

Request for Prior Authorization for Non-TNF Biologic Therapies
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Non-TNF Biologic Therapies require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Non-TNF Biologic Therapies include Orenicia (abatacept), Actemra (tocilizumab), Arcalyst (rilonacept), Cosentyx (secukinumab), Entyvio (vedolizumab), Ilaris (canakinumab), Kineret (Anakinra), Otezla (apremilast), Stelara (ustekinumab), Taltz (ixekizumab), Tremfya (Guselkumab), Siliq (Brodalumab), Ilumya (tildrakizumab-asmn), Olumiant (baricitinib), Kevzara (sarilumab), Skyrizi (risakizumab-rzaa), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib). New products with this classification will require the same documentation.

Non-TNF Biologic Therapies Prior Authorization Criteria:

For all requests for Non-TNF Biologic Therapies all of the following criteria must be met:

- Must be prescribed by or in consultation with an appropriate specialist (ie. rheumatologist, dermatologist, gastroenterologist, oncologist, ophthalmologist).
- 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
- Members who are currently established on therapy will not be required to change to a formulary/preferred product.

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

- Member must have a history of trial and failure, contraindication, or intolerance to ALL of the following
 - Three-month trial with methotrexate or another preferred DMARD.
 - Three-month trial with either Humira* OR Enbrel* with or without MTX unless there is clinical rationale for using a non-TNF over a TNF inhibitor
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria**
 - All reauthorization requests must provide documentation of positive clinical response involving ANY of the following clinical/laboratory parameters:
 - Number of swollen joints
 - Number of tender joints
 - Member's assessment of pain
 - Member's global assessment of disease activity
 - HAQ score and/or
 - CRP (C-reactive protein).
- **Reauthorization Duration of Approval:** 12 months

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

- Member must have a history of trial and failure, contraindication, or intolerance to a three-month trial with BOTH of the following:
 - DMARD (ie. MTX, leflunomide)
 - Humira* OR Enbrel*
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria**
 - Reauthorization benefit will be approved if there is documented, significant improvement in AJC (active joint count) with prior courses of treatment.
- **Reauthorization Duration of Approval:** 12 months

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

- The member must have a history of trial and failure, contraindication, or intolerance to ONE of the following:
 - 1 month of NSAIDs
 - 2 weeks of glucocorticoids
 - 1 month of anakinra (Kineret)* therapy
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria**
 - Reauthorization benefit will be approved if there is evidence of positive clinical response involving ANY of the following clinical/laboratory parameters:
 - Joint count
 - Physician and the member's/parent global assessment
 - ESR (erythrocyte sedimentation rate)
 - CRP (C-Reactive Protein)
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **Moderate to Severe Adult Onset Still's Disease** and the following criteria is met:

- Member must meet ONE of the following:
 - Member has four or more major criteria:
 - Spiking fever $\geq 39^{\circ}\text{C}$
 - Arthralgia
 - Transient erythema
 - Pharyngitis
 - Polymorphonuclear cells $\geq 80\%$
 - Glycosylated ferritin $\leq 20\%$
 - Members has 2 major and ALL minor criteria:
 - Major criteria
 - Spiking fever $\geq 39^{\circ}\text{C}$
 - Arthralgia
 - Transient erythema
 - Pharyngitis

- Polymorphonuclear cells $\geq 80\%$
- Glycosylated ferritin $\leq 20\%$
- Minor criteria
 - Maculopapular rash
 - Leukocytosis $\geq 10,000/\text{mm}^3$
- Member must have a history of trial and failure, contraindication, or intolerance to ALL of the following:
 - One month trial of NSAIDs or a 2 week trial of steroid monotherapy
 - Three week trial of Methotrexate
 - Three-month trial of Humira OR Enbrel*
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria**
 - Reauthorization benefit will be approved if there is evidence of 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:

