Chapter 6

COVERING HOME DRUG INFUSION THERAPY: IMPLICATIONS FOR MEDICARE

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Overview

Introduction

Medicare, the Federal Government's insurance program for the elderly and disabled, does not have a home drug infusion therapy (HDIT) benefit. No part of the Medicare insurance plan states that Medicare will pay for the prolonged administration of drugs in the home. Yet Medicare does indeed pay for many of the components of HDIT some of the time, and during the brief period when the Medicare Catastrophic Coverage Act (MCCA) was law, it was explicit Federal policy to extend coverage to HDIT more generally. The repeal of that act has permitted a second look at the implications of such a benefit.

As with most other aspects of HDIT, there is little direct and unambiguous evidence to shed light on what would happen if Medicare covered the therapy. This chapter draws on small studies, the health economics literature, the experiences of private payers and Medicare carriers, the experiences and statements of providers, and the findings of previous chapters of this report to examine the scenario of Medicare coverage and the various ways it might play out.

To do so, the chapter first examines the costs (and benefits) of HDIT from the perspective of the different actors involved-patients, providers, third-party payers, and the health care system as a whole-and discusses some of the factors that affect those costs. It then describes the extent to which Medicare currently covers components of HDIT and related services. Finally, the chapter discusses some of the issues and implications of extending Medicare coverage for the program, its beneficiaries, providers, and technological change.

Summary of Conclusions

- Most patients who have been treated with HDIT find it preferable to hospital inpatient treatment. For them, any additional patient-related burdens of home treatment (in time, travel, etc.) are more than offset by the advantages of a more normal home and work life.
- HDIT can be expensive to provide. Nonetheless, it is widely believed to be cost-saving to patients, third-party payers, and the health care system alike. For the kind of patient most likely to be on such therapy in the past-typically, a relatively young patient on antibiotic therapy who has no need of medical or assistive care other than the infusion-related care-this belief probably holds true much of the time.
- Under other circumstances, however, HDIT is probably often not less costly to the health care system than institutional alternatives. These circumstances are more likely to occur if the patient is unwilling to bear the responsibilities of home therapy; if the patient has additional medical problems or disabilities besides those that necessitate the infusion therapy; if there is no unpaid caregiver able to assist the patient at home; or if the patient's discharge forces a hospital bed to lie empty.
- Despite the lack of a benefit for HDIT, a substantial amount of it appears already to be paid for in some way by Medicare, but this indirect coverage is neither coordinated nor equitably applied. Existing coverage is so fragmented and variable that its extent is impossible to describe with any accuracy. Nonetheless, under current rules, the actual coverage is increasing and will probably continue to do so in the near future, as Medicare's administrative contractors use their discretion to cover drugs as well as the associated equipment, supplies, and nursing care.
- The absence of a coordinated benefit for HDIT limits the extent of the services that are provided. It also limits the ability of Medicare to assess, monitor, or influence the safety, quality, and effectiveness with which HDIT services are delivered.
- Medicare patients are much more likely than other patients to have social or medical circumstances that would require a paid caregiver to administer HDIT. They are also more likely to need additional assistance with daily living activities. Thus, while some Medicare patients

are ideal and self-sufficient candidates for HDIT, many would probably have total home care costs that exceed institutional costs.

- Medicare coverage of HDIT would offer opportunities for enhanced quality of life during treatment for many beneficiaries. It is possible (though by no means certain) that in the long run such a benefit might also be cost-saving to the program. In the short run, however, the addition of this benefit would raise program costs significantly, because Medicare cannot immediately recoup the financial benefits of shorter hospital stays. The extent of the added short-run costs, and the likelihood of long-term cost savings, would depend on the breadth of the benefit and its administration.
- Decisions regarding the exact drugs and conditions to be covered under an HDIT benefit could be made at the statutory, regulatory, fiscal intermediary (FI),[1] or individual physician level. Of these, decisionmaking placed at the regulatory or FI level are the most consistent with existing Medicare coverage decisions. Compared with FI decisionmaking, coverage decisionmaking at the regulatory level permits more consistency but less rapid accommodation of new drugs and drug protocols that might be appropriate for home use.

The Costs of Home Drug Infusion

The costs of HDIT depend on the perspective of those paying them. For the provider, costs are the costs of inputs-supplies, services, equipment, drugs, and administrative overhead. For payers, costs are payments for the service and administrative time for the benefit. For patients, costs—and benefits-are in dollars, time, and ability to participate in other activities. For the health care system as a whole, costs are overall resource and opportunity costs. HDIT is frequently cited as being cost-saving (see below), but the extent to which it is so depends very much on the context in which it takes place and the perspective from which cost savings are analyzed.

On its face, the literature regarding the costs and cost-effectiveness of HDIT is extremely positive. With very few exceptions, published studies conclude that HDIT is less expensive than institutional therapy for presumably equivalent benefit. Since 1978, when the first two reports appeared, at least 17 studies have reported that charges for antibiotic infusion patients treated at home were less than those for hospital-treated patients (16,78,101,106, 106a,119,136,148,182a,187,188,267,268,278,324,325, 335). The average reported savings per home patient in these studies ranged from $510 to $22,232 (22).

A problem in using these studies to infer cost-effectiveness of HDIT is that most use only provider charges, rather than resource costs, for their comparisons of home and hospital therapy. In addition, in many of the studies, hospital and home patients were apparently unmatched except for the general type of therapy. Hospital charges often included surgery and other inpatient procedures that had no home equivalents, and in some cases, hospital charges were simply rough estimates.

A more rigorous study of once-a-day intravenous (IV) antibiotic administration for osteomyelitis was published in 1986 (101). It, too, found that HDIT resulted in lower per-patient expenditures. Patients in the study were assumed to be entirely self-administering; no allowance was made for outpatient nursing. Collectively, then, the existing literature shows that, for carefully selected patients, charges for home care can average considerably less than charges for hospital care.

The actual resource costs of care, however, do not necessarily bear any relationship to charges. In fact, it is the difference in the perception of what costs are relevant, and changes in who is receiving home care, that explains why HDIT has not diffused even more rapidly despite the extensive literature on its savings potential. The following section discusses these factors.

Provider Costs

HDIT is not inexpensive to provide. It requires special expertise on-the part of nurses; it requires substantial amounts of pharmaceuticals and clinical pharmacy services; and it may require equipment rental as well as a multiplicity of supplies. Once begun, it cannot be abandoned without institutionalizing the recipient or endangering the patient's health. Thus, placing a patient on HDIT requires a substantial financial commitment on the part of the provider. There are no studies of actual provider

[1] Fiscal intermediaries (Part A intermediaries or Part B carriers) are Medicare's local administrative agents.

costs of finishing this service; only anecdotal information is available. One HDIT provider, for instance, believes its average costs of providing all drugs, services, and supplies for IV antibiotic therapy to be roughly $4,000 per month (367).

Costs probably vary considerably among providers. Health care worker wages, for example, are usually higher in urban than in rural areas (48 F.R. 39752). Wages for nursing services also vary among providers depending on the qualifications the provider requires of the nurses. The exclusive use of registered nurses (RNs) with extensive IV therapy experience, for example, is more costly (and possibly of higher quality) than the use of RNs with limited experience who perform both IV and other home health nursing services, because the more highly skilled nurses command higher salaries (364). One survey of infusion specialty companies found that their specialist nurses earned an average of $17.44 to $20.15 per hour, depending on experience (256).

Costs of supplies and equipment can also vary considerably among providers for any given therapy. Some providers, for example, use infusion pumps for almost all the therapies they provide (364). Others use less expensive gravity drip systems to deliver many antibiotics (364). Even among pumps, there can be great variation in costs (table 6-l), with the choice of which pump to use dependent on type of therapy, provider experience, purchasing arrangements, physician and patient preference, and patient characteristics.

Providers' drug costs vary tremendously as well, even within a single category of drugs such as antibiotics. Different antibiotics can have dramatically different average prices. Even for a single drug, providers' costs of acquiring the drug vary depending on their purchasing power (60,331).

The kinds of patients seen will affect both supply and nursing costs. Providers with a high cancer or AIDS[2] caseload, for example, may spend more per patient than other providers because these patients often require multiple therapies and the administration of highly toxic drugs that require pumps to be administered safely (see chs. 2 and 3). Similarly, providers who serve large numbers of elderly or disabled patients are likely to have higher nursing costs per patient than other providers, because these individuals may need more assistance with their therapies and other health and personal care needs (see ch. 3).

