

## Louisiana Fee-for-Service Medicaid Cytokine and CAM Antagonists

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical pre-authorization for preferred and non-preferred cytokine and CAM antagonists.

Abatacept Injection (Orencia® Syringe; Vial; Clickject)  
Adalimumab Injection (Humira® Pen Kit; Humira® Kit)\*  
Anakinra Syringe (Kineret®)  
Apremilast Tablet (Otezla®)  
Brodalumab Syringe (Siliq®)\*^  
Canakinumab/PF Vial (Ilaris®)  
Certolizumab Pegol (Cimzia® Kit; Syringe Kit)\*  
Etanercept Injection (Enbrel® Kit; Pen; Disp Syringe)\*  
Golimumab (Simponi® Pen; Disp Syringe)\*  
Golimumab Intravenous (Simponi® Aria Vial)\*  
Guselkumab Syringe (Tremfya®)  
Infliximab Vial (Remicade®\*, Inflectra®\*, Renflexis®\*)  
Ixekizumab (Taltz® Syringe; Autoinjector)  
Rilonacept (Arcalyst®)  
Sarilumab Injection (Kevzara®)\*  
Secukinumab (Cosentyx® Pen; Syringe)  
Tocilizumab Injection (Actemra® Syringe; Vial)\*  
Tofacitinib Tablet (Xeljanz®)\*  
Tofacitinib ER Tablet (Xeljanz® XR)\*  
Ustekinumab (Stelara® Disp Syringe)  
Vedolizumab Injection (Entyvio®)

\* These agents have **Black Box Warnings**; please refer to individual prescribing information for details.

^ This agent is subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety Regulations; refer to individual prescribing information for details.

**Approval criteria for both preferred and non-preferred cytokine and CAM antagonists (ALL criteria must be met):**

- An appropriate diagnosis code is required, and the agent must be prescribed according to U.S. Food and Drug Administration approved indications, dosing, safety and monitoring regulations; **AND**
- The prescriber states on the request that the recipient will not be receiving the requested medication in combination with any other cytokine or CAM antagonist; **AND**

- By submitting this request, the prescriber is attesting that the recipient has no evidence of an active infection (including Hepatitis B virus and/or tuberculosis) within the last 180 days; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no inappropriate concomitant drug therapies or disease states; **AND**
- For those agents identified as non-preferred, the following conditions apply and is stated on the request:
  - There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc; **AND**
  - The recipient had documented intolerable side effects or a documented failure with an adequate trial (6-12 weeks) of **TWO** preferred agents, if the preferred agents are indicated for the specified diagnosis; **OR**
  - The recipient has a contraindication to all of the preferred agents indicated for the specified diagnosis.

**Initial Approval: 6 months**

**Reauthorization Approval: 12 months**

Authorization renewed based upon the following criteria:

- Recipient continues to meet initial approval criteria; **AND**
- The prescriber states on the request that there is evidence of a positive response to therapy as indicated by either maintenance of the current condition or improvement in signs and symptoms compared to baseline.

### **Approval criteria for specific diagnoses:**

**Ankylosing Spondylitis (Cosentyx®, Cimzia®, Enbrel®, Humira®, Inflectra®, Remicade®, Renflexis®, Simponi®, Simponi Aria®)**

- The recipient is 18 years of age or older; **AND**
- The following is true and is stated on the request:
  - The prescriber is (or has consulted with) a rheumatologist; **AND**
  - The recipient had documented intolerable side effects or a documented failure with a non-steroidal anti-inflammatory agent (NSAID) during a single 3-month period; **OR**
  - The recipient has a contraindication to NSAIDs.

