Updated: 04/2019
PARP Approved: 06/2019

Prior Authorization Criteria

Non-TNF Biologic Therapies

All requests for Brand Name (generic name) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

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

Drugs addressed in this policy: Orencia (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)

Indication	Product
Rheumatoid Arthritis (RA)	Orencia, Actemra, Olumiant, Kevzara, or Kineret
Polyarticular Juvenile Idiopathic Arthritis (JIA	Orencia, Actemra
Systemic Juvenile Idiopathic Arthritis (JIA)	Actemra, Ilaris
Plaque Psoriasis	Cosentyx, Stelara, Taltz, Otezla, Siliq, Ilumya, or Tremfya
Psoriatic Arthritis (PsA)	Orencia, Otezla, Cosentyx, Stelara, or Taltz
Cytokine Release Syndrome (CRS)	Actemra
Giant Cell Arteritis	Actemra
Cryoprin-Associated Periodic Syndrome (CAPS)	Arcalyst, Ilaris, or Kineret
Ankylosing Spondylitis	Cosentyx
Ulcerative Colitis	Entyvio
Crohn's Disease	Entyvio, Stelara
Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)	Ilaris
Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)	Ilaris
Familial Mediterranean Fever (FMF)	Ilaris

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

1) The prescribing physician must be a Rheumatologist, Dermatologist, Gastroenterologist, Oncologist, or Ophthalmologist.
2) The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.
3) 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:

- Prescribed medication is Orencia, Actemra, Olumiant, Kevzara, or Kineret.
- Member is 18 years of age or older
- Member must have a history of trial and failure, contraindication, or intolerance to ALL of the following
    - Three-month trial with methotrexate, or another DMARD.
    - Three-month trial with Xeljanz*
    - 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
      For Actemra:
        - Member must have ALL of the following lab values:
            - ANC ≥ 2000/mm3 at baseline.
            - Platelet count ≥ 100,000/mm3 at baseline.
            - ALT/AST does not exceed 1.5 times the upper limit of normal at baseline.
    - For Olumiant
        - Member must avoid use of live vaccines
        - Member must have ALL of the following lab values
            - Hemoglobin greater than 8g/dL at baseline
            - Absolute Lymphocytic Count greater than 500 cells/mm^3 at baseline
            - Absolute Neutrophil Count greater than 1000 cells/mm^3 at baseline
            - ALT/AST does not exceed 1.5 times the upper limit of normal at baseline.
    - For Kevzara
        - Member must avoid use of live vaccines.
        - Member must have ALL of the following lab values:
            - ANC ≥ 2000/mm^3
            - Platelets ≥ 150,000/mm^3
            - ALT/AST does not exceed 1.5 times the upper limit of normal at baseline.
- **Initial Duration of Approval**:
    - For Olumiant and Kevzara: 3 months
    - For Actemra, Orencia and Kineret: 6 months
- **Reauthorization Criteria**
    - For Olumiant
        - Member must continue to avoid use of live vaccines
        - Member must have ALL of the following lab values following 3 months of therapy:
            - Hemoglobin greater than 8g/dL

- Absolute Lymphocytic Count greater than 500 cells/mm^3
- Absolute Neutrophil Count greater than 1000 cells/mm^3
- ALT/AST does not exceed 1.5 times the upper limit of normal at baseline.

▪ Reauthorization benefit will be approved if there is documented, significant improvement with prior courses of treatment
▪ **Reauthorization Duration of Approval**: 12 months

o For Kevzara
▪ Member must continue to avoid use of live vaccines
▪ Member must have ALL of the following lab values following 3 months of therapy:
- ANC ≥ 2000/mm^3
- Platelets ≥ 100,000/mm^3
- ALT/AST does not exceed 3 times the upper limit of normal at baseline.

