

## CMS has granted NTAP for TERLIVAZ<sup>®</sup>, the only FDA-approved treatment for HRS with rapid reduction in kidney function<sup>1</sup>

Effective October 1, 2023

### What is NTAP?<sup>2,3</sup>

The NTAP is a Medicare reimbursement that financially assists healthcare organizations when they adopt new technology and is part of the Centers for Medicare & Medicaid Services (CMS) Inpatient Prospective Payment System (IPPS).

NTAP is a payment Medicare makes in addition to the Medicare Severity Diagnosis Related Group (MS-DRG) or TRICARE DRG reimbursement.

### Why was TERLIVAZ granted the NTAP?<sup>1</sup>

TERLIVAZ was granted NTAP by CMS as it meets the three criteria for eligibility. CMS noted that:

- **Newness:** TERLIVAZ has a "unique mechanism of action for selective vasoconstrictive effects on the splanchnic vasculature."
- **Cost:** The average standardized cost for cases involving TERLIVAZ "exceeds the case-weighted threshold amount."
- **Substantial clinical improvement:** TERLIVAZ is the "only FDA-approved treatment for HRS patients and significantly improves clinical outcomes among HRS patients by improving renal function, compared to placebo as well as currently available treatments, as demonstrated by statistically significant differences in HRS reversal rates."

### How to code for add-on payment<sup>1,4</sup>

- The International Classification of Diseases 10th Revision Procedure Coding System (ICD-10-PCS) code for TERLIVAZ is XW03367 for peripheral vein administration and XW04367 for central vein administration.
- The National Drug Code (NDC) for TERLIVAZ is 43825-0200-01.
- Hospitals can report these codes on claims forms when TERLIVAZ was administered to receive add-on payment for eligible inpatient cases.

HRS, hepatorenal syndrome.

### 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<sub>2</sub>) before initiating TERLIVAZ.**
- **Do not initiate TERLIVAZ in patients experiencing hypoxia (e.g., SpO<sub>2</sub> <90%) until oxygenation levels improve. Monitor patients for hypoxia using continuous pulse oximetry during treatment and discontinue TERLIVAZ if SpO<sub>2</sub> decreases below 90%.**

#### Contraindications

TERLIVAZ is contraindicated:

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

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including **Boxed Warning**.

## Details of NTAP

<b>Eligible facilities<sup>1,3</sup></b>	<ul style="list-style-type: none"><li>Acute care hospitals participating in the inpatient prospective payment system</li><li>Hospitals under the TRICARE program</li></ul>
<b>Qualified patients<sup>3</sup></b>	<ul style="list-style-type: none"><li>Traditional Medicare and dual-eligible (Medicare-Medicaid) fee-for-service patients or TRICARE patients whose case totals exceed the MS-DRG rate payment</li></ul>
<b>Add-on payment<sup>1</sup></b>	<ul style="list-style-type: none"><li>The NTAP is limited to the lesser of:<ul style="list-style-type: none"><li>65% of the amount by which the costs of the case exceed the MS-DRG payment <b>or</b></li><li>65% of the cost of the new technology</li></ul></li><li>The maximum add-on payment for TERLIVAZ<sup>®</sup> is \$16,672.50 for fiscal year (FY) 2024*</li></ul>
<b>Effective period<sup>1</sup></b>	<ul style="list-style-type: none"><li>October 1, 2023 to September 30, 2024 (FY 2024)</li><li>NTAP is approved for a minimum of 2 years and no more than 3 years; the maximum add-on payment amount is reassessed annually</li></ul>
<b>ICD-10-PCS code<sup>1</sup></b>	<ul style="list-style-type: none"><li>XW03367 (Introduction of terlipressin into Peripheral Vein)</li><li>XW04367 (Introduction of terlipressin into Central Vein)</li></ul>
<b>NDC code<sup>4</sup></b>	<ul style="list-style-type: none"><li>43825-0200-01 (Single-dose vial containing 0.85 mg of terlipressin)</li></ul>

**Institutions are ultimately responsible for determining the appropriate reimbursement strategies and billing codes.**

\*Payment amounts are determined on a case-by-case basis and vary by institution and MS-DRG.

## Multiple DRGs may be applicable for NTAP with the ICD-10 diagnosis code of K76.7.<sup>1,5,6,†</sup>

MS-DRG Code	Title
441	Disorders of liver except malignancy, cirrhosis, or alcoholic hepatitis with MCC
432	Cirrhosis and alcoholic hepatitis with MCC
871	Septicemia or severe sepsis without MV >96 hours with MCC
682	Renal failure with MCC
442	Disorders of liver except malignancy, cirrhosis, or alcoholic hepatitis with CC

Additional information about TERLIVAZ is available at [TERLIVAZ.com](https://www.terlivaz.com)



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<sup>†</sup>Data obtained from 2021 MedPAR file from FY2021 reporting ICD-10-CM code K76.7. Not a comprehensive list of MS-DRG codes.

CC, complication or comorbidity; MCC, major complication or comorbidity; MV, mechanical ventilation.

## SELECT IMPORTANT SAFETY INFORMATION

### 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.

**Please see additional Important Safety Information throughout and full [Prescribing Information](#), including [Boxed Warning](#).**

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terlipressin for injection

## SELECT IMPORTANT SAFETY INFORMATION

### Warnings and Precautions (cont'd)

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  $\geq$ 35), the benefits of TERLIVAZ may not outweigh the 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 ( $\geq$ 10%) include abdominal pain, nausea, respiratory failure, diarrhea, and dyspnea.

Please see full [Prescribing Information](#), including **Boxed Warning**.

### References:

1. 88 Fed. Reg. 58640, 58891-906 (Aug. 28, 2023).
2. Inpatient prospective payment system (IPPS). Centers for Medicare and Medicaid Services. Updated July 7, 2023. [https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/payment/ipps#:~:text=The%20IPPS%20is%20designed%20to,payments%20\(NTAP\)%20for%20hospitals](https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/payment/ipps#:~:text=The%20IPPS%20is%20designed%20to,payments%20(NTAP)%20for%20hospitals). Accessed August 16, 2023.
3. Hospital reimbursement - TRICARE diagnosis related group (DRG)-based payment system (DRG weighting factors). In: *TRICARE Reimbursement Manual 6010.61-M*. Military Health System; 2022:chap 6. <https://manuals.health.mil/pages/DisplayManualHtmlFile/2021-06-30/AsOf/TR15/C6S11.html>. Accessed August 14, 2023.
4. TERLIVAZ<sup>®</sup> (terlipressin). Prescribing Information. Bridgewater, NJ; 2023. Mallinckrodt Hospital Products Inc.
5. MS-DRG Classifications and Software (ICD-10 MS-DRG Definitions). Centers for Medicare and Medicaid Services. Updated August 2, 2023. <https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/ms-drg-classifications-and-software>. Accessed August 16, 2023.
6. FY 2024 IPPS proposed rule home page [FY 2024 table 10.24A]. Centers for Medicare and Medicaid Services. Updated May 8, 2023. <https://www.cms.gov/files/zip/fy2024-ipp-s-p-table-10.zip>. Accessed August 31, 2023.



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