Ann Rheum Dis.* 2016;75:644-651.
110. Ozen S, Kone-Paut I, Gül A. Colchicine resistance and intolerance in familial Mediterranean fever: Definition, causes, and alternative treatments. *Semin Arthritis Rheum.* 2017;47:115-120.
111. Meier-Schiesser B, French LE. Autoinflammatory syndromes. *JDDG: Journal der Deutschen Dermatologischen Gesellschaft.* 2021;19:400-426.
112. Nigrovic PA. Autoinflammatory diseases mediated by inflammasomes and related IL-1 family cytokines (inflammasomopathies). In: UpToDate [internet database]. Orange JS, Sundel R, TePas E, eds. Waltham, MA: UpToDate Inc. Updated November 6, 2020. Accessed August 4, 2021.
113. Nigrovic PA. Cypropyrin-associated periodic syndromes and related disorders. In: UpToDate [internet database]. Orange JS, Kaplan SL, TePas E, eds. Waltham, MA: UpToDate Inc. Updated March 16, 2021. Accessed August 4, 2021.
114. Ben-Chetrit E. Management of familial Mediterranean fever. In: UpToDate [internet database]. Pisetsky DS, Lamont JT, Ramirez Curtis M, Grover S, eds. Waltham, MA: UpToDate Inc. Updated January 14, 2020. Accessed July 23, 2021.

Behçet's Syndrome

115. International Study Group for Behçet's Disease. Criteria for diagnosis of Behçet's disease. *Lancet.* 1990;335(8697):1078-1080.
116. Hatemi G, Melikoglu M, Tunc R, et al. Apremilast for Behçet's syndrome – a phase 2, placebo-controlled study. *N Engl J Med.* 2015;372:1510-1518.
117. Hatemi G, Christensen R, Bang D, et al. 2018 update of the EULAR recommendations for the management of Behçet's syndrome. *Ann Rheum Dis.* 2018;77:808-818.
118. Smith EL, Yazici Y. Treatment of Behçet syndrome. In: UpToDate [internet database]. Merkel PA, Curtis MR, eds. Waltham, MA: UpToDate Inc. Updated February 3, 2020. Accessed July 23, 2021.

Cytokine Release Syndrome

119. National Comprehensive Cancer Network. Management of immunotherapy-related toxicities (Version 3.2021). https://www.nccn.org/professionals/physician_gls/pdf/immunotherapy.pdf. Accessed July 30, 2021.
120. The University of Texas MD Anderson Cancer Center. IEC therapy toxicity assessment and management also known as CARTOX) – pediatric. <https://www.mdanderson.org/documents/for-physicians/algorithms/clinical-management/clinical-management-cytokine-release-pedi-web-algorithm.pdf>. Approved March 23, 2021. Accessed July 30, 2021.
121. The University of Texas MD Anderson Cancer Center. ICE therapy toxicity assessment and management (also known as CARTOX) – adult. <https://www.mdanderson.org/documents/for-physicians/algorithms/clinical-management/clinical-management-cytokine-release-web-algorithm.pdf>. Approved September 15, 2020. Accessed July 30, 2021.

Systemic Sclerosis-Associated Interstitial Lung Disease

122. Kowal-Bielecka O, Franssen J, Avouac J, et al. Update of EULAR recommendations for the treatment of systemic sclerosis. *Ann Rheum Dis.* 2017;76:1327-1339.
123. Roofeh D, Distler O, Allanore Y, Denton CP, Khanna D. Treatment of systemic sclerosis-associated interstitial lung disease: Lessons learned from clinical trials. *J Scleroderma Relat Disord.* 2020;5(2_suppl):61-71.
124. Bernstein EJ, Huggins JT, Hummers LK, Owens GM. Systemic sclerosis with associated interstitial lung disease: Management and future directions. *Am J Manag Care.* 2021;27:S138-S146.
125. Foeldvari I, Culpo R, Sperotto F, et al. Consensus-based recommendations for the management of juvenile systemic sclerosis. *Rheumatology.* 2021;60:1651-1658.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

