

CHAPTER 2

The Business of Cellular Therapy and Hematopoietic Stem Cell Transplantation

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Hematopoietic stem cell transplant (HSCT) is a complex process that is associated with a heavy demand for resources and need for multispecialty teams. The first transplant procedures were performed over 40 years ago. There has been a dramatic increase in the number of procedures performed over the past 10 years (Fig. 2.1).

National Marrow Donor Program (NMDP) projections for growth in unrelated donor transplants are significant with an expected doubling of facilitated transplants projected at 10,000 by the year 2015. These projections can be frightening, but recent analysis of US hospitalization utilization indicates that in the past 5 years, there has already been a doubling of activity. Bone marrow transplant ranked highest among the commonly performed procedures with the most rapidly increasing hospital inpatient costs from 2004 to 2007, with a percentage change in total costs of 84.9% and a percentage change in total hospital stays of 51.3%. In the breakdown, it was observed that specifically inpatient costs for Medicare covered stays increased 90.4% and costs for private payer insured stays increased 100.6% during this period (Table 2.1).

In the settings of increasing demand and increasing cost of technologies, it is critical for providers and hospital systems to assure that contractual arrangements with payers have sufficient complexity to support the provision of the best care while protecting from excessive financial risk, resulting in financial stability of the transplant program.

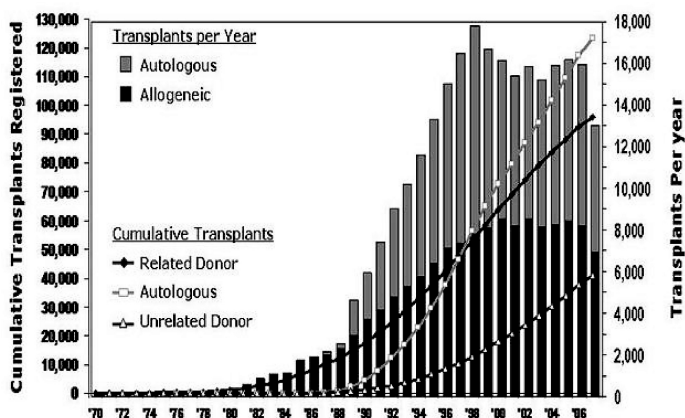


FIG. 2.1. Annual and cumulative transplant procedures reported to the CIBMTR

2.1 COMPLEXITY OF CARE

Hospitals and payers alike typically wish to “carve out” HSCT services from general medical services contracts. Due to the complexity of care delivered, variability in patient care requirements, and potential risk of need for catastrophic care, HSCT services are often divided into phases for the purposes of authorization and reimbursement methodologies. These phases may encompass consultation, evaluation, transplant, and post-transplant.

2.2 PHASES

1. Transplant evaluation

- a. Begins when a new patient is referred for transplant evaluation
- b. Ends when patient is approved as a transplant candidate
- c. Inclusions
 - i. Physician and clinic charges for consultation and physical exam
 - ii. Lab tests
 - iii. Radiology studies
 - iv. Psychiatric evaluation
 - v. Dental evaluation
 - vi. Patient and donor HLA typing
 - vii. Donor infectious disease testing

TABLE 2.1. Commonly performed procedures with the most rapidly increasing hospital inpatient costs, 2004–2007

Principal procedure category	Total costs (2007)	Total hospital stays (2007)	Percentage change	
			Total costs (2004–2007) (%)	Total hospital stays (2004–2007) (%)
Bone marrow transplant	\$1,282,645,000	15,100	84.9	51.3
Open prostatectomy	\$1,032,016,000	88,500	68.6	40.8
Aortic resection; replacement or anastomosis	\$1,872,908,000	61,600	38.5	31.9
Cancer chemotherapy	\$2,616,504,000	187,400	33.2	14.2
Spinal fusion	\$8,863,922,000	350,700	29.5	15.6
Lobectomy or pneumonectomy	\$1,757,748,000	81,400	29.2	24.9
Incision and drainage, skin and subcutaneous tissue	\$1,108,187,000	158,600	28.6	31.5
Arthroplasty knee	\$9,217,740,000	605,200	27.5	25.7
Nephrectomy and nephrostomy	\$682,609,000	38,600	25.3	11.7
Mastectomy	\$660,173,000	70,100	23.8	3.6
Total for top 10 procedures ^a	\$29,094,452,000	1,657,100	32.3	22.2

