

Blood and Marrow Transplantation Compensation: Perspective in Payer and Provider Relations

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ABSTRACT

The high cost per patient of hematopoietic cell transplantation (HCT) causes this therapy to be the focus of much controversy, given the competing societal demands to provide all possible therapy to preserve life while simultaneously limiting global health care expenditures. Treatment and eligibility decisions for HCT often are heavily scrutinized by both governmental and private payers and not simply determined by physicians, facility providers, and the patient. In an effort to control costs, payers have administrative infrastructure to review resource utilization by these patients. Additionally payers have developed payment methodologies, usually in the form of a case rate payment structure, that place facilities and physician providers of HCT at financial risk for adverse patient financial outcomes in an effort to promote optimal utilization and selection of patients for HCT. As providers enter into such financial risk arrangements with payers, the providers need to understand the true cost of care and be able to identify predictable and unpredictable outlier risks for the financial consequences of medical complications. HCT providers try to protect themselves from excessive financial risk by having different payment rates for different types of transplant, eg, autologous versus HLA or genotypically matched related versus HLA mismatched transplants. Because at certain times in the HCT process risk is more unpredictable, HCT providers require different payment system strategies for the different time periods of care such as evaluation, pre-transplant disease management, harvesting, and cell processing, as well as short- and long-term follow-up. Involvement by clinicians is essential for this process to be done well, especially given the rapid changes technological innovation brings to HCT. Constant dialogue and interaction between providers and payers on these difficult financial issues with HCT is essential to preserve patient access to this potentially lifesaving therapy.

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KEY WORDS

Compensation • Managed care • BMT • Center for Medicare and Medicaid Services

For the past 20 years, the leading payers of US health care have been attempting to control growth in health-care spending through managed care strategies, either demanding a clinical review and approval before services are provided or developing new payment methods that cause health-care providers to share in the financial risk of providing care. Health-care payers in the United States are either employer-sponsored health plans or government-sponsored programs, including Medicare and Medicaid. Employer-sponsored payers and, to a lesser extent, government-sponsored payers have established managed

care organizations (MCOs) to manage utilization of clinical services and the costs of providing medical care. Managed care is a response to society's effort to control the cost of medical services. Providers of expensive services such as blood and marrow transplantation (BMT) are particularly scrutinized and find their clinical programs caught up in the whirlwind of new methods for pricing medical services and for financial accountability.

The first efforts to control costs in health-care services involved contracts between providers and MCOs for a percentage discount off charges. Because

these arrangements did not fundamentally address the perception of excessive use of some clinical services driving up health-care costs, MCOs encouraged providers to move into capitated compensation methods in which providers would have the financial risk for providing clinical services (see Appendix A for a glossary of terms). In a fully capitated plan, providers are paid a fixed sum to provide all necessary medical care for a defined population. The logic in capitation is that providers with the financial risk for providing additional clinical services will scrutinize their own treatment policies to optimize cost-effectiveness. Capitation, whether full or limited, has forced providers and MCOs into a mutual effort of trying to identify financial risk and setting limits in contracts.

For providers of BMT services, partial risk arrangements, often termed *case rate* contracts, have been extensively used. These fix reimbursement for various components of the transplantation process, such as pretransplantation workup, collection of autologous or allogeneic cells, transplantation hospitalization, and posttransplantation follow-up care for a defined period of time. Payers prefer to carve out BMT services with case rate agreements to better control and predict the costs associated with BMT services. Case rate reimbursement methods share many features of capitation. Case rates pay a fixed price for all clinical services in a defined time period. Providers are thus at risk for new drugs added to improve outcomes or to treat unexpected complications or comorbidities during this period. To effectively price services, providers must understand these fixed and variable costs during this period and must interpret the risk of any individual patient or group of patients of being an outlier in need of additional services. The most costly services cannot be easily fixed because of the unpredictable consequences of BMT, such as regimen-related toxicities, infections, and graft-versus-host disease (GVHD). Because of this, most contracts include outlier clauses to cover the costs of patients with major complications.