▪ Reauthorization benefit will be approved if there is evidence of positive clinical response involving the following clinical/laboratory parameters: Number of swollen joints, number of tender joints, patient'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

o For Actemra, Orencia and Kineret
▪ 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 **Polyarticular Juvenile Idiopathic Arthritis (PJIA)** and the following criteria is met:

- Prescribed medication is Orencia, or Actemra.
- Member is 2 years of age or older.
- Member must have a history of trial and failure, contraindication, or intolerance to a three-month trial with either Humira*, OR Enbrel*.
- Member must meet ONE of the following:
  - The member has an AJC (active joint count)>0 and continued disease activity after 3 months of MTX of leflonamide.
  - The member has an AJC (active joint count)>0 and continued disease activity after 1 month of anakinra*.
- Specific for Actemra:
  - The member has ALL of the following lab values:
    - ANC ≥ 2000/mm3 at baseline.
    - Platelet count ≥ 100,000/mm3 at baseline.
    - ALT/AST does not exceed 1.5 times the upper limit of normal at baseline.
- **Initial Duration of Approval:** 6 months

- **Reauthorization Criteria**
    - Reauthorization benefit will be approved if there is evidence of positive clinical response involving the following clinical/laboratory parameters: Number of swollen joints, number of tender joints, patient'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 **Systemic Juvenile Idiopathic Arthritis (SJIA)** and the following criteria is met:

- Prescribed medication is Actemra or Ilaris.
- Member is age 2 years of age or older.
- The member must meet ONE of the following:
    - The member has an MD global ≥ 5 and continued disease activity after 1 month of NSAIDs.
    - The member has continued disease activity after 2 weeks of steroid monotherapy.
    - The member has continued disease activity after 1 month of anakinra* therapy.
- Specific for Actemra:
    - The member has ALL of the following lab values:
        - ANC ≥ 2000/mm3 at baseline.
        - Platelet count ≥ 100,000/mm3 at baseline.
        - ALT/AST does not exceed 1.5 times the upper limit of normal at baseline.
- **Initial Duration of Approval:**
    - For Ilaris: 6 months
    - For Actemra: 3 months
- **Reauthorization Criteria**
    - Reauthorization benefit will be approved if there evidence of positive clinical response involving the following clinical/laboratory parameters: Joint count, the physician and the patient's/parent global assessment, ESR (erythrocyte sedimentation rate), and/or CRP (C-Reactive Protien).
    - **Reauthorization Duration of Approval:** 12 months

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

- Prescribed medication is Cosentyx, Stelara, Taltz, Otelza, Siliq, Ilumya, or Tremfya.
- Member is age 18 years of age or older. (12 years or older for Stelara only).
- 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 ALL 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 with either Humira*, OR Enbrel*.
- Specific for Otezla:
    - Will not be used in combination with a strong cytochrome P450 enzyme inducer (e.g. rifampin, phenobarbital, carbamazepine, phenytoin)
- Specific for Siliq
    - Member should not have a diagnosis of Crohn's disease.
- Specific for Siliq, Ilumya, and Tremfya
    - Will avoid use of live vaccines while on medication.
- **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 <u>diagnosis</u> of **Psoriatic Arthritis (PsA)** and the following criteria is met:

- Prescribed medication is Orencia, Otezla, Cosentyx, Stelara, or Taltz
- Member is age 18 years of age or older.
- Member has moderately to severely active psoriatic arthritis which must include documentation of either active psoriatic lesions or documented history of psoriasis.
- Member must have a history of trial and failure, contraindication, or intolerance to ALL of the following:
    - Three-month trial with either Humira* OR Enbrel*
    - Three-month trial with Xeljanz*
- Specific for Otezla:
    - Will not be used in combination with a strong cytochrome P450 enzyme inducer (e.g. rifampin, phenobarbital, carbamazepine, phenytoin)
- **Initial Duration of Approval:** 6 months
- **Reauthorization**:
    - 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 <u>diagnosis</u> of **Cytokine Release Syndrome (CRS)** and the following criteria is met:

- Prescribed medication is Actemra.

