Louisiana Medicaid
Adalimumab-atto (Amjevita™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for adalimumab-atto (Amjevita™).

Additional Point-of-Sale edits may apply.

*This agent 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 (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**
- There is no preferred alternative that is:
  - The exact same chemical entity, formulation, strength, etc.; **OR**
  - An FDA-approved biosimilar to the requested medication that is indicated for the condition being treated; **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 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**
- If request is for a non-preferred agent - **ONE** of the following is required: (See Pain Management – Cytokine and CAM Antagonists on the PDL/NPDL for list of preferred agents)
  - 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:

Ankylosing Spondylitis

- The recipient is 18 years of age or older; **AND**
- The following is true and is **stated on the request**:
    - The medication is prescribed by, or the request states that this medication is being prescribed in consultation 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**
    - The quantity does not exceed 4 syringes every 28 days.

Crohn's Disease

- 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 medication is prescribed by, or the request states that this medication is being prescribed in consultation 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**
    - The quantity does not exceed 6 syringes in the first 28 days of therapy, and 2 syringes every 28 days thereafter.

Hidradenitis Suppurativa

- 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 moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III); **AND**
    - The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a dermatologist; **AND**
    - The quantity does not exceed 6 syringes in the first 28 days of therapy, and 4 syringes every 28 days thereafter; **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.

Plaque Psoriasis

- The recipient is 18 years of age or older; **AND**
- The following is true and is **stated on the request**:
  - The disease is chronic moderate to severe plaque psoriasis; **AND**
  - The medication is prescribed by, or the request states that this medication is being prescribed in consultation 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**
  - The quantity does not exceed 4 syringes in the first 28 days of therapy, and 2 syringes every 28 days thereafter**.**

Polyarticular Juvenile Idiopathic Arthritis

- The recipient is 2 years of age or older; **AND**
- The following is true and is **stated on the request**:
  - The medication is prescribed by, or the request states that this medication is being prescribed in consultation 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**
  - The quantity does not exceed 2 syringes every 28 days.

Psoriatic Arthritis

- The recipient is 18 years of age or older; **AND**
- The following is true and is **stated on the request**:
  - The medication is prescribed by, or the request states that this medication is being prescribed in consultation 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**
  - The quantity does not exceed 4 syringes every 28 days.

Rheumatoid Arthritis

- The recipient is 18 years of age or older; **AND**
- The following is true and is **stated on the request**:
  - The agent is being used to treat moderately to severely active rheumatoid arthritis; **AND**
  - The medication is prescribed by, or the request states that this medication is being prescribed in consultation 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 quantity does not exceed 4 syringes every 28 days.

Ulcerative Colitis

- 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 medication is prescribed by, or the request states that this medication is being prescribed in consultation 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**
  - The quantity does not exceed 6 syringes in the first 28 days of therapy, and 2 syringes every 28 days thereafter.

Reauthorization Criteria

- The 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); **AND**
- If diagnosis is ulcerative colitis, the prescriber **states on the request** that there is evidence of clinical remission.

Initial Approval:

- **Ulcerative Colitis: 8 weeks**
- **All other diagnoses <u>except</u> ulcerative colitis: 6 months**

Reauthorization Approval: 12 months

References

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