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The Honorable William M. Thomas
Chairman, Subcommittee on Health
Committee on Ways and Means
House of Representatives

The Honorable Philip M. Crane
House of Representatives

Subject: Medicare: Coverage of Pumps Used to Administer Intravenous Drugs

Medicare's Supplementary Medical Insurance (part B) provides coverage under its durable medical equipment (DME) benefit for durable (reusable) infusion pumps to administer intravenous (IV) drugs.¹ Supplies and IV drugs used with durable infusion pumps are also covered. In 1997, Medicare paid over \$35 million for home infusion therapy. Although disposable infusion pumps are commercially available, Medicare does not cover them or the supplies and drugs used with them, because they do not meet the definition of DME.²

You asked us to review the advantages and disadvantages of providing Medicare coverage for disposable infusion pumps. More specifically, this letter provides information on (1) the clinical benefits and limitations of disposable infusion pumps, (2) the factors that affect whether a durable or disposable infusion pump is less expensive to use for home infusion, (3) some Medicaid and private insurance plans' home infusion therapy coverage policies, and (4) issues raised by Medicare's policy that links coverage of IV drugs to the use of durable infusion pumps.

¹The DME benefit covers equipment and supplies used when Medicare beneficiaries are at home or in similar settings. Different Medicare coverage rules apply to IV therapy administered in hospitals, physician offices, and other settings.

²DME is one of Medicare's statutorily defined benefit categories. Medicare regulations define DME as equipment that (1) can withstand repeated use, (2) is primarily and customarily used to serve a medical purpose, (3) is generally not useful to a person in the absence of illness or injury, and (4) is appropriate for use in the home. 42 C.F.R. 414.202 (1997).

To address these issues, we researched laws and regulations pertaining to Medicare coverage of DME. We also met with Health Care Financing Administration (HCFA) officials and interviewed officials from two Medicare regional DME carriers (contractors that process and pay DME claims) to discuss Medicare's coverage rules and the rationale for the Medicare policy that links coverage of IV drugs to the use of durable pumps. We also obtained data on Medicare payments for durable infusion pumps and related supplies and IV drugs from Medicare's statistical analysis contractor. We interviewed pharmacists and clinicians associated with local and national infusion therapy suppliers and three national cancer centers. We discussed the clinical benefits and limitations of disposable and durable infusion pumps and how they relate to different IV therapy regimens. We also obtained information on two types of disposable pumps—the most commonly used pump and another pump that represents newer technology. This information came from four manufacturers, a medical products consultant, an infusion industry publication, and a pharmacy journal. To understand other payers' home infusion therapy coverage policies, we interviewed representatives from two Blue Cross/Blue Shield plans, one regional health maintenance organization, and four state Medicaid agencies. While these contacts do not allow us to generalize about other payers' policies, they did give us information about alternatives to Medicare's coverage policies. We performed our field work between May and October 1998 in accordance with generally accepted government auditing standards.

In summary, we found that views on the benefits and limitations of disposable infusion pumps vary across providers and by type of IV drug. For example, most clinicians and pharmacists we interviewed said that disposable infusion pumps can be used to administer IV antibiotics and IV antivirals. They also agreed that disposable pumps were not appropriate for IV pain medications. However, there was no clear consensus on the use of disposable infusion pumps with other infusion drugs, such as certain chemotherapy drugs. We also found that factors affecting the relative cost of disposable versus durable infusion pumps are the type of IV drug being administered and the frequency and duration of the patient's infusion therapy regimen.

Private health insurers we contacted pay suppliers a per diem rate for home infusion therapy regardless of the type of pump used. The per diem rate allows suppliers to choose the type of pump they believe will appropriately deliver the IV drugs at the lowest cost. The IV drugs used with infusion pumps are paid for separately. Medicare, on the other hand, generally does not cover self-administered drugs. However, HCFA's policy is to pay for IV drugs that must be administered with a durable infusion pump. This raises several issues. Under current Medicare policy, if disposable infusion pumps become appropriate for a

broader range of IV drugs, Medicare coverage of some IV drugs could be eliminated. If legislation expands Medicare coverage to include disposable infusion pumps, HCFA may need to reconsider its policy for determining which IV drugs to cover.

