HIGHMARK HEALTH OPTIONS

Updated: 07/2024
Approved: 07/2024

Request for Prior Authorization for Cytokine and CAM Antagonists
Website Form – www.wv.highmarkhealthoptions.com
Submit request via: Fax - 1-833-547-2030.

All requests for Cytokine and CAM Antagonists require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Prior Authorization Criteria:

For all requests the following criteria must be met in addition to the diagnosis specific criteria below:

- Must be prescribed by or in consultation with an appropriate specialist (i.e. rheumatologist, dermatologist, gastroenterologist, oncologist, ophthalmologist).
- Is prescribed for an FDA-approved or medically accepted indication
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.
- Must be age-appropriate according to FDA-approved labeling, nationally recognized compendia, or evidence-based practice guidelines

Coverage may be provided with a diagnosis of **Rheumatoid Arthritis (RA)** and the following criteria is met:

- Must have a history of trial and failure of at least 3 months, contraindication, or intolerance to a conventional non-biologic DMARD (i.e. methotrexate, sulfasalazine, leflunomide)
- For JAK inhibitors documentation of trial and failure, contraindication, or intolerance to a TNF-inhibitor.
- **Initial Duration of Approval**: 6 months
- **Reauthorization Criteria**
  - Must provide documentation of positive clinical response
- **Reauthorization Duration of Approval**: 12 months

Coverage may be provided with a diagnosis of **Juvenile Idiopathic Arthritis (JIA)** and the following criteria is met:

- **Non-Systemic**
  - Polyarthritis:
    - Must have a trial and failure of at least 3 months, contraindication or intolerance to a preferred conventional non-biologic DMARD (i.e. methotrexate, sulfasalazine, leflunomide)
  - Oligoarthritis enthesitis and/or sacroiliitis:
    - Must have a trial and failure of at least 4 weeks or have a contraindication, or intolerance to at least 2 different NSAIDs
- **Systemic (SJIA)**
  - Diagnosis
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria**
  - Must provide documentation of a positive clinical response
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **Psoriatic Arthritis (PsA)** and ONE of the following criteria is met:

- Must meet ONE of the following criteria:
  - Member has peripheral disease and has tried and failed for at least 12 weeks or has a contraindication or intolerance of a conventional non-biologic DMARD (i.e. methotrexate, sulfasalazine, leflunomide)
  - Member has axial disease, and/or enthesitis and has tried and failed for at least 4 weeks or has an intolerance or contraindication to at least 2 NSAIDS.
  - The member has severe disease as defined by the prescriber.
- **Initial Duration of Approval:** 6 months
- **Reauthorization**:
  - Must provide documentation of a positive clinical response.
- **Reauthorization Duration of Approval**: 12 months

Coverage may be provided with a diagnosis of **Ankylosing Spondylitis or Non-Radiographic Axial Spondyloarthritis** and the following criteria is met:

- Must have a trial and failure of at least 4 weeks or have a contraindication, or intolerance to at least 2 different NSAIDs
- **Initial Duration of Approval**: 6 months
- **Reauthorization Criteria**:
  - Must provide documentation of a positive clinical response.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **Plaque Psoriasis** and the following criteria is met:

- Has a severity that is consistent with the FDA-approved indication for the prescribed product
- Must have greater than or equal to 3% body surface involved or disease affecting crucial body areas such as hands, feet, face, or genitals.
- **Initial Duration of Approval**: 6 months
- **Reauthorization Criteria**:
  - Must provide documentation of a decrease in percent of body surface area involvement when compared to baseline
- **Reauthorization Duration of Approval**: 12 months

Coverage may be provided with a diagnosis of **Generalized Pustular Psoriasis (GPP)** and the following criteria is met:

- Must have a flare of GPP with moderate-to-severe intensity defined by meeting all of the following:
  - A GPPPGA (Generalized Pustular Psoriasis Physician Global Assessment) total score ≥ 3 (0=clear, 1=almost clear, 2=mild, 3=moderate, 4=severe)
  - The presence of fresh pustules (new or worsening of pustules)
  - GPPPGA postulation subscore ≥ 2 (mild, moderate, or severe)
  - At least 5% BSA covered with erythema and presence of pustules
- **Duration of Approval**: 1 treatment (up to 2 infusions over 2 weeks)

Coverage may be provided with a diagnosis of **Moderate to Severe Atopic dermatitis** and the following criteria is met:

