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**Cost Effectiveness and
Reimbursement Policy:
Issues and Evidence**

Cost Effectiveness and Reimbursement Policy: Issues and Evidence

In addition to the issues of health status or other health outcome related effects (i.e., safety, efficacy, and effectiveness) of apheresis, efficiency issues must also be addressed. The cost of providing apheresis therapy is a matter of almost universal concern in the available literature. As spiraling health care costs continue to plague medical care delivery in this country and elsewhere, it is important to examine whether there is improvement in the quality of life and which therapies offer the greatest value for the resources invested.

Because of the broad and pervasive influence of third-party payment mechanisms on health care delivery, any discussion of economic effects of therapeutic apheresis must also be closely tied to an examination of funding and reimbursement policies of both private and government insurance programs. Reimbursement policies have profound effects on the adoption and use of medical technologies, as well as the innovation process itself of medical procedures such as therapeutic apheresis. Informed coverage decisions require information concerning medical technologies, that is at least as detailed as that needed for the regulatory decisions of the Food and Drug Administration (FDA) regarding device equipment. Whereas regulatory decisions tend to be of a “go”, “no go” nature, reimbursement decisions are, or at least could be, more related to *appropriate* use of technologies, a much finer distinction (104). Appropriate use decisions would support the provision of effective apheresis therapy and efficient

care. That is, only proven treatment alternatives would be considered for widespread clinical application and the lower cost treatment alternative would not only be available but used (102,104).

Until recently, apheresis was routinely reimbursed for by some third parties when prescribed by a physician. However, concerned about costs and estimates of expansion of use over the next 5 years, third-party payers are now attempting to tailor their policies according to the principle of appropriate use—i.e., to pay for apheresis where and when it is a proven and efficient therapeutic method (80,117). **Medical insurers are, however, far from a consensus on how, when, and if they should cover apheresis (34,49).**

The research and policy issues regarding the costs and benefits of apheresis therapy, including a discussion of third-party reimbursement, form the substance of this chapter. It is a discussion that initially examines the methods that can be used in assessing the economic effects of therapeutic apheresis. Currently, the most visible and potentially most useful of methods is cost-effectiveness analysis (CEA). As CEA is not simply an economic technique, but rather a blend of economic and clinical information, it will serve to conceptually integrate cost concerns with the assessment of safety and efficacy issues in chapter 3. An absence of reliable estimates of the efficacy and safety of apheresis treatment and of its costs and savings prohibits conclusive results, but gaps in present knowledge can be identified and directions for future research can be addressed.

COST EFFECTIVENESS

Two important methods used to assess the costs and benefits of therapeutic apheresis, and developing comparisons among effects, costs, and benefits are cost-benefit analysis (CBA) and cost-effective-

ness analysis (CEA). CEA implies a comparative analysis of the costs and health effects of alternative treatments. In a CEA, a common outcome is specified (e.g., functional status) and the costs

of providing alternative treatments are compared. Treatment costs are typically specified in monetary terms. CBA, on the other hand, requires that both cost and benefits be assigned monetary values. A CBA examines the ratio of resources used (cost) to resources saved (benefits) when particular treatments or even different treatment regimens **or** programs are employed (102, 104).

While CEA/CBA can be thought of as an aid to synthesis of both health effects and economic effects, the value of a CEA/CBA lies more in the process of performing the analysis than in any numerical results. There are a number of reasons for this, among the most important of which are CEA/CBA's inability to adequately address ethical issues and the uncertainty of specifying comprehensively the costs and benefits of alternative treatments. This is clearly the case with therapeutic apheresis because there are no reliable estimates of savings due to treatment benefits that are available or known. In addition, factors other than those qualified in a CEA/CBA (e.g., social, ethical, or value influences) should be considered in making a decision (12,98,102,104).

OTA, in its assessment of the methods of CEA/CBA (98) developed 10 principles to guide the conduct, use or evaluation of CEA/CBA studies (see table 6). The Principles most relevant to the assessment of therapeutic apheresis are that alternative means (technologies) to accomplish the stated objectives should be identified and subjected to analyses; all foreseeable benefits/effects should be defined and, if possible, measured, as should all expected costs; present value discounting should be performed; sensitivity analyses should be conducted to show a range of possible outcome val-

ues; and ethical issues (that have surfaced in significant ways in therapeutic apheresis) should be addressed. The rigorous specification of data sources for quantitative analyses was another important criterion for CBAS.

