Louisiana Medicaid
Pain Management – Cytokine and CAM Antagonists

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

Additional Point-of-Sale edits may apply.

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

When currently posted criteria are not met, a clinical reviewer will consider the most current FDA-approved prescribing information for the requested agent when evaluating the request.

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

- An appropriate diagnosis 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**
    - For all agents except Skyrizi®, 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:
    - 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 *contraindication* to the preferred agents indicated for the specified diagnosis.

Approval criteria for specific diagnoses:

Acute Graft versus Host Disease, Prophylaxis (Orencia®)

- The recipient is 2 years of age or older; **AND**
- The recipient is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor; **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a hematologist or oncologist; **AND**
- The prescriber **states on the request** that Orencia® will be used in combination with a calcineurin inhibitor (e.g., tacrolimus) and methotrexate.

Ankylosing Spondylitis [for Cimzia®, Cosentyx®, and Taltz®, this includes Non-Radiographic Axial Spondyloarthritis] (Avsola®, Cimzia®, Cosentyx®, Enbrel®, Humira®, Inflectra®, Remicade®, Renflexis®, Simponi®, Simponi Aria®, Taltz®, Xeljanz® tablet 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 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; **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^3, an ANC $\geq$ 1,000 cells/mm^3, and hemoglobin level $\geq$ 9 g/dL; **AND**
        - The recipient has had an inadequate response or intolerance to one or more TNF antagonists (e.g., adalimumab, certolizumab pegol, etanercept, golimumab or infliximab).

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

- For Avsola®, 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 recipient has severe or life-threatening chimeric antigen receptor (CAR) T cell-induced CRS; **AND**
    - 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 $\geq$ 2,000/mm^3, a platelet count $\geq$ 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 $\geq$ 30kg;
        - Up to a maximum of 800mg per infusion and a maximum of 4 doses up to at least 8 hours apart.

Deficiency of Interleukin-1 Receptor Antagonist (DIRA) (Arcalyst®, Kineret®)

- The prescriber is (or has consulted with) a specialist in the treatment of DIRA; **AND**
- For Arcalyst®:
    - The recipient weighs at least 10kg (current weight is stated on the request); **AND**

    - The maximum weekly dose does not exceed 320mg; AND
- For Kineret®, the maximum daily dose does not exceed 8mg/kg.

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 $\geq$ 2,000/mm^3, a platelet count $\geq$ 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.

Neuromyelitis Optica Spectrum Disorder (NMOSD) (Enspryng®, Uplizna®)

- The recipient is 18 years of age or older; **AND**
- The following is true and is stated on the request:
    - The recipient has a diagnosis of neuromyelitis optica spectrum disorder; **AND**
    - The recipient is anti-aquaporin-4 (AQP4) antibody positive; **AND**
    - The prescriber is (or has consulted with) a rheumatologist.

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.

Periodic Fever Syndromes:

- **Cryopyrin-Associated Periodic Syndromes (CAPS) (Arcalyst®, Kineret®, 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 (Avsola®, Cimzia®, Cosentyx®, Enbrel®, Humira®, Ilumya®, Inflectra®, Otezla®, Remicade®, Renflexis®, Siliq®, Skyrizi®, Stelara®, Taltz® and Tremfya®)

- For Avsola®, Cimzia®, Humira®, Ilumya®, Inflectra®, Otezla®, Remicade®, Renflexis®, Siliq®, Skyrizi® or Tremfya®, the recipient is 18 years of age or older; **OR**
- For Cosentyx®, Stelara® or Taltz®, the recipient is 6 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**:
  - 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 Skyrizi®, the dose does not exceed 150mg at Week 0, Week 4 and every 12 weeks thereafter; **AND**

- For Cimzia®, Cosentyx®, Enbrel®, Humira®, Otezla®, Siliq®, Stelara®, Taltz®, or Tremfya®, the disease is chronic moderate to severe plaque psoriasis; **OR**
- For Ilumya® or Skyrizi®, the recipient has a diagnosis of moderate-to-severe plaque psoriasis; **OR**
- For Avsola®, 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.