- In addition to pruritic skin, member must have at least three of the following:
  - History of skin creases being involved. These include: antecubital fossae, popliteal fossae, neck, areas around eyes, fronts of ankles.
  - History of asthma or hay fever
  - The presence of generally dry skin within the past year.
  - Symptoms beginning before the age of two years.
  - Visible dermatitis involving flexural surfaces.
- Documentation showing the member has tried and failed or had an intolerance or contraindication to BOTH of the following:
  - Medium to high potency topical corticosteroid
  - Calcineurin inhibitor* [i.e. Protopic (tacrolimus) or Elidel (pimecrolimus)]
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
  - Member has experienced improvement
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **Hidradenitis Suppurativa** and the following criteria is met:

- Must have moderate to severe hidradenitis suppurativa with Hurley Stage II or III disease with at least 3 abscesses or inflammatory nodules
- **Initial Duration of Approval**: 6 months
- **Reauthorization Criteria**:
  - Must provide documentation of a positive clinical response
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **severe alopecia areata** and the following criteria is met:

- Must have ≥ 50% scalp hair loss for more than 6 months
- **Initial Duration of Approval**: 9 months
- **Reauthorization Criteria:**
  - Must provide documentation of a positive clinical response
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **Uveitis** and the following criteria is met:

- Must have non-infectious intermediate, posterior, or panuveitis
- Must have a history of trial and failure, contraindication, or intolerance to conventional treatments including ONE of the following for at least 3 months of each medication:
  - Steroids (*i.e.*, prednisone)
  - Immunomodulators (*i.e.*, Azathioprine, 6-Mercaptopurine, Methotrexate)
- **Initial Duration of Approval**: 6 months
- **Reauthorization Criteria:**
  - Must provide documentation of sustained improvement in ocular inflammation or there was no worsening of ocular co-morbidities.

- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **Ulcerative Colitis** and the following criteria is met:

- For members with mild UC and a poor prognostic factor*, must have a history of trial and failure, contraindication, or intolerance to BOTH of the following:
  - Aminosalicylates, 5-ASAs (i.e., Sulfasalazine, Pentasa, Apriso, Delzicol)
  - Glucocorticoids
- For members with moderate to severe UC, must have a history of trial and failure, contraindication or intolerance to an immunomodulator (i.e., Azathioprine, 6-Mercaptopurine, Methotrexate)
- **Initial Duration of Approval**: 6 months
- **Reauthorization Criteria:**
  - Must provide documentation of a positive clinical response
- **Reauthorization Duration of Approval:** 12 months

*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).

Coverage may be provided with a diagnosis of moderate to severe **Crohn's Disease** and the following criteria is met:

- Must have a history of trial and failure, contraindication, or intolerance to TWO of the following:
  - Glucocorticoids (e.g. prednisone, budesonide)
  - Aminosalicylates (mesalamine, sulfasalazine)
  - Immunomodulators (i.e., azathioprine, 6-mercaptopurine, methotrexate) OR
  - Has a diagnosis of Crohn's disease that is associated with one or more high risk or poor prognostic feature(s)*
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria:**
  - Must provide documentation of a positive clinical response.
- **Reauthorization Duration of Approval:** 12 months

* 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.

Coverage may be provided with a diagnosis of **Adult Onset Still's Disease (AOSD)** and the following criteria is met:

- If the member has predominantly systemic disease, **ONE** of the following:
  - Member must have a history of trial and failure, contraindication or intolerance to glucocorticoids (e.g. prednisone, methylprednisolone)

    - Member has glucocorticoid dependent Still's disease and will be using the requested Cytokine and CAM antagonist with the intent of decreasing or discontinuing the dose of the glucocorticoid
- If the member has predominantly joint disease, must have a history of trial and failure, contraindication or intolerance to a conventional non-biologic DMARD
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria**
    - Must provide documentation of a positive clinical response.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **Familial Mediterranean Fever (FMF)** and the following criteria is met:

- Must have a history of trial and failure, contraindication, or intolerance to colchicine for at least 3 months
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria:**
    - Must provide documentation of a positive clinical response.
- **Reauthorization Duration of Approval**: 12 months

Coverage may be provided with a diagnosis of chimeric antigen receptor T cell (CAR-T) induced severe or life-threatening **Cytokine Release Syndrome (CRS)**

- **Duration of Approval**: 1 month

Coverage may be provided with a diagnosis of **Giant Cell Arteritis** and the following criteria is met:

