Louisiana Medicaid
Adalimumab-ryvk (Simlandi®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for adalimumab-ryvk (Simlandi®).

Additional Point-of-Sale edits may apply.

By submitting the authorization request, the prescriber attests to the conditions available HERE.

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**
- If the request is for a non-preferred agent, 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**
- 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 Initiation of Therapy 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 2 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; **AND**
    - The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a gastroenterologist; **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**.**

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

Uveitis

- The recipient has a diagnosis of non-infectious intermediate, posterior, and panuveitis; **AND**
- 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, an ophthalmologist or a rheumatologist; **AND**
    - The quantity does not exceed 4 syringes in the first 28 days of therapy, and 2 syringes every 28 days thereafter; **AND**
    - The recipient had an inadequate response to conventional treatment for uveitis, which may include corticosteroids.

Approval Criteria for Continuation of Therapy

- 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.

Duration of approval for initiation of therapy:

- **Ulcerative Colitis: 8 weeks**
- **All other diagnoses except ulcerative colitis: 6 months**

Duration of approval for continuation of therapy: 12 months

References

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

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

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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

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Revision / Date	Implementation Date
Policy Created / May 2024	October 2024