Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 153.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Zinplava (bezlotoxumab)

I. Policy:
Zinplava (bezlotoxumab)

II. Purpose/Objective:
To provide a policy of coverage regarding Zinplava (bezlotoxumab)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Zinplava (bezlotoxumab) is a human IgG1 monoclonal antibody that binds to C. difficile toxin B and neutralizes it to prevent its toxic effects; bezlotoxumab does not bind to C. difficile toxin A.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Zinplava (bezlotoxumab) will be considered medically necessary for the commercial, exchange, CHIP and Medicare lines of business when ALL of the following criteria are met:

1. Prescribed by or in conjunction with a recommendation from an infectious disease specialist **AND**
2. Patient age greater than or equal to 18 years **AND**
3. Medical record documentation that patient is at high risk for *Clostridium difficile* (*C. diff*.) infection recurrence, as evidenced by <u>one</u> of the following points:
    - Patient has at least one risk factor for recurrent disease (age greater than or equal to 65 years, greater than or equal to 10 unformed stools per 24 hours, serum creatinine greater than or equal to 1.2 mg/dL, extended use of one or more systemic antibacterial drugs, immunocompromised, clinically severe CDI defined as a ZAR score greater than or equal to 2, or the presence of a hypervirulent strain) **OR**
    - Patient has had at least one previous *C. difficile* infection within the past 6 months **OR**
    - Patient has a history of at least 2 previous *C. difficile* infections ever

    AND
4. Medical record documentation that Zinplava is being administered concurrently with a standard-of-care antibacterial treatment indicated for the treatment of *Clostridium difficile* (e.g. oral vancomycin, oral metronidazole, oral fidaxomicin) **AND**
5. One of the following:
    - Medical record documentation that patient DOES NOT have heart failure **OR**
    - Medical record documentation of rationale for use in a heart failure patient (e.g. The benefits of Zinplava administration outweigh the risks of Zinplava administration)

    AND
6. Medical record documentation that patient has not received a previous dose of Zinplava **AND**
7. Medical record documentation of a therapeutic failure on at least one regimen of pulsed oral vancomycin **OR**
8. (For patients with intolerance to or contraindication to vancomycin) medical record documentation of therapeutic failure on at least one regimen of an appropriate antibacterial treatment for C. diff (e.g. oral metronidazole, oral fidaxomicin).

Note to reviewer: Zinplava is not an antibacterial drug and is not indicated for the treatment of Clostridium difficile infections. Repeat doses have not been studied.

AUTHORIZATION DURATION: If approved, authorization shall be for a one-time authorization of one (1) Zinplava dose (infusion).

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Zinplava [prescribing information]. Rahway, NJ: Merck & Co Inc; May 2023.
2. Johnson S, Lavergne V, Skinner AM, et al. Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of Clostridioides difficile Infection in Adults. Clin Infect Dis 2021; 24:549 [cited 2023 Dec 26]. Available from: https://academic.oup.com/cid/article/73/5/e1029/6298219?login=false

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 5/16/17

Revised: 7/10/17 (per DHS), 1/16/23 (LOB carve out), 12/30/23 (references added), 1/8/24 (Medicaid business segment)

Reviewed: 5/1/18, 3/28/19, 2/1/20, 1/19/21, 1/18/22

MA UM Committee approval: 12/31/23