- Member is age 2 years of age or older.
- 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.
    - Documented diagnosis of chimeric antigen receptor (CAR) T cell-induced severe (grade 3) CRS with any ONE of the following:
        - Defined as: oxygen requirement ≥40%.
        - Hypotension requiring high dose or multiple vasopressors.
        - Grade 3 organ toxicity or grade 4 transaminitis.
    - Life threatening (grade 4) CRS with any ONE of the following:
        - Defined as: requirement for ventilator support.
        - Grade 4 organ toxicity (excluding transaminitis).
- The member has ALL of the following lab values:
    - ANC ≥ 2000/mm3 at baseline.
    - Platelet count ≥ 100,000/mm3 at baseline.
    - ALT/AST does not exceed 1.5 times the upper limit of normal at baseline.
- **Initial Duration of Approval**: 3 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 **Giant Cell Arteritis** and the following criteria is met:

- Prescribed medication is Actemra
- The member is 18 years of age or older
- 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).
- The member has the following lab values:
    - ANC ≥ 2000/mm3 at baseline.
    - Platelet count ≥ 100,000/mm3 at baseline.
    - ALT/AST does not exceed 1.5 times the upper limit of normal at baseline.
- **Initial Duration of Approval**: 3 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 **Cyropyrin-Associated Periodic Syndrome (CAPS)** and the following criteria is met:

- Prescribed medication is Arcalyst, Ilaris, or Kineret
- Specific for Arcalyst:
    - The member is 12 years of age or older
    - The member has genetic evidence of an 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.
- Specific for Ilaris
    - The member is 4 years of age or older.
    - 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.
- Specific for Kineret:
    - The member has a documented diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID)
- **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 **Ankylosing Spondylitis** and the following criteria is met:

- Prescribed medication is Cosentyx.
- Member is age 18 years of age or older.
- Member must have a history of trial and failure, contraindication, or intolerance to ALL 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 the following clinical/laboratory parameters: Patient global assessment, back pain, BASFI (Bath Ankylosing Spondylitis Functional Index, CRP, Modified Schober's test, chest expansion, occiput-to-wall measurement.
    - **Reauthorization Duration of Approval**: 12 months

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

- Prescribed medication is Entyvio
- Member is 18 years of age or older.
- 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, Entocort®)
    - 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.
- Member must have a history of trial and failure, contraindication, or intolerance to Xeljanz* 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:

- Prescribed medication is Entyvio or Stelara.
- Member is 18 years of age or older.
- Member must have a history of trial and failure, contraindication, or intolerance to steroids (e.g. prednisone) for at least 3 months.
- 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 **Fistulizing Crohn's Disease** and the following criteria is met:

- Prescribed medication is Entyvio or Stelara.
- Member is 18 years of age or older.
- 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 documented, significant improvement with prior courses of 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:

- The prescribed medication is Ilaris
- Member is 2 years of age or older.
- **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 **Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD in adults/pediatrics)** and the following criteria is met:

- The prescribed medication is Ilaris.
- Member is 2 years of age or older
- Member must meet ONE of the following:
    - Member has diagnosis 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 documented, significant improvement with prior courses of 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:

- The prescribed medication is Ilaris
- Member is 2 years of age or older
- 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 documented, significant improvement with prior courses of treatment.

  Reauthorization Duration of Approval: 12 months

*Humira, Enbrel, Xeljanz, and Kineret 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.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Gateway Health

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NON-TNF MEDICATIONS
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 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:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a 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)

1) Will the medication be prescribed by a rheumatologist, dermatologist, gasteroenterologist, oncologist, or ophthalmologist?
☐ Yes ☐ No

2) Which of the following diagnoses will the medication be used for
   a. Rheumatoid Arthritis, if yes please answer the following questions:
   ☐ Yes ☐ No

      i. Is member 18 years of age or older?
      ☐ Yes ☐ No

      ii. Does the member have a history of failure, contraindication, or intolerance to a three-month trial with methotrexate, or another DMARD?
      ☐ Yes ☐ No

      iii. Does the member have a history of failure, contraindication, or intolerance to a three-month trial with Xeljanz?
      ☐ Yes ☐ No

      iv. 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

      v. If the request is for Actemra, please provide ALL of the following lab values:

ANC:

Platelet Count:

AST/ALT:

vi. If request is for Olumiant, will prescriber attest that member will avoid use of live vaccines?
☐ Yes ☐ No

vii. If request is for Olumiant, please provide ALL of the following lab values:
Hemoglobin:

