Louisiana Medicaid
Tocilizumab-bavi (Tofidence™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for tocilizumab-bavi (Tofidence™).

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:

Coronavirus Disease 2019 (COVID-19)

- Tofidence™ is indicated for the treatment of coronavirus disease 2019 (COVID-19) in **hospitalized adults** and will not be approved for outpatient treatment of COVID-19.

Giant Cell Arteritis

- 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**
  - Prior to the initiation of treatment, lab testing was performed consisting of an ANC, platelet count, and liver function tests (ALT/AST); **AND**
  - The recipient has an ANC $\geq$ 2,000/mm^3, a platelet count $\geq$ 100,000/mm^3, and the ALT/AST levels do not exceed 1.5 times the upper limit of normal (ULN); **AND**

- The recipient had an inadequate response to systemic corticosteroids (e.g., prednisone).

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.

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).

Systemic 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 or documented intolerance or failure with an adequate trial (6-12 weeks) of **AT LEAST ONE** disease modifying antirheumatic drug (DMARD) (such as methotrexate, corticosteroids, or azathioprine).

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

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

Singh, J, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care and Research 2016;68(1):1-25 DOI: 10.1002/acr.22783

Tofidence (tocilizumab-bavi) [package insert]. Cambridge, MA: Biogen MA Inc; July 2024. https://www.biogencdn.com/us/biosimilars/biib800-pi.pdf

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