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Opinion

Optimal Benefits for Hematopoietic Stem Cell Transplantation: A Consensus Opinion



Richard T. Maziarz^{1,*}, Stephanie Farnia², Patricia Martin³, Krishna V. Komanduri⁴

¹Adult Blood and Marrow Transplant Program, Knight Cancer Institute, Oregon Health and Science University, Portland, Oregon

²National Marrow Donor Program, Minneapolis, Minnesota

³Anthem Blue Cross and Blue Shield

⁴Adult Stem Cell Transplant Program, University of Miami Sylvester Cancer Center, Miami, Florida

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Variability in transplantation benefits may directly affect outcomes of individuals undergoing autologous or allogeneic hematopoietic stem cell transplantation procedures. The Financial Working Group of the National Marrow Donor Program—sponsored System Capacity Initiative addressed the issue of variable benefits and reviewed multiple transplantation benefit packages from both public and private payer organizations. On completion of the review, a consensus was obtained on defining a recipient benefit package that avoids major coverage gaps that could negatively influence patient outcomes. The recommendation was to encourage adoption of these benefits at a national level by payers, benefit brokers/consultants, and sales teams.

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INTRODUCTION

Hematopoietic stem cell transplantation (HCT) remains the standard of care and often the only curative treatment option for a wide range of diseases, including high-risk and relapsed hematologic malignancies [1]. Currently, approximately 20,000 HCT procedures are performed in the United States each year [2–5]. HCT can be performed with either autologous (ie, the patient's own) or allogeneic (from a full or partially HLA-matched family member or unrelated donor) hematopoietic stem cells (HSC). The choice of the optimal HSC source is influenced by the nature of the underlying disorder, its responsiveness to chemotherapy, and its sensitivity to the immunologic effects mediated by an allogeneic donor graft. Medical considerations that may influence the decision to proceed to transplantation and the choice of HSC donor include disease stage and risk of relapse, patient age, and the presence of medical comorbidities. In addition, nonmedical reasons, including socioeconomic factors, such as the availability of a support network and access to financial resources, including payer availability, may influence the decision to perform HCT.

A recognized but understudied issue has been the impact of payer source on transplantation outcomes. In the United States, a multipayer system that includes state and federal governmental payers, as well as commercial ('third party') sources, exists. As the safety and efficacy of transplantation have improved over time for most diseases in which autologous and allogeneic HCT are used, transplantation has dramatically increased. Given the inevitable increases in costs associated with providing care for an increased number of transplantation patients, some payers have placed limitations on transplantation benefits, which may have unintended consequences for key clinical outcomes, including overall survival and quality of life. Studies have documented that HCT outcomes can be influenced by race and financial status, and analyses have suggested that the composition of a payer benefits package can positively or negatively affect outcomes [6]. As an example, it has been recognized that patients who are in need of allogeneic HCT often have benefit policies with inadequate "donor search" benefits—meaning coverage for the costs of finding and typing potential allogeneic donors. Clinical trial coverage varies by payer and may improve somewhat under the new requirements of the Affordable Care Act (ACA) implemented in 2014, but it is often a significant financial barrier, particularly in the case of emerging disease indications for HCT [7]. Finally, coverage for obtaining outpatient post-transplantation medications can be problematic for patients; substantial monthly expenses may be encountered because of high copays and coinsurance for specialized medications, with vast differences in coverage observed between individual self-funded

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* Correspondence and reprint requests: Richard T. Maziarz, MD, Knight Cancer Institute, OR Health & Science University, 3181 SW Sam Jackson Park Road, Portland, OR 97239-3098.

E-mail address: maziarzr@ohsu.edu (R.T. Maziarz).

† On behalf of the Financial Working Group of the National Marrow Donor Program System Capacity Initiative.

private payer plans and in benefits offered by governmental payers (eg, Medicare and state Medicaid plans).

THE NATIONAL MARROW DONOR PROGRAM SYSTEM CAPACITY INITIATIVE FINANCIAL WORKING GROUP

In September 2009, the National Marrow Donor Program (NMDP) organized the System Capacity Initiative (SCI), a 3-year project to assess the current health care system's ability to accommodate the predicted growth in the number of patients who will need an HCT by 2020. The SCI initiative addressed, through the formation of individual working groups, a wide range of HCT-related issues, including workforce availability, care delivery systems, education, access, and reimbursement [8,9]. As part of this initiative, a Financial Working Group (FWG) was assembled to identify and address financial barriers to transplantation. The FWG members represented a cross-section of the transplantation community, including transplantation medical directors, representatives of leading commercial payers, including medical and program directors responsible for payment for complex medical services, transplantation center administrators, and transplantation-specific risk management and contracting organizations leaders.