### **Crohn's Disease (Cimzia®, Entyvio®, Humira®, Inflectra®, Renflexis®, Remicade®, Stelara®)**

- For Humira®, Inflectra®, Renflexis® or Remicade®, the recipient is 6 years of age or older; **OR**
- For Cimzia®, Entyvio®, or Stelara®, the recipient is 18 years of age or older; **AND**
- The following is true and is stated on the request:
  - The disease is moderate to severe (indicated by recent hospitalization, anemia requiring blood transfusion, significant weight loss, fever or malnutrition); **AND**
  - The prescriber is (or has consulted with) a gastroenterologist; **AND**
  - The recipient has a contraindication to or documented intolerance or failure with an adequate trial (6-12 weeks) of **ONE** conventional systemic therapy which includes but is not limited to corticosteroids, 5-aminosalicylates, 6-mercaptopurine, azathioprine, or methotrexate; **AND**
  - For Entyvio®, the recipient:
    - had an inadequate response with, lost response to, or was intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; **OR**
    - had an inadequate response with, was intolerant to, or demonstrated dependence on corticosteroids; **OR**
  - For Stelara®, the recipient:
    - failed or was intolerant to treatment with immunomodulators or corticosteroids, but never failed a TNF blocker; **OR**
    - failed or was intolerant to treatment with one or more TNF blockers.

### **Cytokine release syndrome (CRS), severe or life-threatening (Actemra®)**

- The recipient is 2 years of age or older; **AND**
- The following is true and is stated on the request:
  - The prescriber is (or has consulted with) a rheumatologist or an oncologist or specialist in the area of chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome; **AND**
  - Prior to the initiation of Actemra® therapy, lab testing was performed consisting of an absolute neutrophil count (ANC), platelet count, and liver function tests (ALT/AST); **AND**
  - Adult recipients have an ANC  $\geq 2,000/\text{mm}^3$ , a platelet count  $\geq 100,000/\text{mm}^3$ , and the ALT/AST levels do not exceed 1.5 times the upper limit of normal (ULN); **AND**
  - Actemra® is prescribed according to U.S. Food and Drug Administration labeled dosing for CRS:
    - 12mg/kg for recipients weighing  $< 30\text{kg}$
    - 8mg/kg for recipients weighing  $\geq 30\text{kg}$ ;
    - Up to a maximum of 800mg per infusion and a maximum of 4 doses up to at least 8 hours apart.

### **Giant cell arteritis (Actemra®)**

- The recipient is 18 years of age or older; **AND**

- The following is true and is stated on the request:
  - Prior to the initiation of Actemra® therapy, lab testing was performed consisting of an ANC, platelet count, and liver function tests (ALT/AST); **AND**
  - The recipient has an ANC  $\geq 2,000/\text{mm}^3$ , a platelet count  $\geq 100,000/\text{mm}^3$ , and the ALT/AST levels do not exceed 1.5 times the upper limit of normal (ULN); **AND**
  - The recipient had an inadequate response to systemic corticosteroids (e.g., prednisone).

#### **Hidradenitis Suppurativa (Humira®)**

- The recipient is 12 years of age or older; **AND**
- The following is true and is stated on the request:
  - The recipient has a diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III); **AND**
  - The prescriber is (or has consulted with) a dermatologist; **AND**
  - For Hurley stage II disease, the recipient had an inadequate response to conventional therapy which may include, but is not limited to, oral tetracyclines, oral retinoids, and hormonal therapy.

#### **Systemic Juvenile Idiopathic Arthritis (Actemra®, Ilaris®)**

- The recipient is 2 years of age or older; **AND**
- The following is true and is stated on the request:
  - The prescriber is (or has consulted with) a rheumatologist; **AND**
  - The medication will not be given concurrently with other TNF antagonists (adalimumab, certolizumab pegol, etanercept, infliximab, or golimumab); **AND**
  - For Ilaris®, the maximum dose is 300mg every 4 weeks administered subcutaneously; **AND**
  - The recipient has a contraindication to or documented intolerance or failure with an adequate trial (6-12 weeks) of **AT LEAST ONE** disease modifying antirheumatic drug (DMARD) (such as methotrexate, corticosteroids, or azathioprine).

