



September 11, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1678-P
7500 Security Blvd.
Baltimore, MD 21244-8013

RE: CMS-1678-P Medicare Program: Hospital Outpatient Prospective Payment Policy Changes and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates

Dear Administrator Verma:

On behalf of the National Marrow Donor Program (NMDP)/Be The Match®, we thank you for the opportunity to comment on the proposed rule entitled, “Medicare Program: Hospital Outpatient Prospective Payment Policy Changes and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates” (Proposed Rule).

For the thousands of people diagnosed every year with life-threatening blood cancers like leukemia and lymphoma, a cure exists. During the past 25 years, Be The Match, operated by NMDP, has managed the largest and most diverse marrow registry in the world through a competitively bid contract with the Health Resources and Services Administration (HRSA). Each year Congress appropriates funds to operate this federal program, which is designated by Congress as the C.W. Bill Young Cell Transplantation Program (Program). As the steward of this critical federal public health program, we work to identify and eliminate barriers that face patients in need of life-saving transplants. To that end, under our contract with HRSA to operate the statutorily created Office of Patient Advocacy, we actively assist with third-party payer matters which may limit patient access to transplant.

Addressing Hematopoietic Stem Cell Transplantation (HCT) CPT Coding Issue

NMDP appreciates the attention the Centers for Medicare & Medicaid Services (CMS) has paid to improving outpatient payment of HSCT over the past several years along with releasing dedicated revenue code 0815 and cost center 77 for the reporting of donor related charges and costs. We believe the efforts expended by the agency to date will result in improved reporting by providers and more appropriate payment over time for outpatient HSCT.

With respect to the the CY 2018 OPPTS Proposed Rule, we are concerned with CMS’ proposal to change the status indicator of CPT code 38205 from “B” to “S”. While we understand that CMS’ proposal stems from the agency’s desire to promote consistency among other codes in this series, **we disagree with CMS’ proposal.**

CPT code 38205 has been assigned status indicator “B,” since 2010 and we believe that is because this code describes the harvesting of blood-derived hematopoietic progenitor cells for transplantation and represents the donor acquisition cost for an allogeneic hematopoietic cell transplant. CMS billing guidance instructs that all services provided to the

donor must be held and the charges reported through revenue code 0815 (previously 0819) on the recipient's transplant claim. We presented on this topic to the Advisory Panel on Hospital Outpatient Payment (HOP) and appreciated the Panel's recommendation that CMS maintain status indicator "B" for CPT code 38205 for CY2018. We believe this is necessary otherwise providers might see the proposed status indicator change from "B" to "S" as an indication from CMS that they can bill donors. As CMS knows, donors are not to be charged and therefore maintaining the current status indicator of "B" helps to ensure that inappropriate billing to a donor does not occur. It also helps avoid the potential for erroneous payments made by CMS if this code is billed. If CMS intends to allow separate payment for this service in the future, then we believe a much broader discussion must take place about separate billing and payment of donor acquisition services which we would be pleased to engage in as we've begun this dialogue with the agency already. Additionally, we encourage CMS to look at the entire series of bone marrow and stem cell transplant related CPT codes to ensure consistency in terms of coding, billing guidance, appropriate APC assignment, and payment.

MLN Matters

CMS issued MLN Matters article, SE1624, in November 2016 regarding an Office of the Inspector General (OIG) Report on HCT that incorrectly stated that the vast majority of HCTs should occur in the outpatient setting. This article has since been distributed to the Medicare Administrative Contractors (MACs) and has materially confused the matter of incorrect billing practices by a few specific providers with the broader issue of the most appropriate site of service for HSCT. We have reviewed coverage policies for at least four Medicare Advantage plans that are now requiring review of all allogeneic HCT cases for clinical setting appropriateness. This is time consuming, burdensome, and wasteful for both providers and the government and therefore, we request that CMS address this issue through the Federal Register and specific guidance. While the outpatient setting is frequently utilized for autologous transplantation and for certain subsets of the allogeneic patient population, the vast majority of allogeneic transplants are performed in the inpatient setting, which should come to no surprise to anyone given how sick these patients are. According to 2015 Final MedPAR data, only 38 of nearly 1,200 (approximately 3%) allogeneic transplants were performed in the outpatient setting.