BACKGROUND

There are different types of infusion pumps to administer IV drugs in the home. These infusion devices include durable and disposable pumps. Durable infusion pumps include electronic and mechanical devices, and they are covered under Medicare's DME benefit because they are reusable. Medicare does not cover disposable infusion pumps because, according to HCFA, there is no statutory authority for single-use items, such as the disposable infusion pump, to be included in the Medicare definition of DME.

Electronic infusion pumps range from small, battery-operated, ambulatory pumps to large, electric, stationary pumps mounted on a pole. They are programmed to administer IV drugs at a specific rate and can deliver multiple doses per day. The flow rates can be adjusted, if necessary. Some electronic pumps can be monitored and programmed from a remote location. Multitherapy electronic pumps can administer more than one drug at a time. Some electronic pumps also have controls for the patient to administer pain medication as needed and a control to prevent the patient from using too much medication. Mechanical infusion pumps are nonelectronic, reusable, and portable.³

Medicare pays for electronic and mechanical infusion pumps when they are medically necessary to safely administer prescribed IV drugs. HCFA policy is to cover the IV drugs if they must be administered with a durable infusion pump.⁴ Covered home infusion drugs include some chemotherapy, pain, and antiviral medications. Supplies such as catheter maintenance equipment and the container for the drug are also covered.

³Mechanical pumps are used much less frequently than electronic pumps for home infusion therapy among the Medicare population. In 1997, Medicare paid about \$3,300 in fees for 327 mechanical pumps, compared with almost \$5.9 million for over 35,000 electronic pumps used in the home.

⁴Medicare Part B Reimbursement to Providers for Drugs Used in Conjunction With Durable Medical Equipment, HHS, OIG, A-06-92-00079 (Apr. 1995).

Disposable infusion pumps⁵ are small, lightweight devices that can administer a variety of IV drugs. The patient can carry this pump during infusion. Disposable pumps are used by a single patient to administer one dose of medication. The patient receives the pump prefilled with the medication, and when the infusion dose is complete, the pump is discarded. Medicare does not pay for medication and supplies used with disposable infusion pumps because disposable pumps are not covered. Noncovered drugs include antibiotics because they can be safely and effectively administered with a disposable infusion pump.

Medical directors at HCFA's four regional contractors that process and pay DME claims determine which home infusion drugs must be administered with a durable pump and therefore are covered by Medicare. The enclosure describes Medicare's current coverage policies for home infusion drugs.

BENEFITS AND LIMITATIONS OF DISPOSABLE INFUSION PUMPS

Views on the benefits and limitations of disposable infusion pumps vary across providers and by type of drug to be infused. Most providers we interviewed agreed that disposable infusion pumps can safely infuse IV antibiotics and other IV drugs that require a constant infusion rate. Clinicians and pharmacists generally agreed that disposable infusion pumps are not appropriate to use with pain medications because the flow rates cannot be adjusted to accommodate the patient's changing medication needs. However, for administering chemotherapy in the home, some pharmacists and clinicians preferred electronic pumps, while others chose disposable infusion pumps. For example, for the same chemotherapy drug, doxorubicin, two cancer centers provided disposable pumps for home infusion and one cancer center provided electronic pumps.

Some infusion therapy suppliers and manufacturers said that disposable infusion pumps have certain advantages over electronic infusion pumps. For example, disposable pumps are lightweight and concealable, and therefore offer advantages to patients who travel or work. According to some suppliers and manufacturers, disposable pumps are also easy to use because they do not require programming or have electronic components that may intimidate some patients. Patients do not need as much training to learn to use disposable

⁵There are different types of disposable infusion pumps. One type, the elastomeric pump, consists of an inflatable balloon inside a plastic container with tubing attached. The drug is infused as the balloon deflates. A newer type of disposable pump, the vacuum pressure pump, has a drug container made of rigid plastic and uses atmospheric pressure to infuse the drug solution. Other types of disposable pumps may be available as pump technology continues to evolve.

infusion pumps because the drug container and tubing are preattached. Also, unlike electronic pumps, disposable pumps do not require batteries that need to be replaced or recharged. Disposable pumps are also convenient for suppliers because suppliers do not need to retrieve them from patients' homes and clean them for use by other patients.