#### **Periodic Fever Syndromes:**

- **Cryopyrin-Associated Periodic Syndromes (CAPS) (Kineret®, Arcalyst® and Ilaris®)**
  - The following is true and is stated on the request:
    - For Kineret®:
      - The medication is being prescribed for the treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID), which has been confirmed by one of the following:
        - NLRP-3 [nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3] gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation; **OR**

- Evidence of active inflammation which includes both clinical symptoms (e.g., rash, fever, arthralgia) and elevated acute phase reactants (e.g., ESR, CRP); **AND**
    - The prescriber is (or has consulted with) a rheumatologist or a specialist in the treatment of NOMID; **OR**
  - For Arcalyst® and Ilaris®:
    - The medication is being prescribed for the treatment of either Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS); **AND**
    - The prescriber is (or has consulted with) a rheumatologist or a specialist in the treatment of FCAS and MWS; **AND**
  - For Arcalyst®:
    - The recipient is 12 years of age or older; **OR**
  - For Ilaris®:
    - The recipient is 4 years of age or older; **AND**
    - The maximum dose is 150mg every 8 weeks.
- **Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS); OR Hyperimmunoglobulin D Syndrome (HIDS); OR Mevalonate Kinase Deficiency (MKD); OR Familial Mediterranean Fever (FMF) (Ilaris®)**
  - The recipient is 2 years of age or older; **AND**
  - The maximum dose is 300mg every 4 weeks.

**Plaque Psoriasis (Cimzia®, Cosentyx®, Enbrel®, Humira®, Inflectra®, Otezla®, Remicade®, Renflexis®, Siliq®, Stelara®, Taltz® and Tremfya®)**

- For Cimzia®, Cosentyx®, Humira®, Inflectra®, Otezla®, Remicade®, Renflexis®, Siliq®, Taltz®, or Tremfya®, the recipient is 18 years of age or older; **OR**
- For Stelara®, the recipient is 12 years of age or older; **OR**
- For Enbrel®, the recipient is 4 years of age or older; **AND**
- The following is true and is stated on the request:
  - For Cimzia®, Cosentyx®, Enbrel®, Humira®, Otezla®, Siliq®, Stelara®, Tremfya® or Taltz®, the disease is chronic moderate to severe plaque psoriasis; **OR**
  - For Inflectra®, Remicade® or Renflexis®, the disease is chronic severe plaque psoriasis; **AND**
  - The prescriber is (or has consulted with) a rheumatologist or dermatologist; **AND**
  - The recipient has Body Surface Area (BSA) involvement of at least 3% or involvement of the palms, soles, head and neck or genitalia, causing disruption in normal activities and/or employment; **AND**
  - The recipient has a contraindication to or documented intolerance or failure with an adequate trial (6-12 weeks) of **AT LEAST ONE** of the following therapies: phototherapy, methotrexate, and/or cyclosporine; **AND**

- For Siliq®, the following criteria must be met:
  - The recipient has signed the Siliq recipient-prescriber agreement form; **AND**
  - The recipient has at least 10% or more of the body surface area (BSA) or 5% or more of BSA if psoriasis involves sensitive areas (hands, feet, face, or genitals); **AND**
  - All approval criteria for the REMS (Risk Evaluation and Mitigation Strategy) program have been met; **AND**
  - The recipient has tried at least at least one traditional systemic agent for psoriasis (e.g., methotrexate, cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light) for at least 3 months, unless intolerant; **OR**
  - The recipient has a contraindication to or documented intolerance or failure with an adequate trial (3 months) of a non-biologic agent; **AND**
  - The recipient does not have Crohn’s Disease.

**Polyarticular Juvenile Idiopathic Arthritis (Actemra®, Enbrel®, Humira®, Orencia®)**

- The recipient is 2 years of age or older; **AND**
- The following is true and is stated on the request:
  - The prescriber is (or has consulted with) a rheumatologist; **AND**
  - The recipient has a contraindication to or documented intolerance or failure with an adequate trial (6-12 weeks) of methotrexate or corticosteroids.