Absolute Lympocytic Count

Absolute Neutrophil Count

AST/ALT:

b. Polyarticular Juvenile Idiopathic Arthritis, if yes please answer the following questions:
☐ Yes ☐ No

i. Is the member 2 years of age or older?
☐ Yes ☐ No

ii. Does the member have a history of trial and failure, contraindication, or intolerance to a three-month trial with either Humira, OR Enbrel?
☐ Yes ☐ No

iii. Does member meet any of the following:

- The member has an AJC (active joint count)>0 and continued disease activity after 3 months of MTX of leflonamide.
  ☐ Yes ☐ No

- The member has an AJC (active joint count)>0 and continued disease activity after 1 month of anakinra*.
  ☐ Yes ☐ No

iv. If requested medication is Actremra, please provide ALL of the following lab values"
ANC:

Platelet Count:

ALT/AST:

c. Systemic Juvenile Idiopathic Arthritis, if yes please answer the following questions:
☐ Yes ☐ No

i. Is member 2 years of age or older?
☐ Yes ☐ No

ii. Does the member have an MD global score of ≥ 5 and continued disease activity after 1 month of NSAIDs?
☐ Yes ☐ No

iii. Does the member have continued disease activity after 2 weeks of steroid monotherapy?
☐ Yes ☐ No

iv. Does the member have continued disease activity after 1 month of anakinra therapy?
☐ Yes ☐ No

v. If the medication being requested is Actemra, please provide ALL of the following lab values:
ANC:

Platelet Count:

ALT/AST:

d. Plaque Psoriasis, if yes if yes please answer the following questions:
☐ Yes ☐ No

i. If requested medication is Cosentyx, Taltz, Otelza, Siliq, Ilumya, or Tremfya; is member 18 years of age or older?
☐ Yes ☐ No

ii. If requested medication is Stelara, is member 12 years of age or older?
☐ Yes ☐ No

iii. Is there clinical documentation that member has 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?
☐ Yes ☐ No

iv. Does the member have a therapeutic failure of a three or more month trial or a contraindication to ANY of the following:
- Psoralens with UVA light (PUVA) or UVB light
  ☐ Yes ☐ No

- Systemic treatments including ONE of the following:
  a. Immunomodulators (i.e. Methotrexate, Cyclosporine)
     ☐ Yes ☐ No

  b. Retinoids (i.e. Soriatane)

☐ Yes ☐ No

v. Does the member have a history of trial and failure, contraindication, or intolerance to a three-month trial with either Humira*, OR Enbrel*?
☐ Yes ☐ No

vi. Specific for Otezla: Will medication be used in combination with a strong cytochrome P450 enzyme inducer (e.g. rifampin, phenobarbital, carbamazepine, phenytoin)?
☐ Yes ☐ No

vii. Specific for Siliq: Does the member should have a diagnosis of Crohn's disease?
☐ Yes ☐ No

viii. Specific for Siliq, Ilumya, and Tremfya: Will prescriber avoid use of live vaccines while on medication?
☐ Yes ☐ No

e. Psoriatic Arthritis (PsA)
☐ Yes ☐ No

- Is member age 18 years of age or older?
  ☐ Yes ☐ No
- Does the member have moderately to severely active psoriatic arthritis which must include documentation of either active psoriatic lesions or documented history of psoriasis?
  ☐ Yes ☐ No
- Does the member have a history of trial and failure, contraindication, or intolerance to ALL of the following?
  ☐ Yes ☐ No
  - Three-month trial with either Humira* OR Enbrel*
  - Three-month trial with Xeljanz*
- Does the member have a history of trial and failure, contraindication, or intolerance to ALL of the following:
  ☐ Yes ☐ No
  - Member without axial disease:
    - Four- week trial each of at least 2 NSAIDs.
    - Eight week trial of methotrexate or other DMARD
  - Member with axial disease
    - Four- week trial each of at least 2 NSAIDs.
  - Member with psoriatic arthritis with enthesitis
    - Four- week trial each of at least 2 NSAIDs.
- Specific for Otezla: The prescriber attests that medication will not be used in combination with a strong cytochrome P450 enzyme inducer (e.g. rifampin, phenobarbital, carbamazepine, phenytoin)?
  ☐ Yes ☐ No

f. Cytokine Release Syndrome (CRS)