Polyarticular Juvenile Idiopathic Arthritis (Actemra®, Enbrel®, Humira®, Orencia®, Simponi Aria®, Xeljanz® tablet and Xeljanz® oral solution)

- 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; **AND**
  - For Xeljanz® tablet and Xeljanz® oral solution:
    - 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/mm3, an ANC ≥ 1,000 cells/mm3, and hemoglobin level ≥ 9 g/dL~~.~~; **AND**
    - The recipient has had an inadequate response or intolerance to one or more TNF antagonists (e.g., adalimumab, certolizumab pegol, etanercept, golimumab or infliximab).

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

- For Avsola®, Cimzia®, Cosentyx®, Enbrel®, Humira®, Inflectra®, Orencia®, Otezla®, Remicade®, Renflexis®, Rinvoq®, Simponi®, Stelara®, Taltz®, Tremfya®, Xeljanz® tablet and Xeljanz® XR, the recipient is 18 years of age or older; **OR**
- For Simponi Aria®, 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 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 Rinvoq®:
  - The dose does not exceed 15mg per day; **AND**
  - 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 ≥ 8 g/dL; **AND**
  - The recipient has a contraindication to, documented intolerance or treatment failure with an adequate trial (6-12 weeks) of methotrexate; **AND**
  - The recipient has had an inadequate response or intolerance to one or more TNF antagonists (e.g., adalimumab, certolizumab pegol, etanercept, golimumab or infliximab); **OR**
- 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; **AND**
  - The recipient has had an inadequate response or intolerance to one or more TNF antagonists (e.g., adalimumab, certolizumab pegol, etanercept, golimumab or infliximab).

Recurrent Pericarditis (Arcalyst®)

- The recipient is 12 years of age or older; **AND**
- The following is true and is **stated on the request**:
  - The prescriber is (or has consulted with) a cardiologist; **AND**
  - The recipient has a contraindication to, documented intolerance or treatment failure with an adequate trial of at least one standard of care therapy (such as NSAIDS and colchicine).

Rheumatoid Arthritis (Actemra®, Avsola®, Cimzia®, Enbrel®, Humira®, Inflectra®, Kevzara®, Kineret®, Olumiant®, Orencia®, Remicade®, Renflexis®, Rinvoq®, Simponi®, Simponi Aria®, Xeljanz® tablet 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 Rinvoq®:
    - The dose does not exceed 15mg per day; **AND**

        - 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 ≥ 8 g/dL; **AND**
        - The recipient has a contraindication to, documented intolerance or treatment failure with an adequate trial (6-12 weeks) of methotrexate; ~~**OR**~~**AND**
        - The recipient has had an inadequate response or intolerance to one or more TNF antagonists (e.g., adalimumab, certolizumab pegol, etanercept, golimumab or infliximab); **OR**
    - For Xeljanz® tablet 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; **AND**
        - The recipient has had an inadequate response or intolerance to one or more TNF antagonists (e.g., adalimumab, certolizumab pegol, etanercept, golimumab or infliximab); **OR**
    - For Avsola®, Inflectra®, Remicade®, Renflexis®, Simponi®, or Simponi® Aria, 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.

Still's Disease (Ilaris®) [Including Adult-Onset Still's Disease]

- 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 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).

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).

Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) (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 pulmonologist; **AND**
  - The maximum dose is 162mg given subcutaneously once a week.

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

- For Entyvio®, Simponi®, Stelara®, Xeljanz® tablet or Xeljanz® XR, the recipient is 18 years of age or older; **OR**
- For Avsola®, Inflectra®, Remicade® or Renflexis®, the recipient is 6 years of age or older; **OR**
- For Humira®, the recipient is 5 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® tablet 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; **AND**~~.~~
    - The recipient has had an inadequate response or intolerance to one or more TNF antagonists (e.g., adalimumab, certolizumab pegol, etanercept, golimumab or infliximab).

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.

Reauthorization criteria for both preferred and non-preferred cytokine or CAM antagonists (Except for Orencia® when used for prophylaxis of acute graft vs host disease) ~~(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 (no progression of disease signs and symptoms as compared to baseline).

