

Medicare Coverage of Outpatient Ambulatory Intravenous Antibiotic Therapy: A Program that Pays for Itself

Alan D. Tice, Donald Poretz, Francesca Cook,
Darren Zinner, and Michael J. Strauss

From *Infections Limited P. S.*, Tacoma, Washington; *Infectious Disease Physicians, Inc.*, Annandale, Virginia; and *Covance Health Economics and Outcomes Services Inc.*, Washington, D.C.

A number of studies have documented the safety, efficacy, and cost-effectiveness of outpatient intravenous (iv) antibiotic therapy for patients with infectious diseases. Nevertheless, Medicare policy prohibiting coverage of outpatient, self-administered drugs has severely limited access of Medicare patients to ambulatory iv therapy, thus forcing them to rely on more costly, inpatient hospital care. To test the hypothesis that a new Medicare benefit providing coverage for ambulatory iv antibiotic therapy could significantly reduce the program's expenditures for the treatment of infectious diseases (including pneumonia, osteomyelitis, cellulitis, and endocarditis), a cost model was constructed with use of patient care information from the clinical literature as well as clinical experts, Medicare data, and other medical claims databases. The model shows cumulative 5-year savings of nearly \$1.5 billion associated with the new Medicare benefit. Policy makers should consider implementing such a benefit.

Patients with serious infections that require iv antibiotic therapy have traditionally been treated in the hospital setting. Over the past decade in the United States, however, increasing numbers of these patients have received outpatient iv antibiotic therapy, with an estimated 300,000 treated in 1994 [1]. Recent advances in antibiotic therapy [2] and vascular access [3], as well as increasing acceptance of the therapy's safety and efficacy, have paved the way for this growth [4]. Many physicians now move patients out of the hospital once their condition is stabilized with an appropriate antibiotic regimen [5]. Indeed, some physicians may prefer to forego hospitalization altogether, thus allowing patients to return to normal work or school routines [6, 7] and decreasing their chances of nosocomial infection or exposure to multidrug-resistant organisms [8]. There is also some evidence that patients treated in ambulatory settings return to work and usual function more rapidly [9].

See editorial response by Wenzel and Nettleman
on pages 1422–3.

Although coverage of outpatient ambulatory care is common among private health plans and Medicare health maintenance

organizations (HMOs) [10], the traditional Medicare fee-for-service program relies heavily on inpatient hospital care. For example, according to Medicare inpatient claims data, ~650,000 Medicare beneficiaries were hospitalized with a primary diagnosis of pneumonia, endocarditis, cellulitis, or osteomyelitis in 1995 (table 1). This reliance on hospital care is due, at least in part, to Medicare statutory provisions that prohibit coverage of most prescription drugs administered in the home and outpatient setting.

Although patients can be reimbursed for iv antibiotics administered by a physician in his or her office, daily office visits are not only inconvenient and time-consuming but also are not feasible for patients who require two or more infusions a day. Moreover, iv antibiotics administered in the home, with the exception of those that require the use of durable medical equipment, are not covered by Medicare. The net result of these Medicare policies is the creation of disparate treatment patterns. Medicare patients receive mostly inpatient iv antibiotic therapy, while privately insured patients receive iv therapy in both inpatient and outpatient settings.

This study investigates the economic implications of a newly designed Medicare benefit for home-based iv antibiotic therapy. Although the new program is essentially a home benefit, it differs significantly from the current Medicare home health benefit. To minimize confusion, the term *ambulatory iv antibiotic therapy* was coined to describe the benefit.

The proposed benefit includes four components. (1) The specific infections chosen for inclusion in the model were cellulitis, pneumonia, osteomyelitis, and endocarditis, which represent an estimated 80% of all bacterial infections treated in hospitals, thus highlighting the potential advantage of ambulatory therapy [11–17]. (2) Eligible patients must be alert, ambulatory, and able to self-administer iv antibiotic therapy or must have a caregiver to do so. This requirement distinguishes the

Received 27 March 1998; revised 22 July 1998.

