Widespread Prepayment Probe for HCPCS Code J2260 (Milrinone Lactate Injection)

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DME MAC A will be initiating a widespread prepayment probe of claims for HCPCS code J2260 (INJECTION, MILRINONE LACTATE, 5 MG).

This review is being initiated due to an increase in billing identified by data analysis.

Per the Local Coverage Determination (LCD) for External Infusion Pumps (L5044) an external infusion pump is covered for use with J2260 for the following indications:

Administration of other drugs if either of the following sets of criteria (1) or (2) are met:

Criteria set 1:
- Parenteral administration of the drug in the home is reasonable and necessary.
- An infusion pump is necessary to safely administer the drug
- The drug is administered by a prolonged infusion of at least 8 hours because of proven improved clinical efficacy
- The therapeutic regimen is proven or generally accepted to have significant advantages over intermittent bolus administration regimens or infusions lasting less than 8 hours

Criteria set 2:
- Parenteral administration of the drug in the home is reasonable and necessary
- An infusion pump is necessary to safely administer the drug
- The drug is administered by intermittent infusion (each episode of infusion lasting less than 8 hours) which does not require the beneficiary to return to the physician’s office prior to the beginning of each infusion
- Systemic toxicity or adverse effects of the drug are unavoidable without infusing it at a strictly controlled rate as indicated in the Physicians Desk Reference, or the U.S. Pharmacopeia Drug Information

Coverage for the administration of J2260 using an external infusion pump is limited to the following situations:

Administration of parenteral inotropic therapy, using the drugs dobutamine, milrinone and/or dopamine for beneficiaries with congestive heart failure and depressed cardiac function if a beneficiary meets all of the following criteria:

1. Dyspnea at rest or with minimal exertion is present despite treatment with maximum or near maximum tolerated doses of digoxin, a loop diuretic, and an angiotensin converting enzyme inhibitor or another vasodilator (e.g., hydralazine or isosorbide dinitrate), used simultaneously (unless allergic or intolerant), and

2. Doses are within the following ranges (lower doses will be covered only if part of a weaning or tapering protocol from higher dose levels):
   - **Dobutamine** - 2.5-10 mcg/kg/min
   - **Milrinone** - 0.375-0.750 mcg/kg/min
   - **Dopamine** - less than or equal to 5 mcg/kg/min, and
3. Cardiac studies by either invasive hemodynamic technique or using thoracic electrical bioimpedance (impedance cardiography),
performed within 6 months prior to the initiation of home inotropic therapy showing (a) cardiac index (CI) is less than or equal
to 2.2 liters/min/meter squared and/or pulmonary capillary wedge pressure (PCWP) is greater than or equal to 20 mm Hg
before inotrope infusion on maximum medical management and (b) at least a 20% increase in CI and/or at least a 20%
decrease in PCWP during inotrope infusion at the dose initially prescribed for home infusion, and

4. There has been an improvement in beneficiary well being, (less dyspnea, improved diuresis, improved renal function and/or
reduction in weight) with the absence of dyspnea at rest at the time of discharge and the capability of outpatient evaluation by the
prescribing physician at least monthly, and

5. In the case of continuous infusion, there is documented deterioration in clinical status when the drug(s) is tapered or discontinued
under observation in the hospital, or in the case of intermittent infusions, there is documentation of repeated hospitalizations for
congestive heart failure despite maximum medical management, and

6. Any life threatening arrhythmia is controlled prior to hospital discharge and there is no need for routine electrocardiographic
monitoring at home, and

7. The beneficiary is maintained on the lowest practical dose and efforts to decrease the dose of the drug(s) or the frequency/ duration
of infusion are documented during the first 3 months of therapy, and

8. The beneficiary’s cardiac symptoms, vital signs, weight, lab values, and response to therapy are routinely assessed and documented
in the beneficiary’s medical record.

External infusion pumps and related drugs and supplies will be denied as not reasonable and necessary when the criteria described by
indication (I), (II), (III), (IV) or (V) are not met.

When an infusion pump is covered, the drug necessitating the use of the pump and necessary supplies are also covered. When a pump has
been purchased by the Medicare program, other insurer, the beneficiary, or the rental cap has been reached, the drug necessitating the use of
the pump and supplies are covered as long as the coverage criteria for the pump are met.

Suppliers will be sent a documentation request for information listed below. The requested documentation must be
returned within 45 days from the date of the letter to avoid claim denials.

Documentation should include the following:

1. Physician order for the item. Include both the dispensing order (if applicable) and the detailed written order
which include the following elements:
   • Description of the item
   • Beneficiary’s name
   • Prescribing Physician’s name
   • Date of the order and the start date, if the start date is different from the date of the order
   • Physician signature (if a written order) or supplier signature (if verbal order)

2. For items provided on a periodic basis, including drugs, the written order must include:
   • Item(s) to be dispensed
   • Dosage or concentration, if applicable
   • Route of Administration
   • Frequency of use
   • Duration of infusion, if applicable
   • Quantity to be dispensed
   • Number of refills
3. A DME Information Form (DIF) which has been completed, signed, and dated by the supplier.

4. Information from the medical record that demonstrates the reasonable and necessary coverage criteria for the item(s) are met. This includes information relating to each of the criteria (D1-D8) defined in the Indications and Limitations of Coverage section. This must include the before and after inotropic drug infusion values defined in D3.

5. Proof of delivery which meets the required criteria as outlined in the External Infusion Pumps LCD.

6. Any other pertinent information that would justify payment for the item(s) provided.

7. Advanced Beneficiary Notice (ABN) if one was obtained, this must be submitted with the above requested documentation.

To avoid unnecessary denials for missing or incomplete information, please ensure when submitting documentation requests that all requested information is included with your file and respond in a timely manner.

It is important for suppliers to be familiar with the coverage criteria and documentation requirements as outlined in the LCD and Policy article. Suppliers can review the LCD for External Infusion Pumps (L5044) and Policy Article (A19713). Also refer to NHIC, Corp. Bulletin, “Drugs Used With External Infusion Pumps - Coverage and Billing Reminders”