Potential costs and benefits can be assessed with varying degrees of comprehensiveness. Further, means for estimating them vary (102,104). Thus, in a CBA, the cost of a treatment procedure includes not only the direct costs of salaries of treatment providers and support staff, disposable, replacement fluids, drug therapies, administrative and overhead costs, but also indirect costs such as lost productivity due to patient's time missed in work. Additionally, it should be noted that uncritical use of market prices can lead to large gaps between cost estimates and true costs. Illustrative of this problem is the use of hospital charge data to reflect the costs of hospital care. A common practice, this form of "pricing" ignores the known idiosyncrasies of hospital accounting in which hospitals charge well above true marginal costs for certain services and **use** the profits to subsidize other services for which charges do not cover marginal costs. For example, hospital pharmacy charges can vary from 10 to 1,000 percent of the true cost of drugs depending on the frequency of their use, their level of cost, purpose, etc. (104). In the case of apheresis therapy, replacement fluids such as albumin, saline solutions, and fresh frozen plasma are particularly vulnerable to such pricing practices. For example, a recent survey by Levy (74) of Los Angeles hospitals showed almost all paid \$28 to \$29 for one unit of albumin. In turn, these hospitals charged the patient anywhere from a low price of **\$90** to a high of \$175 per unit.

In conducting a CBA **or** CEA one must decide which benefits to measure and how to measure them, if measurement is at all possible. For example, it has been argued that substantial savings from reduced expenditures on drugs, surgery, and hospitalization accrue from therapeutic apheresis treatments, although this will vary depending on the differing lengths and intensity of the disease remission.

Unemployment and lost productivity could be reduced in the long-term as well. Limiting analyses

**Table 6.—Ten General Principles of Analysis
(for CEA/CBA Methodology)**

1. Define problem
2. State objectives
3. identify alternatives
4. Analyze benefits/effects
5. Analyze costs
6. Differentiate perspective of analysis
7. Perform discounting
8. Analyze uncertainties
9. Address ethical issues
10. Interpret results

SOURCE: Office of Technology Assessment, 1980.

to work-related measures, however, may have the effect of underestimating the potential benefits of apheresis therapy to a significant number of individuals not currently in the work force—e.g., the chronically ill, the retired elderly, students, full-time homemakers, etc. A further point is that the efficiency of apheresis may decline—as evidenced by frequent usage as a treatment of last resort—with severity of impairment. In addition, savings on such items as reduced expenditures for quack remedies need to be calculated. It is reported that rheumatoid arthritis patients, for example, spend over \$1 billion a year on purported remedies ranging from the “night shade diet,” which prohibits tomatoes, eggplant, and potatoes, to devices such as vibrators and drugs such as DMSO (dimethyl sulfoxide). Some arthritic sufferers even sit in uranium mines in their search for relief (34). Other benefits, such as the sense of well-being that apheresis reportedly generates in many patients (108), may be more difficult to quantify.

Despite problems, when it is done well, the use of CEA/CBA does aid the complete listing of expected costs and benefits as well as the explicit consideration of assumptions underlying them. Assuming such specification is possible, such analyses provide a better scientific basis to aid in making decisions. Given the current debate over the relative costs and benefits of apheresis, and the increasing debate over reimbursement policy, such information does indeed appear to be essential.

Estimating Costs

While no reliable estimates of savings due to treatment benefits are available or generally known (12), the present task of evaluating treatments can include the context of costs, for which there have been several general estimates. There has additionally been a more specific study concerning the costs of reimbursing for apheresis of rheumatoid arthritis patients under the Medicare program.

By almost any standard, the costs of providing this therapy are a concern. It is the issue of costs that has aroused the greatest controversy surrounding the technology and is the most obvious explanation for the increasing scrutiny of apher-

esis by a variety of health care professionals. The concerns over costs have focused not only on the price of a single treatment session, but also the dramatically rising use of apheresis for therapeutic purposes in recent years.

