HIGHMARK HEALTH OPTIONS

Updated: 04/2021
DMMA Approved: 06/2021

Request for Prior Authorization for Cytokine and CAM Antagonists
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

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.

Cytokine and CAM Antagonists include Actemra (tocilizumab), Arcalyst (rilonacept), Cimzia (certolizumab pegol), Cosentyx (secukinumab), Enbrel (etanercept), Entyvio (vedolizumab), Humira (adalimumab), Ilaris (canakinumab), Ilumya (tildrakizumab-asmn), Kevzara (sarilumab), Kineret (Anakinra), Olumiant (baricitinib), Orencia (abatacept), Otezla (apremilast), Remicade (infliximab), Rinvoq (upadacitinib), Siliq (Brodalumab), Simponi/Simponi Aria (golimumab), Skyrizi (risakizumab-rzaa), Stelara (ustekinumab), Taltz (ixekizumab), Tremfya (Guselkumab), Xeljanz/Xeljanz XR (tofacitinib). New products with this classification will require the same documentation. Biosimilar agents do not require prior authorization.

Cytokine and CAM Antagonists 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 (ie. rheumatologist, dermatologist, gastroenterologist, oncologist, ophthalmologist).
- Must have a therapeutic failure, contraindication, or intolerance to the preferred biosimilar agent(s) FDA-approved or medically accepted for the member's diagnosis
- For non-preferred agents, must have a therapeutic failure, contraindication, or intolerance to the preferred agent(s) FDA-approved or medically accepted for the member's diagnosis
- 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)
- **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:

- JIA with 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)
- JIA with 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
- **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:

- Must have moderate to severe plaque psoriasis characterized by greater than or equal to 5% body surface involved or disease affecting crucial body areas such as hands, feet, face, or genitals.
- Must have a history of trial and failure, contraindication, or intolerance to a three-month trial of BOTH of the following:
  - One non-biologic systemic treatment (i.e. methotrexate, cyclosporine, acitretin)

  - Phototherapy (i.e. Psoralens with UVA light (PUVA) or UVB light) **except** for members who also have Psoriatic Arthritis
- **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 **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
- Member has tried and failed the following if applicable:
  - Weight reduction in patients who are obese
  - Cessation of cigarette smoking
- Must have an inadequate response, intolerance or contraindication to at least two of the following conventional treatment measures:
  - Use of antiseptic washes (e.g., chlorhexidine, benzoyl peroxide) to cleanse skin in the affected areas
  - Oral antibiotic therapy (e.g., tetracyclines, clindamycin and rifampin)
  - Oral antiandrogenic agents if assigned female at birth (e.g., estrogen-containing contraceptives, spironolactone, metformin, etc.)
  - Light/laser therapy (Nd:YAG laser, CO_2 laser, etc.)
- **Initial Duration of Approval**: 6 months
- **Reauthorization Criteria**:
  - Must provide documentation of at least 50% reduction in total abscess and inflammatory nodule count with no increase in draining fistula count relative to baseline
- **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

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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 **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)
- **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 moderate to severe **Systemic Juvenile Idiopathic Arthritis (SJIA).**

- **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 **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 **Cryopyrin-Associated Periodic Syndrome (CAPS)** and the following criteria is met:

- Diagnosis is confirmed by genetic testing for NALP3 mutations
- Must have documented signs and symptoms including raised inflammatory markers (C-reactive protein and serum amyloid A) in addition to at least two of six typical CAPS manifestions:
  - Urticaria-like rash
  - Cold-triggered episodes
  - Sensorineural hearing loss
  - Musculoskeletal symptoms
  - Chronic aseptic meningitis
  - Skeletal abnormalities
- **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 **Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) in adults/pediatrics** and the following criteria is met:

- Diagnosis is confirmed by ONE of the following:
  - Presence of a confirmatory *TNFRSF1A* genotype and ONE of the following:
    - Duration of episodes ≥7 days
    - Myalgia
    - Migratory rash
    - Periorbital edema
    - Relatives affected
  - Presence of a not confirmatory *TNFRSF1A* genotype and TWO of the following:
    - Duration of episodes ≥7 days
    - Myalgia
    - Migratory rash
    - Periorbital edema
    - Relatives affected
- Member must be on concurrent glucocorticoid therapy