Table 6-l—Prices for Ambulatory Infusion Pumps: Examples From Two Manufacturers, 1991

Manufacturer/pump	Pump price[a]
Pharmacia Deltec	
CADD-HFX	$2,595
CADD-PIUS	3,395
CADD PCA2	3,495
CADD-TPN pump	3,595
CADD-TPN system	3,995
Ivion Corp.	
Walkmed 300	1,860
Walkmed 410	2,095
Walkmed 420	2,695
Walkmed 430	2,695
Walkmed 440	3,095
IntelliJect@	5,400

[a]Prices are those quoted to the Office of Technology Assessment by the manufacturers in October 1991. It is possible that the actual prices paid by some providers are lower than the prices listed here (e.g., if the providers obtained discounts from the manufacturers).

SOURCES: M. Moraczewski, Pharmacia Deltec, St. Paul MN, personal communication, Oct. 7, 1991; R.P. Nelson, Ivion Corp., Broomfield, CO, personal communication, Oct. 7, 1991.

There may be some tradeoff between nursing and supply costs. The use of a preprogrammed pump, for example, may allow an elderly patient to go home on therapy without the need for a paid nurse to administer each dose. The actual extent to which more sophisticated drug delivery systems may reduce nursing costs, and for which patients, is undocumented and apparently unknown.

Payer Costs

The costs of HDIT to a third-party payer-e.g., Medicare, Medicaid, or private insurance-are the amount that the insurer pays for the therapy *and any associated health care services necessary to provide it.*[3] *This* amount may simply be the providers' charges for the therapy and associated services, minus any coinsurance or deductible paid by the patient. Alternatively, the insurer may pay on some other basis, such as a fee schedule or a rate negotiated beforehand with the provider.

Much of HDIT's early success and rapid diffusion into the health care system has derived from

[2]Acquired immunodeficiency syndrome.

[3]In some cases—e.g., in some health maintenance organizations—the provider and the insurer maybe the same entity. In this case, the insurer's costs are simply the costs of providing the service.

providers' ability to convince insurers their payments will be less for home than for hospital therapy. But in 1992 this is not always the case, despite the evidence that home care charges have historically been lower.

Insurers' home care payments are sometimes higher than hospital payments for two reasons. First, the most important contributor to the lower historical charges for home infusion is the replacement of paid room, board, and labor in the hospital with their unpaid equivalents in the home. All of the studies that reported lower charges for HDIT required that home patients be able and willing to carry out their infusions with the help of a family caregiver. But HDIT in the 1990s is by no means limited to self-infusing patients (250,364), and total home charges for patients who require paid assistance may exceed hospital charges for equivalent care (204). This may be particularly true if, in order to substitute home for hospital care, the patient needs not only assistance with the infusion but help with other activities as well (e.g., dressing and bathing).

Second, the relationship between payments and charges differs for hospital and home therapy. Medicare, Medicaid, and private insurers now often pay hospitals much less than actual charges.[4] But insurers that pay directly for HDIT often still do so on the basis of home provider charges, because they have little other basis for establishing payment rates (55). Consequently, according to insurers, payment for HDIT can sometimes exceed payment for equivalent hospital care even for the most self-sufficient patients.

For example, one insurer told the Office of Technology Assessment (OTA) that it had received claims for a patient with Lyme disease in which the charge for self-administered home IV antibiotic therapy was over $650 per day. Based on its hospital payment experience, the insurer believed that hospital care for this patient would have been considerably cheaper than home care at the charged rate (367).

The difficulty in realizing cost savings to the payer is particularly acute for third-party payers that reimburse for hospital inpatient care at a fixed rate per patient discharged. In this case, the hospital payment remains the same regardless of whether the patient is discharged home after a few days or remains hospitalized for several weeks. From the payer's perspective, home care payments simply add to, rather than substitute for, hospital payments under such a system (243). Only when hospital care is averted altogether can the payer reduce its costs.

Patient Costs

Patient-associated costs of HDIT fall into three categories. First, and most obvious, are direct *medical costs. In the* extreme, when no third-party coverage applies, these costs include the purchase prices for all of the products and services directly related to the therapy. Because these costs are very high for most patients, HDIT is probably rarely provided to such patients except as charity care. When the patient's insurer does cover home therapy, the patient's direct medical costs include any insurance copayments (i.e., coinsurance and deductibles) and any provider charges uncovered by the insurer (e.g., charges greater than the payer's allowed charge and charges for any luxury or nonprescribed items).

Nonmedical costs (e.g., food, electricity, and transportation costs) can be equally important to home patients. Some of these, such as food, become "medical costs" and are covered by insurance when provided in a hospital. Finally, patients on prolonged infusion therapy also bear *indirect costs* associated with the therapy, such as time lost from family responsibilities and leisure activities, lost income, family stress, and psychological discomfort.

It is the lessened indirect costs often associated with HDIT that account for its popularity with patients. Patients with strict school, work, or home responsibilities (e.g., caring for another family member) can be very vocal and articulate in their preference for HDIT (364). In studies reporting on patient satisfaction and activities during HDIT, most home patients were able to resume their normal activities while on treatment (106,188). Even those without employment or other outside commitments may find home infusion attractive because it permits the patient to engage in outside recreational activities and a normal social life (364). No studies have

[4] Medicare and Medicaid have paid less than actual charges for many years. More recently, the increase in managed-care programs such as preferred provider and health maintenance organimations (which together make up over one-fourth of the group insurance market) (150) means that many private insurers also receive substantial discounts off of hospitals full charges.

been performed on the extent to which elderly patients requiring infusion therapy prefer one site of care over another, but there is no reason to think they would value the relative freedom of home care less than most other patients.

Costs to the Health Care System

Whether paying for HDIT costs more or less to the overall health care system than not paying for this service cannot be answered by examining either provider, payer, or patient costs in isolation. HDIT is cost-saving to the system if (and only if) the net health care resources required to provide this service, and any adjunct services needed at home, are fewer than those required to provide equivalent therapy and services in alternative settings.

The comprehensiveness of this requirement is critical. *It is the total package of care required by a patient in order to be treated at home just the infusion therapy-that must be compared with care in alternative settings in an evaluation of relative health system costs. If* a patient needs help with bathing and N site dressing (bandage) changes in order to be treated at home, the costs of providing those home services must be counted as part of the costs of being able to receive HDIT. Depending on the way benefits are defined and paid, HDIT can be cost-saving to any individual payer without necessarily saving health system resources overall, and vice versa.

The three basic settings for drug infusion therapy that are alternatives to the home are hospitals, while the patient is an inpatient; ambulatory care settings, such as outpatient clinics and physician offices; and skilled nursing facilities (SNFs) (including self-defined subacute care facilities). There are no studies of the resource costs of providing drug infusion therapies in any of these settings. However, it is possible to explore some of the factors that influence relative costs under different circumstance.

Need for Professional Services

In the extreme, if a patient needs 24-hour skilled nursing in order to be able to receive drug infusion therapy at home, the home is highly unlikely to be a cost-saving setting for treatment. In this instance, the nurse can care for only a single patient, a situation that is very resource-intensive and that can be more expensive than most hospital care (204,362a).

In contrast, the home is likely to be a relatively efficient setting for a patient who requires no professional care at all except for the initial training. Since the training itself is a resource cost not incurred by institutionalized patients, the relative cost savings for such patients increases with the length of time on therapy. This potential for great savings over time for independent and relatively healthy patients was one of the spurs behind the decision by Medicare in 1977 to pay for home therapy for patients requiring long-term total parenteral nutrition (TPN) (359).

Cost of Travel and Care Coordination

Home therapy, in contrast to inpatient- or clinic-based therapy, requires a considerable amount of provider time spent in activities other than direct patient care, such as travel between patients and coordination among relevant providers (physician, pharmacist, nurse, etc.). Where the costs of conducting these activities are high, home care may be relatively more resource-intensive. For example, if a patient needs professional supervision for a 4-times-a-day infusion regimen, requiring multiple daily trips by the nurse, home care may be more costly to the health care system than equivalent care provided in an SNF. Patients with many complex health care needs, of which infusion therapy is only one, may be similarly less expensive to care for in a health care setting that can offer the array of needed services on-site.