Source: AHRQ, Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project, Nationwide Inpatient Sample, 2004 and 2007

^a 2004 costs were adjusted to 2007 dollars using the overall Consumer Price Index

- d. Exclusions
 - i. Non-transplant-related services
- 2. Pre-transplant
 - a. Begins when a patient is identified as a transplant candidate
 - b. Ends the day prior to the transplant admission
 - c. Inclusions
 - i. All inpatient and outpatient facility, professional, ancillary, and laboratory services related to routine surveillance of patient to assure maintenance of transplant-ready status
 - d. Exclusions
 - i. Disease-related services
- 3. Harvest/acquisition (typically included in pre-transplant phase or transplant phase)
 - a. Inclusions
 - i. Mobilization
 - ii. Bone marrow or peripheral blood stem cell harvest
 - iii. Acquisition charges for unrelated donor product procurement
 - iv. Cell processing
- 4. Transplant stay
 - a. Begins on the day of admission; or for outpatient transplants, with the initiation of preparative regimen
 - b. Ends on the day of discharge; or for outpatient transplants, x number of days following stem cell infusion
 - c. Inclusions
 - i. All facility, professional, and ancillary charges
- 5. Post-transplant
 - a. Begins on the day of discharge; or for outpatient transplants, x number of days following stem cell infusion
 - b. Ends x number of days post-infusion or post-discharge
 - c. Inclusions
 - i. All transplant-related outpatient and inpatient facility and professional charges
 - ii. Inpatient readmissions
 - d. Exclusions
 - i. Non-transplant-related services
- 6. Special circumstances

There are some HSCT-associated activities that require special arrangements or should be addressed separately from case rate provisions in contracts due to their unpredictability and/or variation in occurrence.

 - a. Sequential transplants (pre-planned)

- b. Donor leukocyte infusions
- c. Re-transplants
- d. Reduced intensity transplants
- e. High-cost pharmacy items (e.g., plerixafor)

2.3 CONTRACTS AND REIMBURSEMENT STRATEGIES

If structured appropriately, contracts should reflect mutual exposure to financial risk.

Reimbursement methodologies vary in the degree to which financial risk is shared.

1. Reimbursement methodologies
 - a. Discount off charges – a flat percent discounting of billed charges
 - b. Case rate – fixed fee that covers all transplant-related services for a specified period of time
 - c. Global case rate – fixed fee that includes hospital and physician charges for a specified period of time; typically includes post-transplant care
2. Case rate and global case rate methodologies typically include provisions that protect the transplant center from financial risk. These provisions vary in the amount of financial protection they provide.
 - a. Outlier days – per diem for each inpatient day in a defined post-infusion time period
 - b. Outlier threshold – percentage of billed charges once a specified threshold beyond the case rate is reached
 - c. Floor provision – at no time shall hospital be reimbursed less than $x\%$ of billed charges. This provision is usually used in tandem with the outlier day provision to provide added financial risk protection
3. Given the variation in patients' clinical circumstances that may impact evaluation and work-up, patients' geographic locations and the willingness and expertise of the referring physician to be involved in pre-transplant testing, consideration should be given to structuring the reimbursement rate for the evaluation, pre-transplant period, and post-transplant time periods on a percentage discount off billed charges basis.
4. The case rate time period typically includes related donor or autologous harvest, the transplant stay, and a specified number of post-infusion days.

5. Reimbursement for unrelated donor testing and stem cell acquisition may be based on invoice or invoice plus mark-up to cover costs related to administration of the unrelated donor search.
6. The setting in which the HSCT procedure is performed, inpatient or outpatient, can influence reimbursement. Pharmaceuticals may be reimbursed at a higher level per dollar of charge in the outpatient setting. The differences in reimbursement based on setting can have a significant impact on the financial performance of the HSCT program.