Initial Approval: 6 months
Reauthorization Approval: 12 months
Orencia® for prophylaxis of acute graft vs host disease: 28 days

References

Actemra (tocilizumab) [package insert]. South San Francisco, CA: Genentech, Inc; March 2021. https://www.gene.com/download/pdf/actemra_prescribing.pdf

Arcalyst (rilonacept) [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc; May 2021. https://www.regeneron.com/sites/default/files/Arcalyst_FPI.pdf

Avsola (infliximab-axxq) [package insert]. Thousand Oaks, CA: Amgen Inc; December 2019. https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/avsola/avsola_pi_english.ashx

Chiabrando JG, Bonaventura A, Vecchié A, et al. Management of Acute and Recurrent Pericarditis. J Am Coll Cardiol 2020;75:76-92. https://www.jacc.org/doi/abs/10.1016/j.jacc.2019.11.021

Cimzia (certolizumab pegol) [package insert]. Smyrna, GA: UCB, Inc; September 2019. https://www.cimzia.com/sites/default/files/docs/CIMZIA_full_prescribing_information_1.pdf

Cosentyx (secukinumab) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; May 2021. www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/cosentyx.pdf

Donahue, K, et al. Drug Therapy for Early Rheumatoid Arthritis: A Systematic Review Update. Comparative Effectiveness Review No. 211. AHRQ Publication No. 18-EHC015-EF. PCORI Publication No. 2018-SR-02. Rockville, MD: Agency for Healthcare Research and Quality; July 2018. https://doi.org/10.23970/AHRQEPCCER211

Enbrel (etanercept) [package insert]. Thousand Oaks, CA: Immunex Corporation; April 2021. https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/enbrel/enbrel_pi.pdf

Enspryng (satralizumab-mwge) [package insert]. South San Francisco, CA: Genentech, Inc; August 2020. https://www.gene.com/download/pdf/enspryng_prescribing.pdf

Entyvio (vedolizumab) [package insert]. Deerfield, IL: Takeda Pharmaceuticals; August 2021. https://general.takedapharm.com/ENTYVIOPI

Gottlieb, A, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol. 2008 May;58(5):851-64. https://www.aad.org/practicecenter/quality/clinical-guidelines/psoriasis

Humira (adalimumab) [package insert]. North Chicago, IL: AbbVie Inc; February 2021. https://www.rxabbvie.com/pdf/humira.pdf

Ilaris (canakinumab) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; September 2020. https://www.novartis.us/sites/www.novartis.us/files/ilaris.pdf

Ilumya (tildrakizumab-asmn) [package insert]. , Cranbury, NJ: Sun Pharmaceutical Industries; July 2020. https://www.ilumya.com/pdfs/Sun_Pharma_ILUMYA_US_Prescribing_Information.pdf

Inflectra (infliximab-dyyb) [package insert]. New York, NY: Pfizer Labs; June 2021. http://labeling.pfizer.com/ShowLabeling.aspx?id=9271

Kevzara (sarilumab) [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; April 2018. http://products.sanofi.us/kevzara/kevzara.pdf

Kineret (anakinra) [package insert]. Stockholm, Sweden: Swedish Orphan Biovitrum AB; December 2020. https://www.kineretrx.com/pdf/Full-Prescribing-Information-English.pdf

Olumiant (baricitinib) [package insert]. Indianapolis, IN: Lilly USA, LLC; December 2021~~July 2020~~. http://pi.lilly.com/us/olumiant-uspi.pdf

Orencia (abatacept) [package insert]. Princeton, NJ: Bristol-Myers Squibb; December 2021~~June 2020~~. https://packageinserts.bms.com/pi/pi_orencia.pdf

Otezla (apremilast) [package insert]. Summit, NJ: Celgene Corporation; June 2020. https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/otezla/otezla_pi_english.ashx

Remicade (infliximab) [package insert]. Horsham, PA: Janssen Biotech; May 2020. http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/REMICADE-pi.pdf

Renflexis (infliximab-abda) [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; February 2021. https://www.merck.com/product/usa/pi_circulars/r/renflexis/renflexis_pi.pdf

Rinvoq~~®~~ (upadacitinib) [package insert]. North Chicago, IL: AbbVie Inc; December 2021~~August 2019~~. https://www.rxabbvie.com/pdf/rinvoq_pi.pdf

Siliq (brodalumab) [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals; April 2020. https://www.bauschhealth.com/Portals/25/Pdf/PI/Siliq-pi.pdf

Simponi (golimumab) [package insert]. Horsham, PA: Janssen Biotech; September 2019. http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SIMPONI-pi.pdf

Simponi Aria (golimumab) [package insert]. Horsham, PA: Janssen Biotech; February 2021. http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SIMPONI+ARIA-pi.pdf

