Louisiana Medicaid
Cytokine and CAM Antagonists

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

Additional Point-of-Sale edits may apply.

*Some of these agents have **Black Box Warnings** and/or are subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety Regulations. Please refer to individual prescribing information for details.*

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

- An appropriate ~~ICD-10~~ 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**
- By submitting the authorization request, the prescriber attests to the following:
  - The recipient will not receive the requested medication in combination with any other cytokine or CAM antagonist; **AND**
  - The recipient has no evidence of an active infection (including Hepatitis B virus and/or tuberculosis) within the last 180 days; **AND**
  - The recipient was tested for latent tuberculosis in the past 30 days, and test results are documented in the medical record. If the recipient tested positive for latent TB, treatment for TB will begin prior to starting the requested medication; **AND**
  - The recipient was tested for Hepatitis B infection within the past 30 days, and test results are documented in the medical record. If the recipient is an inactive carrier of the Hepatitis B virus (with no clinically overt liver disease), he/she will be closely monitored for reactivation of Hepatitis B infection during and after treatment with the requested drug; **AND**
  - 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 concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling; **AND**
- For those agents identified as non-preferred on the PDL, the following conditions apply:

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- There is no preferred alternative that is exactly the same chemical entity, formulation, strength, etc.; **AND**
- **ONE** of the following is true and is **stated on the request**
  - The recipient had documented *intolerable side effects* or a documented *treatment 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 *contraindications* to the preferred agents indicated for the specified diagnosis.

Approval criteria for specific diagnoses:

Ankylosing Spondylitis [for Cimzia®, this includes Non-Radiographic Axial Spondyloarthritis] (Cosentyx®, Cimzia®, Enbrel®, Humira®, Inflectra®, Remicade®, Renflexis®, Simponi®, Simponi Aria®, Taltz®)

- 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 treatment 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, documented intolerance or treatment failure with an adequate trial (6-12 weeks) of **ONE** conventional systemic treatment for Crohn's disease 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 treatment with Actemra®, 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 ≥ 2,000/mm^3, a platelet count ≥ 100,000/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 < 30kg
    - 8mg/kg for recipients weighing ≥ 30kg;
    - 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**:
  - The prescriber is (or has consulted with) a rheumatologist; **AND**
  - Prior to the initiation of treatment with Actemra®, lab testing was performed consisting of an ANC, platelet count, and liver function tests (ALT/AST); **AND**
  - The recipient has an ANC ≥ 2,000/mm^3, a platelet count ≥ 100,000/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 treatment for Hidradenitis Suppurativa, which may include, but is not limited to, oral tetracyclines, oral retinoids, and hormonal therapy.

Oral Ulcers Associated with Behçet's Disease (Otezla®)

- The recipient is 18 years of age or older; **AND**
- The recipient has a diagnosis of Behçet's Disease; **AND**
- The prescriber is (or has consulted with) a rheumatologist; **AND**
- The request states that the recipient has active oral ulcers.

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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 prescriber is (or has consulted with) a rheumatologist or a specialist in the treatment of TRAPS, HIDS, MKD and FMF; **AND**
  - The maximum dose is 300mg every 4 weeks.

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

- For Cimzia®, Cosentyx®, Humira®, Ilumya®, 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**:

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- The prescriber is (or has consulted with) a rheumatologist or dermatologist; **AND**
- The recipient has a contraindication to, documented intolerance or treatment failure with an adequate trial (6-12 weeks) of **AT LEAST ONE** of the following therapies: phototherapy, methotrexate, and/or cyclosporine; **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**
- For Cimzia®, Cosentyx®, Enbrel®, Humira®, Otezla®, Siliq®, Stelara®, Tremfya® or Taltz®, the disease is chronic moderate to severe plaque psoriasis; **OR**
- For Ilumya®, the recipient has a diagnosis of moderate-to-severe plaque psoriasis; **OR**
- For Inflectra®, Remicade® or Renflexis®, the disease is chronic severe plaque psoriasis; **OR**
- For Siliq®, the following criteria must be met:
  - The recipient has tried 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, documented intolerance or treatment failure with an adequate trial (3 months) of a non-biologic agent indicated for psoriasis; **AND**
  - By submitting the authorization request, the prescriber attests to the following:
    - The recipient does not have Crohn's Disease; **AND**
    - The recipient has signed the Siliq recipient-prescriber agreement form; **AND**
    - All approval criteria for the REMS (Risk Evaluation and Mitigation Strategy) program have been met.