Calculations

There are two dimensions (124) to expenditure determination—price and quantity. Many technologies become expensive because of high cost even when applied to a small number of patients (e.g., end stage renal disease), while others generate large expenditures because the procedure is so extensively used even though the cost per patient is relatively low (e.g., routine in-hospital lab tests). Apheresis represents an interesting combination of a technology which is, on the one hand, extremely expensive per patient, but is simultaneously of potential benefit to great numbers of patients.

Simple cost projections for therapeutic apheresis can be said to depend on three variables: the price of each unit of service (cost per treatment), the quantity of services that would be used (treatments per patient), and the size of the population potentially benefiting from treatment (patient populations). By multiplying these variables together, an estimate of total expenditures can then be determined.

Cost per Treatment

Estimates of the costs of individual apheresis treatments are very much available, but vary widely according to individual author and analysis from \$400 to \$1,200. (A midpoint estimate, then, is \$800 per treatment.) An investment of \$19,000 to \$32,000 for a blood cell separator is the initial cost here, and disposable sets produced by manufacturers will vary between \$40 and \$90 per treatment. (Membrane disposable prices may be substantially higher—as much as \$400—at first.) Space (overhead expense), trained staff, and a physician-director are also essential (\$27 to \$300). Replacement fluids (at an average volume of 2.8 liters), such as albumin or fresh frozen plasma, make up the remainder of the costs, running \$125 to \$600 per treatment (the exception is cytapheresis, which usually does not require re-

placement proteins because volume loss is small) (2,8,12,22,34,42,108,117,75,125) .

Treatments per Patient

Most studies estimate the number of treatments per patient as averaging about 10 per year, though a few estimate that number to be as low as and as high as 15 to 20 per year. As already discussed, apheresis protocols for various diseases will differ dramatically in number and frequency of treatments. Some applications will entail single treatments for emergencies, while it is likely that chronic diseases such as rheumatoid arthritis will generally require 15 to 20 treatments, although more than 30 will be used in some cases (2,34,73, 108,42,117).

Patient Populations

The potential patient population for apheresis can be appreciated in a number of different ways. If the potential patient population is defined as those persons with any of more than 75 diseases currently treated with apheresis, the potential population is significant. There are an estimated 5 million to 7 million people with rheumatoid arthritis, 400,000 to 500,000 persons with multiple sclerosis, 400,000 to 500,000 persons with systemic lupus erythematosus, 100,000 myasthenia gravis patients, and at least **50,000 to 60,000 others** with one of the other diseases. However, many patients in each disease category are presently being treated satisfactorily with drug therapy, and thus they may not now be considered candidates for apheresis (though in some diseases, such as multiple sclerosis and Goodpasture's syndrome, effective alternative therapy is very limited, so that virtually the entire patient population could eventually become candidates

for apheresis). If apheresis is used only on patients who have failed to respond to traditional forms of therapy, the potential total patient population is reduced to about 5 percent of its original size, and estimates place this population at from **325,000 to 427,000 (22,34,73,80,117,125)**. These must be considered conservative estimates because they limit the potential candidate population to those patients who have reached a severely debilitating or life-threatening state in these disease states. If apheresis therapy replaces other therapy modes in routine maintenance programs for various disorders, the patient population would be much higher (117).

Results

Having determined estimates for each of these several variables, and multiplying these variables together, total cost estimates for apheresis therapy per year can be projected to range from \$650 million to \$7.69 billion, with a midpoint estimate of \$3.01 billion (see table 7). Importantly, these **projections are simple cost calculations that carry with them a number of methodological caveats.**

Caveats

For one, there are no cost calculations of accompanying hospitalization, ancillary services or essential adjuvant therapies, such as immunosuppressive drugs, which would increase cost estimates. Secondly, there is no determination here of "adoption share," a yearly measure of market penetration, defined as the proportion of eligible candidates for which treatment was indicated and on which it would have actually been performed. Calculation of the adoption share requires fairly accurate procedural use data, as well as projecting what the diffusion rate for the procedure is

Table 7.—Estimating Costs of Apheresis Therapy

	High estimate	Midpoint	Low estimate
Costs per treatment	\$1,200	\$800	\$400
Treatments per year	15	10	5
Patient population	427,000	376,000	325,000
Total costs	\$7.69 billion	\$3.01 billion	\$650 million

SOURCE: Off Ice of Technology Assessment, 1983.