The 1997 United States House and Senate Appropriations Conference Report required the Health Care Financing Administration (HCFA) to study the cost-effectiveness of Medicare coverage of outpatient antibiotic therapy. In order to parallel the HCFA study, the Infectious Diseases Society of America and Hoffman-LaRoche commissioned Covance Health Economics and Outcome Services to construct a similar model.

Reprints or correspondence: Dr. Alan D. Tice, 240 Stadium Way South, Tacoma, Washington 98402.

Clinical Infectious Diseases 1998;27:1415–21

© 1998 by the Infectious Diseases Society of America. All rights reserved.
1058-4838/98/2706-0014\$03.00

Table 1. Current and anticipated lengths of therapy, percentage of patients hospitalized, and lengths of stay for the four target conditions.

Variable	Cellulitis	Endocarditis	Osteomyelitis	Pneumonia
No. of admissions*	330,488	10,685	16,578	315,256
Mean length of therapy (d)	10	30	28	14
Percentage of patients hospitalized				
Physician estimates, current [†]	60	100	90	70
Model estimates				
Year 1	54	100	81	63
Year 2	48	100	72	56
Year 3	42	100	63	49
Year 4	36	100	54	46
Years 5–10	36	100	50	46
Mean length of stay (d)				
Current Medicare* recipients	9.4	17.4	15.7	12.3
Current private-pay patients [‡]	5.5	16.5	11.9	12.0
Model estimates				
Year 1	8.1	17.1	14.4	12.2
Year 2	6.8	16.8	13.1	12.1
Years 3–10	5.5	16.5	11.9	12.0
“Woodwork” effect [§]	10%	10%	10%	10%

* From the Medicare Provider Analysis and Review (MEDPAR) file of 1995, which contains hospital discharge data for all Medicare beneficiaries using inpatient hospital services.

[†] From interviews of infectious disease specialists.

[‡] From the National Hospital Discharge Survey (NDHS) of 1994, which contains hospital discharge data from a random sampling of inpatient, short-stay, nongovernmental hospitals in the United States.

[§] See Methods section in text for explanation.

new plan from current Medicare home coverage, which requires recipients to be homebound and in need of skilled nursing services.

(3) All services necessary for self-administration of iv antibiotics are covered, including training and education of patients, appropriate clinical services, supplies, laboratory tests, and durable medical equipment. It is anticipated that physicians and home health or home infusion companies will be best equipped to provide the new benefits. (4) Service providers will receive a per diem payment plus reimbursement for drug costs, based on the average wholesale price of the antibiotic. This payment design was viewed as reasonable for the scope of services provided, on the basis of interviews with home health agencies and private insurers. As is the current policy for most outpatient services, Medicare will cover 80% of per diem and drug costs, with patients responsible for the remaining 20%.

Methods

Medicare costs associated with treating the four medical conditions (cellulitis, pneumonia, osteomyelitis, and endocarditis) were estimated on the basis of both the current Medicare benefits structure and the proposed new benefits structure that includes ambulatory iv antibiotics. The new model assumes a specific duration of antibiotic treatment (in days) for each medical condition, although the treatment setting (inpatient, skilled

nursing facility, or outpatient) may vary. Figure 1 depicts the basic care patterns modeled under each scenario. Under the current Medicare system, most patients are hospitalized to receive iv antibiotic therapy. Some remain in the hospital throughout the entire treatment; others, once their condition is stabilized, receive care in a skilled nursing facility, a physician's office, or at home. In addition, some patients may receive all iv therapy in a physician's office.

In allowing self-administration of iv antibiotics at home, the new ambulatory iv antibiotic therapy benefit would change current treatment pathways in two ways. Some stable patients would forego hospitalization altogether to receive all iv antibiotics at home, and some inpatients would be discharged early to continue iv antibiotic treatment at home. Although most patients who are discharged early will be able to make the transition to the ambulatory benefit, those who require more advanced care will go to a skilled nursing facility. However, patients who need home health care in addition to iv antibiotics will not be covered by the new ambulatory iv therapy benefit.