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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, documented intolerance or treatment 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, documented intolerance or treatment 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) ≥ 500 cells/mm^3, an ANC ≥ 1,000 cells/mm^3, and hemoglobin level ≥ 9 g/dL.

Rheumatoid Arthritis (Actemra®, Cimzia®, Enbrel®, Humira®, Inflectra®, Kevzara®, Kineret®, Olumiant®, 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, documented intolerance or treatment failure with an adequate trial (6-12 weeks) of at least one non-biologic DMARD (such as methotrexate, leflunomide, or azathioprine); **AND**
  - The agent is being used to treat moderately to severely active rheumatoid arthritis; **AND**
  - For Actemra®, the dose does not exceed 800mg per infusion; **OR**
  - For Xeljanz® and ~~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 ≥ 500 cells/mm^3, an ANC ≥ 1,000 cells/mm^3, and hemoglobin level ≥ 9 g/dL; **OR**
  - For Inflectra®, Remicade®, Renflexis®, Simponi® Aria, or Simponi®, the medication is being used in combination with methotrexate; **OR**
  - For Kevzara®, the recipient has an ANC ≥ 2000/mm^3, a platelet count ≥150,000/mm^3 and liver transaminases do not exceed 1.5 times the upper limit of normal (ULN); **OR**
  - For Olumiant®:
    - The recipient has had an inadequate response to one or more TNF antagonists (e.g., adalimumab, certolizumab pegol, etanercept, golimumab or infliximab); **AND**
    - The agent is not being given in combination with other JAK inhibitors (e.g., tofacitinib), biologic DMARDS, or with potent immunosuppressants such as azathioprine and cyclosporine; **AND**
    - The recipient has an ANC ≥ 1000/mm^3, an ALC ≥ 500/mm^3, and hemoglobin ≥ 8 g/dL.

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**
  - 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).

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

- For Entyvio®, Humira®, Simponi®, Stelara®, Xeljanz® or Xeljanz® XR the recipient is 18 years of age or older; **OR**
- For Inflectra®, Remicade® or Renflexis®, 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 documented intolerance or treatment failure with an adequate trial (6-12 weeks) of **AT LEAST ONE** conventional treatment for ulcerative colitis 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 ≥ 500 cells/mm3, an ANC ≥ 1,000 cells/mm3, and hemoglobin level ≥ 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 treatment for uveitis, which may include antibiotics, antiviral medications, or corticosteroids.

General reauthorization criteria for both preferred and non-preferred cytokine or CAM antagonists (ALL criteria must be met):

- Recipient continues to meet initial approval criteria (general and drug/diagnosis specific); **AND**
- The prescriber **states on the request** that there is evidence of a positive response to treatment ~~-~~as indicated by improvement in signs and symptoms compared to baseline, or by halting of disease progression ~~symptoms compared to baseline, or by halting of disease progression ((~~no progression of disease signs and symptoms as compared to baseline).

Initial Approval: 6 months
Reauthorization Approval: 12 months

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~~*Additional edits may apply at Point-of-Sale (POS). Override options may be available. For more information, refer to the Louisiana Department of Health Pharmacy Benefits Management Services Manual at*~~
~~www.lamedicaid.com/provweb1/Providermanuals/manuals/PHARMACY/PHARMACY.pdf~~

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Revision	Date
Removed diagnosis requirement at POS, add non-radiographic axial spondyloarthritis for Cimzia®, add max dose for Actemra® for RA, add severity to RA criteria.	August 2019
Incorporated Otezla® new indication for oral ulcers associated with Behçet's Disease, modify age for ulcerative colitis for Inflectra® and Renflexis®	November 2019
Added Stelara® to ulcerative colitis (new indication) and Taltz® to Ankylosing Spondylitis (new indication), added specialists to giant cell arteritis, oral ulcers with Bechet's disease and TRAPS, HIDS, MKD and FMF	?January 2020
~~Add Taltz® to Ankylosing Spondylitis (new indication)~~	~~January 2020~~

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