- Must meet ONE of the following:
    - Has a history of trial and failure, contraindication, or intolerance to systemic glucocorticoids
    - Has glucocorticoid-dependent disease and will be using the requested medication with the intent of discontinuing or decreasing the systemic glucocorticoid
- **Initial Duration of Approval**: 6 months
- **Reauthorization Criteria**
    - Must provide documentation of a positive clinical response
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **Behcet's Disease** and the following criteria is met:

- Must provide documentation of recent oral ulcerations that recurred at least 3 times in one 12 month period
- Must provide documentation of TWO of the following:
    - Recurrent genital ulcerations
    - Eye lesions
    - Skin lesions
    - Positive pathergy test (Behcetine test) read by physician
- Must have a history of trial and failure, contraindication, or intolerance to BOTH of the following:
    - Colchicine for at least 4 months

    - Topical corticosteroids
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria:**
    - Must provide documentation of a positive clinical response
- **Reauthorization Duration of Approval**: 12 month

Coverage may be provided with a diagnosis of **Recurrent Pericarditis (RP)** and the following criteria is met:

- Must have a history of trial and failure of at least 1 month, contraindication, or intolerance to colchicine in combination with an NSAID or aspirin.
- **Initial Duration of Approval**: 6 months
- **Reauthorization Criteria**
    - Must provide documentation of positive clinical response
- **Reauthorization Duration of Approval**: 12 months

Coverage may be provided for use as prophylaxis of **acute graft versus host disease (aGVHD)** and the following criteria is met:

- Must be undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor
- Must be used in combination with a calcineurin inhibitor and methotrexate
- **Duration of Approval**: for first month after HSCT

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

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CYTOKINE AND CAM ANTAGONISTS
PRIOR AUTHORIZATION FORM – PAGE 1 of 3

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX: (833)-547-2030**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6251 Mon – Fri 8 am to 7 pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Health Options ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:

Rheumatoid Arthritis (RA)
Has the member tried a conventional non-biologic DMARD (i.e. methotrexate, sulfasalazine, leflunomide) for at least 3 months?
☐ Yes ☐ No

Juvenile Idiopathic Arthritis (JIA)
☐ JIA with **polyarthritis**: Has the member tried a preferred conventional non-biologic DMARD (i.e. methotrexate) for at least 3 months? ☐ Yes ☐ No
☐ JIA with **oligoarthritis**, **enthesitis and/or sacroiliitis**: Has the member tried 2 different NSAIDs for at least 4 weeks? ☐ Yes ☐ No

Systemic Juvenile Idiopathic Arthritis (SJIA)
Does the member have moderate to severe SJIA? ☐ Yes ☐ No

Psoriatic Arthritis (PsA)
Which of the following apply to the member? Check all that apply:
☐ **Mild-Moderate Peripheral** Disease: Has the member tried a conventional non-biologic DMARD (i.e. methotrexate, sulfasalazine, leflunomide) for at least 3 months? ☐ Yes ☐ No
☐ **Mild-Moderate Axial** Disease and/or **Enthesitis**: Has the member had a trial and failure for at least 4 weeks, contraindication, or intolerance to at least 2 different NSAIDs? ☐ Yes ☐ No
☐ **Severe** Disease

Ankylosing Spondylitis or Non-Radiographic Axial Spondyloarthritis
Has the member tried at least 2 different NSAIDs for at least 4 weeks? ☐ Yes ☐ No

Uveitis
Does the member have non-infectious intermediate, posterior, or panuveitis? ☐ Yes ☐ No
Has the member had a trial and failure, contraindication, or intolerance to either a 3 month trial of steroids (e.g. prednisone) OR immunomodulators (e.g. azathioprine, 6-mercaptopurine, methotrexate)? ☐ Yes ☐ No

Plaque Psoriasis
Is the psoriasis moderate to severe (≥5% BSA) or affecting crucial body areas (e.g. hands, feet, face, genitals)? ☐ Yes ☐ No

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CYTOKINE AND CAM ANTAGONISTS
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 3

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If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6251 Mon – Fri 8 am to 7 pm

MEMBER INFORMATION

Member Name:	DOB:	
Health Options ID:	Member weight:	Height:

MEDICAL HISTORY (Complete for ALL requests)

Moderate to Severe Atopic Dermatitis
Which of the following apply to the member? Please check all that apply.
- ☐ Pruritic skin
- ☐ Involvement of skin creases
- ☐ History of asthma or hay fever
- ☐ Generally dry skin within the past year
- ☐ Symptoms beginning before age 2
- ☐ Visible dermatitis involving flexural surfaces