Providers of clinic-based outpatient infusion therapy maintain that this setting is more efficient than home care for treating many patients (340,340a). The ability of outpatient clinics to maintain all needed services on site, with personnel in constant communication, suggest that this assertion may well be true for at least some patients.

Institutional Occupancy Rates

Treating patients at home rather than in the hospital cannot be cost-saving to the health care system if hospitals are unable to either eliminate beds and associated services or put the beds and services to better use (e.g., by transferring into the now-open bed a patient previously being treated in the intensive care unit). Where hospitals have unoccupied beds and underutilized staff, continuing treatment in the hospital may well be less expensive

Box 6-A—The NAIT Survey

The National Alliance for Infusion Therapy (NAIT), an association of "providers and manufacturers of home infusion services, equipment, and products," sponsored a survey of data from nine of its members in 1990. The survey' goal was to "identify types of available data and obtain preliminary information about industry and patient characteristics.' It included the following components:

1. National ***patient census. The*** contractor performing the survey (Coopers & Lybrand) collected cross-sectional data for March and September 1990 to obtain a complete census of all home infusion therapy patients considered "on service" at that time in eight participating companies. This census (42,700 patients on Sept. 30, 1990) was then analyzed according to variables of interest (e.g., geographic location).
2. *Patient-specific data sample.* From a stratified sample of 86 branch offices of companies participating in the survey, the contractor then sampled 2,506 patient records to identify patient-specific demographic, clinical, service, and therapy information. Patients were selected for the sample only if they received one or more of the following infusion therapies during the 2-week sample period: antibiotics, antineoplastics, pain management, total parenteral nutrition, and enteral nutrition.
3. *Patient education survey. The* contractor separately surveyed a small sample of previously hospitalized patients who were receiving services from participating companies regarding the infusion-related education and training they received in the hospital before discharge.
4. *Site visits* to four branches of three companies and one corporate office to obtain operation and service delivery information.
5. *A review of the published literature* regarding home infusion therapy services, costs, and wages for skilled employees.
6. *Longitudinal data* for a subset of all previously surveyed patients who were discharged from home infusion service during the period Sept. 9, 1990 through May 31, 1991. (Late reporting and incompleteness made these data of questionable reliability.)

SOURCE: A.K. Parver and K. Lind, National Alliance for Infusion Therapy, Washington, DC, memorandum to E. Power, Office of Technology Assessment, Oct. 30,1991.

to the health care system than treating that patient at home (at least in the short run). Conversely, if institutional beds are fully occupied, home care becomes a relatively more efficient setting, because the alternative is to build more institutional beds.

HDIT Coverage by Non-Medicare Payers

Most health care third-party payers cover HDIT at least some of the time. Coverage increased substantially during the 1980s, as the technology became more developed, providers became more adept at convincing payers of its worthiness, and payers became more familiar with it. In a 1990 survey of records of some infusion companies that are members of the National Alliance for Infusion Therapy (NAIT), less than 4 percent of patients had no third-party coverage of any kind for their therapy (257). (Box 6-A describes the NAIT survey.)

Private Insurers

Most HDIT is paid for through private insurance. Several providers who specialize in home drug infusion (as opposed to TPN) report anecdotally that over three-fourths of their patients have private third-party coverage (83,343).[5] The NAIT survey found that almost 64 percent of patient records sampled listed private insurance as the payer and an additional 14 percent had a combination of private insurance and Medicare (256).

Similarly, most private insurers cover HDIT to at least some extent. A 1987 *survey* of coverage for home IV antibiotic therapy found that of 50 Blue Cross/Blue Shield programs, 47 covered this service, although 34 required that it receive prior authorization before coverage commenced (21). This survey likewise found that most commercial insurers and all of the 19 responding health maintenance organizations covered this therapy, with about

[5] **Because Medicare covers TPN, providers specializing in this form of infusion therapy would be expected to have a higher proportion of Medicare patients (and a lower proportion of privately insured patients) than those specializing in HDIT.**

half of each group requiring prior authorization (21). These results, now 4 years old, probably understate current coverage; the continued expansion and financial well-being of the HDIT industry suggests that coverage for the therapy is widespread.[6]

Medicaid

Medicaid is a federally aided, State-administered program that provides medical assistance to roughly 26 million low-income people (114). Although the Federal Government sets some minimum standards, the actual services offered by individual State Medicaid programs vary widely among the programs.

All State Medicaid programs cover the basic components of HDIT in some fashion (although they do not necessarily pay generously). Durable medical equipment (DME) and home care services for adults, for example, are federally mandated benefits under the program. Prescription drugs are optional, but as of 1990 all 50 States and the District of Columbia covered them (373).

More comprehensive coverage of HDIT, however, is not so universal. A 1987 survey of the 50 State Medicaid programs, sponsored by Hoffmann-La Roche, found that 48 of the 50 States paid for home IV antibiotic therapy (21). Of these 48 programs, 29 required that the service receive prior approval before it would be covered. At least one Medicaid program has documented that HDIT has been cost-saving to the program (box 6-B).

Box 6-B—Home Infusion Therapy in the Colorado Medicaid Program

A review of claims for home infusion therapy **submitted** to Colorado's Medicaid program found satisfactory results of this coverage for that program. Researchers found that 61 patients were treated at home, based on claims submitted over a 26-month period. Most of these patients were treated with anti-infective drugs. The remainder received either other infused drugs or total parenteral nutrition (TPN) (85).

program savings for the period were estimated to be at least $125,000 (1988 dollars). The program resulted in a significant shift of Medicaid resources, from hospital spending (which decreased by au estimated $430,000 due to the program) to expenditures for nonhospital pharmacy services (which increased by nearly $100,000). Anti-infective therapy was the greatest overall contributor to savings, due to its large share of patients, while pain management resulted in the greatest per-patient savings. In this study, home TPN was found to result in little or no program cost savings (i.e., it did not reduce Medicaid expenditures) (85).

CHAMPUS

The Civilian Health and Medical program of the Uniformed Services (CHAMPUS), operated by the Department of Defense, is an example of another government health care program that covers HDIT in at least some cases. CHAMPUS pays for the medical care needed by dependents of active and retired military personnel when that care cannot be obtained from a military hospital. The program covers home infusion therapy both under its basic benefit package and through two ongoing home health care demonstration projects. Coverage is generally broad, but it is probably somewhat erratic in its implementation due to the individualized nature of many coverage decisions.

CHAMPUS basic home health benefits include medical equipment, skilled nursing care, drugs and medical supplies, and physician visits. The program has little formal policy regarding what types of home infusion therapies are covered; all decisions are made on a case-by-case basis, and informal coverage policies (mostly in the form of specific exclusions) are based on accumulated claims experience (20). However, coverage for HDIT appears fairly broad. Except for beneficiaries requiring custodial care (to whom limits on nursing services apply), unlimited home health visits to CHAMPUS beneficiaries are covered if they are medically necessary and if the patient is either "homebound" or services are otherwise determined to be needed in the home.[7] Infused drugs are covered, but only if they are approved by the Food and Drug Administration

[6] The financial well-being of the HDIT market is suggested by the fact that, according to market analyst estimates, industry revenues grew by over 30 percent per year between 1986 and 1988 and were predicted to continue to grow by over 25 percent per year through 1991 (275). Companies likewise continue to perceive the HDIT industry as a growing one, and of the top 10 companies in the home care industry (defined by total revenue), 7 derive at least a quarter of their revenue from home infusion therapy, including HDIT (392).

[7] CHAMPUS has no working definition of "homebound," and fiscal intermediaries may be applying the restriction rather liberally (20).

(FDA) for both the particular route of administration and the particular condition (19).[8]

In contrast, under the ongoing demonstration projects, drugs may (on a case-by-case basis) be covered for unapproved uses if they are widely used for those purposes (269).[9] In general, the demonstration projects require that a patient have an alternate caregiver in order to receive home infusion therapy. However, CHAMPUS has paid for additional assistive services on occasion (269).

Current Medicare Coverage of HDIT

Applicable Existing Benefits

Medicare, the Federal Government's health insurance program for aged and disabled individuals, has no defined benefit that covers HDIT. Infusion therapy of any kind has been considered in the past to be an institutional rather than a home service. Even TPN, which has been covered by Medicare since 1977, is covered under the prosthetic device benefit (as a replacement for the digestive system) rather than as a home infusion therapy benefit.