and will be. * Prediction of adoption share is one of the most difficult tasks, but one of the most important for predicting future costs. The **adoption share subsequently allows for the discounting back of future costs over a determined patient care time horizon, and the accumulation of a present value.**

Currently, apheresis is performed on only selected patients. Unfortunately, no accurate data exists on national figures, with estimates placing the number of procedures performed at from 80,000 to 200,000 per year (22,34,73,80,117). These estimates, if accurate, would mean that, using OTA treatment estimates (see table 7), current national expenditures on apheresis range from \$3.2 million to \$240 million. According to Schweitzer and Foxman (124), however, if one assumes availability of reimbursement for this therapy, then one must also assume expansion of availability of service, and utilization would increase over time to essentially the point where all who could derive benefit from treatment would do so. The importance of reimbursement policies covering apheresis becomes apparent, then, if such policies push the adoption share to 100 percent. Given present reimbursement policies (see section on “Third-Party Reimbursement”), this represents an extreme estimate but is useful for cost purposes here.

The economic and cost implications of a decision by a third-party payer to reimburse for apheresis is a last but crucial caveat to cost estimates. As Schweitzer and Foxman (124) **further point out, if medical services were not linked to one another, and criteria determining appropriateness or need for a service were unambiguous, the relationship between reimbursement**

● The classical pattern of diffusion has been the ascending logistic curve, which indicates that the proportion of adopters for a new technology rises with time according to an S-shaped pattern. This pattern is appropriate for technologies for which continued **ascendancy is likely** over the immediate horizon, and for which subsequent high utilization can be expected. For many applications of **apheresis**, however, the pattern is probably more complex. Warner (141) has proposed a three-stage “desperation-reaction” model of medical diffusion, in which initial enthusiasm is followed in the second stage by an adjustment, followed subsequently by informed decisions. The informed decisions could represent mature, high use (as in accepted innovation) or zero use (for an unacceptable innovation). Furthermore, disapproval of reimbursement could occur at any point in this process (19).

and expenditure would be a simple one. Under these conditions, one would simply identify the quantity and price of the service in question prior to a change in the reimbursement policy, and assume that these expenditures would be shifted to the new payer. However, both the demand for and the supply of medical care are price sensitive. A decision to reimburse, by lowering the net price to consumers and raising it to those who produce medical care—physicians and hospitals—will, therefore, have a tendency to increase the quantity of the service consumed. In addition, price effects will arise involving not only the service in question, but other services which are either substitutes for or complements to it. Failure to fully appreciate these quantity and price effects contributed to the serious underestimate of the End-Stage Renal Dialysis program in 1972 (113).

Cost Studies

Only one known study, prepared under contract to the National Center for Health Care Technology (NCHCT) in 1981, **has systematically examined the costs of apheresis. The study only estimated savings, if any, anticipated as a result of the disapproval of coverage for a medical procedure. The study was carried out following NCHCT’s recommendation to the Health Care Financing Administration (HCFA) not to reimburse for therapeutic apheresis in the treatment of rheumatoid arthritis. The cost projections, by most sensibilities, were considered startling. The study used a Wallace, et al. (140), estimate that as many as 700,000 Americans might be candidates for apheresis at a first-year cost of \$40,000 per patient and \$18,000 per patient each year thereafter. This implied a cost of up to \$28 billion in the first year. If 5 to 10 percent of the nearly 1 million Medicare-eligible patients with rheumatoid arthritis were to be given apheresis, it would cost between \$2 billion and \$4 billion (124). NCHCT noted that these were gross cost projections, and could be modified by projected savings from reduced expenditures for hospitalized bed rest, medication, and joint surgery. Maintenance of, or return to, a productive lifestyle would also have to be considered (as noted previously in this section) if apheresis were shown to be effective (107).**

The NCHCT study of potential costs, by comparison, casts OTA cost estimates as conservative, both from the standpoint of potential patient population and cost per treatment estimates. **The NCHCT study**, however, has been criticized for **usage** of “inflated” estimates pertaining to potential patient population. More widely accepted figures come from **Max** Hamburger, in concurrence with the American Society for Apheresis (49), who estimates the potential RA patient population at less than **70,000**, or about 10 percent of NCHCT estimates.