The new model also includes adjustments for a “woodwork” effect. This term is commonly used for unexpected cost effects that “come out of the woodwork.” In this case it would apply to a change in behavior, where physicians might prescribe ambulatory iv antibiotic therapy for patients who would otherwise have received oral antibiotic treatment, either because of easier access to iv therapy or because oral antibiotic therapy

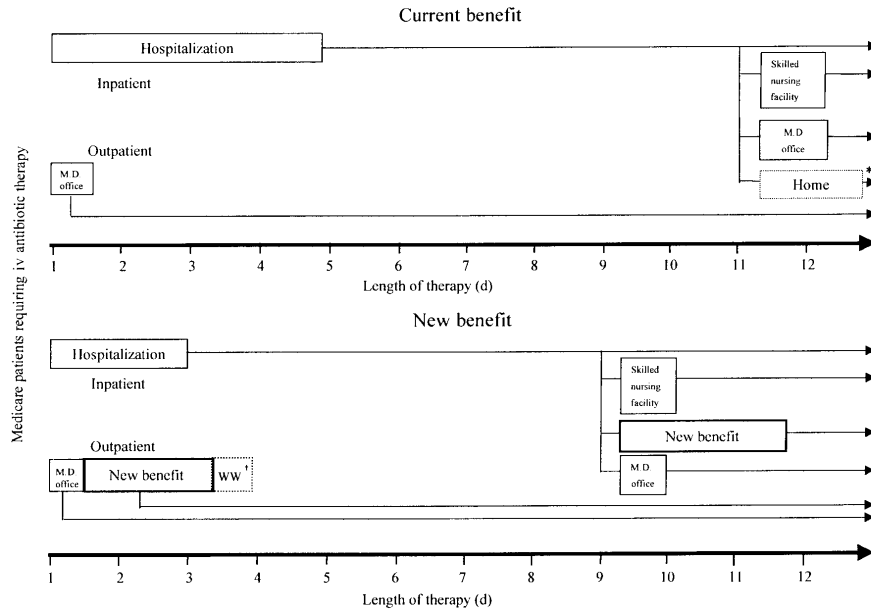


Figure 1. Present and proposed options for iv antibiotic therapy for Medicare beneficiaries. (*Medicare does not cover drugs that can be self-administered in the outpatient setting. 'WW = "woodwork" effect; see Methods section of text.)

would not be covered. To account for this phenomenon, the model assumes the benefit would cover 10% more patients than are currently receiving treatment under Medicare.

Parameter estimates for the new model came from three principal sources: the clinical literature, claims databases, and a panel of infectious disease experts. Two national claims databases, the National Hospital Discharge Survey (NHDS) and the Medicare Provider Analysis and Review (MEDPAR) file, were used to determine length of stay and number of admissions for privately insured and Medicare beneficiaries with the four targeted infections.

The NHDS database contains hospital discharge data from a random sampling of inpatient, short-stay, nongovernmental hospitals in the United States. The MEDPAR file contains hospital discharge data for all Medicare beneficiaries using inpatient hospital services. Four nationally recognized infectious disease physicians were surveyed to identify current treatment pathways for the four target conditions and likely changes in treatment patterns that would be created by the new benefit.

Table 1 compares current hospitalization and length-of-stay information for each target condition with physician estimates of what would happen if the new benefit were instituted. The length-of-therapy estimate reflects the number of antibiotic-treatment days necessary for each condition, with length of

hospitalization assumed to drop from current Medicare averages to levels for non-Medicare patients (an assumption supported by interviews with three medical directors of private and Medicare risk plans). Table 2 summarizes cost estimates and their sources.

To predict changes in Medicare expenditures over several years, the model incorporates the March 1997 Congressional Budget Office (CBO) growth forecasts for Medicare enrollment and costs, as well as an assumed 5% annual price increase for iv antibiotics.