While CMS revised the MLN Matters article in May 2017, we encourage CMS to further revise the guidance to state that HCT should occur in the most appropriate clinical setting as determined by the physician and his/her clinical team at the transplant center.

Aligning Payment Policies Across Transplant

Current Medicare rates do not adequately cover the costs hospitals incur when providing transplants in either the inpatient or outpatient settings. One of the most significant reasons for this problem is the fact that CMS includes the cost of the cell acquisition in the MS-DRG and C-APC. We ask that CMS align its transplant policies, consistent with its long-held position that in order to incentivize transplant acquisition costs need to be reimbursed outside of the MS-DRG payment.

The current reimbursement rate in the outpatient setting is \$27,752. While an improvement over previous years due in part to CMS work with the NMDP to address technical issues with

the payment system, this amount still does not cover the cost of acquiring cells for transplant, let alone the cost of providing all of the necessary outpatient services. The average cost for acquiring bone marrow or peripheral blood stem cells is \$48,436, while it is \$65,117 for acquiring cord blood (this includes double cord blood transplants, which are necessary for adults to receive the volume of cells needed for transplant). The negative differential of \$20,000-\$37,000 is simply something hospitals cannot absorb.

While there may only be 30 or so outpatient allogeneic transplants annually, the NMDP and researchers around the country continue to develop new treatment protocols that allow patients to remain outside of the hospital. It would be unfortunate if Medicare payment policy constrains the use of this care setting when appropriate as an option for Medicare beneficiaries, while patients with commercial insurance are able to access the very same treatment when medically appropriate in the outpatient setting due to appropriate reimbursement being available.

In an effort to solve this problem, we recommend that CMS align HCT payment policy with solid organ transplant with respect to how acquisition cost are handled. By separating the costs of acquisition from the current C-APC payment, CMS could pay for cell acquisition on a reasonable cost-basis apart from the C-APC, as it does for kidneys acquired from living kidney donors and keep the remainder of the services under the C-APC so that hospitals continue to have an incentive to manage the costs within their control. By making this change, CMS would be able to provide more appropriate reimbursement for this very important and costly service. This change would also be consistent with our current recommendations for the inpatient hospital payment system as well. We have provided regulatory language in the appendix of this comment letter for CMS to utilize in making our recommended change, which we strongly believe the agency has the statutory authority to do. As noted, payment for solid organ acquisition costs incurred by transplant centers is already made “on a reasonable basis.”¹ The current regulatory definition of “organ” is limited to solid organs.² CMS established this payment methodology through regulation exercising its general authority. There is no statutory reference as to how acquisition costs will be reimbursed for either solid organs or HCT used in transplantation.³ When a statute is silent or ambiguous, then courts will defer to the agency’s interpretation of the statute, if reasonable.⁴ Thus, CMS has the authority to expand the reasonable cost basis payment methodology to HCT.

This interpretation of the statutory authority is confirmed by the history of the implementation of the reasonable cost basis for solid organ acquisition. When the Healthcare Financing Administration (HCFA) – the precursor to CMS – established the IPPS in 1983, it originally intended to include the cost of acquiring within the IPPS. For example, the Office of Inspector General reported in 1987 that HCFA “was planning to include kidney acquisition services in Diagnosis Related Group (DRG 302), which also included inpatient services associated with kidney transplant surgery.”⁵ In the final rule, however, the Agency concluded that the “unique

¹42 C.F.R. § 412.113(d); *see also* §412.1(a).

²*Id.* at § 486.302 (regulations related to the operation of Organ Procurement Organizations).

³*See* 42 U.S.C. § 1395ww.

⁴*See, Chevron U.S.A. v. NRDC*, 467 U.S. 837, 842–843 (1984) (“[I]f the statute is silent or ambiguous with respect to the specific question, the issue for the court is whether the agency’s answer is based on a permissible construction of the statute”).