☐ Yes ☐ No

i. Is the member 2 years of age or older?
☐ Yes ☐ No

ii. Does the member meet one of the following criteria for Cytokine Release Syndrome (CRS):
- Grade 1 CRS with persistent or refractory fever
☐ Yes ☐ No

- Grade 2 with any ONE of the following:
  a. Hypotension refractory to fluid boluses
  ☐ Yes ☐ No

  b. Presence of hypoxia.
  ☐ Yes ☐ No

  c. Organ toxicity.
  ☐ Yes ☐ No

- Is there documented diagnosis of chimeric antigen receptor (CAR) T cell-induced severe (grade 3) CRS with any ONE of the following:
  a. Defined as: oxygen requirement ≥40%.
  ☐ Yes ☐ No

  b. Hypotension requiring high dose or multiple vasopressors.
  ☐ Yes ☐ No

  c. Grade 3 organ toxicity or grade 4 transaminitis.
  ☐ Yes ☐ No

- Life threatening (grade 4) CRS with any ONE of the following:
  a. Defined as: requirement for ventilator support.
  ☐ Yes ☐ No

  b. Grade 4 organ toxicity (excluding transaminitis).
  ☐ Yes ☐ No

iii. Please provide ALL of the following lab values:
ANC:

Platelet count:

ALT/AST:

g. Giant Cell Arteritis

☐ Yes ☐ No

i. Is the member 18 years of age or older?
☐ Yes ☐ No

ii. Is the diagnosis confirmed by ONE of the following:
- Temporal artery biopsy or cross-sectional imaging
☐ Yes ☐ No

- Acute-phase reactant elevation (i.e. high erythrocyte sedimentation rate and/ or high serum C-reactive protein
☐ Yes ☐ No

- 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

- Please provide the following lab values:
ANC:

Platelet Count:

ALT/AST

h. Cyropyrin-Associated Periodic Syndrome (CAPS)
☐ Yes ☐ No

i. Specific for Arcalyst
- Is the member 12 years of age or older?
☐ Yes ☐ No

- Does the member have genetic evidence of a CIAS1 (NLRP3) mutation based on DNA sequencing?
☐ Yes ☐ No

- Does the member have documented signs and symptoms associated with ONE of the following conditions:
  a. Familial Cold Autoinflammatory Syndrome (FCAS).
     i. Recurrent, intermittent fever
     ☐ Yes ☐ No

     ii. Rash that is often exacerbated by exposure to generalized cool ambient temperature
     ☐ Yes ☐ No

  b. Muckle-Wells Syndrome (MWS)

i. Rash of waxing and waning intensity sometimes exacerbated by exposure to generalized cool ambient temperature.
☐ Yes ☐ No

ii. Specific for Ilaris
- Is the member 12 years of age or older?
☐ Yes ☐ No

- Does the member have genetic evidence of a CIAS1 (NLRP3) mutation based on DNA sequencing?
☐ Yes ☐ No

- Does the member have documented signs and symptoms associated with ONE of the following conditions:
  a. Familial Cold Autoinflammatory Syndrome (FCAS).
     i. Recurrent, intermittent fever
     ☐ Yes ☐ No

     ii. Rash that is often exacerbated by exposure to generalized cool ambient temperature
     ☐ Yes ☐ No

  b. Muckle-Wells Syndrome (MWS)
     i. Rash of waxing and waning intensity sometimes exacerbated by exposure to generalized cool ambient temperature.
     ☐ Yes ☐ No

iii. Specific for Kineret
- Does the member have a documented diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID)?
☐ Yes ☐ No

i. Ankylosing Spondylitis
☐ Yes ☐ No

i. Is the member 18 years of age or older?
☐ Yes ☐ No

- Does the member have a history of trial and failure, contraindication, or intolerance to ALL of the following?
☐ Yes ☐ No