BMT providers continue to experience pressure from payers to compete for inclusion in Centers of Excellence networks, which involve both a review of quality of care delivered and competitive financial terms. The patients covered in these arrangements have their choices limited by the contracted network of transplantation programs. From the provider perspective, these contracts involve discounted pricing in exchange for increased patient volumes. To market these networks as quality providers to employer groups, payers require in-network providers to meet comprehensive clinical quality standards and to participate in national reporting of outcomes to an outcomes reporting registry, such as the International Bone Marrow Transplant Registry [1]. Payers generally require in-network providers to have their cell-

processing laboratory accredited separately by the American Association of Blood Banks [2] or to have the entire program—including the physicians, the facility, and the cell-processing laboratory—accredited as an integrative program by the Foundation for Accreditation of Cellular Therapies. Foundation for Accreditation of Cellular Therapies credentialing assesses the integration of a clinical program, the program's ability to follow its standard operating procedures, and, most importantly, the quality-improvement procedures and policies [3,4]. For a clinical service as complex as BMT, the ability of a program to maintain a continuing quality-improvement program is vital. This demand by payers for credentialing of programs has probably improved the quality of care in this field.

BMT patients may have coverage with 2 or more insurance companies. Typically, there is a primary insurance company, which may be a self-funded plan by their employer, and a reinsurance plan for catastrophic coverage. Involvement of multiple payers is complex, and there is frequently conflicting benefit language among the reinsurance, the primary health insurance, and the self-funded insurance plans. Most patients are unaware of these benefit language limitations. The BMT program provider must understand how these limitations will affect care before starting the BMT procedure.

To remain competitive with the market, it is essential for BMT programs to identify and fully understand the true costs of providing patient care. Costs vary greatly by diagnosis, patient age, comorbidities, type of transplantation, histocompatibility, and other patient- and disease-related factors. The provider must be familiar with the types of patients being treated, the special needs of those patients, and the risks of major complications, which result in increased costs.

There are many cost drivers for BMT: the foremost is patient expectations. Patients are aware that a BMT is a once-in-a-lifetime event, and they desire to have the transplantation at the best facility featuring the latest technologic innovations and with the best possible outcomes. At the same time, patients want to have the transplantation where they can be surrounded by their social support system, including family and friends. Hospitals strive to provide the most effective, state-of-the-art health care. As with all new technology challenges, there are escalating costs for incorporating new technologies and drugs.

BMT is typically performed for patients with life-threatening diseases and malignancies, often in an advanced stage. BMT is frequently a patient's last chance for life. BMT involves substantial risks, but it is typically performed with curative intent. Treatment standards are rapidly evolving and poorly defined. Most transplantations are performed on a clinical re-

search protocol to address important therapeutic questions and so that outcomes can be studied and reported. Typically, centers study a modification of components of the basic transplantation regimen designed to improve the safety and efficacy of the procedure. It is self-evident that continued clinical research is necessary to improve the standard of care involving BMT. Most insurance plans, however, have exclusions for investigational and experimental procedures. There is considerable tension between providers and payers regarding inclusion of patients in clinical research studies. In many cases, carriers will micromanage the preparative regimen or other treatment administered by the transplant centers, and some carriers forbid patients from participating in any clinical trials. These considerations seriously impair the conduct of clinical research needed to advance the standard of care for hematologic malignancies and for hematopoietic transplantation in general. It is particularly difficult to obtain insurance authorization for clinical trials evaluating hematopoietic transplantation for novel indications, such as selected solid tumors and autoimmune diseases, for which this approach seems promising. In many cases, the payers are sympathetic to the needs for ongoing clinical research but are constrained by the patient's policy contract language, which precludes their participation in any research studies.