Results

Figure 2 displays projected Medicare expenditures over 10 years under both current and proposed benefit plans. For the new benefit, the graph displays costs by major resource component. Table 3 summarizes the savings generated by the new benefit. Inpatient hospitalization frequency and costs decline over time as the new ambulatory iv antibiotic benefit phases in. During the first year, slightly increased Medicare costs are anticipated, since it will be necessary to develop and implement the new benefit. The break-even point occurs in year 2, as the number of hospital admissions for the target infections falls by nearly 20% and the average length of stay is reduced to that

Table 2. Medicare costs and sources used in the model for the proposed benefit plan.

Variable	Cost*	Source
Iv antibiotics	\$42.88	AWP; RedBook, 1997 [†]
Hospitalization		
Facility fee, cellulitis	\$4,100	HCFA, 1996 [‡]
Facility fee, endocarditis	\$12,900	HCFA, 1996 [‡]
Facility fee, osteomyelitis	\$7,000	HCFA, 1996 [‡]
Facility fee, pneumonia	\$6,500	HCFA, 1996 [‡]
Professional fees	\$28.43	RBRVS, 1996 [§]
Skilled nursing facility		
Facility cost	\$334.00	Average SNF Medicare charge per day; NAHC, 1996
Professional fees	\$6.07	Average physician fee under RBRVS, 1996 [§]
Laboratory costs	\$3.65	Medicare clinical laboratory fee schedule, 1996**
Physician office		
Professional fees	\$43.17	RBRVS, 1996
Laboratory costs	\$3.65	Medicare clinical laboratory fee schedule, 1996**
Home care		
Home health care provider	\$25.14	Two visits a week at \$88, the average home care medicare charge per visit; NAHC, 1996
Professional fees	\$10.06	RBRVS, 1996
Laboratory costs	\$3.65	Medicare clinical laboratory fee schedule, 1996**
Ambulatory iv benefit		
Basic benefit	\$90	...
Professional fees	\$10.06	RBRVS, 1996 ^{§§}

NOTE. When appropriate, estimates have been reduced to reflect the 20% patient coinsurance. AWP = average wholesale price; CPT = Current Procedural Terminology; DRG = diagnosis-related group; HCFA = Health Care Financing Administration; NAHC = National Association of Home Care; RBRVS = resource-based relative value system; SNF = skilled nursing facility.

* All costs (U.S.) are per day except for hospitalization, which is the average Medicare DRG payment.

[†] Average cost of four outpatient regimens, based on AWP for a daily regimen of cefazolin (1,000 mg t.i.d.), ceftriaxone (1,000 mg daily), cilastin (500 mg b.i.d.), and cefuroxime (750 mg t.i.d.).

[‡] National average of DRG payment for one admission.

[§] One physician visit per day (CPT 99231: Evaluation and management, low complexity).

^{||} NAHC's "Basic Statistics about Home Care, 1996."

[¶] One physician visit per week (CPT 99312: Subsequent nursing facility care).

** Laboratory tests once a week (CPT 85025: CBO [hemogram and platelet count] plus CPT 85615: SED RATE [sedimentation rate, erythrocyte] plus CPT 80019: CHEM 24 [clinical chemistry tests]).

^{††} Two physician visits per week (CPT 99214: Evaluation and management, moderate complexity) plus five nurse/infusion visits per week (CPT 99211: Evaluation and management, no physician, plus CPT 90780: iv infusion, first hour).

^{‡‡} One and one-half physician visits per week (CPT 99214: Evaluation and management, moderate complexity).

^{§§} One and one-half physician visits per week (CPT 99214: Evaluation and management, moderate complexity).

of private-pay patients. By year 3, coverage of ambulatory therapy saves the Medicare program \$369 million and fully recoups the costs associated with implementation. Five-year cumulative savings associated with the new benefit are nearly \$1.4 billion.