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

j. Ulcerative Colitis
☐ Yes ☐ No

i. Is member 18 years of age or older?
☐ Yes ☐ No

ii. Does the member have a history of trial and failure, contraindication, or intolerance to conventional treatments including all of the following for at least 3 months:
☐ Yes ☐ No

- Aminosalicylates, 5-ASAs (*i.e.*, Sulfasalazine, Pentasa®, Asacol®, Colazal®)
- Steroids (*i.e.*, prednisone, Entocort®)
- Immunomodulators (*i.e.*, Azathioprine, 6-Mercaptopurine, Methotrexate)
- Humira

k. Crohn's Disease
☐ Yes ☐ No

i. Is member 18 years of age or older?
☐ Yes ☐ No

ii. Does the member have a history of trial and failure, contraindication, or intolerance to conventional treatments including two or more of the following for at least 3 months of each medication:
☐ Yes ☐ No

- Aminosalicylates, 5-ASAs (*i.e.*, Sulfasalazine, Pentasa®, Asacol®, Colazal®)
- Antibiotics (*i.e.*, Metronidazole, Ciprofloxacin)
- Steroids (*i.e.*, prednisone, Entocort®)
- Immunomodulators (*i.e.*, Azathioprine, 6-Mercaptopurine, Methotrexate)
- Humira

l. Fistulizing Crohn's Disease
☐ Yes ☐ No

i. Is member 18 years of age or older?
☐ Yes ☐ No

ii. Is there clinical documentation of Crohn's disease with actively draining fistulas?
☐ Yes ☐ No

iii. Does the member have a history of trial and failure, contraindication, or intolerance to conventional treatments including ALL of the following for at least 3 months of each medication?
☐ Yes ☐ No

- Antibiotics (*i.e.*, Metronidazole, Ciprofloxacin)
- Immunomodulators (*i.e.*, Azathioprine, 6-Mercaptopurine, Methotrexate)
- Humira

m. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) in adults/pediatrics
☐ Yes ☐ No

i. Is the member 2 years of age or older?
☐ Yes ☐ No

n. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD in adults/pediatrics)
☐ Yes ☐ No

i. Is the member 2 years of age or older?
☐ Yes ☐ No

ii. Has the member's diagnosis been confirmed by either genetic genetic mevalonate kinase gene (MVK) or enzymatic (MKD) findings?

o. Familial Mediterranean Fever (FMF)
☐ Yes ☐ No

i. Is the member 2 years of age or older?
☐ Yes ☐ No

ii. Does the member have a history of trial and failure, contraindication, or intolerance to colchicine for at least 3 months?
☐ Yes ☐ No

p. Other:_____

CURRENT or PREVIOUS THERAPY			
Medication Name	**Strength/ Frequency**	**Dates of Therapy**	**Status (Discontinued & Why/Current)**

REAUTHORIZATION

1) For reauthorization of Rheumatoid Arthritis?
   a. Has the member experienced a significant improvement with treatment?
   ☐ Yes ☐ No
   Please describe:

   b. If request is for Olumiant, will prescriber attest that member will avoid use of live vaccines?
   ☐ Yes ☐ No

   c. If request is for Olumiant, please provide ALL of the following lab values:
   Hemoglobin:

   Absolute Lympocytic Count:

   Absolute Neutrophil Count:

   AST/ALT:

2) For reauthorization of Polyarticular Juvenile Idiopathic Arthritis?

   a. Is there documented, significant improvement in AJC (active joint count) with prior courses of treatment?
   ☐ Yes ☐ No
   Please describe:

3) For reauthorization of Plaque Psoriasis?
   a. Is there clinical documentation that supports a decrease in percent of body surface area involvement when compared to baseline?
      ☐ Yes ☐ No

   b. Please provide the following:
      i. Baseline Body Surface Area Involvement:

      ii. Current Body Surface Area Involvement:

4) For all other diagnoses:
   a. Has the member experienced a significant improvement with treatment?
      ☐ Yes ☐ No
      Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date