

Cumberland Pharmaceuticals 750 mg single-dose vial (only size) 10 mg/kg IV over 60 min q24h Reviewed: Jul 14, 2026 Payment limit: Q2 2026

#1 BILLER RULE — only the 750 mg vial is marketed, so weight-based doses discard drug. A non-750 mg dose opens an extra vial and leaves a large, payable JW discard. Exact multiple of 750 mg = JZ, zero waste. Not a routine OPAT drug: two boxed warnings (nephrotoxicity + embryo-fetal toxicity).

|                                         |                                                          |                                              |                                                      |                                                        |                                                                                     |
|-----------------------------------------|----------------------------------------------------------|----------------------------------------------|------------------------------------------------------|--------------------------------------------------------|-------------------------------------------------------------------------------------|
| HCPCS<br><b>J3095</b><br>1 unit = 10 mg | STANDARD DOSE<br><b>10 mg/kg</b><br>q24h, actual body wt | INFUSION TIME<br><b>60 min</b><br>once daily | ADMIN CPT<br><b>96365</b><br>therapeutic IV infusion | VIAL / WASTE<br><b>750 mg SDV</b><br>only size → JW/JZ | MEDICARE PMT LIMIT<br><b>\$7.032</b><br>/10mg, Q2 2026 (ASP-based, incl. 6% add-on) |
|-----------------------------------------|----------------------------------------------------------|----------------------------------------------|------------------------------------------------------|--------------------------------------------------------|-------------------------------------------------------------------------------------|

UNIT MATH — 750 MG VIAL ONLY (WORKED)

75 kg → 750 mg = one vial = 75 units, 0 discard → JZ  
allowed = 75 × \$7.032 = \$527.40 (pmt limit incl. 6%) → pt 20% ≈ \$105.48  
80 kg → 800 mg → TWO vials (1,500 mg), give 800 mg (80u, no mod)  
discard 700 mg = 70u JW; allowed = 150u × \$7.032 = \$1,054.80 → pt 20% ≈ \$210.96

JW and JZ are mutually exclusive (same drug, same DOS). Non-multiples of 750 mg produce a large, payable JW line; JZ alone only when the dose is an exact multiple of 750 mg.

DOSING & RENAL ADJUSTMENT

| CRCL     | DOSE                                | FREQUENCY |
|----------|-------------------------------------|-----------|
| ≥50      | 10 mg/kg                            | q24h      |
| 30–49    | 7.5 mg/kg                           | q24h      |
| 10–29    | 10 mg/kg                            | q48h      |
| <10 / HD | Not recommended (insufficient data) |           |

INDICATIONS

| INDICATION                               | STATUS      |
|------------------------------------------|-------------|
| MRSA cSSSI                               | FDA-labeled |
| HABP/VABP — when alternatives unsuitable | FDA-labeled |
| S. aureus bacteremia (salvage)           | Off-label   |

ADMIN CODES

| CODE  | WHEN                               |
|-------|------------------------------------|
| 96365 | 60-min IV infusion (primary code)  |
| 96413 | NOT appropriate — not chemotherapy |

NDC

| PRODUCT | NDC (11-DIGIT) | PACKAGE                |
|---------|----------------|------------------------|
| Vibativ | 66220-315-11   | 750 mg SDV (only size) |

Legacy 250 mg vial no longer marketed — FDA NDC directory + vibativ.com/order list 750 mg only (Jul 2026). Rebuild any 250 mg-based vial mix on 750 mg vials.

ICD-10 — INDICATION ANCHORS

| CODE    | FOR                             |
|---------|---------------------------------|
| L03.90  | Cellulitis/erysipelas (cSSSI)   |
| L02.91  | Cutaneous abscess (cSSSI)       |
| B95.62  | MRSA as documented organism     |
| J15.212 | MRSA pneumonia (HABP)           |
| J95.851 | Ventilator-associated pneumonia |

TOP DENIALS

1. JW/JZ missing or units don't reconcile to whole 750 mg vials

2. Step therapy / salvage rationale (prior vancomycin failure) undocumented

3. Boxed-warning docs missing (renal fn / pregnancy test)

4. Copay card applied to a government payer (commercial-only)

5. HABP/VABP use with baseline CrCl ≤50 without rationale

BOXED WARNINGS: nephrotoxicity (increased mortality vs vancomycin in HABP/VABP with baseline CrCl ≤50) + embryo-fetal toxicity (verify pregnancy before use). Coag labs (PT/INR/aPTT/ACT) artifactually elevated — draw immediately before next dose; IV unfractionated heparin CONTRAINDICATED.

Vibativ Co-Pay Program (commercial only): \$0/therapy day; cap \$135/therapy day, \$1,200/calendar year. Excludes govt payers (877-683-6110). Free-drug PAP currently CLOSED.