Louisiana Medicaid
Infliximab-dyyb (Zymfentra™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for infliximab-dyyb (Zymfentra™).

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 for initiation of therapy (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:

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**
  - The recipient has completed an intravenous induction regimen with an infliximab product.

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 recipient has completed an intravenous induction regimen with an infliximab product.

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).

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

Reference

Infliximab-dyyb (Zymfentra) [package insert]. Jersey City, NJ: CELLTRION USA, Inc; October 2023. https://zymfentra.b-cdn.net/zymfentra_prescribing_information_final.pdf

Revision / Date	Implementation Date
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