

Louisiana Medicaid
Ustekinumab-kfce (Yesintek™)

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

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 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 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

References

Yesintek (ustekinumab-kfce) [package insert]. Cambridge, MA: Biocon Biologics Inc; November 2024.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761406s0001bl.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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