- Member must have clinical documentation of a diagnosis of 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.
- Members must have therapeutic failure of a three or more month trial or a contraindication to BOTH of the following:
 - Psoralens with UVA light (PUVA) or UVB light
 - Systemic treatments including ONE of the following:
 - Immunomodulators (i.e. Methotrexate, Cyclosporine)
 - Retinoids (i.e. Soriatane)
- Member must have a history of trial and failure, contraindication, or intolerance to a three-month trial of Humira* OR Enbrel*
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria:**
 - Clinical documentation that supports a decrease in percent of body surface area involvement when compared to baseline must be submitted
 - **Reauthorization Duration of Approval:** 12 months

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

- Member has moderately to severely active psoriatic arthritis indicated by the presence of at least ONE of the following:
 - Erosive Disease
 - Elevated Markers of inflammation attributable to psoriatic arthritis
 - Long-term damage that interferes with function (i.e., joint deformities)
 - Highly active disease that causes a major impairment in quality of life
 - Active PsA at many sites including dactylitis, enthesitis
 - Function-limiting PsA at a few sites

- Rapidly progressive disease.
- Member must have a history of trial and failure, contraindication, or intolerance to BOTH of the following:
 - A four-week trial each of at least 2 NSAIDs
 - Three-month trial with either Humira* OR Enbrel*
- **Initial Duration of Approval:** 6 months
- **Reauthorization:**
 - Reauthorization benefit will be approved if there is evidence of positive clinical response involving ANY of the following clinical/laboratory parameters:
 - Number of swollen joints
 - Number of tender joints
 - Member's assessment of pain
 - Member's global assessment of disease activity
 - HAQ score and/or
 - CRP (C-reactive protein).
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **Cytokine Release Syndrome (CRS)** and the following criteria is met:

- Member meets one of the following criteria for Cytokine Release Syndrome (CRS):
 - Grade 1 CRS with persistent or refractory fever
 - Grade 2 with any ONE of the following:
 - Hypotension refractory to fluid boluses
 - Presence of hypoxia.
 - Organ toxicity.
 - Grade 3 Documented diagnosis of chimeric antigen receptor (CAR) T cell-induced severe CRS with any ONE of the following:
 - Defined as: oxygen requirement $\geq 40\%$.
 - Hypotension requiring high dose or multiple vasopressors.
 - Grade 3 organ toxicity or grade 4 transaminitis.
 - Grade 4 Life threatening CRS with any ONE of the following:
 - Defined as: requirement for ventilator support.
 - Grade 4 organ toxicity (excluding transaminitis).
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria**
 - Must provide documentation that member still meets the hemodynamic and liver function values specified in initial criteria.
 - Reauthorization benefit will be approved if there is documentation that member is tolerating and responding to treatment.
- **Reauthorization Duration of Approval:** 12 months

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

- Diagnosis is confirmed by ONE of the following:
 - Temporal artery biopsy or cross-sectional imaging

- Acute-phase reactant elevation (i.e. high erythrocyte sedimentation rate and/ or high serum C-reactive protein)
- Member must have a history of trial and failure, contraindication, or intolerance to a one-week trial of glucocorticoids (e.g., prednisone, methylprednisone).
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria**
 - Must provide documentation that member still meets the hemodynamic and liver function values specified in initial criteria.
 - Reauthorization benefit will be approved if there is documentation that member is tolerating and responding to treatment.
- **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:

- For Arcalyst or Ilaris:
 - The member has genetic evidence of a CIAS1 (NLRP3) mutation based on DNA sequencing.
 - The member has documented signs and symptoms associated with ONE of the following conditions:
 - Familial Cold Autoinflammatory Syndrome (FCAS).
 - Recurrent, intermittent fever
 - Rash that is often exacerbated by exposure to generalized cool ambient temperature
 - Muckle-Wells Syndrome (MWS).
 - Rash of waxing and waning intensity sometimes exacerbated by exposure to generalized cool ambient temperature.
- For Kineret, must have a diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID)
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria:**
 - Reauthorization benefit will be approved if there is documentation that member is tolerating and responding to treatment.
- **Reauthorization Duration of Approval:** 12 months

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

- Member must have a history of trial and failure, contraindication, or intolerance to BOTH of the following:
 - Four-week trial each of at least 2 NSAIDs
 - Three-month trial with either Humira* OR Enbrel*
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria:**
 - Reauthorization benefit will be approved if there is evidence of positive clinical response involving ANY of the following clinical/laboratory parameters:
 - Member global assessment
 - Back pain

