

Request for Prior Authorization for Cytokine and CAM Antagonists Website Form – <u>www.wv.highmarkhealthoptions.com</u> 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 <u>diagnosis</u> 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)
- 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 <u>diagnosis</u> 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:
 - Diagnosis
- Systemic (SJIA)
 - \circ 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 <u>diagnosis</u> 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
 - 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 <u>diagnosis</u> 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 <u>diagnosis</u> 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 <u>diagnosis</u> 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 <u>diagnosis</u> 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 <u>diagnosis</u> 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 <u>diagnosis</u> of **severe alopecia areata** and the following criteria is met:

- Must have $\geq 50\%$ 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 <u>diagnosis</u> 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)
 - o 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 <u>diagnosis</u> 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
- 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 <u>diagnosis</u> 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 ONE of the following:
 - Glucocorticoids (e.g. prednisone, budesonide)
 - Aminosalicylates (mesalamine, sulfasalazine)
 - o 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 <u>diagnosis</u> 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 <u>diagnosis</u> 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 <u>diagnosis</u> 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 <u>diagnosis</u> 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 <u>diagnosis</u> 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.



	AM ANTAGONISTS			
	ON FORM – PAGE 1 of 3			
Please complete and fax all requested information below including as applicable to Highmark Health Options				
If needed, you may call to speak to a Pharmacy Services Rep				
PROVIDER INFORMATION				
Requesting Provider:	NPI:			
Provider Specialty:	Office Contact:			
Office Address:	Office Phone:			
	Office Fax:			
MEMBER IN	FORMATION			
Member Name:	DOB:			
Health Options ID:	Member weight:	Height:		
REQUESTED DRU	JG INFORMATION			
Medication:	Strength:			
Directions:	Quantity:	Refills:		
Is the member currently receiving requested medication?		ation Initiated:		
Is this medication being used for a chronic or long-term condition	for which the medication ma	ay be necessary for the life of the		
patient? Yes No				
	formation			
	cally, JCODE:			
	er's home 🗌 Other			
	ce Information			
Name:	NPI:			
Address:	Phone:			
MEDICAL HISTORY (C	omplete for ALL requests)			
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Diagnosis:	omplete for ALL requests) ICD Code:			
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CYTOKINE AND CAM ANTAGONISTS PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 3				
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 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				
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 Generally dry skin within the past year				
Involvement of skin creases Symptoms beginning before age 2				
History of asthma or hay fever 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? \Box Yes \Box No				
Generalized Pustular Psoriasis (GPP)				
How much BSA is covered with erythema and/or pustules? $\square < 5\%$ $\square \ge 5\%$				
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? $\square < 50\%$ $\square \ge 50\%$				
How long has this level of hair loss persisted? $\square \le 6$ months $\square > 6$ months				
Ulcerative Colitis (UC)				
Mild UC and a poor prognostic factor*: has the member tried aminosalicylates (e.g. sulfasalazine, pentasa, apriso, delzicol)				
AND glucocorticoids? TYes 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				
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 Cytaking Palaese Syndrome (CPS)				
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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PRIO	R AUTHORIZATION FO	RM (CONTINUED) –	PAGE 3 OF 3		
			aboratory test results, or chart documentation		
	to Highmark Health Options				
If needed, you may call to speak			(844) 325-6251 Mon – Fri 8 am to 7 pm		
	MEMBER I	NFORMATION			
Member Name:		DOB:			
Health Options ID:		Member weight:	Height:		
	MEDICAL HISTORY (Complete for ALL req	uests)		
Giant Cell Arteritis		· · · ·			
Has the member tried glucocorticoid					
		ll be using the requested	medication with the intent of decreasing or		
discontinuing the dose of the glucoco	orticoids? 🗌 Yes 🗌 No				
Bechet's Disease					
Has the member experienced recent		1 at least 3 times in one	12 month period? Yes No		
Please select all that apply to the mer	mber:				
Recurrent genital ulcerations	· · · · · · · · · · · · · · · · · · ·	Eye lesions			
Positive pathergy test (Behcet					
Which of the following have been tri		ply:			
Colchicine for at least 4 month	ns				
Topical corticosteroids					
Acute graft versus host disease (aGVHD)					
Acute graft versus host disease (aC		matched unrelated-dong	or? 🗌 Ves 🔲 No		
Acute graft versus host disease (aC Is the member undergoing HSCT fro	om a matched or 1 allele-mis				
Acute graft versus host disease (aC	m a matched or 1 allele-mis n combination with a calcing	eurin inhibitor and meth			
Acute graft versus host disease (aC Is the member undergoing HSCT fro	m a matched or 1 allele-mis n combination with a calcing				
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