What has been tried? (Please list below)
- ☐ Medium to high potency topical corticosteroid
- ☐ Calcineurin Inhibitor [e.g. tacrolimus, Elidel (pimecrolimus)]

Hidradenitis Suppurativa (HS)
Is the disease moderate to severe (Hurley Stage II or III) with ≥3 abscesses or inflammatory nodules? ☐ Yes ☐ No

Generalized Pustular Psoriasis (GPP)
How much BSA is covered with erythema and/or pustules? ☐ < 5% ☐ ≥ 5%
Are there any new or worsening pustules? ☐ Yes ☐ No
Provide the following Generalized Pustular Psoriasis Physician Global Assessment scores:
Total GPPPGA: ☐ 0 (clear) ☐ 1 (almost clear) ☐ 2 (mild) ☐ 3 (moderate) ☐ 4 (severe)
BPPPGA postulation subscore: ☐ 0 (clear) ☐ 1 (almost clear) ☐ 2 (mild) ☐ 3 (moderate) ☐ 4 (severe)

Alopecia Areata
What is the disease severity? ☐ Mild ☐ Moderate ☐ Severe
What is the extent of scalp hair loss? ☐ < 50% ☐ ≥ 50%
How long has this level of hair loss persisted? ☐ ≤ 6 months ☐ > 6 months

Ulcerative Colitis (UC)
☐ **Mild** UC and a poor prognostic factor*: has the member tried aminosalicylates (e.g. sulfasalazine, pentasa, apriso, delzicol) AND glucocorticoids? ☐ Yes ☐ No
** 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).*
☐ **Moderate to Severe** UC: has the member tried an immunomodulator (e.g. azathioprine, 6-mercaptopurine, methotrexate)? ☐ Yes ☐ No

Crohn's Disease (CD)
Which of the following have been tried? Please select all that apply:
- ☐ Glucocorticoids (e.g. prednisone, budesonide)
- ☐ Aminosalicylates (e.g. mesalamine, sulfasalazine)
- ☐ Immunomodulators (e.g. azathioprine, 6-mercaptopurine, methotrexate)

Adult Onset Still's Disease (AOSD)
☐ Predominantly **Systemic Disease**:
Has the member tried glucocorticoids (e.g. prednisone, methylprednisolone)? ☐ Yes ☐ No
Does the member have glucocorticoid dependent disease and will be using the requested medication with the intent of decreasing or discontinuing the dose of the glucocorticoid? ☐ Yes ☐ No
☐ Predominantly **Joint Disease**: Has the member tried a conventional non-biologic DMARD? ☐ Yes ☐ No

Cytokine Release Syndrome (CRS)
Does the member have chimeric antigen receptor T cell (CAR-T) induced severe or life-threatening CRS? ☐ Yes ☐ No

Familial Mediterranean Fever (FMF)
Has the member tried colchicine for at least 3 months? ☐ Yes ☐ No

Recurrent Pericarditis (RP)
Has the member tried colchicine for at least 1 month in combination with an NSAID or aspirin? ☐ Yes ☐ No

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CYTOKINE AND CAM ANTAGONISTS
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 3 OF 3

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MEMBER INFORMATION

Member Name:	DOB:	
Health Options ID:	Member weight:	Height:

MEDICAL HISTORY (Complete for ALL requests)

Giant Cell Arteritis
Has the member tried glucocorticoids (e.g. prednisone, methylprednisolone)? ☐ Yes ☐ No
Does the member have glucocorticoid dependent disease and will be using the requested medication with the intent of decreasing or discontinuing the dose of the glucocorticoids? ☐ Yes ☐ No

Bechet's Disease
Has the member experienced recent oral ulcerations that recurred at least 3 times in one 12 month period? ☐ Yes ☐ No
Please select all that apply to the member:
☐ Recurrent genital ulcerations
☐ Positive pathergy test (Behcetine test) read by physician
☐ Eye lesions
☐ Skin lesions
Which of the following have been tried? Please select all that apply:
☐ Colchicine for at least 4 months
☐ Topical corticosteroids

Acute graft versus host disease (aGVHD)
Is the member undergoing HSCT from a matched or 1 allele-mismatched unrelated-donor? ☐ Yes ☐ No
Is the requested product being used in combination with a calcineurin inhibitor and methotrexate? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member experienced a positive clinical response with treatment? ☐ Yes ☐ No
For **plaque psoriasis**, has there been a decrease in percent of body surface area involvement? ☐ Yes ☐ No
For **uveitis**, has there been sustained improvement in ocular inflammation or no worsening of ocular co-morbidities? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date