Singh, J, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care and Research 2016;68(1):1-25 DOI: 10.1002/acr.22783

Skyrizi (risankizumab-rzaa) [package insert]. North Chicago, IL: AbbVie Inc.; April 2021. https://www.rxabbvie.com/pdf/skyrizi_pi.pdf

Stelara (ustekinumab) [package insert]. Horsham, PA: Janssen Biotech December 2020. http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/STELARA-pi.pdf

Taltz (ixekizumab) [package insert]. Indianapolis, IN: Eli Lilly and Company; May 2020. http://uspl.lilly.com/taltz/taltz.html#pi

Tremfya (guselkumab) [package insert]. Horsham, PA: Janssen Biotech; July 2020. http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TREMFYA-pi.pdf

Uplizna (inebilizumab-cdon) [package insert]. Gaithersburg, MD: Viela Bio, Inc; July 2021. https://www.hzndocs.com/Uplizna-Prescribing-Information.pdf

U.S. National Library of Medicine. Neonatal Onset Multisystem Inflammatory Disease. https://ghr.nlm.nih.gov/condition/neonatal-onset-multisystem-inflammatory-disease#sourcesforpage

Ward, M, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Care and Research 2016;68(2): 151-166. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5123844/pdf/nihms822816.pdf

Wu, J. Contemporary Management of Moderate to Severe Plaque Psoriasis. American Journal of Managed Care 2017;23:S403-S416. https://www.ajmc.com/journals/supplement/2017/contemporary-management-of-moderate-to-severe-plaque-psoriasis/contemporary-management-of-moderate-to-severe-plaque-psoriasis

Xeljanz~~,~~ oral solution, Xeljanz tablet and Xeljanz XR (tofacitinib) [package insert]. New York, NY; Pfizer Labs; December 2021~~October 2020~~. http ://labeling.pfizer.com/ShowLabeling.aspx?id=959

Zouboulis C, et al. European S1 Guideline for the Treatment of Hidradenitis Suppurativa/Acne Inversa. Journal of European Academy of Dermatology and Venereology. 2015 Apr. 29 (4):619-44. https://onlinelibrary.wiley.com/doi/abs/10.1111/jdv.12966

Revision / Date	Implementation 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 / May 2019	August 2019
Incorporated Otezla® new indication for oral ulcers associated with Behçet's Disease, modify age for ulcerative colitis for Inflectra® and Renflexis® / August 2019	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	May 2020
Combined Skyrizi® criteria with Cytokine and CAM Antagonists criteria, formatting changes / July 2020	July 2020
Modified age for Taltz® for plaque psoriasis, added diagnosis of non-radiographic axial spondyloarthritis to Cosentyx® and Taltz®, added diagnosis of Still's Disease for Ilaris®, clarified diagnosis for Actemra®, updated references, formatting changes / June 2020	October 2020
Modified age for Stelara® for plaque psoriasis, added indication of active psoriatic arthritis to Tremfya®; updated references; incorporated Skyrizi® into the document / September 2020	January 2021
Modified age to Simponi Aria® for active psoriatic arthritis, added indication of polyarticular juvenile idiopathic arthritis; updated reference / September 2020	April 2021
Incorporated new formulation of Xeljanz® oral solution, added indication of polyarticular juvenile idiopathic arthritis; modified age for Simponi Aria®; formatting changes, updated references / November 2020	April 2021
Added Deficiency of Interleukin-1 Receptor Antagonist (DIRA) to Kineret® and Arcalyst®, updated references / January 2021	July 2021
Added Avsola®, Enspryng® and Uplizna®; updated age for Humira®, updated references / February 2021	July 2021
Added Recurrent Pericarditis to Arcalyst®, updated references / March 2021	July 2021
Added Systemic Sclerosis-Associated Interstitial Lung Disease for Actemra®, updated reference / March 2021	July 2021
Updated Cosentyx® age for plaque psoriasis, updated references / June 2021	January 2022

Updated criteria for Rinvoq® and all Xeljanz® formulations to include treatment failure with one or more TNF antagonist, added Rinvoq® to psoriatic arthritis (new indication) and Xeljanz® to ankylosing spondylitis (new indication), updated references / December 2021	April 2022
Added indication of prophylaxis for acute graft vs host disease for Orencia®, updated references / December 2021	April 2022