The magnitude of the Medicare savings is directly tied to a number of factors, including the number of hospitalizations that can be eliminated, the ambulatory iv antibiotic per diem rate, the number of patients who receive both inpatient hospital care and ambulatory therapy, and the "woodwork" effect. Sensitivity analyses conducted to determine the effect of these variables on Medicare expenditures are summarized in table 4.

The majority of the Medicare savings is achieved by the elimination of hospital stays. Thus, if hospital admissions can-

not be decreased to the level forecast in the model, Medicare savings will be significantly diminished. For example, a 25% reduction in eliminated hospitalizations will produce savings of \$514 million, \$875 million less than the baseline estimate. If the benefit reduces hospitalizations by only 50% of the forecast reduction, Medicare expenditures will increase by \$362 million over 5 years, since the reduction in hospitalizations would not be sufficient to pay for the new benefit's phase-in cost.

Although Medicare savings would be reduced by increases in the "woodwork" effect and per diem rate over time, program savings remain significant. It is interesting to note that if the Medicare population fails to achieve the shorter length of stay common for privately insured patients, overall Medicare savings will actually increase, because patients who remain hospitalized require less ambulatory iv antibiotic therapy.

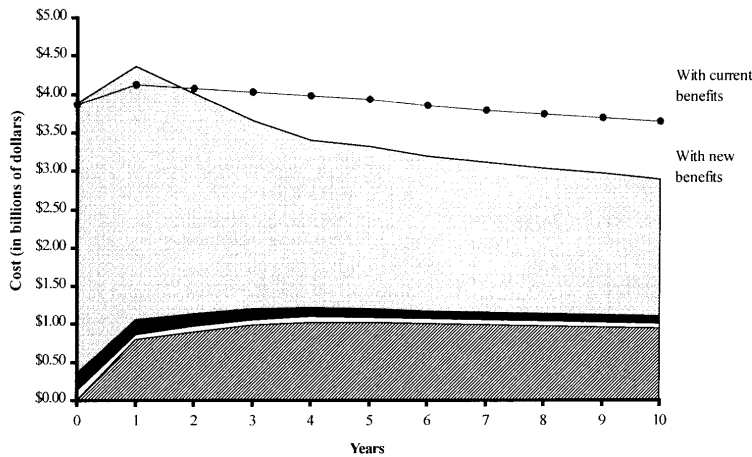


Figure 2. Annual Medicare costs of an ambulatory iv therapy benefit over a 10-year phase-in period: breakdown of medicare expenditures, with and without an ambulatory iv antibiotic benefit. Values are presented in 1997 U.S. dollars with use of a 5% discount factor (□ = inpatient hospital; ■ = inpatient physician; ▨ = subacute care/outpatient visits; ▩ = new benefit).

Discussion

The huge potential Medicare savings associated with a new ambulatory iv benefit underscores the present outdated Medicare coverage policies for outpatient antibiotic therapy. The program pays for inpatient care but excludes equally effective, less costly outpatient alternatives. This situation not only ignores the wide acceptance of outpatient iv antibiotic therapy by the medical community and private health plans but also illustrates the need for a change in Medicare’s benefit structure, which fails to take advantage of cost-effective medical advances. Medicare’s blanket prohibition of outpatient self-administered drugs also is inconsistent with recent congressional efforts to provide more care options to Medicare beneficiaries and to slow the increase in Medicare expenditures.

Table 3. Annual Medicare savings that could be generated by coverage of outpatient iv antibiotic therapy.

Phase-in period	Annual Medicare savings (costs), in millions*
Year 1	(\$242)
Year 2	\$71
Year 3	\$369
Year 5	\$611
Year 10	\$748
Cumulative 5-year savings	\$1,389
Cumulative 10-year savings	\$4,886

* Values are presented in 1997 dollars (U.S.) with use of a 5% discount factor.