Disposable infusion pumps also have limitations that make some pharmacists and clinicians reluctant to use them to administer certain IV drugs, such as pain medications and some chemotherapy drugs. Some pharmacists and a clinician said that some disposable infusion pumps are not as dependable as electronic pumps, so they were concerned about using them to administer chemotherapy drugs in the home. One pharmacist, for example, claimed that the drug container of some disposable pumps can burst during use. Also, disposable pumps do not have alarms to alert patients to problems with medication flow, therefore the patient must monitor a disposable pump to make sure that the medication continues to flow. According to one pharmacist, detecting a problem with a disposable pump can be difficult when the rate of the infusion is slow, such as with chemotherapy. Also, unlike some electronic pumps, disposable infusion pumps cannot be remotely programmed or monitored.

FACTORS AFFECTING THE RELATIVE COSTS OF DISPOSABLE AND ELECTRONIC INFUSION PUMPS

The frequency and duration of the patient's IV therapy regimen affect the relative costs of using disposable and electronic infusion pumps. Various individuals with knowledge of home infusion therapy services said that regimens requiring few doses of medication over a short period of time can be administered less expensively with a disposable infusion pump. Conversely, an electronic infusion pump is less costly for administering multiple doses of medication in a day.⁶

Some pharmacists and clinicians we interviewed said that for certain IV drugs, disposable pumps may be economical substitutes for durable pumps. For these drugs, the relative costs of using disposable and electronic infusion pumps depend on the number of doses, the duration of each dose, and the length of the

⁶Medicare pays a monthly rental rate of up to \$252.64 in 1998 for an electronic pump (this fee includes delivery, retrieval, and maintenance costs). The drug is reimbursed separately. The retail price of a disposable pump for chemotherapy ranges from about \$25 for a single-day infusion to \$98 for a 7-day infusion. This retail price does not include the price of the drug. Because of the difficulty of obtaining comparable data on the costs of disposable and durable pumps and related supplies, we relied on suppliers' testimony for information on the factors influencing the relative costs of using disposable and durable pumps.

course of treatment. In general, if fewer doses are required, a disposable pump may be less costly than an electronic pump. One pharmacist affiliated with a cancer center said that disposable infusion pumps are less costly when the patient requires a single, monthly dose of a chemotherapy drug administered over 24 hours. If, however, the IV therapy regimen requires the patient to receive multiple, daily doses of a drug, an electronic infusion pump is usually less costly than a disposable pump. Disposable infusion pumps are a more expensive delivery system for multiple-dose therapies because each additional dose requires a new disposable pump.

COVERAGE OF DISPOSABLE PUMPS BY OTHER PAYERS

Private health insurers we interviewed pay infusion therapy suppliers a per diem rate for home infusion services. The per diem rate typically does not include the cost of the drug and does not vary by infusion method. Under this financial arrangement, suppliers have an incentive to deliver services at the lowest cost. The suppliers usually employ pharmacists to determine the type of infusion device to use for the prescribed IV drug. Some suppliers we interviewed said that per diem rates for home infusion services have declined and that, because of this decline, these suppliers have decreased their use of disposable infusion pumps. This indicates that other infusion methods may be more economical. For example, durable pumps may be the least expensive option if the supplier already owns or rents the equipment.

Medicaid coverage policies vary from state to state. Two state Medicaid agencies we contacted generally do not cover disposable infusion pumps unless prior authorization is obtained. One state agency reviews requests for disposable infusion pumps to determine whether the patient will benefit from this infusion device compared with other delivery methods. After prior authorization, one state Medicaid agency pays a negotiated rate for a disposable pump, and the other pays the supplier's acquisition cost for a disposable pump plus a dispensing fee. Two other states follow Medicare coverage policies and do not pay for disposable infusion pumps.

LINKAGE BETWEEN MEDICARE COVERAGE OF INFUSION PUMPS AND IV DRUGS RAISES COVERAGE QUESTIONS AS PUMP TECHNOLOGY EVOLVES

Medicare generally does not pay for self-administered drugs.⁷ However, HCFA established a policy to cover home infusion drugs that must be administered with a durable infusion pump. HCFA considers these infusion drugs to be "supplies" necessary for the use of durable infusion pumps. HCFA's policy does not provide coverage of home infusion drugs that can be administered safely and effectively with a disposable pump. The medical directors of the four Medicare regional contractors that process and pay DME claims decide which drugs require the use of durable infusion pumps and are therefore covered under Medicare's DME benefit. Once a drug is covered, there is no systematic review of current medical practices to determine whether disposable infusion pumps are being used to administer the drug.