Nonetheless, there are a number of existing benefits under which patients can get certain components of drug infusion therapy covered at home. The total number of Medicare patients who receive some coverage for home infusion therapy is unknown but probably extensive. However, the coverage that exists is also highly fragmented, nearly always incomplete, and varies enormously depending on the location and circumstances of the patient.

Medicare is separated into two parts: Part A, which covers hospital, skilled nursing facility, home health, and hospice care; and Part B, which covers physician and related services, hospital outpatient services, nonhospital laboratory services, and medical equipment and supplies.[10] Existing benefits that currently serve as "back door" mechanisms for HDIT coverage include:

1. Part B DME benefit,
2. Part A home health benefit,
3. Part B diagnostic laboratory services benefit,
4. Part B physician services benefit,
5. Part B hospital outpatient benefit, and
6. Part A hospice benefit.

Each of these benefits and its relation to HDIT is described below.

Part B Durable Medical Equipment

The Medicare DME benefit is the most broadly available mechanism through which Medicare covers some of the components of HDIT. To be eligible for this benefit, a beneficiary usually need only have a physician certify that the equipment: 1) is furnished to that person in his or her home,[11] and 2) is medically necessary to ameliorate illness or injury or to improve functioning of a malformed body part. Infusion pumps and IV poles qualify as DME.

Medicare also covers medical supplies and accessories necessary for the proper functioning of the equipment (74). Thus, supplies such as tubing, needles, and alcohol swabs would be covered when a pump is covered.

Equipment must be capable of withstanding repeated use to qualify as DME. Single-use infusion control devices (e.g., elastomeric infusers-see ch. 3) do not qualify. Also, equipment with certain convenience or luxury features are covered in full only if those features are deemed medically necessary for the patient's condition (74). Thus, Medicare presumably would not cover a sophisticated infusion pump if the drug to be infused could be delivered safely and effectively through a less expensive gravity drip system. Furthermore, because a gravity drip system (with the exception of the IV pole) is not considered DME, related medical supplies would usually also be excluded from coverage in this instance.

The coverage of supplies and accessories related to the DME explicitly includes "drugs and biologicals that must be put directly into the equipment to assure proper functioning of the equipment" (74).

[8] CHAMPUS does not cover dregs for unapproved uses; for example, the FDA has not approved terbutaline for use in preventing preterm labor, so it is excluded from CHAMPUS coverage (20). The only exception to this general policy is that, under a proposed and soon to be final rule, CHAMPUS will cover class III investigational cancer drugs listed by the National Cancer Institute (20).

[9] For example, CHAMPUS does cover home-infused terbutaline for high-risk obstetric patients under the demonstration program. They have experience with about 60 patients, and staff believe the therapy to be effective in prolonging pregnancy (269).

[10] Home health services can also be covered under Part B for beneficiaries who are ineligible for Part A benefits.

[11] For the purposes of this benefit, a "home" is defined as the patient's place of residence, but the definition excludes institutions or distinct parts of institutions that meet the basic definition of a hospital or a skilled nursing facility.

Box 6-C—Defining "Homebound" Under the Medicare Home Health Benefit

For much of Medicare's history, "homebound" was written in the statute as "confined to the home" and appeared at only two places in the Social Security Act (sections 1814(a) and 1835(a)). Over the years, the Health Care Financing Administration (HCFA) attempted to clarify the definition through guidelines and examples in the Medicare Intermediaries' Manual. The guidelines essentially restricted qualifying beneficiaries to those unable to leave the house by any means to get medical care, although the manual specified a few exceptions (e.g., trips to church, trips to the doctor for medical care that couldn't be delivered at home) (379). Still, intermediaries' interpretations of "homebound" were apparently highly varied (167).

The omnibus Budget Reconciliation Act of 1987 (Public Law 100-203) attempted to further clarify the meaning of "homebound" by specifying in statute that:

> . . . an individual shall be considered to be 'confined to his **home' if the individual has a condition, due to an illness or in., that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be** bedridden to be considered 'confined to his home,' the condition of the individual should be such that there exists a normal inability to leave the home, that **leaving home requires a considerable** and taxing effort by the individual, and that absences of the **individual** from home are infrequent or of relatively short duration, or are attributable to the need to receive medical treatment" (SSA secs. 1814(a), 1835(a)).

Despite this effort to bring some uniformity to the application of the "homebound" restriction, continued ambiguity in the definition of "confined to his home' will most likely lead to continued differences in intermediary interpretation and practice. HCFA intends to publish regulations that attempt to explain the new statutory language in more detail (167).

The interpretation of this clause, however, is left to the discretion of the FI (i.e., the Part B carrier) (155). To clarify what drugs might be appropriately covered through this provision, the Health Care Financing Administration (HCFA) inserted language in the Medicare Carriers Manual that instructs carriers to cover the cost of external infusion pumps *and associated drugs* when used for the administration of:

- deferoxamine to treat acute iron poisoning or iron overload;
- heparin to treat thromboembolic disease and/or pulmonary embolism (in institutional settings only);
- antineoplastic therapy to treat liver cancer patients who cannot or will not undergo surgical treatment; and
- morphine to treat cancer patients for intractable pain (378).

This language neither requires nor prohibits carriers from covering other drugs under this same general rubric .[12]

Part A Home Health Services[13]

The Medicare home health benefit is a source of coverage for skilled nursing services associated with home infusion for Medicare beneficiaries. To be eligible for Medicare-covered home health services, however, a beneficiary must be "confined to his home'—i.e., unable to leave his home without the assistance of another person or a supportive device (379). The legislative definition of "confined to his home' has been broadened in recent years (see box 6-C). However, it is still both fairly restrictive and somewhat ambiguous, and there is still variation among Medicare intermediaries in interpretation of the rule (167).

The homebound requirement effectively eliminates a large number of the least disabled patients on drug infusion therapy from any nursing coverage offered under the home health benefit. For example, patients who are otherwise healthy and nondisabled but require continuation of an 8-week course of antibiotic therapy would not qualify for any home health services because they are not homebound.

12 HCFA does explicitly prohibit coverage of external infusion pumps for the subcutaneous administration of insulin to diabetic patients (378).

13 "Home health services" are covered under Part A unless the beneficiary has exhausted his or her Part A coverage, in which case coverage is under Part B (74).

Beneficiaries eligible for home health benefits also must be under a physician's written plan of care and must be in need of either part-time or intermittent skilled nursing care or skilled physical or speech therapy services (379). Nearly all patients requiring home infusion would meet this qualification. Thus, most infusion patients who were also homebound would be eligible for other home health benefits not related to the infusion therapy as well.[14]

Two home health benefits are especially relevant to HDIT patients. These are:

- *Part-time or intermittent skilled nursing services* provided by or under the supervision of a registered nurse (RN) (379). Patients qualify if they need up to 28 hours per week of skilled nursing and home health aide services combined at less than 8 hours per day, or up to full-time (8 hours per day) on a temporary basis (up to 3 weeks). The need for services up to 35 hours per week of skilled nursing and home health aide services combined at less than 8 hours per day (or on less than a daily basis) may be approved on a case-by-case basis (379). Through this benefit, most skilled nursing services required for HDIT would be covered.
- *DME and medical supplies.* Covered supplies include presumptively medical supplies (e.g., needles, wound dressing supplies) as well as ordinarily nonmedical supplies that are deemed necessary for the patient's medical condition (e.g., lotions or soaps that serve a particular therapeutic purpose). Unlike the part B DME benefit, drugs and biological are specifically excluded from DME provided under the home health benefit (379). Nonetheless, this benefit permits the rental or purchase cost of an infusion pump and all HDIT-related medical supplies except the drugs (e.g., tubing, catheter replacements, dressing supplies, alcohol swabs) to be covered.

The home health benefit also covers:

- skilled physical, speech, and occupational therapy services,
- part-time or intermittent services of a qualifed home health aide,[15]
- medical social services,[16] and
- home medical services of residents and interns in approved teaching programs with which the home health agency is affiliated (74).

All covered services must be furnished by or under arrangement with a Medicare-certified home health agency (HHA) (74).

Part B Diagnostic Laboratory Services

Medicare's Part B diagnostic laboratory services benefit covers nonhospital diagnostic laboratory services that are ordered by a physician, including laboratory tests to monitor the status of an HDIT patient (74,378).[17] Skilled health professional services required to obtain laboratory specimens (e.g., a lab technician to draw blood) and travel costs of laboratory personnel for the purpose of collecting specimens from homebound persons are also covered (378).