The proposed ambulatory iv antibiotic therapy benefit can reduce Medicare expenditures while providing good clinical outcomes. Moreover, hospitals would continue to benefit since under the Medicare diagnosis-related group (DRG) system, they are paid a fixed amount per case, regardless of how long a patient is hospitalized. For each day of inpatient care eliminated by early discharge to ambulatory iv therapy, a hospital may realize savings of \$200–\$400/day [18], savings that, according to our cost model, could reach \$5 billion to \$6 billion over 5 years.

Thus, overall potential savings associated with the new benefit are significant and consistent with findings in the literature [19–21]. These savings are based on model assumptions, however. To evaluate the validity of model results, it is crucial to understand both those assumptions and the limitations they impose.

First, model results are predicated on the March 1997 CBO estimates of projected Medicare growth. Since that time, the CBO has revised the estimate downward. Furthermore, the recently passed Balanced Budget Act of 1997 includes many initiatives that will further slow projected Medicare growth. However, despite the effect of these events on overall growth of the program, neither should have a significant impact on the magnitude of savings attributable to the ambulatory benefit.

Second, the model uses physician estimates (informed by Medicare claims data) to predict future treatment patterns. Although any convenience sample has the potential for bias, all physicians interviewed were considered to be infectious disease experts, had substantial experience in treating both Medicare and privately insured patients, and were familiar with both

Table 4. Data from sensitivity analyses to determine the effect of certain variables on Medicare expenditures.

Variable	Change	5-Year cumulative Medicare savings (costs), in millions*
Baseline		\$1,389
"Woodwork" effect (baseline value = 10%)	20%	\$638
	30%	(\$113)
Per diem rate (baseline value = \$90 per diem)	\$60 Per diem	\$2,306
	\$120 Per diem	\$472
Percentage of hospitalizations eliminated (baseline value varies by condition; see table 1 for values)	25% Less than anticipated	\$514
	50% Less than anticipated	(\$362)
	No change	(\$2,112)
Hospital length of stay (LOS) (baseline value: 3-year phase-in to LOS of private-pay patients)	110% of private-pay patients	\$1,409
	No change	\$1,544

* Values are presented in 1997 dollars (U.S.) with use of a 5% discount factor.

hospital and ambulatory iv therapy. Furthermore, a panel of infectious disease and Medicare reimbursement experts have reviewed the model's assumptions.

Third, the model assumes a 3-year phase-in period. It is not known how long the medical community will require to adjust practice patterns. The program savings demonstrated in the model are tied directly to the reduced use of hospital care; therefore, educational efforts may be needed to help physicians feel comfortable with the early discharge of elderly patients to home or outpatient care. Although education of physicians may be necessary to the success of the program, costs associated with such an initiative are not included in the model. In addition, major market changes may be necessary to expand the capacity of current ambulatory care settings to absorb the influx of new outpatients.

Fourth, the model includes a 10% "woodwork" effect. Given the new benefit, physicians may be more likely to use iv antibiotic therapy instead of oral so that the cost would be covered. This practice would increase the number of people receiving the new benefit. However, there are at least two reasons to believe that the increase would be limited: (1) there is a 20% coinsurance requirement of \$20–\$50/day for iv therapy, vs. the \$0.50–\$7.00/day cost of oral drugs, and (2) iv therapy often must be administered more than once a day, making it inconvenient and cumbersome for patients. Thus, any drug switches from oral to iv therapy are likely to be made for clinical rather than economic or quality-of-life reasons.

Conclusion

Because ambulatory iv antibiotic therapy is safe, effective, and less expensive than inpatient hospital care, private insurers and Medicare HMOs have promoted home care for stable patients requiring iv antibiotic therapy. Medicare fee-for-service

coverage of ambulatory therapy could also result in substantial cost savings. Furthermore, the new benefit would be fully self-financing. As Congress and the President continue to consider Medicare program changes that will reduce expenditures and expand beneficiaries' care options, an ambulatory iv antibiotic benefit that meets both goals should receive serious consideration.