THIRD-PARTY REIMBURSEMENT

Reimbursement policies by third parties, like other aspects of therapeutic apheresis, has been the subject of some debate because of the competing factors of cost and therapeutic promise that this case study has variously discussed. The development of most of these policies has been recent, and there would appear to be the groundwork for an even more intensified period of evaluation, debate, and formulation of these policies in the near future. The following review elaborates on these developments and issues.

Federal Policies

The Federal Government has been substantially involved in the funding of apheresis through research support (see ch. 3); benefit programs such as Medicare, Medicaid, military, and Veterans' Administration hospitals; and employee insurance packages such as the Department of Defense's Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) and the Federal Employee Health Benefit Plans.

Medicare*

Although the cost of apheresis has focused attention on reimbursement, cost information has not been explicitly or directly considered in

Regardless of which estimate is selected, the effect of reimbursement policy on potential direct expenditure estimates is clear from both studies. Furthermore, as alluded to earlier, the expenditure implications of a reimbursement decision are intertwined with the technology's diffusion, producing direct and indirect effects, some of which may be wide-reaching. The magnitude of the direct cost estimates alone suggests that the procedure's safety and efficacy should be closely scrutinized because of the potential cost of possibly premature diffusion.

Medicare coverage determinations. The legislatively mandated practice of paying usual and customary fees does not easily accommodate such analyses. Instead, Medicare coverage determinations have relied on safety and efficacy criteria in an effort to “sketch the boundaries of accepted good medical practice” (98).

Formal Federal policies for reimbursement of apheresis under its Medicare program have developed almost completely over just the past few years, probably reflecting the fact that HCFA procedures for making coverage decisions were highly informal until early 1980. The staff of the Office of Coverage Policy, often with assistance from the Health Standards and Quality Bureau, would review the issue, consult experts in the field with whom they were acquainted, and come to a decision (104). **Three or four regional office inquiries concerning coverage positions on apheresis surfaced during that period, but no national instructions were issued.**

Although a formal agreement between HCFA and the Public Health Service had existed since around 1966, a somewhat more formal, systematic, and credible assessment process involving a panel of physicians within HCFA and from NCHCT was established in early 1980. When

● On Apr. 20, 1983, Public Law 98-21 provided for extensive changes in Medicare reimbursement policies for hospital-based care. Under the statute, whose provisions will be phased in over 3 years, hospitals will receive a flat fee per patient, set prospectively, on the basis of patient diagnosis in one or more of 467 diagnosis-related groups (DRGs). It is unclear at this point how the DRG-based payment system will affect the adoption and use of apheresis. What is certain, however, is that information on the effectiveness of this treatment will be even more important as physicians and patients face increasingly scarce resources.

HCFA decided that a procedure involved a question of national importance, a request for a technology assessment was sent to NCHCT. Usually such a request asked NCHCT to determine the safety and efficacy of a particular technology and to recommend whether HCFA should reimburse (103,104). Because the number of questions about coverage of apheresis increased substantially beginning in 1979-80 (56), HCFA, on the advice of NCHCT, issued its first national instructions on apheresis in August 1981. **Effective September 15 of that year, HCFA announced the coverage of therapeutic apheresis for the following indications (52):**

1. plasma exchange for acquired myasthenia gravis;
2. leukapheresis in the treatment of leukemia; and
3. plasmapheresis in the treatment of primary macroglobulinemia (Waldenstrom) and hyperglobulinemias, including multiple myeloma.

The HCFA policy statement went on to say that apheresis should be denied for other indications, but that information on claims for what seems to be other nonexperimental uses should be provided to HCFA'S central office (53).

Even before the August policy release—in May of 1981—HCFA requested that NCHCT evaluate the safety and clinical effectiveness of apheresis for the treatment of (38):

1. Goodpasture's syndrome;
2. systemic lupus erythematosus;
3. membranous and proliferative glomerulonephritides;
4. multiple sclerosis;
5. potentially life-threatening complications of rheumatic diseases (rheumatoid arthritis, systemic lupus erythematosus, polymyositis/dermatomyositis, and progressive systemic sclerosis); and
6. thrombotic thrombocytopenic purpura (TTP).

NCHCT issued formal assessments on the indications of multiple sclerosis, rheumatoid arthritis, rheumatoid vasculitis, and TTP. Two other indications— Goodpasture's syndrome and mem-

branous proliferative glomerulonephritides—were evaluated in early 1983 by the Center's organizational successor, the Office of Health Technology Assessment (OHTA) (28). (NCHCT and OHTA assessments are discussed in ch. 3.) HCFA has yet to implement instructions on any of these six categories for national coverage policies.

