TERLIVAZ® (terlipressin) for Hepatorenal Syndrome with Rapid Reduction in Kidney Function:

Drug Utilization Review Considerations

GOAL

This drug utilization review (DUR) document is designed to collect data that may be helpful for a DUR of TERLIVAZ. By collecting the following information, the institution will be able to better assess the utilization of TERLIVAZ within their institution and make more informed decisions for TERLIVAZ management.

Disclaimer Statements:

- The purpose of this document is to provide considerations for a retrospective drug utilization review (DUR) of TERLIVAZ. This resource is for informational purposes only, and institutions should individualize their approach to a DUR based on institutional formulary management.
- This material is intended solely for use by population-based decision makers with knowledge and expertise in the area of healthcare economic analysis.
- This document is not intended to inform or otherwise influence billing and reimbursement activities. Mallinckrodt makes no statement, promise, or guarantee concerning levels of reimbursement, payment, or charge.

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 throughout. Please see accompanying full Prescribing Information, including Boxed Warning, or visit Terlivaz.com.

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Collect the following information for every patient who received at least one dose of TERLIVAZ®.

PATIENT INFORMATION

1. **Medical Record Number (MRN):**

   _____

2. **Admission date:** _____

3. **Date of birth:** _____

4. **What is the patient's insurance status?**

   ☐ Private/commercial
   ☐ Medicare
   ☐ Medicaid
   ☐ Other
   ☐ Unknown

5. **What is the admitting diagnosis for the patient?**

   _____

6. **Was the patient directly admitted to the institution or transferred from an outside hospital?**

   ☐ Direct admission
   ☐ Outside hospital

7. **Was there a diagnosis of HRS with rapid reduction in kidney function?**

   ☐ Yes Diagnosis code(s): _____
   ☐ No (HRS-AKI suspected)
   ☐ No (no HRS-AKI indication)

8. **Does the patient have a history of severe cardiovascular conditions or cerebrovascular or ischemic disease?**

   ☐ Yes Please list: _____
   ☐ No _____

9. **Does the patient have shock, sepsis, or uncontrolled bacterial infections?**

   ☐ Yes
   ☐ No

10. **What is the patient's baseline SCr?**

    _____

11. **What was the calculated MELD score prior to the first dose of TERLIVAZ?**

    _____

12. **Did the patient receive any vasopressors during treatment with TERLIVAZ?**

    ☐ Yes Drug: _____
    ☐ No _____

13. **What were the patient's ACLF score and SpO_2 level prior to the first dose of TERLIVAZ?**

    ACLF score: _____

    SpO_2 level: _____

SELECT IMPORTANT SAFETY INFORMATION

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.

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TERLIVAZ® DRUG ORDER INFORMATION[1]

1. **Who authorized the use of TERLIVAZ?**
   - ☐ Hepatology/Gastroenterology
   - ☐ Critical Care
   - ☐ Nephrology
   - ☐ Other
   - ☐ Authorization not needed

2. **Did the patient receive an albumin fluid challenge prior to administration of TERLIVAZ?**
   - ☐ Yes
   - ☐ No
   - ☐ Unknown

3. **What dose did the patient receive during the initiation phase?**
   - ☐ 0.85 mg (1 vial) every 6 hours
   - ☐ Other: _____

4. **How was TERLIVAZ administered?**
   - ☐ Peripheral line
   - ☐ Central line

5. **What were the total number of doses given during the 3-day initiation period?**

   _____

6. **What was the patient's SCr value at the completion of the 3-day initiation period?**

   _____

7. **Did the SCr value decrease?**
   - ☐ Yes By what percent? _____
   - ☐ No

8. **What dose did the patient receive during the maintenance phase?**
   - ☐ TERLIVAZ 0.85 mg (1 vial) every 6 hours
   - ☐ TERLIVAZ 1.7 mg (2 vials) every 6 hours
   - ☐ N/A

9. **How many doses did the patient receive during the maintenance phase?**
   - ☐ _____
   - ☐ N/A

10. **Did the patient experience HRS reversal?[a]**
    - ☐ Yes
    - ☐ No

11. **What was the total change in MELD score?**

    Baseline: _____

    After completion of TERLIVAZ: _____

    Change: _____

12. **How many total days of TERLIVAZ therapy did the patient receive?**

    _____

13. **What was the total number of vials the patient received over the course of treatment with TERLIVAZ?**

    _____

[a]HRS reversal defined as a single SCr measurement of ≤1.5 mg/dL by Day 14 of TERLIVAZ.[2] The primary endpoint in the CONFIRM Trial was Verified HRS Reversal, defined as 2 consecutive SCr values of ≤1.5 mg/dL, obtained at least 2 hours apart while on treatment by Day 14 or discharge and survival without RRT (eg, dialysis) for ≥10 days.[1]

ACLF, acute-on-chronic liver failure; AKI, acute kidney injury; HRS, hepatorenal syndrome; MELD, model for end-stage liver disease; N/A, not applicable; RRT, renal replacement therapy; SCr, serum creatinine; SpO_2, oxygen saturation.

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **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.

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QUALITY AND OUTCOMES MEASURES[1]

1. **How many days was the patient diagnosed with HRS-AKI prior to receiving TERLIVAZ®?**

   ☐ _____

   ☐ N/A

2. **How many days did the patient receive TERLIVAZ on a non-intensive care unit (non-ICU) floor and ICU-level floor?**

   Non-ICU days: _____

   ICU days: _____

3. **Did the patient receive renal replacement therapy (RRT) while receiving TERLIVAZ?**

   ☐ Yes
   ☐ No

4. **Did the patient receive a liver transplant during the hospitalization?**

   ☐ Yes
   ☐ No

5. **What was the total hospital length of stay (LOS)?**

   LOS: _____

6. **Was TERLIVAZ used in accordance with institutional criteria for use?**

   ☐ Yes
   ☐ No Describe: _____

7. **Was NTAP captured for TERLIVAZ use during this admission?**

   ☐ Yes
   ☐ No

NTAP, new technology add-on payment.

SELECT IMPORTANT SAFETY INFORMATION

Adverse Reactions

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

Please see accompanying full Prescribing Information, including Boxed Warning, or visit Terlivaz.com.

References:

1. TERLIVAZ® (terlipressin). Prescribing Information. Bridgewater, NJ; 2023: Mallinckrodt Hospital Products Inc.
2. Data on File — REF-05035. Mallinckrodt Pharmaceuticals.

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