- **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 **Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD in adults/pediatrics)** and the following criteria is met:

- Diagnosis is confirmed by either genetic mevalonate kinase (MVK) gene or enzymatic (MKD) findings.
- Must have a history of trial and failure, contraindication, or intolerance to BOTH of the following:
  - NSAIDs
  - Glucocorticoids
- **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 months

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 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:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6251 Monday through Friday 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 **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:
☐ **Peripheral** Disease: Has the member tried a conventional non-biologic DMARD (i.e. methotrexate, sulfasalazine, leflunomide) for at least 3 months? ☐ Yes ☐ No
☐ **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

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Does the member have non-infectious intermediate, posterior, or panuvetis? ☐ 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

***** Continued on next page *****

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PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 3

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MEMBER INFORMATION

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

MEDICAL HISTORY (Complete for ALL requests)

Plaque Psoriasis
Does the member have moderate to severe psoriasis (≥5% BSA) or disease affecting crucial body areas (e.g. hands, feet, face, genitals)? ☐ Yes ☐ No
Which of the following have been tried for at least 3 months? Check all that apply:
- ☐ Non-biologic systemic treatment (i.e. methotrexate, cyclosporine, acitretin)?
- ☐ Phototherapy (i.e. Psoralens with UVA (PUVA) or UVB light)?

Hidradenitis Suppurativa (HS)
Does the member have moderate to severe disease (Hurley Stage II or III) with at least 3 abscesses or inflammatory nodules?
☐ Yes ☐ No
Please indicate if the following have been tried:
Weight reduction: ☐ Yes ☐ No ☐ Not applicable (not obese)
Cessation of cigarette smoking: ☐ Yes ☐ No ☐ Not applicable (non-smoker)
Please select all therapies that have been tried:
- ☐ Use of antiseptic washes (e.g., chlorhexidine, benzoyl peroxide)
- ☐ Oral antibiotic therapy (e.g., tetracyclines, clindamycin and rifampin)
- ☐ Oral antiandrogenic agents (e.g., estrogen-containing contraceptives, spironolactone, metformin
- ☐ Light/laser therapy (Nd:YAG laser, CO2 laser, etc.)

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

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Cryopyrin-Associated Periodic Syndrome (CAPS)
Has the diagnosis been confirmed by genetic testing for NALP3 mutations? ☐ Yes ☐ No
Does the member have documented signs and symptoms? Please select all that apply to the member:
- ☐ Urticaria-like rash
- ☐ Cold-triggered episodes
- ☐ Sensorineural hearing loss
- ☐ Raised inflammatory markers (C-reactive protein and serum amyloid A)
- ☐ Musculoskeletal symptoms
- ☐ Chronic aseptic meningitis
- ☐ Skeletal abnormalities

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

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PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 3 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:** (855) 476-4158
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MEMBER INFORMATION

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

MEDICAL HISTORY (Complete for ALL requests)

Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) in adults/pediatrics
Has the diagnosis been confirmed by the presence of a confirmatory *TNFRSF1A* genotype? ☐ Yes ☐ No
Please select all that apply to the member:
- ☐ Duration of episodes ≥7 days
- ☐ Myalgia
- ☐ Migratory rash
- ☐ Periorbital edema
- ☐ Relatives affected

Is the member on concurrent glucocorticoid therapy? ☐ Yes ☐ No

Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD in adults/pediatrics)
Has the diagnosis been confirmed by either genetic mevalonate kinase (MVK) gene or enzymatic (MKD) findings? ☐ Yes ☐ No
Has the member tried both NSAIDs AND glucocorticoids? ☐ Yes ☐ No

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

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

Recurrent Pericarditis (RP)
Has the member tried colchicine for at least 2 month in combination with an NSAID or aspirin? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

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

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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 **Hidradenitis Supperativa (HS)**, has there been ≥ 50% reduction in total abscess and inflammatory nodule count with no increase in draining fistula count? ☐ 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