2.4 INTEGRATED STRUCTURE FOR CONTRACT MANAGEMENT

The significant complexity of contracting for HSCT services can be demonstrated by the implementation of separate transplant specialty contracting personnel by hospitals and payers. Development of rate structures that support the center's strategic initiatives, monitoring of the center's performance on each contract, and providing assistance to patients in understanding their benefits as they relate to the contract require an integrated team approach.

1. A typical team for contract management would include
 - a. Managed care contracting
 - b. HSCT program medical director
 - c. HSCT program administrator
 - d. Patient billing services
 - e. Financial counseling personnel
 - f. Program's managed care clinical liaison/coordinator:
 - i. Review of patient referral insurance information
 - ii. Review of patients' benefits
 - Lifetime maximum
 - Transplant maximum
 - Prescription coverage
 - iii. Communication with patient regarding benefits
 - iv. Liaison with insurance company in communication of patients' status in the process
 - g. Medical social worker

2.5 PRIVATE PAYERS

There is significant variability among commercial insurers in all aspects of coverage for HSCT. Private payers often follow

Medicare guidelines for coverage determinations for indications for transplant. Reimbursement structures, benefit packages, donor search and acquisition, financial caps, and clinical trial coverage are examples of areas in which this variation is evident.

1. Centers of Excellence and National Transplant Networks

- a. Many of the large insurance and reinsurance companies have Center of Excellence (COE) or National Transplant Network programs. These programs vary in size depending on the types of transplants, the number of insured lives, and the geographic region covered by those insured lives.
- b. Participation in COE programs and national transplant networks allows a transplant center to have access to a greater number of patients. Patients may be directed to the transplant center because they are a participant in the COE. Participation is based on meeting selection criteria typically based on volumes and outcomes. The selection process typically includes submission of program-specific information and disease-specific outcomes information, as well as an onsite inspection of facilities and review of program standards.
- c. Selection criteria vary among payer networks. In return for a potential increase in patient volumes, transplant centers may agree to package their transplant procedures at rates which cause them to assume some financial risk for above-average costs.

2.6 GOVERNMENTAL PAYERS

1. Medicare DRG Reimbursement

- a. Medicare coverage is limited to items and services that are within the scope of a Medicare benefit category. HSCT is a procedure for which Medicare has developed a National Coverage Determination (NCD). Local Coverage Determinations (LCD) may also apply. These local determinations are developed in the absence of regulation or a national coverage policy. Familiarity with coverage information is of obvious importance and is a critical responsibility of the managed care specialists. The national coverage information is available online from the Medicare Coverage Database (MCD). The NCD for HSCT is in Section 110.81 of this database.

- b. Under the Medicare Hospital Acquired Conditions (HAC) initiative, hospitals will be penalized with decreased or no reimbursement for services to Medicare patients if the patient has what is considered a preventable event (e.g., hospital-acquired infection, central line infection, falls resulting in harm). This can be problematic for the HSCT program, given the HSCT patient's proclivity to infection due to immune system compromise. Number of readmissions and time between discharge and readmission are also critically examined.
2. Medicaid

There is wide state-to-state variation in Medicaid coverage for HSCT. There may be limitations based on indication for transplant, maximum allowable inpatient days, and inpatient vs. outpatient service provision. Familiarity with coverage information is of obvious importance and is a critical responsibility of the managed care specialists.

2.7 REGULATORY

1. FACT
 - a. The Foundation for the Accreditation of Cellular Therapies (FACT) accreditation is voluntary, but has become an almost necessary qualification for a program to be accepted and competitive. Many insurers, Centers of Excellence programs, and National Transplant Networks include FACT accreditation as a requirement for selection/inclusion.
 - b. FACT accreditation addresses clinical care, donor management, cell collection, cell processing, and cell administration.
 - c. Accreditation is awarded after successful documentation of compliance with FACT standards. Compliance is judged by evaluation of written documentation and through on-site inspections.
2. CIBMTR

The Center for International Blood and Marrow Transplant Research (CIBMTR), chosen by Health Resources and Services Administration (HRSA), is the contractor for implementation and ongoing management of the Stem Cell Therapeutic Outcomes Database (SCTOD). As one of four components of the C.W. Bill Young Cell Transplantation Program, the SCTOD provides information about allogeneic

blood and marrow transplant outcomes. Submission of patient data to the CIBMTR for the SCTOD is a requirement of all transplant centers that perform allogeneic transplants.

