EXTERNAL INFUSION PUMPS FOR PARENTERAL MEDICATIONS

Physician Information Sheet

doxorubicin, vincristine or vinblastine by continuous infusion over at least 8 hours when
the regimen is proven or generally accepted to have significant advantages over intermittent
administration regimens. (Because National HCFA Policy supersedes DMERC RMRP, should
chemotherapeutic regimens be used in the treatment of primary hepatocellular carcinoma
or liver metastases from colorectal carcinoma, the regimen would not have to meet the test
of proven increased efficacy over shorter duration protocols.)

B. The administration of narcotic analgesics (except meperidine) in place of morphine to a
patient with intractable pain caused by cancer who has not responded to an adequate
oral/transdermal therapeutic regimen and/or cannot tolerate oral/transdermal narcotic
analgesics. **There are two types of morphine, that which is preservative-free (J2275),
and that which contains preservatives (J2270). The preservative-free morphine
(J2275) is far more expensive and is only necessary for epidural infusions.**

C. The administration of foscarnet, amphotericin B, acyclovir and ganciclovir.

D. Administration of parenteral inotropic therapy, using the drugs dobutamine, milrinone
and/or dopamine for patients with congestive heart failure and depressed cardiac function
if a patient has **all** of the following conditions:

1. Dyspnea at rest 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);

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):

   a. Dobutamine 2.5 - 10 mcg/kg/min
   b. Milrinone 0.375 - 0.750 mcg/kg/min
   c. Dopamine < 2 mcg/kg/min, and

3. Invasive hemodynamic studies performed within 6 months prior to the initiation of
home inotropic therapy show

   a. cardiac index (Cl) 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;

4. An improvement in patient 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;

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 a hospital,
or in the case of intermittent infusions, there is documentation of repeated
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hospitalizations for congestive heart failure despite maximum medical management;

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

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

Equipment

The following equipment is billed to the DMERC using the Health Care Financing Administration Common Procedure Coding System (HCPCS) codes (shown in parentheses). These codes should appear on Certificates of Medical Necessity (see below), and should accurately reflect the equipment you have ordered.

An ambulatory infusion pump (E0781) is an electrical device which is used to deliver solutions containing parenteral medication under pressure at a regulated flow rate. It is small, portable and designed to be carried by the patient.

A stationary infusion pump (E0791) is an electrical device which serves the same purpose as an ambulatory pump but is larger and typically mounted on a pole.

A reusable mechanical infusion pump (K0284) is a device used to deliver solutions containing parenteral medication under pressure at a constant flow rate determined by the tubing, a portion of which has a fixed rigid diameter. The pressure may be produced by a spring, air bladder, etc. It is small, portable and designed to be carried by the patient. It must be capable of a single infusion cycle of at least 8 hours.

Code (K0417) describes a mechanical infusion pump which is similar to the above (K0284) pump, but which is only capable of a single infusion cycle of less than 8 hours.

Approximate Medicare allowance for the electrical infusion pumps (E0781/E0791) is $2,700 purchased ($270/month). Approximate Medicare allowance for the mechanical infusion pumps (K0284/K0417) = $100 to 200 ($10 to $20/month). The mechanical infusion pumps usually offer equally acceptable infusion rate control (except perhaps, in the case of analgesia delivery).

Elastomeric pumps are disposable delivery systems using the elastic property of the medication container to supply pressure for the infusion. Because they are disposable, they are not considered durable medical equipment, and therefore, are not covered by the DMERCs under the DME benefit.

Dressings and solutions used in the care of the infusion site, such as a peripheral or centrally inserted intravenous site, peripherally inserted central catheter (PICC), or an epidural catheter, are all to be billed under one code (A4221) as a single kit per week during the time a pump is being used for medication infusions, as well as for the weeks between infusions, not to exceed four weeks at a time. Supplies should not be separately billed aside from using the A4221 code.

Code (A4222) includes the cassette or bag which holds the medication, diluting solutions, tubing and other administration supplies, port cap changes, compounding charges, and preparation charges, all
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associated with administration of the medication. Again, these items should not be separately charged, but all included in the one administration kit code. Allowance for these (A4222) supplies is based on the number of cassettes or bags prepared. For intermittent infusions, no more than one cassette or bag is covered for each dose of medication. For continuous infusion, the concentration of the drug and the size of the cassette or bag should be maximized to result in the fewest cassettes or bags in keeping with good pharmacologic and medical practice. Medications and supplies that are dispensed but not used for completely unforeseen circumstances (e.g., emergency admission to hospital, drug toxicity, etc.) are covered. Suppliers are expected to anticipate changing needs for drugs (e.g., planned hospital admissions, drug level testing with possible dosage change, etc.) in their drug and supply preparation and delivery schedule.

The DMERC only processes claims for external infusion pumps; the local Part B Medicare carriers process claims for implantable devices and their supplies.

Certificate of Medical Necessity (CMN)

The Certificate of Medical Necessity (CMN) for external infusion pumps is DMERC CMN 09 (OMB Form 851). Physicians are expected to review Section A of the CMN for accuracy of patient and physician name, address, physician identification number etc.

