Louisiana Medicaid
Ustekinumab-srlf (Imuldosa™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for ustekinumab-srlf (Imuldosa™).

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**
- The requested dose does not exceed the quantity limit (if applicable) listed in Table 1; **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 the request is for Stelara®, **ONE** of the following is required:
  - The recipient has a documented treatment failure with an adequate trial (26 weeks) of an FDA-approved biosimilar to Stelara®; **OR**
  - The provider **states on the request** clinical justification why **EACH** biosimilar for Stelara® cannot be used; **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:

Crohn's Disease

- 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**

- **ONE** of the following:
  - The recipient failed or was intolerant to treatment with immunomodulators or corticosteroids, but never failed a TNF blocker; **OR**
  - The recipient failed or was intolerant to treatment with one or more TNF blockers.

Plaque Psoriasis

- The recipient is 6 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.

Psoriatic Arthritis

- The recipient is 6 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.

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.

Approval Criteria for Continuation of Therapy

- The recipient continues to meet initial approval criteria (general and drug/diagnosis specific); **AND**
- The requested dose does not exceed the quantity limit (if applicable) listed in Table 1; **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).

Duration of approval for initiation of therapy: 6 months
Duration of approval for continuation of therapy: 12 months

Table 1. Quantity Limits for Selected Cytokine/CAM Antagonists	
Generic (Brand Example)	**Quantity Limit**
Ustekinumab-srlf Syringe, Vial (Imuldosa™)	Syringe (starting dose) – 1 injection per 28 days for 2 months
	Syringe (maintenance dose) – 1 injection per 56 days
	Vial – 4 vials (as 56-day supply) per 365 days

References

Imuldosa (ustekinumab-srlf) [package insert]. Raleigh, NC: Accord BioPharma Inc; October 2024 https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761364s000lbl.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

Revision / Date	Implementation Date
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