Part B Services Incident to a Physician's Services

Services and supplies (including drugs and biologicals that cannot be self-administered[18]) furnished incident to a physician's professional services are covered under Part B of Medicare. Nonphysician services (e.g., nursing services) covered under this provision usually must be performed under the direct supervision of the physician by individuals under that physician's employ (378).

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14 The NAIT survey found that 12 percent of all patients in its sample were nonambulatory (and thus might qualify as homebound) (256). The proportion of elderly patients on HDIT who might qualify is probably considerably higher, since most patients in the NAIT sample were under age 65.

15 'rhepww of home health aide visits must be to provide hands-on personal care or services necessary for the health or treatment Of the beneficiary (e.g., simple dressing changes, assistance with oral medications). Services of a home health aide are not considered reasonable and necessary if there is a family member or other caregiver available and willing to perform them; however, it is customary to presume that no caregiver is available unless the beneficiary or a family member indicates otherwise or the home health agency has knowledge to the contrary (379).

16 Examples of medical social services include: counseling services, community resource identification, assessment of resource coordination, and assessment of social and emotional factors related to the beneficiary's condition and treatment (379).

17 A clinical laboratory that is part of a hospital is considered an independent laboratory when it provides services to nonpatients (378). If the same hospital laboratory provides services to the hospital's outpatients, such services are covered under the Part B outpatient hospital services benefit (74).

18 Intravenously administered drugs are generally not considered by HCFA to be @f&-" tered drugs (378).

In certain unusual circumstances, however, Medicare can waive the direct supervision requirement.[19] Specifically, for homebound patients who live in areas not served by any Medicare-certified HHA, Medicare will cover a number of skilled services when provided by nonphysicians, including injections, venipuncture, dressing changes, and patient training activities (378). HCFA has no information regarding the extent to which services are billed under this waiver (76,143). The increase in the number of certified HHAs (from 2,212 in 1972 to 5,673 in 1990) (353), however, suggests at least that the need for such a provision has decreased.

Medicare coverage of services furnished incident to a physician's services are more commonly relevant to infusion services in the context of outpatient infusion. Through this coverage rule, Medicare covers the nursing services and supplies for infusions performed in physicians' offices. Some carriers apparently restrict such outpatient infusion coverage, however. For example, an IV antibiotic provider in the State of Washington reports that its carrier will cover office-based infusion only for certain medical conditions (146).

Part B Hospital Outpatient Services

As with physicians' offices, hospital outpatient departments already qualify for payment for their various nursing activities and medical supplies, and outpatient infusion provided in this setting is reimbursable. Medicare covers laboratory services, durable medical equipment, visits, medications, and medical supplies provided in hospital outpatient departments (273). Furthermore, payment for most services in this setting is on the basis of reasonable costs, making it potentially financially attractive to hospitals able to organize and maintain an outpatient clinic.

Through this mechanism, Medicare may cover not only infusions performed in the clinic itself but the costs of visits for skilled nursing services (e.g., catheter site changes) when a patient is performing the daily infusions at home. The extent to which the benefit is used for either purpose is unknown.

Box 6-D—Services and Supplies Covered Under the Medicare Hospice Benefit

Supplies and services covered under the Medicare hospice benefit include:

- nursing care;
- medical social services;
- physicians' services;
- counseling services for the patient and familly members;
- short-term inpatient hospice care;
- drugs and biological that are used primarily for pain and symptom control;
- medical equipment and supplies related to pain and symptom management;
- physical, occupational, and speech therapy; and
- home health aide and personal care services (including personal comfort and custodial care items as necessary).

Nursing and home health aide services are covered on a 24-hour basis only during periods of crisis.

SOURCE: Commerce Clearing House, Inc., *Medicare and Medicaid Guide* (Chicago, IL: CCH, Inc., 1990).

Part A Hospice Care

Terminally ill patients (those with a life expectancy of 6 months or less) are eligible for the Medicare hospice benefit. This benefit focuses on palliative treatment, symptom control, and home care rather than on curative treatment. When a beneficiary elects hospice care, he or she becomes ineligible for most other Medicare benefits.[20]

Hospice care must be provided by a Medicare-certified hospice program. Hospice care services and supplies (see box 6-D) are covered by Medicare if they are reasonable and necessary for the palliation or management of the patient's terminal illness and are included in a written plan of care that is reviewed periodically by the patient's physician. The hospice program must provide all these services directly or through arrangements with other approved entities.

Any home infusion services provided by the hospice are covered under a daily rate. Hospices may

[19] The services must still be provided under general physician supervision. "General supervision" requires that the service(s) be ordered by the physician, that the physician maintain contact with the professionals performing the service(s), and that the physician maintain professional responsibility for the service(s) (378). (In contrast, "direct supervision" requires that the physician be on site.)

[20] Services of such a physician the patient's attending physician who is not an employee of the hospice continue to be reimbursable under Medicare Part B (74).

be discouraged from providing such services either because they are too costly, too complicated to provide, or both (26). Some hospices, for example, do not accept patients who are on TPN (30). (Although TPN is covered under the Part B prosthetic device benefit, beneficiaries who have elected the hospice benefit are no longer eligible for such coverage.) The bulk of home infusion therapy provided under the hospice benefit is believed to be for pain management (26). Pain management administered by infusion pump is considered a "high-cost" service by providers, and although hospices generally prefer less costly alternatives, they will generally pay for a pump system if it is requested by the physician (26).[21]

The Extent of Current Medicare Coverage of Home-Infused Drugs

The primary means by which Medicare currently covers HDIT are the home health benefit, which enables homebound persons to receive coverage for infusion-related nursing, and the DME benefit, which permits Medicare beneficiaries who need them to receive infusion pumps and related supplies. It is the latter benefit that allows patients to receive some drugs, with the extent of drug coverage dependent on the Medicare carrier's discretion. These two complementary benefits can, at times, enable a Medicare patient to receive reasonably comprehensive (but uncoordinated) home infusion benefits. The patient, if homebound, may qualify for the home health benefit through the need for intermittent infusion-related nursing, while billing for drugs, equipment, and supplies through the Part B DME benefit.

To assess the extent to which carriers actually cover home-infused drugs through the DME benefit, OTA conducted a survey of all 43 carriers in the United States.[22]

As of February 1991, all of these carriers had policies to cover at least the three drugs explicitly permitted by HCFA for home treatment of specified conditions: morphine for intractable cancer pain, antineoplastic therapies for certain cancers, and deferoxamine for iron overload. Seventeen carriers covered only the drugs and conditions specified by HCFA, and some placed additional explicit restrictions on coverage (e.g., treatment was covered only it begun in a health care setting). At the opposite extreme, however, many carriers covered not only the drugs permitted by HCFA but a wide variety of other drugs as well. For example, 24 carriers reported that they at least sometimes cover analgesics other than morphine; 18 at least sometimes covered antibiotics; and 3 carriers covered dobutamine (365).

A few carriers even reported covering, through the DME benefit, certain drugs that are *not* administered via infusion pumps. One carrier covered antibiotics when administered through a gravity drip system, and one covered hydration therapy in terminally ill patients when the therapy was administered by gravity drip (365).[23]

The results of this survey prompt two conclusions. First, there is clearly great variability in DME coverage policy among carriers, from carriers who cover only the HCFA-listed drugs under the most stringent conditions to carriers who cover even drugs not administered through a pump. Second, the amount of HDIT that is already being covered by Medicare is significant and is increasing rapidly. Both the categories of drugs that carriers are willing to cover and the number of claims for drugs in those categories appear to be rising.

Antibiotics and dobutamine coverage policies present striking examples of the rapidity with which coverage-and claims-are increasing:

- Three of the 18 carriers that covered at least some antibiotics had begun doing so only very recently, and one noncovering carrier was considering extending coverage to antibiotics at the time of the survey.
- Seven carriers said that claims for antibiotics were frequent and submitted in increasing numbers.
- Of the three carriers that said they would cover dobutarnine at home, one had yet to see a claim

21 The issue of high-cost services provided by hospices is currently Waler examination at Project HOPE as part of a congressionally requested study (26).

22 These constitute all of the carriers covering the United States and the District of Columbia. Attempts to include Puerto Rico's carrier in the survey were unsuccessful.