**Psoriatic Arthritis (Cimzia®, Cosentyx®, Enbrel®, Humira®, Inflectra®, Orencia®, Otezla®, Remicade®, Renflexis®, Simponi®, Simponi Aria®, Stelara®, Taltz®, Xeljanz® and Xeljanz® XR)**

- The recipient is 18 years of age or older; **AND**
- The following is true and is stated on the request:
  - The prescriber is (or has consulted with) a dermatologist or rheumatologist; **AND**
  - The recipient has a contraindication to or documented intolerance or failure with an adequate trial (6-12 weeks) of at least one non-biologic DMARD (such as methotrexate or leflunomide); **AND**
  - For Xeljanz® and Xeljanz® XR:
    - The agent is not being given in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine; **AND**
    - The recipient has an absolute lymphocyte count (ALC)  $\geq 500$  cells/mm<sup>3</sup>, an ANC  $\geq 1,000$  cells/mm<sup>3</sup>, and hemoglobin level  $\geq 9$  g/dL.

**Rheumatoid Arthritis (Actemra®, Cimzia®, Enbrel®, Humira®, Inflectra®, Kevzara®, Kineret®, Orencia®, Remicade®, Renflexis®, Simponi®, Simponi Aria®, Xeljanz® and Xeljanz® XR)**

- The recipient is 18 years of age or older; **AND**
- The following is true and is stated on the request:
  - The prescriber is (or has consulted with) a rheumatologist; **AND**

- The recipient has a contraindication to or documented intolerance or failure with an adequate trial (6-12 weeks) of at least one non-biologic DMARD (such as methotrexate, leflunomide, or azathioprine); **AND**
- For Kineret® or Orencia®, the medication will not be given concurrently with TNF antagonists (adalimumab, certolizumab pegol, etanercept, infliximab, or golimumab); **AND**
- For Xeljanz® and Xeljanz® XR:
  - The agent is not being given in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine; **AND**
  - The recipient has an ALC  $\geq 500$  cells/mm<sup>3</sup>, an ANC  $\geq 1,000$  cells/mm<sup>3</sup>, and hemoglobin level  $\geq 9$  g/dL; **AND**
- For Inflectra®, Remicade®, Renflexis®, Simponi® Aria, or Simponi®, the medication is being used in combination with methotrexate; **AND**
- For Kevzara®, the recipient has an ANC  $\geq 2000$ /mm<sup>3</sup>, a platelet count  $\geq 150,000$ /mm<sup>3</sup> and liver transaminases do not exceed 1.5 times the upper limit of normal (ULN).

**Ulcerative Colitis (Entyvio®, Humira®, Inflectra®, Remicade®, Renflexis®, Simponi®, Xeljanz® and Xeljanz® XR)**

- For Entyvio®, Humira®, Inflectra®, Renflexis®, Simponi®, Xeljanz® or Xeljanz® XR the recipient is 18 years of age or older; **OR**
- For Remicade®, the recipient is 6 years of age or older; **AND**
- The following is true and is stated on the request:
  - The disease is moderate to severe (indicated by recent hospitalization, anemia requiring blood transfusion, significant weight loss, fever or malnutrition); **AND**
  - The prescriber is (or has consulted with) a gastroenterologist; **AND**
  - The recipient has a contraindication to or had documented intolerance or failure with an adequate trial (6-12 weeks) of **AT LEAST ONE** conventional therapy which may include but is not limited to 6-mercaptopurine, corticosteroids (such as prednisone or methylprednisolone), or azathioprine; **AND**
  - For Entyvio®, the recipient had an inadequate response with, lost response to, or was intolerant to a TNF blocker or immunomodulator; or had an inadequate response with, was intolerant to, or demonstrated dependence on corticosteroids; **AND**
  - For Xeljanz® and Xeljanz® XR:
    - The agent is not being given in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine; **AND**
    - The recipient has an ALC  $\geq 500$  cells/mm<sup>3</sup>, an ANC  $\geq 1,000$  cells/mm<sup>3</sup>, and hemoglobin level  $\geq 9$  g/dL.

**Uveitis (Humira®)**

- The recipient has a diagnosis of non-infectious intermediate, posterior, and panuveitis; **AND**
- The recipient is 2 years of age or older; **AND**
- The following is true and is stated on the request:

- The prescriber is (or has consulted with) an ophthalmologist or a rheumatologist; **AND**
- The recipient had an inadequate response to conventional therapy which may include antibiotics, antiviral medications, or corticosteroids.

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