He or she must complete or review for accuracy, answers to the questions # 1-7 in Section B, including the correct diagnoses codes, and estimated length of need. Section B should not have been completed by the supplier of the items/supplies, nor should the physician sign an incomplete CMN.

The physician should also examine Section C, to ascertain that only the equipment and supplies he or she has actually ordered are accurately listed, along with the CHARGES associated with the pump, accessories, supplies, and drugs.

The physician attests to all of the above by signing and dating the CMN in Section D. Signature stamps are not to be used.

If the infusion pump is being ordered for home infusion of dobutamine, extra documentation instructions are available from the supplier which will be necessary to assure proper claims adjudication for medical necessity.
Effective December 1, 1996, only entities licensed to dispense prescription drugs may bill for drugs used with durable medical equipment or prosthetic devices. The Health Care Financing Administration has provided a list of the most commonly asked questions and responses on this subject to assist you.

1. Why was this change in payment policy made? What is the background for the requirement that only licensed pharmacies may bill for drugs used in durable medical equipment?

This revision states only entities licensed to dispense prescription drugs and have Medicare supplier numbers may bill for this service when it is provided in conjunction with durable medical equipment (DME) or prosthetic devices. These drugs typically include nebulizer drugs, intravenous (IV) medications for pain management, antiviral drugs, cancer treatments, parenteral nutrients and oxygen. A DME supplier, that is not also a pharmacy, may only bill for the equipment.

The purpose of this revision is to bring Medicare billing practices into conformity with state and federal law, which require only a licensed pharmacy, or other licensed entity, may legally dispense drugs. In addition, since a prescription for a drug is written for a specific individual, according to current Medicare reassignment restrictions, it may not be purchased by a DME supplier for resale to a beneficiary. The revised policy will require that in order for prescription drugs used in conjunction with DME or prosthetic devices to be covered by Medicare, a pharmacy that dispenses such drugs must have a Medicare supplier number, must be licensed in the state in which the drug is dispensed, and must bill and receive payment in the pharmacy's own name.

We believe this new requirement, which is effective December 1, 1996, will help protect the health and safety of Medicare's beneficiaries, will eliminate inappropriate Medicare payments and will strengthen HCFA's partnership with all state Boards of Pharmacy to more closely monitor pharmacy practices.

2. The industry needs a minimum of 60 days advance notice of operational requirements prior to implementation.

We recognize that the DME supplier community requires sufficient time to adjust their business arrangements to comply with the new policy. The policy was issued July 30, 1996, and the Durable Medical Equipment Regional Carriers (DMERCs) informed suppliers of the revised instruction in their quarterly bulletins/advisories which were mailed mid-September. We believe this provides suppliers with adequate notice to adjust to the new billing requirements.

3. If December 1, 1996, is the effective date, is this date for the "date-of-service" or the date the claim is submitted/received by Medicare?

This policy applies to drugs that are dispensed with "dates-of-service" on and after December 1, 1996. This policy does not apply to claims submitted on or after December 1, 1996, for services that were furnished prior to the December 1 effective date.
4. Define the terms “licensed pharmacy” and “dispense.”

A licensed pharmacy is a business entity that has a valid pharmacy permit indicating the business entity has met licensure requirements by successfully completing the statutory pattern of qualifications for pharmaceutical practice which the State has established. State boards of pharmacy typically license all pharmacists and pharmacy departments within their state. Pharmacy boards also regulate the operation of pharmacy departments by owners, and the practice of pharmacy by pharmacists. Your State Board of Pharmacy should have a current copy of the laws and regulations that govern the practice of pharmacy in your state.

The National Association of Boards of Pharmacy (NABP) defines dispense or dispensing of a drug to mean "the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug."

5. How much time does it take Medicare to issue a provider number? Will there be a separate “pharmacy only” provider number? Who will issue the number?

The average time for processing a Medicare supplier application is 30 days if the application is complete and no additional development is required. A separate “pharmacy only” number is not required. Specific questions concerning the application process should be directed to:

National Supplier Clearinghouse
PO Box 100142
Columbia, SC 29202-3142

(803) 754-3951
8 a.m. to 8 p.m. Eastern Standard Time
Monday through Friday

6. Must a pharmacy be physically located in the state in which the drugs are dispensed, or must they simply be licensed by the state in which the drugs are dispensed?

A pharmacy must be licensed in the state in which the drugs are dispensed. For mail order pharmacies, this would be the state in which the pharmacy is physically located. In addition, current regulations at 42 CFR 424.57 (c) (9) require all suppliers to comply with applicable state and federal licensure and regulatory requirements. Therefore, if a pharmacy sends drugs to a state in which it is not located, the pharmacy would have to comply with any applicable state requirements that pertain to mail order dispensing.