Selection of candidates for hematopoietic transplantation is another area of tension between transplant centers and the medical insurance industry. Third-party payers have a financial interest to limit payments and generally advocate conservative policies restricting patient selection to favorable risk categories. Transplantation may still offer an opportunity for long-term survival in high-risk patients and those with advanced disease. Many clinical trials focus on measures to improve the outcome in these patients. Often these high-risk patients have no alternative options for long-term survival other than BMT.

Allogeneic BMT services must account for donor costs. The donor is having a medical procedure that is not for his or her benefit, and, logically, the recipient's health-care provider—not the donor's—should be billed for these costs. Initially, most insurance providers accepted this responsibility, but donor expenses are beginning to be denied. Donors frequently have coexisting medical problems that may not be appreciated before transplant donation. Untreated medical problems such as diabetes, hypertension, and cardiovascular disease are often identified. These donors may require additional testing to medically clear them for the transplantation. Additionally, if the donor has a complication as a result of this procedure, the recipient or recipient's insurance should be obligated to pay the cost of treatment.

Allogeneic BMT generally requires identification

of a related or unrelated donor who is closely matched for the human HLA histocompatibility antigens. Histocompatibility testing of potential donors is usually inadequately covered in a capitated model. Many payers either do not cover histocompatibility typing costs or have restrictions on the numbers of individuals who can be tested. In addition to siblings, parents and children should be HLA-typed. If there is no histocompatible donor in the family, an unrelated donor search must be performed. It is very difficult to accept full typing capitation risk, because families are of different sizes and because HLA typing is expensive. New molecular-based typing methods appeared quickly, adding to provider difficulty in predicting cost. Most insurance plans stipulate that the National Marrow Donor Program registry charges be a pass-through without compensating the transplant center for administrative costs associated with the donor search.

The patient's private insurance carrier must preauthorize nearly all BMT procedures. This process generally requires a letter of medical necessity in which the transplant center describes the patient's characteristics, diagnosis, age, comorbidities, prior treatment and response, and current disease status. Detailed patient-specific correspondence must be prepared and mailed to the insurance provider. Authorization generally takes 2 to 4 weeks and may require outside review by a panel appointed by the insurance carrier. This review often delays implementation of appropriate therapy, and in many cases an additional course of standard chemotherapy is needed to stabilize the patient's disease until insurance authorization is obtained to proceed with the transplantation.

Providers offer different case rates for each distinct type of transplantation. Typically, transplantation contracts have separate case rates for autologous transplantations, HLA-identical sibling transplantations, HLA-mismatched transplantations, and unrelated transplantations. A transplant center must understand its risk and cost for all types of BMT. To assist in billing this complex transplantation procedure, most agreements are divided into phases of service—evaluation, pretransplantation care, donor search, harvest, transplantation phase (which includes the preparative regimen, cell infusion, and hospitalization until the patient has recovered from neutropenia), short-term follow-up care (1-3 months), and long-term follow-up care. Unfortunately, each insurance plan designates these phases differently; this complicates the transplant centers' efforts to develop a standardized billing and accounting system. The BMT evaluation usually occurs in the context of cancer management and in the context of pretransplantation care for the malignancy. The reimbursement by payers for costs of general disease management must be separated from any reimbursement case rate costs

associated with BMT evaluation and the transplantation, because costs for management of this disease are very unpredictable.

During the pretransplantation process, decisions must be made regarding the type of transplant needed—autologous, syngeneic, or allogeneic. For allogeneic transplantations, the donor (related or unrelated) and cell source (bone marrow, peripheral blood stem cells, or cord blood) must be determined. Cell harvesting should be considered separately from the transplantation in contracts because of the issue of donor charges and, in the case of autologous transplantations, the possibility of a “harvest and hold,” in which the donor cells are harvested while the patient’s disease is in remission, to be used at a later date.

The next phase is the transplant hospitalization, during which the preparative regimen is administered and the hematopoietic progenitor cells are infused. This usually includes the preparative chemotherapy regimen, the period of cytopenia, and the period leading up to the immediate time of graft recovery. There are short-term follow-up issues for autologous transplantations but more so for allogeneic transplantations, for which the patients cannot go back to a community hospital after hematopoietic recovery and must remain at the transplant facility because of management of GVHD and viral infection. This phase usually ends 100 days after cell infusion.

