

**Brand Name:** Zinplava

**Generic:** bezlotoxumab

**Type:** monoclonal antibody

**Year Accepted/Phase:** 2016

**Mechanism:**

Bezlotoxumab is a human monoclonal antibody that binds to and neutralizes toxin B produced by *Clostridium difficile*, preventing the recurrence of CDI.

**Chemical Structure:** N/A

**Indication:**

Zinplava is indicated to reduce the recurrence of CDI in patients 18 years of age or older who are receiving antibacterial drug treatment for CDI and are at high risk of CDI recurrence.

## **Clinical trials:**

### **MODIFY I and MODIFY II Trials (Phase III)**

**Pubmed:** <https://pubmed.ncbi.nlm.nih.gov/29234211/>

**Purpose:** Evaluate the efficacy and safety of bezlotoxumab in reducing the recurrence of Clostridium difficile infection (CDI) compared to placebo.

**Dates:** Conducted from 2011 to 2015.

**Results:** The MODIFY I and MODIFY II trials demonstrated that bezlotoxumab significantly reduced the recurrence of CDI compared to placebo. In MODIFY I, the recurrence rate was 17% in the bezlotoxumab group compared to 28% in the placebo group. In MODIFY II, the recurrence rate was 16% in the bezlotoxumab group compared to 26% in the placebo group.

**Impact:** These results led to the approval of Zinplava by the FDA for the prevention of recurrent CDI in patients 18 years and older who are receiving antibacterial drug treatment for CDI and are at high risk of CDI recurrence.