TERLIVAZ® is the first and only FDA-approved treatment to improve kidney function in adults with HRS with rapid reduction in kidney function.

Terlivaz® terlipressin for injection

Information for hospital system or individual hospital customers about the LOC discount program for TERLIVAZ

The Letter of Commitment (LOC) program provides a discount on purchases of TERLIVAZ for inpatient use by hospital system or individual hospital customers that

- **Include TERLIVAZ on their formulary,** treatment protocol, or other internal treatment selection criteria
- **Have submitted a signed LOC agreement** to Mallinckrodt Pharmaceuticals that has been subsequently approved and executed
- **Do not restrict or otherwise disadvantage** the use of TERLIVAZ as a first-line treatment option in appropriate patients for the approved indication as set forth in the FDA-approved label for TERLIVAZ

These discount criteria do not reflect an obligation imposed on customers participating in the LOC discount program, but instead are conditions of eligibility for the discount.

No exclusivity required

Hospital system or individual hospital customers who are participating in the LOC discount program for TERLIVAZ are free to change their formulary, treatment protocol, or other internal treatment selection criteria at any time. LOC discount is not impacted by these changes unless the LOC discount criteria are no longer satisfied.

How to request an LOC

Contact your GPO; the LOC may be available on the GPO website

OR

Request the LOC directly from Mallinckrodt by sending an email request to hospital.contracting@sbiopharma.com

Additional Questions

Contact your Mallinckrodt Representative for more information about the LOC discount program

Ready to submit an LOC agreement for your hospital system or individual hospital?

Email it to hospital.contracting@sbiopharma.com

INDICATION AND LIMITATION OF USE

TERLIVAZ® is indicated to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function.

- Patients with a serum creatinine >5 mg/dL are unlikely to experience benefit.

SELECT IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS OR FATAL RESPIRATORY FAILURE

- **TERLIVAZ may cause serious or fatal respiratory failure. Patients with volume overload or with acute-on-chronic liver failure (ACLF) Grade 3 are at increased risk. Assess oxygenation saturation (e.g., SpO_2) before initiating TERLIVAZ.**
- **Do not initiate TERLIVAZ in patients experiencing hypoxia (e.g., SpO_2 <90%) until oxygenation levels improve. Monitor patients for hypoxia using continuous pulse oximetry during treatment and discontinue TERLIVAZ if SpO_2 decreases below 90%.**

Please see additional Important Safety Information on the following page and full Prescribing Information, including Boxed Warning.

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SELECT IMPORTANT SAFETY INFORMATION (continued)

Contraindications

TERLIVAZ is contraindicated:

- In patients experiencing hypoxia or worsening respiratory symptoms.
- In patients with ongoing coronary, peripheral, or mesenteric ischemia.

Warnings and Precautions

- **Serious or Fatal Respiratory Failure:** Obtain baseline oxygen saturation and do not initiate TERLIVAZ in hypoxic patients. Monitor patients for changes in respiratory status using continuous pulse oximetry and regular clinical assessments. Discontinue TERLIVAZ in patients experiencing hypoxia or increased respiratory symptoms.

  Manage intravascular volume overload by reducing or discontinuing the administration of albumin and/or other fluids and through judicious use of diuretics. Temporarily interrupt, reduce, or discontinue TERLIVAZ treatment until patient volume status improves. Avoid use in patients with ACLF Grade 3 because they are at significant risk for respiratory failure.
- **Ineligibility for Liver Transplant:** TERLIVAZ-related adverse reactions (respiratory failure, ischemia) may make a patient ineligible for liver transplantation, if listed. For patients with high prioritization for liver transplantation (e.g., MELD ≥35), the benefits of TERLIVAZ may not outweigh its risks.
- **Ischemic Events:** TERLIVAZ may cause cardiac, cerebrovascular, peripheral, or mesenteric ischemia. Avoid use of TERLIVAZ in patients with a history of severe cardiovascular conditions or cerebrovascular or ischemic disease. Discontinue TERLIVAZ in patients who experience signs or symptoms suggestive of ischemic adverse reactions.
- **Embryo-Fetal Toxicity:** TERLIVAZ may cause fetal harm when administered to a pregnant woman. If TERLIVAZ is used during pregnancy, the patient should be informed of the potential risk to the fetus.

Adverse Reactions

- The most common adverse reactions (≥10%) include abdominal pain, nausea, respiratory failure, diarrhea, and dyspnea.

Please see full Prescribing Information, including Boxed Warning.

Reference: TERLIVAZ® (terlipressin). Prescribing Information. Bedminster, NJ: Mallinckrodt Hospital Products Inc.

Mallinckrodt Pharmaceuticals