7. For the purpose of this instruction, is oxygen considered a drug that must be dispensed by a pharmacy?

The revised instructions do not require that a supplier of oxygen services be a licensed pharmacy. However, oxygen suppliers must meet appropriate state licensure requirements. While oxygen is considered a “drug” by the Food and Drug Administration and is prescribed by a physician in precise quantities of flow rate and concentration, it is not
regulated in the same manner as "other drugs." The regulation of oxygen involves inspection of the company's physical plant, storage and safety, purity of the oxygen, transport as well as transfilling. Therefore, those billing Medicare for the supply of oxygen equipment and contents to beneficiaries must be licensed according to applicable state and federal regulations. Because the delivery of oxygen requires the ongoing monitoring of equipment function in terms of reliable delivery to the beneficiary, oxygen suppliers must be licensed in the state in which the beneficiary resides.

8. May Medicare certified home health agencies and hospices continue to bill Medicare Part A for pharmaceuticals used in conjunction with DME, when the drugs are obtained from licensed pharmacies that have contractual arrangements with the agency?

Yes. The Medicare conditions of participation require that home health agencies, hospices and their employees be in compliance with applicable state, federal and local laws. Therefore, because state or local law require drugs to be dispensed by a pharmacy for the pharmacy to be licensed, we expect that the home health agency or hospice is using a licensed pharmacy. This revised manual provision applies only to suppliers that are billing for services covered under Part B of the Medicare program. This manual provision does not apply to providers that bill Part A for DME and the prescription drugs. For this reason, this change to Medicare's reassignment rules was only made in the Part B Carriers Manual and was not made in the Part A Intermediary Manual. However, we will continue to review the Part A issues raised to determine if any additional action is necessary.

9. Can Medicare certified home agency and hospice personnel deliver Part A home health covered pharmaceuticals, which have been packaged and labeled by a licensed pharmacy for specific patients, to eligible patients?

Yes. As previously indicated, the Medicare conditions of participation require that home health agencies, hospices and their employees be licensed in accordance with federal, state and local laws. Therefore, to the extent that home health agency or hospice health care personnel are allowed under state or local law to deliver drugs, they are permitted to do so for Medicare patients, as long as the drugs are compounded by a pharmacy licensed in the state to dispense such drugs.

10. May DME companies with supplier numbers deliver and bill under Medicare Part B for pharmaceuticals used in conjunction with DME, if the drugs are prepared and labeled by licensed pharmacies that have contractual arrangements with the DME companies?

After November 30, 1996, the answer is no. The revision to section 3060.D of the Medicare Coverage Issues Manual states only entities licensed to dispense prescription drugs and have Medicare supplier numbers may bill for this service when it is provided in conjunction with durable medical equipment or prosthetic devices. Therefore, a DME supplier that is not also a pharmacy may only bill for the equipment or device.
11. Can Medicare certified home health agencies with supplier numbers bill Medicare Part B for pharmaceuticals used in conjunction with DME or a prosthetic device if the drugs are secured through contracts with licensed pharmacies?

No. As stated above, this policy limits the DME supplier to bill only for the DME, and does not allow the Part B supplier (unless it is a licensed pharmacy) to bill for prescription drugs used in conjunction with DME or a prosthetic device. Only a pharmacy legally authorized to operate in the state in which the drug is dispensed and has a Medicare supplier number is allowed to bill for these prescription drugs beginning December 1, 1996.

12. If an entity (e.g. a DME company, a home health agency or a hospice) acts as the network manager and contractor for delivery and administration of pharmaceuticals used in conjunction with DME, may that entity submit a consolidated Medicare Part B bill using its supplier number for the professional services, such as drugs from a licensed pharmacy, and the equipment from a DME company?

No. Beginning December 1, 1996, the licensed pharmacy must bill Medicare Part B for the prescription drugs. If a non-pharmacy entity meets the supplier standards requirements and has a Medicare supplier number, then it may bill Part B for the equipment only. In other words, a third party that has contracts with a DME company and a licensed pharmacy may not submit a consolidated bill in its own name to Medicare Part B for the DME and the drugs. Each entity that provides the covered service must bill in their own name. The DME company that supplies the equipment or an agency that acts as a supplier must bill for the equipment only, and the licensed pharmacy that provides the drugs used with the equipment must bill for the drugs.

13. Can a physician bill for both the DME equipment and the prescription drugs when the physician directly furnishes these services?

If a physician is licensed under state law to dispense drugs for home use with medical equipment, the physician could bill Medicare for these drugs. In addition, if the physician is acting as a retailer for the DME equipment, then the physician may also continue to bill Medicare Part B for the equipment.

14. Does this new policy apply to both enteral and parenteral products when they are covered under the prosthetic device benefit?

This policy does not apply to enteral nutrients, which are considered to be food products rather than drugs. However, it does apply to parenteral nutrients, which are considered to be drugs. The policy, which was published in a HCFA memorandum dated July 30, 1996, applies to the dispensing and billing of prescription drugs only.

15. How is a home health agency and a skilled nursing facility affected by this revision to section 3060.D concerning who can bill for prescription drugs used in conjunction with DME and/or prosthetic devices?

If a home health agency or skilled nursing facility is furnishing services