126. Roofeh D, Lin CJF, Goldin J, et al. Tocilizumab prevents progression in early systemic sclerosis-associated interstitial lung disease. *Arthritis Rheumatol.* 2021;73(7):1301-1310.
127. Varga J. Clinical manifestations, evaluation, and diagnosis of interstitial lung disease in systemic sclerosis (scleroderma). In: UpToDate [internet database]. King TE, Axford JS, Hollingsworth H, eds. Waltham, MA: UpToDate Inc. Updated March 8, 2021. Accessed July 27, 2021.
128. Varga J, Montesi S. Treatment and prognosis of interstitial lung disease in systemic sclerosis (scleroderma). In: UpToDate [internet database]. Lee JS, Dieffenbach P, eds. Waltham, MA: UpToDate Inc. Updated March 29, 2022. Accessed May 31, 2022.

Sarcoidosis

129. Ungprasert P, Ryu JH, Matteson EL. Clinical manifestations, diagnosis, and treatment of sarcoidosis. *Mayo Clin Proc Inn Qual Out.* 2019;3(3):358-375.
130. King TE Jr. Treatment of pulmonary sarcoidosis: Disease refractory to glucocorticoid therapy. In: UpToDate [internet database]. Flaherty KR, Hollingsworth H, eds. Waltham, MA: UpToDate Inc. Updated December 4, 2019. Accessed June 25, 2021.
131. Berman JS, Govender P. Gastrointestinal, hepatic, pancreatic, and peritoneal sarcoidosis. In: UpToDate [internet database]. Flaherty KR, King TE Jr., Feldman M, Hollingsworth H, eds. Waltham, MA: UpToDate Inc. Updated August 14, 2019. Accessed June 25, 2021.
132. Stern BJ. Neurologic sarcoidosis. In: UpToDate [internet database]. Aminoff MJ, King TE Jr., Wilterdink JL, eds. Waltham, MA: UpToDate Inc. Updated February 11, 2020. Accessed June 25, 2021.
133. Sequeira W, Aggarwal R. Sarcoid arthropathy. In: UpToDate [internet database]. Schur PH, Romain PL, eds. Waltham, MA: UpToDate Inc. Updated October 12, 2020. Accessed June 25, 2021.
134. Blankstein R, Cooper LT Jr. Management and prognosis of cardiac sarcoidosis. In: UpToDate [internet database]. Calkins H, McKenna WJ, Yeon SB, eds. Waltham, MA: UpToDate Inc. Updated June 10, 2021. Accessed June 25, 2021.
135. Sequeira W, Aggarwal R. Sarcoid myopathy. In: UpToDate [internet database]. Targoff IN, Shefner JM, Romain PL, eds. Waltham, MA: UpToDate Inc. Updated October 16, 2020. Accessed June 25, 2021.
136. Rizzato G, Choukroun G. Renal disease in sarcoidosis. In: UpToDate [internet database]. Curhan GC, Motwani S, eds. Waltham, MA: UpToDate Inc. Updated April 3, 2019. Accessed June 25, 2021.
137. Sequeira W, Aggarwal R. Sarcoidosis of bone. In: UpToDate [internet database]. Schur PH, Rosen CJ, Romain PL, eds. Waltham, MA: UpToDate Inc. Updated October 9, 2020. Accessed June 25, 2021.
138. Prystowsky S, Sanchez M. Cutaneous sarcoidosis: Management. In: UpToDate [internet database]. Callen J, Ofori AO, eds. Waltham, MA: UpToDate Inc. Updated April 2, 2021. Accessed June 25, 2021.

Graft Versus Host Disease

139. Zeiser R. Prevention of graft-versus-host disease. In: UpToDate [internet database]. Negrin RS, Chao NJ, Rosmarin AG, eds. Waltham, MA: UpToDate Inc. Updated May 16, 2022. Accessed June 7, 2022.