23 Two carriers reported that they even covered aerosolized pentamidine under the DME benefit. OTA did not follow up survey responses and so cannot confirm this.

for it. The other two had both instituted coverage only very recently; one had seen only a single claim so far, while the other carrier estimated that dobutamine already accounted for 10 percent of its drug claims under the DME benefit (365).

An interesting characteristic of current coverage of home-infused drugs is that because changes are made incrementally at the local level, and because two of the three drugs sanctioned by HCFA are for cancer therapy, patients with severe cancer have the greatest coverage. In the survey, all carriers covered morphine and some antineoplastics, and most also covered some other related drugs (e.g., other analgesics). Furthermore, where carriers covered additional categories of drugs, coverage was sometimes limited to patients already receiving other therapies. For example, four carriers covered adjunct therapies (e.g., hormonal therapies) for patients currently receiving home antineoplastic infusion; two carriers covered antibiotics only as adjuncts to antineoplastic therapy; and the two carriers that covered hydration did so only for patients already receiving infusion therapies (365).

The logic behind such coverage is that patients who are receiving home antineoplastic therapy should not be forced back into the hospital simply because of the need for additional related therapies. The result, however, is that under the present system, the sickest patients have the greatest coverage for HDIT, while the healthiest patients (e.g., needing only simple antibiotic therapy administered through a gravity drip) usually must remain hospitalized for the duration of their therapy.

Impact of Extending Coverage for HDIT

Extending Medicare coverage to include HDIT would increase the treatment options available to Medicare beneficiaries and the market possibilities for HDIT providers. It would also have more complex potential implications for Medicare expenditures, hospitals who provide inpatient infusion therapy, and the development of new health care technologies. These three issues are described below.

Implications for Medicare Expenditures

Whatever its advantages, an HDIT benefit would almost certainly raise Medicare expenditures in the first few years of its implementation. The major reason for this is that Medicare currently pays for hospital inpatient services on a per-case basis, according to a patient's diagnosis-related group (DRG). This payment system, as it currently stands, does not permit hospital payments to decrease in a given year even if more patients are discharged early to HDIT. In the longer run some offsetting inpatient savings might occur, as the hospital inpatient payment rate schedule is recalibrated to account for the lower hospital costs of serving these patients and hospital payments are reduced accordingly.

A 1987 study examined some of the potential effects on Medicare of extending coverage to home IV antibiotic therapy. This study included 150 home patients and 144 hospital patients who met the clinical criteria for home therapy but were treated in the hospital.[24] All home patients had to be able to self-infuse and had to be well enough to return home except for the need for continued therapy (e.g., no fever) (285).

The study found little difference in outcome between home and hospital therapy. Therapy was judged successful in 83 percent of home patients and 88 percent of hospital patients. Of patients for whom data from laboratory and other tests were available, results were nearly identical for the two settings (285).

To estimate potential Medicare expenditures, the study examined 1984 Medicare data on hospitalized patients in five DRGs that include an estimated two-thirds of the Medicare patients on long-term antibiotic therapy.[25] The researchers then simulated Medicare expenditures under various assumptions of the extent of home therapy and the ability of Medicare to adjust hospital inpatient rates.

In the base model, the researchers assumed that at equilibrium (i.e., several years after implementation of home IV antibiotic coverage), only 78 percent of patients would be hospitalized for their entire course of therapy. Of the remaining 22 percent, 12 percent would receive some hospitalization (e.g., for the initiation of therapy), and 10 percent would avoid

[24] Because of the difficulty id@@@ elderly home patients, some patients in the home group were under age 65.

[25] The DRGs examined were those for endocarditis, cellulitis, cellulitis with comorbidities, osteomyelitis, and osteomyelitis with wound debridement.

hospitalization entirely. The researchers also assumed that "treatment shifts" from oral to infused antibiotics would be minimal. Net savings (including savings from fewer physician visits in the home) were projected to be $16.9 million under baseline conditions. Changing baseline assumptions to reflect fewer home patients and fewer patients who could avoid hospitalization entirely reduced, but did not eliminate, the projected savings (285).

The results of this study imply that, for relatively independent Medicare patients on antibiotic therapy, Medicare expenditures would be equal or lower in the long run if infusion therapy were covered. To achieve this outcome, however, Medicare must first withstand greater expenditures in early years (until hospital payment rates can be readjusted to reflect the shorter inpatient stays). In addition, there must be no extra program costs incurred as a result of inequities among hospitals with differing abilities to discharge patients early (see below).

One factor not included in this study was dual coverage-i.e., Medicare beneficiaries who also have extensive private insurance benefits. Approximately 35 percent of elderly persons[26] are covered by private employer-based health insurance (242). Although the extent to which these Medicare beneficiaries are currently receiving privately covered HDIT is unknown, it may be substantial; one provider, for example, reports that 20 percent of its privately insured patients (who are 85 percent of their caseload) are also eligible for Medicare (83). Any Medicare coverage expansion for HDIT would probably result in some shift in spending from private payers to Medicare.

Implications for Hospitals

All else equal, implementing an HDIT benefit should result in reduced average lengths of hospital stay (ALOS) in the DRGs that include home-treated patients. The reductions would not apply equally to all people in those DRGs, however, nor would they be distributed equally among all hospitals.

Within any individual DRG, the advent of an HDIT benefit would result in some proportion of patients being discharged home after a short stay, while the remaining patients' stays are unchanged. Those patients in the first group will have lengths of stay lower than the average, generally leading to higher profits for the hospital. Patients in the second group, however, will often have longer lengths of stay than the average, and hospitals will lose money on most of them. Implementing an HDIT benefit thus would have a natural spiraling effect; as more patients were discharged early, ALOS in the DRG would decline, and the remaining sicker patients would come under ever-increasing pressure to leave the hospital early.

If there were no counterbalancing pressures or restrictions, the tendencies of the system could logically continue the spiral until even the sickest patients needing continuous care were discharged to home treatment. Counterbalancing pressures do exist, of course; they include Medicare payment restrictions for home care, physician disincentives to provide home care, home providers' unwillingness to accept severely ill patients, and hospitals' fear of legal liability for adverse outcomes in severely ill home patients.

Variability among hospitals' abilities to discharge patients to HDIT would prove to be a more serious and difficult problem to solve. Some hospitals—those with their own home infusion therapy companies, or with established arrangements with other providers of such care-are already well-positioned to take advantage of an HDIT benefit by discharging as many patients home as possible. Other hospitals do not yet have such arrangements but can make them reasonably quickly once a benefit is established. It is likely, however, that a third group of hospitals also exists: those that cannot discharge patients home because of the absence of an HDIT provider in the area they serve, or because the patients live in homes that are inadequate settings for such therapy. Furthermore, if these hospitals are located in very low-income or low-density areas, there may be little hope of home infusion providers being established in the future.

Where this is the case, hospitals will be forced to treat home-eligible patients as inpatients. The more successful other hospitals are at discharging patients home, the greater the financial losses of these hospitals in whom the ALOS remains unchanged through no fault of their own. The hospitals likely to suffer the most are those already facing fiscal

[26] Approximately 95 percent of the elderly (age 65 and over) are covered by Medicare.

difficulties: those that serve primarily rural or poor populations.[27]

For rural hospitals, swing beds may be a solution for some discharge difficulties related to HDIT. Medicare permits small rural hospitals to designate a proportion of their acute-care beds as "swing beds" and to receive reimbursement for either acute-or skilled-nursing-level care provided to patients in those beds. As of 1987, about 1,000 hospitals-roughly half of all eligible hospitals—had Medicare-certified swing beds (310). In these hospitals, patients needing only drug infusion therapy could be "discharged' to long-term care within the hospital itself and without changing the infusion-related services provided to the patient. This strategy might require some guidelines regarding at what point patients could be "discharged" from acute care, and it might require some changes in swing-bed payment rates, but it would probably relieve most rural hospitals from the most extreme effects of having no HDIT provider in their areas.

Urban hospitals serving large numbers of poor beneficiaries with inadequate homes do not have the swing-bed option. These hospitals will require additional payments (e.g., through the disproportionate share adjustment) or other alternative settings to discharge patients (e.g., nursing homes willing to accept infusion patients) if they are not to suffer undue losses.

Implications for Technological Change

Unless it is limited to a very few patients, Medicare coverage of HDIT would affect virtually every aspect of the home infusion industry. Medicare not only represents an enormous segment of the user market, but its benefit policies often serve as the boilerplate for other public and private insurance programs. In addition, Medicare's other policies and the special needs of its population may drive the market to respond to its own unique characteristics. Some of the possible areas for technological change are outlined below.