- BASFI (Bath Ankylosing Spondylitis Functional Index)
- CRP (C-reactive protein)
- Modified Schober's test
- Chest expansion or
- Occiput-to-wall measurement.
- **Reauthorization Duration of Approval:** 12 months

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

- Member has had chronic back pain for 3 or more months with age at onset of less than 45 years of age.
- Must meet one of the following criteria:
 - Member has sacroiliitis on imaging which is defined active (acute) inflammation on MRI highly suggestive of sacroiliitis associated with spondyloarthritis or definite radiographic sacroiliitis according to modified New York criteria with ONE of the following:
 - Inflammatory back pain
 - Arthritis
 - Enthesitis
 - Uveitis
 - Dactylitis
 - Psoriasis
 - Response to NSAIDS
 - Family history of SpA
 - HLA-B27 positive
 - Elevated CRP
 - Inflammatory bowel disease
 - Member is HLA-B27 positive with at least TWO of the following:
 - Inflammatory back pain
 - Arthritis
 - Enthesitis
 - Uveitis
 - Dactylitis
 - Psoriasis
 - Response to NSAIDS
 - Family history of SpA
 - HLA-B27 positive
 - Elevated CRP
 - Inflammatory bowel disease
- Member must have a history of trial and failure, contraindication, or intolerance to BOTH of the following:
 - Four-week trial of at least 2 NSAIDS
 - Three-month trial with either Humira* OR Enbrel*
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria:**

- Reauthorization benefit will be approved if there is evidence of positive clinical response.
- **Reauthorization Duration of Approval: 12 months**

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

- Member must have a history of trial and failure, contraindication, or intolerance to conventional treatments including ONE of the following for at least 3 months:
 - Aminosalicylates, 5-ASAs (*i.e.*, Sulfasalazine, Pentasa, Asacol, Colazal)
 - Steroids (*i.e.*, prednisone,)
 - Immunomodulators (*i.e.*, Azathioprine, 6-Mercaptopurine, Methotrexate)
- Member must have a history of trial and failure, contraindication, or intolerance to Humira* for at least 3 months.
- **Initial Duration of Approval: 6 months**
- **Reauthorization Criteria:**
 - Reauthorization benefit will be approved if there is documented, significant improvement with prior courses of treatment.
- **Reauthorization Duration of Approval: 12 months**

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

- Member must have a history of trial and failure, contraindication, or intolerance to BOTH of the following:
 - Steroids (e.g. prednisone) for at least 3 months
 - Humira* for at least 3 months
- **Initial Duration of Approval: 6 months**
- **Reauthorization criteria:**
 - Reauthorization benefit will be approved if there is documentation that member is tolerating and responding to treatment.
- **Reauthorization Duration of Approval: 12 months**

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

- Member must have clinical documentation of Crohn's disease with actively draining fistulas.
- Member must have a history of trial and failure, contraindication, or intolerance to Humira* for at least 3 months.
- **Initial Duration of Approval: 6 months**
- **Reauthorization Criteria:**
 - Reauthorization benefit will be approved if there is documentation that member is tolerating and responding to treatment.
- **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:

- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria:**
 - Reauthorization benefit will be approved if there is documentation that member is tolerating and responding to treatment.
- **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 must be confirmed by either genetic mevalonate kinase gene (MVK) or enzymatic (MKD) findings.
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria:**
 - Reauthorization benefit will be approved if there is documentation that member is tolerating and responding to treatment.
- **Reauthorization Duration of Approval:** 12 months

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

- Member 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:**
 - Reauthorization benefit will be approved if there is documentation that member is tolerating and responding to treatment.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **Oral Ulcers Associated with 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 at least two of the following:
 - Recurrent genital ulcerations
 - Eye lesions
 - Skin lesions
 - Positive pathergy test (Behcet's test) read by physician
- Member must have a history of trial and failure, contraindication, or intolerance to colchicine for at least 4 months and oral topical steroids
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria:**
 - Reauthorization benefit will be approved if there is documentation that member is tolerating and responding to treatment.
- **Reauthorization Duration of Approval:** 12 months

*May require a prior authorization

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.