Alopecia Areata

140. Strazzulla LC, Wang EHC, Avila L, et al. Alopecia areata: An appraisal of new treatment approaches and overview of current therapies. *J Am Acad Dermatol.* 2018;78(1):15-24. doi: 10.1016/j.jaad.2017.04.1142.
141. Cranwell WC, Lai VW, Photiou L, et al. Treatment of alopecia areata: An Australian expert consensus statement. *Australas J Dermatol.* 2019;60(2):163-170. doi: 10.1111/ajd.12941.
142. Rossi A, Muscianese M, Piraccini BM, et al. Italian guidelines in diagnosis and treatment of alopecia areata. *G Ital Dermatol Venereol.* 2019;154(6):609-623. doi: 10.23736/S0392-0488.19.06458-7.
143. Ramos PM, Anzai A, Duque-Estrada B, et al. Consensus on the treatment of alopecia areata – Brazilian Society of Dermatology. *An Bras Dermatol.* 2020;95(S1):39-52.
144. Fukuyama M, Ito T, Ohyama M. Alopecia areata: Current understanding of the pathophysiology and update on therapeutic approaches, featuring the Japanese Dermatological Association guidelines. *J Dermatol.* 2022;49(1):19-36. doi: 10.1111/1346-8138.16207.
145. King B, Ohyama M, Kwon O, et al. Two phase 3 trials of baricitinib for alopecia areata. *N Engl J Med.* 2022;386(18):1687-1699.
146. Messenger AG. Alopecia areata: Management. In: UpToDate [internet database]. Dellavalle RP, Hordinsky M, Ofori AO, eds. Waltham, MA: UpToDate Inc. Updated November 29, 2021. Accessed June 2, 2022.

Generalized Pustular Psoriasis

147. Fujita H, Terui T, Hayama K, et al. Japanese guidelines for the management and treatment of generalized pustular psoriasis: The new pathogenesis and treatment of GPP. *J Dermatol.* 2018;45(11):1235-1270. doi: 10.1111/1346-8138.14523.
148. Bachelez H, Choon SE, Marrakchi S, et al. Trial of spesolimab for generalized pustular psoriasis. *N Engl J Med.* 2021;385:2431-2440.
149. Choon SE, Lebowitz MG, Marrakchi S, et al. Study protocol of the global Effisayil 1 phase II, multicentre, randomized, double-blind, placebo-controlled trial of spesolimab in patients with generalized pustular psoriasis presenting with an acute flare. *BMJ Open.* 2021;11:e043666.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

150. Morita A, Strober B, Burden AD, et al. Efficacy and safety of subcutaneous spesolimab for the prevention of generalized pustular psoriasis flares (Effisayl 2): an international, multicentre, randomised, placebo-controlled trial. *Lancet*. 2023;402:1541-1551.
151. Navarini AA, Burden AD, Capon F, et al. European consensus statement on phenotypes of pustular psoriasis. *J Eur Acad Dermatol Venereol*. 2017;31:1792-1799.
152. Kalb RE. Pustular psoriasis: management. In: UpToDate [internet database]. Callis Duffi K, Ofori AO, eds. Waltham, MA: UpToDate Inc. Updated October 21, 2022. Accessed August 16, 2024.

Gout

153. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology guideline for the management of gout. *Arthritis Care Res (Hoboken)*. 2020;72(6):744-760.
154. Richette P, Doherty M, Pascual E, et al. 2016 updated EULAR evidence-based recommendations for the management of gout. *Ann Rheum Dis*. 2017;76:29-42.
155. Schlesinger N, Alten RE, Bardin T, et al. Canakinumab for acute gouty arthritis in patients with limited treatment options: results from two randomised, multicentre, active-controlled, double-blind trials and their initial extensions. *Ann Rheum Dis*. 2012;71:1839-1848.
156. Gaffo AL. Treatment of gout flares. In: UpToDate [internet database]. Dalbeth N, Case SM, eds. Waltham, MA: UpToDate Inc. Updated August 24, 2023. Accessed September 1, 2023.