Although Medicare's national coverage is relatively new, it is not unlikely that many hospital apheresis treatments for Medicare patients with covered and noncovered disease indications have been performed and reimbursed without official sanction of HCFA. Because Professional Standards Review Organizations do only a limited job of surveillance, because descriptions in the line item billings are very general, and because new procedures often do not have a procedure code number, the identity of Medicare reimbursements for apheresis therapies may have been concealed (104,117).

Medicare provides coverage for apheresis regardless of whether or not it is performed at a hospital (108). It has been reported, however, that independent, freestanding settings are less likely to receive reimbursement at this time, fueling speculation that HCFA hopes to control the use of apheresis by limiting reimbursement to hospital-based therapy (73). There is no known intention by HCFA to implement such a regulation at this time or in the near future.

Medicaid

Medicaid provides medical assistance to low-income individuals. Treatment costs are shared by the States and the Federal Government. Each participating State must provide certain basic health services, but the States have a great deal of leeway concerning specific coverage (102). Medi-Cal (California Medicaid), for example, will approve payment only for apheresis conducted in the treatment of certain diseases, including myasthenia gravis, lupus, and Goodpasture's syndrome. Treatment of such disorders as rheumatoid arthritis and multiple sclerosis, on the other hand, are at present considered investigational and are thus not covered (108). As of August 1982, Medi-Cal was in the midst of a review of all its apheresis coverage policies, and was ex-

pected to formulate a new policy statement concerning its coverage policies (58).

Veterans' Administration (VA) and Department of Defense (DOD)

The extent of VA and DOD involvement in the use of apheresis is reflected in a hospital and blood bank survey by Scoville Associates (108). That survey revealed that 30 VA and military hospitals performed therapeutic apheresis, on 260 patients, and a total number of 1,350 procedures. No breakdown of usage by disease, or whether use was for clinical or research purposes, is available.

Under DOD's CHAMPUS program, the use of apheresis in the treatment of any condition prior to August 1981 was considered investigational and not a CHAMPUS benefit. Since then, however, the CHAMPUS program has taken the basic Medicare policy and expanded it somewhat. CHAMPUS now extends coverage to use of the procedure as a "last resort treatment of certain medical conditions." The specified indications are (8):

1. myasthenia gravis during a life-threatening crisis;
2. anti-basement membrane antibody nephritis (i.e., as a result of Goodpasture's syndrome);
3. life-threatening immune complex vasculitis;
4. hyperviscosity of the blood associated with multiple myeloma, Waldenstrom's macroglobulinemia, and hypergammaglobulinemia purpura; and
5. TTP.

Private Sector Policies

Like their Federal counterparts, private insurers historically reimbursed on a routine basis for both apheresis procedures and replacement fluids, but have recently begun to examine apheresis procedures more closely and issue explicit policy statements concerning coverage. In March of 1981, **Blue Shield of California approved payment for therapeutic plasma exchange and lymph-apheresis** in the treatment of severe cases of rheumatoid arthritis if there are acute life-threatening complications or if conventional drug therapy has failed (80,117).

At present coverage under Blue Cross insurance programs varies greatly from State to State. For example, the Southern California, Texas, and South Carolina Blue Cross organizations generally follow the Medicare guidelines and will normally approve payment for apheresis. Illinois Blue Cross indicated that their reimbursement schedule depends on the disease being treated and what other therapies have been tried, but that in general, they will approve most requests. Massachusetts Blue Cross covers apheresis for 14 different disease indications. The Greater New York Blue Cross, on the other hand, does not cover apheresis therapy under any of their plans (61, 79,108).

The National Blue Cross/Blue Shield Association issued a policy statement in May 1982 as a guideline to local Blue Cross/Blue Shield plans. That policy recommends coverage—in hospital settings only—of nine disease categories including severe myasthenia gravis and leukemia (34). The National Blue Cross-Blue Shield Association policy does not necessarily mandate acceptance and implementation by individual plans, however, and is subject to a possible future review at an appropriate time (16).