Development of Drugs and Drug Protocols

Most employer-based insurance policies pay for oral outpatient prescription drugs (19). At present, drug development favors oral drugs over other forms of administration because of their broad patient acceptance and large market. Developers go to some lengths to manufacture oral formulations; for example, despite the proven effectiveness of subcutaneous insulin, manufacturers continue to strive for an effective noninjectable form of the drug (301,303,304).

Medicare, however, does not presently cover most oral outpatient drugs. If Medicare does begin to pay for HDIT, it would add substantially to the already growing demand for parenteral drugs, while the oral drug market would remain the same. This disparity in demand by drug type would probably not cause developers to ignore oral formulations where these appear easily feasible, but it would make it less worthwhile to undertake additional research once a satisfactory parenteral form has been developed. One possible consequence of this incentive is to decrease investment in research aimed at oral drug delivery-the method that is ultimately least expensive for the health care system to deliver.

Medicare HDIT coverage would also probably fuel the existing trend toward longer, continuous or intermittent infusions rather than the short, intensive drug administration that is more suitable to the hospital. The greater potential market could lead not only to different protocols for newly developed parenteral drugs but to new uses of existing drugs (e.g., broader use of IV immune globulin) (see ch. 2).

Technological Change in Equipment and Supplies

Once a technology of drip bags and simple peripheral catheters, HDIT now can boast of an ever-expanding array of medical supplies and devices. Any Medicare coverage expansion is likely to add to the general incentives to develop new technologies for the HDIT market. In addition, it could stimulate technologies aimed more specifically at the special needs of the Medicare population, within the constraints of Medicare coverage policy.

Many Medicare patients, for example, may not be able to master or manipulate sophisticated infusion pumps. The need for simple, easily mastered equipment and supplies among this population is likely to direct device manufacturers' resources toward such areas as one-time, disposable infusion "pumps"; catheters pretreated with antibiotics to reduce infection; prepackaged and premeasured supplies that minimize handling needs; and other developments

27 In 1989, small rural hospitals (with fewer than 50 beds) and large urban hospitals with a disproportionate number Of poor patients had lower total hospital financial margins than any other hospital types (274).

that increase supply costs but might reduce the need for detailed patient training and professional assistance. Alternatively, if Medicare coverage incentives tended to encourage outpatient rather than home infusion, manufacturers would probably respond by developing more devices that could deliver a sophisticated variety of drugs in the home unaided but that might require intensive nursing attention as often as once a day.

Issues in Extending Coverage

Making Drug Coverage Decisions

As discussed in chapter 2, many drugs are being administered safely and effectively at home. However, some drugs are being used for which the evidence on effectiveness is ambiguous (e.g., dobutamine). Others are effective but may be dangerous in the home if not closely monitored and administered with proper precautions (e.g., many antineoplastics). Even within categories of relatively safe drugs there can be drugs that require especially strict precautions to be administered safely (e.g., the anti-infective amphotericin B), and drugs that are extremely costly for the benefit they confer to some patients (e.g., immune globulin).

Under an HDIT benefit, two basic questions regarding drug coverage decisionmaking would arise:

1. *Who should decide what drugs to cover?* And who should decide what limitations to place on the drugs that are covered?
2. *How should the drug coverage decisions be* made? How should the initial set of covered drugs be determined, and how should future drugs (or indications for existing drugs) be incorporated into those decisions?

Policy Under the Medicare Catastrophic Coverage Act

The MCCA (Public Law 100-360), passed in 1988, would have allowed Medicare to cover drugs that were safe and effective for IV administration in the home. The law required coverage for all antibiotics unless the Secretary of Health determined that a specific antibiotic could not be administered in the home setting in a safe and effective manner. Drugs which are not antibiotics were covered only if the *Secretary did determine* them to be safe and effective in the home. The drugs and accompanying diagnoses for which they were to be covered were published in the *Federal Register in* September 1989, just before the act was repealed. (This notice is reproduced in appendix C.)

Under the MCCA, Congress took on the responsibility for setting the categories of drugs to be covered, while delegating the responsibility for deciding on specific drugs and indications to HCFA. To produce the list of covered drugs and accompanying indications, HCFA obtained a list of drugs that were currently approved by the FDA for IV use. This list was then examined by individuals from HCFA, with advise from various professional groups and other sources, to determine the appropriateness of each particular drug for home infusion (368). Each drug was evaluated ad hoc and included or excluded on its own merits; no standardized process for review was used. Because HCFA has few physicians or pharmacists on staff, and received little assistance from FDA clinicians, the evaluators had little clinical expertise at their disposal.

This system produced a list that was plagued with seeming inconsistencies. For example, dilantin, an anticonvulsant agent used to control seizures, was included on the list of approved drugs despite the possibility of fatal adverse effects of this drug when given intravenously (216).[28] In contrast, erythromycin, an antibiotic with comparatively minor side effects, was not included.

The list of conditions for which approved drugs could be covered showed similar potential inconsistencies. HCFA omitted pulmonary infections from the list of approved conditions treatable with home antibiotics, for example, despite the fact that recurrent pulmonary infection related to underlying cystic fibrosis was one of the first indications for which home IV drugs were successfully administered (290).

The list of approved drugs and conditions was to be updated through a periodic review, with the timeframe for review unspecified in legislation. HCFA was prepared to update the list on an annual or semi-annual basis using a format that was not yet determined (368). FIs had very little discretion regarding drug coverage; their main function in this

[28] The potential for these adverse effects are so great that the manufacturer stresses that ' 'continuous monitoring of the electrocardiogram and blood pressure is essential" (216). Practically, this usually means administration of the drag in a hospital intensive care unit.

regard was to bring new drugs or indications to the attention of HCFA in order that they be incorporated to the next update.

Future Policies: Who Should Decide on Appropriate Drugs?

The final decision of which drugs are approved for home infusion could theoretically be made at any point on the regulatory spectrum, from Congress (through statute) to the individual physician (based on personal experience and opinion).

Congress could potentially not only establish categories of drugs to be covered but directly authorize which drugs and which conditions were appropriate for HDIT. Setting the drugs to be covered in statute eliminates ambiguity but makes updating the list extremely cumbersome. Such a level of legislative involvement in Medicare coverage decisions is unusual and, given the quantity of drugs to be considered and the rapidity of technological change in the pharmaceutical industry, probably undesirable. Congress could, however, set some general guidelines regarding the relative risks and benefits that are appropriate for Medicare to underwrite in the home.

HCFA has traditionally undertaken coverage tasks similar to those involved in HDIT. The list of procedures that are reimbursable if performed in an ambulatory surgical center, for example, is established in regulation and has been updated once since established in 1983 (see 53 F.R. 31468). Under the MCCA, however, HCFA's attempt to fill this role was troubled by a relatively short deadline and a lack of qualified clinical personnel. HCFA has little experience in drug evaluation and is not currently involved in any drug approval process. Requiring HCFA to approve drugs for home infusion use means that either HCFA must retain additional personnel who have detailed knowledge of the risks and benefits associated with drugs, or that HCFA must receive assistance from another agency with such expertise, such as the FDA.

Alternatively, the FDA itself could stipulate what constitutes safe and effective therapy in the home, using a similar process to its current approval process. In effect, this would amount to approval for labelling the drug for that use. The many drugs not specifically approved for home use thus could not be covered.

Fiscal intermediaries could decide what is proper infusion therapy for home use, making not only patient-specific decisions on appropriateness but establishing the general drug coverage categories as well. Many local medical carriers have already been involved in this activity to some extent through making drug decisions as part of the DME benefit, and some also may perform similar functions for their private insurance business.

FI-level drug coverage decisions permit relatively rapid updates to accommodate new therapies. This flexibility, however, would be purchased at the expense of some consistency; in contrast to a single HCFA list, the covered drugs and indications would probably differ somewhat among carriers depending on the expertise and practices of providers in their areas. Some of these differences might be justified; what can be safely provided at home may well often depend on provider experience with that drug. Other difference might be minimized with HCFA-mediated communication among carriers.

Finally, coverage could simply be made universally applicable for any drugs that *individual physician providers* prescribed for use in the home. This alternative is the most flexible and allows for rapid incorporation of new drugs and new procedures. On the other hand, individual provider responsibility for home infusion would probably result in a tremendous variation of practice which mayor may not be appropriate to the home setting. This level of decisionmaking also directly permits payment for experimental and untested drugs (or existing drugs being used in novel ways), without making any provisions that these experimental therapies be administered as part of an established protocol.