The initial efforts of the FWG were focused on identifying the scope of its activities, and, ultimately, in defining areas which the multidisciplinary FWG could provide guidance to the transplantation and payer communities. Under the auspices of the US Health Resources and Services Administration, an initiative to define a modern list of diseases appropriately treated with HCT, and for which coverage should be provided, was already underway and continues at present; therefore, it was felt that the group should support and not duplicate its efforts. Endorsement was provided for the need to create a catalogue of individual state Medicaid benefits, and this effort was individually pursued by the health services research division of the NMDP [10]. Ultimately, the entire committee decided to focus on 4 major issues, with the recognition that the effort could be completed within the 36-month period and yield working products that reflected a consensus opinion of the members of the diverse group. These projects included the following: (1) the creation of consensus guidelines that would define the appropriate benefit package for the HCT recipient, (2) the development of tools to enhance the efficiency of the pre-authorization process for private payers, (3) the creation of materials and tools to educate transplantation centers on the complexity of coding in reimbursement, and (4) the generation of a plan to communicate these consensus opinions and tools for the broader HCT community, including transplantation medical directors, center administrators, leadership within groups of public and commercial payers, and the greater health care purchaser industry involved in transplantation benefits formulation and administration, including plan managers, benefit consultants, and reinsurers.

METHODS

Process of Benefits Analysis and Development of a Consensus Benefits Package

An FWG subcommittee was formed to define the key elements of a consensus benefit package. The first step was the confirmation and ascertainment of the need for a clear set of recipient benefits for patients undergoing allogeneic and autologous HCT, based on available clinical and administrative best practices. This deliverable was identified as a priority effort because of the readily discernible, wide variation in benefits packages known to the subcommittee members. The group acquired, and reviewed in detail, information regarding individual benefit packages from a wide range of commercial payers and the available benefits provided by various state

Medicaid agencies and Medicare coverage standards. There was a consensus that many governmental payers, particularly state Medicaid plans, provided limited and often inadequate HCT benefits, an observation that led to an independent NMDP policy team analysis, which confirmed this view [9]. The group also recognized that there has been extensive growth in the number of self-funded plans that, although often administered by major commercial payers, were the ultimate arbiters of benefits provided to their own employees. There was also recognition that HCT-associated benefits may not be entirely defined by the primary payer, but that reinsurer groups can also be responsible for transplantation and other complex services carved out of the primary benefits package. Specifically, there was a focused effort to examine both benefits provided by entities that provide reinsurance coverage to an employer's self-insured benefit plan (the circumstance where the reinsurer does not define benefits under the employer's plan but rather establishes which benefits are covered under the reinsurance coverage) and a second group of payer entities that provide insurance (not reinsurance) coverage for transplantation benefits that have truly been carved out of the medical benefit set. In this latter circumstance, the entity is providing fully insured (not self-insured) coverage for a defined set of transplantation services that has been carved out—ie, excluded—under the employer's self-insured benefit plan, thus protecting the employer from the financial risk associated with variability in delivery of transplantation services.

As a next step, the working group documented benefits that were universally included within multiple plans. The group then generated a process map required by the transplant recipient, recognizing the high variability of clinical course, based upon the type of transplantation that was to be undertaken. With these steps completed, the group assessed frequent incongruities between benefit plans and also identified common gaps in coverage. The potential clinical consequences of coverage gaps were then discussed and evaluated, with consideration of the costs associated with coverage and the potential unintended consequences (clinical and financial) of benefit limitations. The final steps of the process were to create a document defining a recommended set of insurance benefits derived from clear consensus of all stakeholders and of sufficiently high visibility to encourage near-universal adoption by all payers, benefit brokers/consultants, and account sales teams.

RESULTS

Recommended Benefits for HCT

Benefits described are those that the committee felt provided appropriate support to a patient and his/her care team to maximize the likelihood of achieving optimal HCT outcomes (Table 1). Coverage for HCT and all subsequent therapeutic interventions, and support for travel and lodging, as well as for outpatient care and caregiver requirements, should be provided for any patient with a medically necessary indication and adequate physiologic reserve such that acceptable long-term outcomes could be achieved. Transplantation indications are expanding rapidly and it is recognized that HCT may be either a curative option or life-extending procedure for many patients. Limiting or delaying access to transplantation may result in increased costs and poor patient outcomes, including death. Financial limits for reimbursement of HCT costs, either for the procedure or for medical costs over a patient's lifetime, should not have predetermined restrictive ceilings. Determination of the diagnostic indications for HCT procedures was not felt to be the purview of the subcommittee, but rather, deferred to national organizations or payer bodies performing evidence-based assessments of the value of HCT compared with alternate strategies that are continually evolving.

Donor Search

In the case of an allogeneic HCT, coverage should be provided for HLA typing of the patient and potential donors to identify the best possible "match" or best available cellular product. Related donors will primarily include fully HLA-matched siblings but may also be extended to other family members, while recognizing that less than fully HLA-matched donors are acceptable in selected situations. Unrelated donor HCT procedures have been increasing dramatically over the

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