Patients undergoing hematopoietic transplantation may develop late complications, particularly after allogeneic transplantation. Long-term follow-up evaluation is necessary to monitor patients for disease recurrence and for late complications of the procedure, particularly chronic GVHD, infections, and delayed toxicities of chemoradiotherapy. Community oncologists and other physicians are generally not familiar with these late effects and the necessary care for transplant recipients. Patients are best served by follow-up care at their transplant center by professionals most knowledgeable about the risk and management of these complications. Many insurance carriers do not cover follow-up care by the transplant center after the immediate posttransplantation period, and this clearly compromises patients’ overall management. Patients who are having transplant-specific management problems, such as chronic GVHD or infections unique to the transplant population, cannot be effectively managed in the community. Appropriate provisions need to be made for the necessary long-term evaluation and care of these patients. Transplant centers usually are inadequately reimbursed for costs of care for BMT patients with long-term complications under a “full service” agreement.

The other issue faced with transplantations is contending with patients who undergo relapse of their malignancy after allogeneic transplantation. This generally requires additional chemotherapy treatment

and, often, donor lymphocyte infusion to boost immune graft-versus-malignancy effects. There is a high degree of variability in the cost of this care.

There are also new issues related to advances in the standards of care in hematopoietic transplantation, such as the use of double transplantations for multiple myeloma, which involve either tandem autologous transplantations or an autologous followed by an allogeneic transplantation. The use of nonmyeloablative allogeneic transplantation has some potential for reducing costs for the initial transplantation, although the major costs are the management of posttransplantation GVHD and the general costs of care for the comorbidities in the older and more debilitated patients who are generally considered for this approach.

BMT is an area of rapid progress and incorporates new drugs, biologicals, and technologies. These new modalities typically are associated with additional cost, which is a source of tension with third-party payers. For example, the addition of rituximab to an autologous or allogeneic transplantation regimen adds thousands of dollars to charges, generally without any change in fixed rate or capitated contracts.

Several high-cost pharmacy items have now come in to the transplant arena. These include new drugs for the preparative regimen, such as rituximab, gemtuzumab ozogamicin, ibritumomab tiuxetan, and trastuzumab. New drugs are also being used for posttransplantation complications, such as recombinant activated factor VII and palivizumab. These drugs often have a cost potential equivalent to that of the full historic case rate prices previously negotiated. Acquisition costs for the transplant center for some of these drugs are equivalent to the full case rate prices previously negotiated.

One important aspect of hematopoietic transplantation contracts is the consideration for outlier risks: patients with major complications that result in long-term hospitalization, intensive care unit care, or both. Catastrophic complications such as graft rejection, veno-occlusive disease, early acute GVHD, early severe viral infections, or pulmonary hemorrhage may occur. Payers and providers should provide terms for payment for these cases; this has generally been handled as a discount off charges once the total charges exceed a threshold value. Even in the best-risk patients, catastrophic complications can occur, and charges may exceed \$1 million. Although it is possible to identify high-risk groups, such as older patients, those with comorbidities, and those with advanced hematologic malignancies, these patients may still benefit from a transplantation procedure, which may be the only lifesaving treatment option available. Recent advances such as reduced-intensity and nonmyeloablative transplantation have made this form of treatment feasible for patients who were previously considered ineligible.

New electronic billing systems and Health Insurance Portability and Accountability Act regulations are forcing payers and providers back in to an exchange of financial information that very much resembles the old indemnity format. However, payers are not willing to pay the previous prices associated with indemnity formats. For example, pharmaceutical payers are demanding to pay the drug-acquisition cost. For providers, this raises the question of how to best obtain adequate compensation for complex nursing and facility services that have not been historically well compensated and have used surrogate laboratory or pharmacy charges for indirect or cost-sheltered compensation.