⁵Office of Inspector General, “Organ Acquisition Costs: An Overview” (September 1987).

characteristics of organ procurement activities and the desirability of maintaining an adequate supply of kidneys,” that the acquisition costs would be reimbursed outside of the IPPS.⁶

Despite recommendations from the OIG in 1987⁷, HCFA chose to maintain the policy of reimbursing solid organ acquisition costs on a reasonable costs basis because, as it stated: “the hospital cost report data on kidney acquisition costs [were] incomplete and unreliable,” which resulted in “insufficient data available to determine how to calculate a DRG incorporating those costs.”⁸ Additionally, the Agency viewed the organ acquisition programs as “still quite fragile” and found “good reason to be concerned that cost generated pressures might jeopardize efforts to retrieve organs.”⁹ The Agency’s comments suggest a concern that paying only for transplanted organs would discourage harvesting of all potentially viable organs, including those organs with only a “small chance of being successful.”

The desire to ensure access to medically necessary HCT for those Medicare beneficiaries in need should be an equally high priority for the Medicare program, as it was and continues to be the case for solid organs. First, the scientific advancements that have allowed the Medicare population to utilize this treatment are relatively new. Second, search and cell acquisition costs are included in the C-APC reimbursement rate in a way that compresses the true costs because of the methodology. With the recent medical advances that make these types of cellular transplants a viable, life-saving option for American over the age of 65, it is important that Medicare set a reimbursement rate that does not create a disincentive to provide such treatments. Thus, similar to the case of solid organs, it is important to establish a payment mechanism that does not jeopardize efforts to support access to HCT.

We appreciate the opportunity to offer comments on the CY 2018 OPPTS Proposed Rule. We welcome future discussion with the Agency on these important issues. If you have any questions, please contact me at blindber@nmdp.org or (763) 406-8566 or our counsel in Washington, Kathy Lester, at klester@lesterhealthlaw.com or (202) 534-1773.

Sincerely,



Brian L. Lindberg
Chief Policy Officer

⁶*Id.* at 1.

⁷*Id.* at 14.

⁸*Id.*

⁹*Id.*

Suggested Regulatory Language

“Special Payment Rule for Hematopoietic Stem Cell Transplants.

“(a) **In General.**—(1) For discharges occurring in fiscal year 2018 and subsequent fiscal years, CMS adjusts the prospective payment rates for inpatient operating costs determined under this section for hospitals performing hematopoietic stem cell transplants (as defined in subparagraph (C)) to remove the estimated net expenses associated with hematopoietic stem acquisition.

(2) HCT cell acquisition costs are treated apart from the prospective payment rate for inpatient operating costs and adjusts payments to the hospital in each reporting period to reflect an amount necessary to compensate the hospital for reasonable expenses of hematopoietic stem cell acquisition. Where appropriate, such payment shall recognize the difference in cost of the cell sources used in hematopoietic stem cell transplants.

“(b) **Costs of hematopoietic stem cell acquisition.**—Expenses recognized under this section include costs of acquiring cells from a live donor by the hospital including through the C.W. Bill Young Cell Transplantation Program (as defined at section 42 USC § 274k) for allogeneic transplants, including:

“(1) Tissue typing, including tissue typing furnished by independent laboratories;

“(2) Donor evaluation;

“(3) Other costs associated with excising hematopoietic stem cells, such as donor general routine and special care services;

“(4) Operating room and other inpatient ancillary services applicable to the donor;

“(5) Preservation and perfusion costs;

“(6) Transportation;

“(7) Costs associated with the services of the C.W. Bill Young Cell Transplantation Program;

“(8) Hospital costs normally classified as outpatient costs applicable to cell collection (services include donor and patient tissue typing, work-up, and related services furnished prior to admission);

“(9) Costs of services applicable to cell collection which are rendered by residents and interns not in approved teaching programs;

“(10) All pre-admission physicians services, applicable to cell collection including the costs of physicians services; and

“(11) Other costs determined to be appropriate by the Secretary.

“(c) **Definitions of Hematopoietic Stem Cell Transplant.**—For purposes of this paragraph, the term “hematopoietic stem cell transplant” means the infusion of allogeneic hematopoietic cells (such as bone marrow, peripheral blood stem cells, and cord blood units, but not embryonic stem cells) that are not more than minimally manipulated and are intended to reestablish

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hematopoietic function in patients whose bone marrow or immune system is damaged or defective, or adversely affected by a congenital disorder.”