How Should Drug Coverage Decisions Be Made?

The ad hoc decisionmaking under the MCCA resulted in an irreproducible process that was heavily susceptible to criticism, and which HCFA might have been hard-pressed to defend in any legal challenge. To avoid this problem in the event of a new benefit, guidelines could be established (e.g., by Congress or HCFA) that would outline the approval process and the standard of evidence that a drug would have to meet to be approved.

Levels of Evidence-Achieving consistency in drug coverage decisionmaking requires adherence to an agreed-upon standard of evidence for establishing the safety and effectiveness of an infused drug in the

home. This standard would apply regardless of who actually made the drug-specific coverage decisions.

The most stringent standard would be that required by the FDA for approving the label of any drugs for marketing. In essence, this standard would be equivalent to saying that Medicare would pay only for drugs whose label specified that they were safe and effective when administration in that form, for that condition, in the home.

A second level of evidence could require that the drug be FDA-approved for the condition and that some data on its use at home be presented. This approach is entirely feasible, but it prohibits payment for "off-label" use-i.e., use of an FDA-approved drug for an indication not specifically approved by the FDA for the label. Off-label use is implicitly reimbursed in hospitalized patients, and a substantial proportion of the actual use of many drugs is for off-label use. A recent survey by the General Accounting Office, for example, found that nearly half of all cancer patients treated by oncologists receive, as part of their therapy, at least one drug whose label does not include that particular type of cancer (354). In the same survey, a number of oncologists reported having admitted patients to hospitals solely to have an off-label drug reimbursed (354). Thus, requiring this level of evidence would probably affect the actual therapies that physicians prescribed, and it would probably also result in fewer patients being treated at home than would otherwise be the case.

A third level of evidence could be to require that the drug be FDA-approved and that the particular indication be listed for that drug in common reference sources of drug information in order to be reimbursed. This standard would require less rigorous documentation in supporting the "possible" effectiveness of a drug and would probably have less effect on actual prescribing practices than more stringent standards. There might, however, be some pressure on the organizations that publish such reference books to make accommodations to manufacturers in order for a drug to qualify for Medicare reimbursement.

Finally, the level of evidence required could be one of a consensus of clinical experts, based on their personal judgment and knowledge of the literature. This is a formalized version of the practice of many local carriers, which use local clinical consultants to advise them regarding whether a particular procedure, for example, is generally considered safe and effective (i.e., nonexperimental) (359). This standard would have the least impact on actual prescribing practices but holds the greatest potential for leading to great variations in coverage decisions across geographic regions.

Applying Consistent Judgment—Whatever the stated standard of evidence to which decisionmakers would adhere, drug coverage decisions would inevitably require judgment on the part of those involved in the decision. For any given drug, they must decide whether the risk to patients of delivering a specific drug in the home is worth the potential benefit. The fact that a drug is risky does not itself eliminate the need to make this decision. Even drugs with unpleasant and sometimes severe side effects (e.g., most antineoplastics) are often considered worth using if the untreated disease is often fatal and there are few more benign alternatives.

The degree to which an evaluator considers the level of risk in a drug "acceptable' is likely to vary among individuals. Given this, one way to adhere to a consistent standard of tolerable risk would be to ensure that the same set of decisionmakers is responsible for each separate drug coverage decision. Within this group, decisionmakers could make a conscious attempt to apply individual and group judgments consistently. Thus, if HCFA were making the coverage decision, applying a consistent process might mean appointing an outside board of advisory experts to judge the relative risks and benefits of various drugs for various indications in the home. Alternatively, the advisory group might comprise FDA clinicians, or clinical and other employees of the Agency for Health Care Policy and Research. If FIs were to be the decisionmakers, the clinical advisors to the coverage decision might be advisory panels composed of local community physicians, pharmacists, and nurses.

Although clinical experience is not the only necessary skill to be represented in the group making the coverage decisions, it is a vital one. Deciding on an acceptable tolerance of risk requires clinical input, because it depends on a knowledge of the alternative treatments for that medical condition. Since the Medicare population is hugely elderly, knowledge of the drug's likely effects in the elderly population is also a valuable input that requires clinical experience.

HDIT Eligibility and Home Health Services

Many Medicare beneficiaries who might qualify medically for HDIT might also need assistive services-i.e., help with the infusion and any other needed care-if they were treated at home rather than in a health care setting. An estimated 40 percent of elderly persons need assistance with at least one basic activity of daily living (e.g., eating, dressing) (see ch. 3). Family caregivers would not necessarily be available or able to shoulder the burden of providing assistive health services; of the noninstitutionalized elderly, one-third live alone (386).

Because providing paid assistive health services increases the payer's costs of care for a patient on HDIT, the extent to which Medicare covers these services for HDIT beneficiaries would greatly affect Medicare expenditures. One way to affect the demand for assistive care by HDIT beneficiaries would be to institute payment mechanisms that discourage (or encourage) the provision of these services. Another, more direct alternative would be to design eligibility and coverage policies for the HDIT and the home health benefits to affect the use of such services (or the discharge of patients who would need such services). Some possible policies, and their potential implications, are described here.

Atone end of the spectrum, Medicare could cover HDIT only for patients who can demonstrate the capacity to administer the infusion without the assistance of a paid caregiver.[29] This alternative would restrict the benefit to a small number of patients who were alert and relatively healthy or who had family or fiends able to perform the administration. In the absence of more information about the relative costs of home and institutional care, this alternative offers the surest opportunity to achieve program cost savings. However, it restricts the ability of homebound patients, or those who might be able to avoid hospitalization altogether, to receive HDIT from a professional caregiver. It would also eliminate from eligibility for the benefit a large number of Medicare patients who would prefer to be treated at home but are unable to take responsibility for their own care.

At the opposite extreme, Medicare could extend eligibility for an HDIT benefit to any patient meeting some basic medical appropriateness criteria (e.g., the patient requires a parenteral drug and is medically stable). This criterion would permit the maximum number of beneficiaries to make use of the benefit. However, it would permit unlimited use of assistive home services, no matter how expensive, unless adjunct policies were also in place to limit these services.

Policies intermediate to these two extremes also exist, in which the covered benefits rather than the eligibility criteria would be restricted. These policies take the form of restricting both the assistive services covered under the HDIT benefit itself and the home health care benefits for which the patient might be concurrently eligible. For example, the HDIT benefit might include coverage of daily nursing to accommodate patients with needs for occasional nurse-administered infusions (e.g., up to 10 visits or 20 hours of home skilled nursing per week).

This alternative assumes that at some low level of professional assistance, home care is still less costly than institutional care. It might be particularly relevant if relatively low-cost outpatient care or institutional care in SNFs were not available, making hospital inpatient care the only real alternative to the home. However, this alternative also leaves open the possibility that program expenditures may actually increase under this alternative if the coverage is generous.

To avoid unwittingly paying for assistive services through the home health benefit in this example, HDIT patients could be disqualified from concurrent eligibility for that benefit. Thus, any infusion patient who also required unrelated skilled nursing care or other professional therapy or assistive services (e.g., physical therapy) could not be discharged home. This restriction would eliminate the possibility of paying for home care for patients who need very extensive services, but it raises the possibility that many patients might be discharged home and then rehospitalized (at Medicare's additional expense) if they developed a need for occasional additional care. It might also prevent many terminal or homebound patients, who currently qualify for home care services, from receiving their infusion at home as well. This policy might require that the home infusion and home health benefits be administered

[29] For example, a physician might be required to certify that the patient or family member could perform the infusion as a prerequisite for eligibility for the benefit.

by the same FI so that concurrent benefit eligibility could be detected.

Alternatively, the HDIT benefit could be very limited in its coverage of assistive services but beneficiaries could be permitted (if they qualified) to retain home health benefit eligibility at the same time. Under this scenario, coverage for concurrent home health benefits could itself be limited to restrain utilization of assistive services. For example, HDIT patients who were homebound could be covered for home health services up to a stated maximum limit (e.g., 50 percent of the average per-patient home health payment in that area). This alternative would allow for some assistance while providing an incentive for home providers to accept patients only if their anticipated assistive needs were few. However, it might also result in some underservice or rehospitalization of patients whose assistive needs were eventually greater than originally anticipated.