BMT is an area of active clinical research. In many centers, all patients are treated on clinical research protocols designed to address disease- and treatment-related problem areas. The standards of care in allogeneic and autologous transplantations have markedly improved over the last several decades as a result of clinical investigations, and continued support for clinical trials by the medical insurance industry is critical. Under the Health Insurance Portability and Accountability Act, tracking transplantation outcomes without entering all patients on efficacy documentation studies, which are essentially phase II studies, has become increasingly difficult. Many payers strongly desire that institutions report transplantation outcomes to them. The best way to analyze and report outcomes and still meet regulatory requirements would be to enroll all patients in clinical research studies.

President Clinton signed an executive memorandum on June 7, 2000, that directed the Secretary of Health and Human Services to “explicitly authorize (Medicare) payment for routine patient care costs and costs due to medical complications associated with participation in clinical trials” [5]. This was a landmark executive order. The executive order was not overturned by the George W. Bush administration, but implementation of the executive order has been problematic. The Centers for Medicare and Medicaid Services benefits for transplantation include both autologous and allogeneic transplantation for aplastic anemia and acute and chronic leukemia and autologous transplantation for Hodgkin disease, lymphoma, or multiple myeloma [6]. Additionally, there are BMT benefits for children with genetic disorders of immunity. There is a Center for Medicare and Medicaid Services national coverage decision restricting multiple myeloma patients to autologous transplantation only; a new congressional act will probably be necessary to offer Medicare patients an allogeneic transplantation for this disease. Studying the efficacy of BMT for noncovered areas has been seen as a benefits coverage issue for Centers for Medicare and Medicaid Services and not as a clinical trials issue. Thus, the following is problematic for Medicare beneficiaries:

allogeneic transplantations are not covered for myelodysplastic syndrome, multiple myeloma, and lymphoma, settings in which the transplantation can be curative. Although Medicare generally covers patients older than 65 years of age, younger patients who are Medicare beneficiaries because of disability from malignancy are also denied access to services that a routine commercial insurance would pay as standard of care for their condition.

In summary, developing contracts with third-party providers for BMT is an increasingly challenging process. BMT providers must have an integrated contracting process with clinical services, financial counselors, and billing services. Good communications among payers, providers, and human resource officers from employers are required to successfully meet patient needs. Payer evaluation and approval for transplantation services need to be accomplished rapidly for these acutely ill patients. BMT providers must realistically price their services to meet society’s health-care funding restraints. Transplantation providers have historically not entered the policy arena, but active engagement is necessary to update and improve government payment policies. BMT sits on the cutting edge of societal health-care finance issues, and its providers must engage MCOs and federal and state payers to ensure patient access to this lifesaving form of treatment.

APPENDIX A: GLOSSARY OF TERMS

Capitation: Fixed payment arrangements for members are made on the basis of the population for services. This is often expressed as payment per member per month.

Carve-out services: Certain services are carved out or not included in the global payment price for patients for whom there is a global payment for a service.

Fixed and marginal variable costs: In any given institution’s cost structure, there are fixed costs, such as buildings, beds, and infrastructure. There are marginal variable costs associated with taking care of additional incremental patients in a specified infrastructure. For example, running a night shift of technicians to perform additional laboratory tests or hiring an extra nursing shift to manage clinics that overflow into the evening would be included in marginal variable costs.

Fixed risk case rates: A fixed amount of money for a give type of service.

Outlier risks: There is often specific language to cover patients who are under a global payment structure or a capitation system. Frequently the costs for these patients become outliers because they are very different from those of most patients.

Partial risk arrangements: A specific payment per service versus a fixed global payment.

Reinsurance: Third-party administrators run most health insurance organizations, and their primary function is to process claims for self-insured health plans. Most corporations have a reinsurance policy that kicks in to cover health-care benefits for catastrophic claims, such as when a member's health-care expenses exceed \$50000 or when the global health-care expenses for that corporation exceed a certain cap.

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