**NON-TNF BIOLOGIC THERAPIES
PRIOR AUTHORIZATION FORM (6 PAGES)**

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 8:30am to 5:00pm

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: _____ pounds or _____ kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? <input type="checkbox"/> Yes <input type="checkbox"/> 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? <input type="checkbox"/> Yes <input type="checkbox"/> No	

Billing Information

This medication will be billed: <input type="checkbox"/> at a pharmacy OR <input type="checkbox"/> medically, JCODE: _____
Place of Service: <input type="checkbox"/> Hospital <input type="checkbox"/> Provider's office <input type="checkbox"/> Member's home <input type="checkbox"/> Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:

☐ **Rheumatoid Arthritis (RA)**

- Does the member have a history of failure, contraindication, or intolerance to a three-month trial with methotrexate, or another DMARD? ☐ Yes ☐ No
- Does the member have a history of failure, contraindication, or intolerance to a 3-month trial with either Humira OR Enbrel with or without MTX unless there is clinical rationale for using a non-TNF over a TNF inhibitor? ☐ Yes ☐ No

☐ **Polyarticular Juvenile Idiopathic Arthritis (PJIA)**

- Which of the following have been tried? Please provide additional information in the medication section:
 - ☐ DMARD
 - ☐ Humira or Enbrel

☐ **Systemic Juvenile Idiopathic Arthritis (SJIA)**

- Which of the following have been tried? Please provide additional information in the medication section:
 - ☐ 1 month of NSAIDs
 - ☐ 2 weeks of steroid monotherapy?
 - ☐ 1 month of anakinra (Kineret)

☐ **Moderate to Severe Adult Onset Still's Disease (AOSD)**

- Please indicate which of the following that apply to this member:
 - ☐ Spiking fever $\geq 39^{\circ}\text{C}$
 - ☐ Arthralgia
 - ☐ Transient erythema
 - ☐ Pharyngitis
 - ☐ Polymorphonuclear cells $\geq 80\%$
 - ☐ Glycosylated ferritin $\leq 20\%$

- ☐ Maculopapular rash
- ☐ Leukocytosis $\geq 10,000/\text{mm}^3$

2. Which of the following have been tried? Please provide additional information in the medication section:

- ☐ One month trial of NSAIDs or a 2 week trial of steroid monotherapy
- ☐ Three week trial of Methotrexate
- ☐ Three-month trial of Humira OR Enbrel

☐ **Plaque Psoriasis**

3. Is there clinical documentation of 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? ☐ Yes ☐ No

4. Which of the following have been tried? Please provide additional information in the medication section:

- ☐ Psoralens with UVA light (PUVA) or UVB light
- ☐ Immunomodulators (i.e. Methotrexate, Cyclosporine)
- ☐ Retinoids (i.e. Soriatane)
- ☐ Humira* or Enbrel*

☐ **Psoriatic Arthritis (PsA)**

5. Does the member have moderately to severely active psoriatic arthritis with ANY of the following:

- ☐ Erosive Disease
- ☐ Elevated Markers of inflammation attributable to psoriatic arthritis
- ☐ Long-term damage that interferes with function (i.e., joint deformities)
- ☐ Highly active disease that causes a major impairment in quality of life
- ☐ Active PsA at many sites including dactylitis, enthesitis
- ☐ Function-limiting PsA at a few sites
- ☐ Rapidly progressive disease

6. Which of the following have been tried? Please provide additional information in the medication section:

- ☐ Four- week trial each of at least 2 NSAIDs
- ☐ Three-month trial with either Humira* OR Enbrel*

☐ **Cytokine Release Syndrome (CRS)**

1. Which type of CRS does the member have?

- ☐ Grade 1 CRS with persistent or refractory fever
- ☐ Grade 2 with the following:
 - ☐ Hypotension refractory to fluid boluses
 - ☐ Presence of hypoxia
 - ☐ Organ toxicity
- ☐ Grade 3: Chimeric antigen receptor (CAR) T cell-induced severe CRS with the following:
 - ☐ Oxygen requirement $\geq 40\%$
 - ☐ Hypotension requiring high dose or multiple vasopressors
 - ☐ Grade 3 organ toxicity or grade 4 transaminitis
- ☐ Grade 4: Life threatening (grade 4) CRS with the following:
 - ☐ Requires ventilator support
 - ☐ Grade 4 organ toxicity (excluding transaminitis)