3. FDA

- a. The Food and Drug Administration's (FDA) mission is to protect the public health. In May 2005, the FDA created a registration system for establishments that collect, manipulate, and manufacture cellular therapy products. The registration system was created to establish procedures to prevent the introduction, transmission, and spread of communicable disease by cellular therapy products. HSCT programs are required to register and submit a list of all types of cellular therapy products collected or infused in their institution. The registration must be updated annually.
- b. The FDA requires documentation of complaints that involve distributed cellular therapy products which allegedly involve transmission of a communicable disease to the recipient of the product.
- c. Enforcement of the registration and reporting requirements is accomplished by FDA inspections.

2.8 QUALITY

Assessment of a transplant center's quality is performed internally to evaluate all systems and elements that influence the quality of the HSCT product and service, and performed by external agencies to assess conformance with pre-established specifications or standards.

1. Typical measures of quality – overall mortality and non-relapse mortality – can be difficult to compare between transplant centers due to the potentially significant variability between patient populations managed by individual centers.
 - a. Independent bodies such as the University Health Care Consortium attempt to bridge the center-to-center variation by creating assessment tools that normalize the data across centers.
 - b. Algorithms for risk assessment based on patient characteristics (co-morbidities) prior to transplant and categorization of disease-related characteristics are used to provide enhanced assurance of valid comparison of outcomes across transplant programs.

- c. Standardized determinations of severity of illness (SOI) for the transplant stay are derived from the discharge diagnostic codes. Tools have been generated which use this information to make predictions of expected percentage mortality that can be compared to the observed percentage mortality, with the observed:expected ratio used to comparatively standardize outcomes between centers.

2.9 DATA MANAGEMENT

A transplant program's data management enterprise supports compliance with regulatory standards, internal assessment of quality and quality improvement initiatives, and research development. HSCT programs are expected to contribute data regarding transplant procedures to the NMDP, CIBMTR, or similar data repositories. These data are then available for research purposes on outcomes.

2.10 SUMMARY

The ability to maintain and expand an HSCT program requires the efforts of a specialized business team to develop, implement, and manage contracts; personnel knowledgeable of the most current regulatory standards and data reporting requirements; and a clinical team dedicated to the critical ongoing communication with the referring physician. The partnership between referring physicians and the transplant program is supported by communication related to the pre-transplant workup, the transplant stay, and the requirements of ongoing care post-transplant. This partnership is critical to the promotion of long-term survivorship for the HSCT patient.

2.11 RESOURCES

2.11.1 Websites

Foundation for the Accreditation of Cellular Therapies
www.thefactwebsite.org

National Marrow Donor Program www.bethematch.com

Center for International Blood and Marrow Transplant
Research www.cibmtr.org

American Society for Blood and Marrow Transplantation
www.asbmt.org

European Group for Blood and Marrow Transplantation
www.ebmt.org

Stem Cell Therapeutic Outcomes Database <http://bloodcell.transplant.hrsa.gov>

Blood and Marrow Transplant Clinical Trials Network
www.bmtctn.net

Medicare <http://www.cms.gov/mcd>

Reference

- Stranges, E. (Thomson Reuters), Russo, C.A. (Thomson Reuters), Frideman, B. (AHRQ). *Procedures with the Most Rapidly Increasing Hospital Costs, 2004–2007*. HCUP Statistical Brief #82. December 2009. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.hcup-us.ahrq.gov/reports/statbriefs/sb82.pdf>

<http://www.springer.com/978-1-4419-7505-8>

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