Many private insurance companies, too, including Pacific Mutual and Prudential, provide coverage for apheresis regardless of whether or not it is performed at a hospital. As with Federal policies, uniform private third-party coverage is pivotal to the future development of the procedure, particularly in freestanding and commercial settings. The growth of commercial centers has been slowed in some States by the fact that some insurance organizations do not provide benefit payments for apheresis procedures performed outside the hospital. FDA has yet to establish licensing procedures for apheresis centers, and many private insurers have indicated a reluctance to provide reimbursement for therapy under uncontrolled conditions, which could lead to possible treatment overuse and abuse. There appears to be less overall concern, though, in the case of private payers, about future restrictions on reimbursement for apheresis treatment (108).

CONCLUSIONS

Acknowledgment of apheresis as a safe and effective treatment application, as an acute therapy in a small group of relatively uncommon diseases, is reflected in present Medicare reimbursement policy. Suggestive evidence of the safety and efficacy of apheresis in a host of other disorders has also forced a flurry of reimbursement policy reviews and formulations among both government and private party insurers.

Reimbursement policies to the present have revealed an increasingly cautious and explicit approach to coverage of apheresis for almost all disease indications, and understandably so. Apheresis is still not a proven cure for any disorder. It may need to be done repeatedly for certain disease conditions, at a cost of up to \$1,200 or more each time. Total cost estimates potentially run into the billions of dollars. Nevertheless, by treating certain disease complications, apheresis has reportedly lessened suffering and helped prolong lives. Reliable estimates of these benefits have yet to be determined and quantified. As a result, cost-benefit ratios and CEAS have not yet been conducted.

It should be reemphasized that the formation of cost-benefit ratios and CEAS should not be considered only economic tools. This point is not negated by the fact that CEA/CBA is described as an efficiency-based technique. Measurement of the efficiency of therapeutic apheresis will depend as much on output as on resources used to produce the output. One of the critical output or outcome measures that can be addressed by CEA/CBA is the effect of apheresis on health status or other health outcome related effects. Any CEA/CBA that attempts to analyze such outcomes for an evaluation of therapeutic apheresis will only be as comprehensive and valid as the data on the efficacy and safety of apheresis. Thus, health outcome related CEA/CBAs for apheresis are dependent on the existence of an adequate efficacy and safety information base. The status of such information for many disease indications for which therapeutic apheresis has been used, however, is inadequate. As a result, it may be exceedingly difficult to demonstrate therapeutic

apheresis a cost-effective technology for which third-party payment is justified.

Medical insurers are presently far from a consensus on which disease indications should be covered, probably stemming from a less than consistent scrutiny of the evidence on safety and efficacy. A widening of Medicare and private insurer coverage of therapeutic apheresis for specific life-threatening complications (e.g., rheumatoid vasculitis) is probable in the near future. But direct cost estimates and the potential cost of possibly premature diffusion alone make it unlikely and unwise that third-party payers will support any broad extension of benefits for apheresis treatment until more valid data is generated. Until evidence is available, therapeutic apheresis will largely be viewed as an experimental technique, not to be considered as a part of routine care. In light of such a situation, present research and clinical trials being carried out assume even greater importance. It will be several years, though, before all the results are in.

Lastly, a significant (but still speculative) factor amidst the cost and reimbursement policy debate is the potential cost reductions of new apheresis equipment and treatment modalities. The present trend towards plasma perfusion (more selective removal of undesirable plasma fractions) offers the possibility of eliminating the need for replacement fluids which could reduce the present cost per treatment by 20 to 50 percent. Staffing charges are presently based on a large proportion of acute treatments which are usually performed on an in-patient basis, often at the patient's bedside. Some observers predict the future growth in apheresis to involve increases in maintenance therapies which could be performed on an out-patient basis, with reduced involvement of hospital staff (74,108).

On the other hand, there seems to be a trend toward in-hospital use in areas such as Washington, D.C. In that region, after the Red Cross started doing therapeutic apheresis in March 1978, only one of the first 16 months' 106 procedures was done in a hospital. But from July 1980 to

April 1981, nearly five out of six were. Future decisions regarding treatment settings will no doubt depend on a number of factors such as hospital charges, regulation and standard setting ac-

tivities for freestanding, independent commercial clinics, reimbursement policies, and whether apheresis is administered largely for reasons of acute or maintenance therapy in specific disorders.