As pump technology continues to evolve, disposable infusion pumps may be appropriate for a broader range of drugs. Medicare coverage of some home infusion drugs could be eliminated if Medicare's medical directors review current medical practices and determine that disposable pumps can safely administer these drugs. For example, in September 1996, Medicare stopped paying for home infusion of vancomycin, an antibiotic, when HCFA determined that it could be safely and effectively administered with a disposable infusion pump.

Medicare coverage of only durable pumps may create incentives for pharmacists and clinicians to continue to use electronic pumps for beneficiaries receiving home infusion, even when the use of disposable pumps is appropriate. For example, a pharmacist at one clinic said that because of Medicare's coverage policy, Medicare patients on chemotherapy in the home receive electronic pumps, while non-Medicare patients sometimes receive disposable pumps to administer the same drugs.

If Medicare law is changed to provide coverage of disposable infusion pumps, HCFA would have to reconsider its policy for determining coverage of home infusion drugs. Currently, HCFA's policy linking payment for IV drugs to the use of durable pumps limits which IV drugs Medicare covers. Changing Medicare law to pay for disposable pumps raises questions about whether IV drugs used with these pumps should be covered as well.

⁷The Congress has enacted legislation to provide Medicare coverage of some self-administered drugs such as certain oral chemotherapy drugs and antiemetic drugs.

AGENCY COMMENTS

We made a draft of this letter available to the HCFA Administrator for review and met with HCFA officials from the Center for Health Plans and Providers to obtain their oral comments. They emphasized the following points. First, legislation would be required to change Medicare coverage policy to include disposable pumps. Second, Medicare part B generally does not cover self-administered drugs, except for certain drugs mandated by statute and drugs used in conjunction with DME. Finally, the medical directors of the four DME contractors should identify changes in medical practice regarding how Medicare covered drugs are being administered. In response to these comments, we made technical changes to this letter, where appropriate.

As agreed with your offices, unless you release its contents earlier, we plan no further distribution of this letter for 30 days. At that time, we will make copies available to other congressional committees, the Secretary of Health and Human Services, and the Administrator of HCFA.

Please call William Reis at (617) 565-7488 or me at (202) 512-7114 if you or your staffs have any questions about the information in this letter. Other contributors were Teruni Rosengren and Kathryn Linehan.



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Enclosure

MEDICARE-COVERED HOME INFUSION DRUGS

Medicare covers certain home infusion drugs that are considered supplies to durable infusion pumps. Medicare contractors approve coverage of IV drugs when they determine these drugs must be used with durable infusion pumps. These coverage decisions are based on whether the IV drug can be safely administered in the home and whether the therapeutic regimen requires prolonged administration (over 8 hours) or shorter infusions at a strictly controlled rate.

Durable infusion pumps are covered to administer the following medications in the home:

- deferoxamine for chelation therapy, which removes excess iron in cases of chronic iron overload;
- chemotherapy for treating primary liver carcinoma or colorectal cancer in cases where the cancer is unresectable or the patient refuses surgical removal of the tumor;
- chemotherapy agents: cladribine, fluorouracil, cytarabine, bleomycin, floxuridine, doxorubicin, vincristine, or vinblastine when administered by continuous infusion over at least 8 hours, when this regimen has significant advantages over intermittent regimens;
- morphine for the treatment of intractable cancer pain;
- narcotic analgesics (except meperidine) in place of morphine for treatment of intractable cancer pain when the patient does not respond to oral and/or transdermal treatment or when oral and/or transdermal regimens cannot be tolerated;
- antifungal or antiviral drugs: acyclovir, foscarnet, amphotericin B, and ganciclovir;
- inotropic therapy using dobutamine, milrinone, or dopamine to make the heart beat stronger in patients with congestive heart failure and depressed cardiac function; and
- epoprostenol sodium for treatment of primary pulmonary hypertension.

For inotropic therapy or epoprostenol sodium to be covered, the patient's condition must meet specific criteria that are articulated in the coverage and payment rules. If an inotropic drug or epoprostenol is ordered, the initial claim must include documentation of the patient's condition with respect to the qualifying coverage criteria.

ENCLOSURE

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The coverage rules state that external infusion pumps, drugs, and supplies will be denied as not medically necessary when the criteria are not met. In addition, the rules state that when the pump is covered, the medication requiring the use of the pump and the necessary supplies are also covered items.

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