

Policy: MBP 271.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Terlivaz (terlipressin)

I. Policy:

Terlivaz (terlipressin)

II. Purpose/Objective:

To provide a policy of coverage regarding Terlivaz (terlipressin)

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 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:

Terlivaz (terlipressin), a synthetic vasopressin analogue, has intrinsic activity; however, a majority of the activity results from conversion to lysine-vasopressin via slow enzymatic cleavage, producing an extended duration of systemic vasoconstriction. Reduces portal pressure and blood flow into portal vessels, increasing effective arterial blood volume and mean arterial pressure, thereby increasing blood flow to the kidneys.

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

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Terlivaz (terlipressin) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Documentation of age greater than or equal to 18 years **AND**
 - Prescribed by or in consultation with a hepatologist or nephrologist **AND**
 - Medical record documentation of a diagnosis of hepatorenal syndrome causing a rapid reduction in kidney function **AND**
 - Medical record documentation of a serum creatinine less than or equal to 5.0 mg/dL **AND**
 - Medical record documentation that Terlivaz will be given in combination with intravenous albumin OR intolerance or contraindication to albumin **AND**
 - Medical record documentation that the patient does NOT meet any of the following conditions:
 - Baseline oxygen saturation (SpO2) less than 90% **OR**
 - Volume overload **OR**
 - Acute-on-chronic liver failure (ACLF) Grade 3 **OR**
 - Ongoing coronary, peripheral, or mesenteric ischemia
- AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

AUTHORIZATION DURATION: Approval will be for up to 14 days of treatment and the authorization duration will be sufficient to cover the complete treatment course. Subsequent authorizations will be considered using the criteria outlined above.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

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. Terlivaz [prescribing information]. Bridgewater, NJ: Mallinckrodt Hospital Products Inc; April 2023.

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

Devised: 1/17/23

Revised: 12/28/23 (references added)

Reviewed: 1/9/24

MA UM Committee approval: 12/31/23