☐ **Giant Cell Arteritis**

1. How was the diagnosis confirmed?

- ☐ Temporal artery biopsy or cross-sectional imaging
- ☐ Acute-phase reactant elevation (i.e. high erythrocyte sedimentation rate and/ or high serum C-reactive protein)
- ☐ Other, please describe: _____

2. Does the member have a history of trial and failure, contraindication, or intolerance to a one-week trial of glucocorticoids (e.g., prednisone, methylprednisone)? ☐ Yes ☐ No

☐ **Cryopyrin-Associated Periodic Syndrome (CAPS)**

1. For Arcalyst and Ilaris:

- a. Is there genetic evidence of a CIAS1 (NLRP3) mutation based on DNA sequencing? ☐ Yes ☐ No
- b. Does the member have documented signs and symptoms associated with ONE of the following conditions:

- i. Familial Cold Autoinflammatory Syndrome (FCAS).
 - a. Recurrent, intermittent fever ☐ Yes ☐ No
 - b. Rash that is often exacerbated by exposure to generalized cool ambient temperature ☐ Yes ☐ No
 - ii. Muckle-Wells Syndrome (MWS)
 - a. Rash of waxing and waning intensity sometimes exacerbated by exposure to generalized cool ambient temperature. ☐ Yes ☐ No
2. For Kineret: Does the member have a documented diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID)? ☐ Yes ☐ No

☐ **Ankylosing Spondylitis (AS)**

1. Which of the following have been tried? Please provide additional information in the medication section:
 - ☐ Four-week trial each of at least 2 NSAIDs
 - ☐ Three-month trial with either Humira* OR Enbrel*

☐ **Ulcerative Colitis**

1. Which of the following have been tried for at least 3 months? Please provide additional information in the medication section:
 - ☐ Aminosalicylates, 5-ASAs (*i.e.*, Sulfasalazine, Pentasa, Asacol, Colazal)
 - ☐ Steroids (*i.e.*, prednisone, Entocort)
 - ☐ Immunomodulators (*i.e.*, Azathioprine, 6-Mercaptopurine, Methotrexate)
 - ☐ Humira

☐ **Non-Radiographic Axial Spondyloarthritis (nr-axSpA)**

1. Has the member had chronic back pain of 3 or more months with age of onset of less than 45 years of age? ☐ Yes ☐ No
2. Does member have sacroiliitis on imaging? ☐ Yes ☐ No
3. Please indicate which of the following apply:
 - ☐ Inflammatory back pain
 - ☐ Arthritis
 - ☐ Enthesitis
 - ☐ Uveitis
 - ☐ Dactylitis
 - ☐ Psoriasis
 - ☐ Response to NSAIDS
 - ☐ Family history of SpA
 - ☐ HLA-B27 positive
 - ☐ Elevated CRP
 - ☐ Inflammatory bowel disease
4. Which of the following have been tried? Please provide additional information in the medication section:
 - ☐ Four-week trial of at least 2 NSAIDs
 - ☐ Three-month trial with either Humira or Enbrel

☐ **Crohn's Disease**

1. Which of the following have been tried? Please provide additional information in the medication section:
 - ☐ Steroids (*i.e.*, prednisone) for at least 3 months
 - ☐ Humira for at least 3 months

☐ **Fistulizing Crohn's Disease**

1. Is there clinical documentation of Crohn's disease with actively draining fistulas? ☐ Yes ☐ No
2. Does the member have a history of trial and failure, contraindication, or intolerance to Humira for at least 3 months? ☐ Yes ☐ No

☐ **Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)**

☐ **Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)**

1. Has the member's diagnosis been confirmed by either genetic mevalonate kinase gene (MVK) or enzymatic (MKD) findings? ☐ Yes ☐ No