References

1. Winters RW. Home infusion therapy industry: an overview. In: Conners RB, Winters RW, eds. Home infusion therapy: current status and future trends. Chicago: American Hospital Publishing, 1995:1–15.
2. Craig WA. Kinetics of antibiotics in relation to effective and convenient outpatient parenteral therapy. *Int J Antimicrob Agents* 1995; 5:19–22.
3. Gilbert DN, Dworkin R, Raber SR, Leggett JE. Outpatient parenteral antimicrobial-drug therapy. *N Engl J Med* 1997;337:829–38.
4. Tice AD, ed. Handbook of outpatient parenteral therapy for infectious diseases. Scientific American Medicine. New York: Scientific American, 1997.
5. Tice AD. Alternate site infusion: the physician-directed, office-based model. *J Intraven Nurs* 1996;19:188–93.
6. Poretz DM, Eron LJ, Goldenberg RI, et al. Intravenous antibiotic therapy in an outpatient setting. *JAMA* 1982;248:336–9.
7. Stiver HG, Telford GO, Mossey JM, et al. Intravenous antibiotic therapy at home. *Ann Intern Med* 1978;89:690–3.
8. Martone WJ, Jarvis W, Culver DH, Haley RW. Incidence and nature of endemic and epidemic nosocomial infections. In: Bennett JV, Brachman PS, eds. Hospital infections. 3rd ed. Boston: Little, Brown & Co., 1992: 577–96.
9. Fine MJ, Singer DE, Marrie TJ, et al. Medical outcomes of ambulatory and hospitalized low risk patients with community-acquired pneumonia. *J Gen Intern Med* 1994;9(Apr suppl 2):29A.
10. Dalovisio JR, Dodd K. OPAT, the physician, and the nurse specialist in managed care. In: Outpatient parenteral antimicrobial therapy: current status. Scientific American Medicine. New York: Scientific American, 1997;July:22–7.
11. Kunkel MJ. Outpatient treatment of endocarditis. In: Outpatient parenteral antimicrobial therapy: current status. Scientific American Medicine. New York: Scientific American, 1997;July:60–4.

12. Stambouliau D. Outpatient treatment of endocarditis in a clinic-based program in Argentina. *Eur J Clin Microbiol Infect Dis* 1995;14:16-22.
13. Powers RD. Infections of skin and soft tissue. In: Outpatient parenteral antimicrobial therapy: current status. Scientific American Medicine. New York: Scientific American, 1997;July:65-8.
14. Tice AD. Osteomyelitis. In: Outpatient parenteral antimicrobial therapy: current status. Scientific American Medicine. New York: Scientific American, 1997;July:55-9.
15. New PB, Swanson GF, Bulich RG, Taplin GC. Ambulatory antibiotic infusion devices: extending the spectrum of outpatient therapies. *Am J Med* 1991;91:455-61.
16. Dalovisio JR. OPAT for community-acquired pneumonia. In: Outpatient parenteral antimicrobial therapy: current status. Scientific American Medicine. New York: Scientific American, 1997;July:69-72.
17. Fine MJ, Medsger AR, Stone RA, et al. The hospital discharge decision for patients with community-acquired pneumonia. *Arch Intern Med* 1997;157:47-56.
18. Prospective Payment Assessment Commission (ProPAC). An analysis of outlier payments: Rand Study. Washington D.C.: Pro PAC, March, 1990:xiv.
19. Hinds R, Winkler C, Kane P, Kunkel M. Outpatient intravenous antibiotic therapy in Medicare patients: cost-savings analysis. *Infect Dis Clin Pract* 1995;4:211-7.
20. Kane RE, Jennison K, Wood C, Black PG, Herbst JJ. Cost savings and economic considerations using home intravenous antibiotic therapy for cystic fibrosis patients. *Pediatr Pulmonol* 1988;4:84-9.
21. Williams DN, Bosch D, Boots J, Schneider J. Safety, efficacy, and cost savings in an outpatient intravenous antibiotic program. *Clin Ther* 1993;15:169-79.