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September 10, 2017

Administrator Seema Verma
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

Re: File CMS-1678-P

Administrator Verma:

The American Society for Blood and Marrow Transplantation (ASBMT) is a professional membership association of more than 2,200 physicians, scientists and other healthcare professionals promoting blood and marrow transplantation and cellular therapy research, education, scholarly publication and clinical standards. ASBMT is dedicated to improving the application and success of blood and marrow transplantation and ensuring access to all patients who need hematopoietic cell transplants.

Blood and marrow transplantation has several pseudonyms, including bone marrow transplantation, stem cell transplantation, cord blood transplantation, peripheral blood stem cell transplantation and hematopoietic cell transplantation. For purposes of simplification and scientific comprehensiveness, we will utilize hematopoietic cell transplantation for the remainder of this document.

Hematopoietic cell transplantation (HCT) is a medical sub-specialty comprised of physicians with Board Certifications in Internal Medicine, Medical Oncology, Pediatrics, Hematology and/or Immunology. Despite common misconceptions, HCT physicians are not surgeons and the introduction of hematopoietic cells into patients is performed via infusion, not open incision or other surgical procedures. HCT is a procedure that involves the infusion of either autologous (self) or allogeneic (donor) hematopoietic stem (progenitor) cells into a patient to reconstitute the patient's immune system as part of a larger treatment course for three primary clinical purposes: 1) treatment of malignancy, 2) replacement or modulation of an absent or poorly functioning

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hematopoietic immune system, 3) treatment of certain genetic diseases.[1] CMS recognized the unique role and qualifications of HCT physicians by designating a unique code for Hematopoietic Cell Transplant and Cell Therapy (HCTCT) physicians in November 2016.[2]

HCT Utilization in the United States

By Federal mandate, the Center for International Blood & Marrow Transplant Research (CIBMTR) records data on each of the allogeneic HCTs performed within the United States each year. In 2015, the most recent verified data year, approximately 8,000 allogeneic HCTs and 14,000 autologous HCTs were performed on patients in the United States.[3] Of these, approximately 50% were performed in individuals 60 years of age or older. There has been substantial growth in the number of transplants performed in older individuals in the last 20 years due to advancements in preparative regimens and the ability to manage common age-associated co-morbidities. While allogeneic HCT is primarily performed in the inpatient setting, 348 autologous transplants and 11 allogeneic transplants were performed on Medicare beneficiaries as outpatient procedures in CY2016, according to the CPT cost statistics file released with the CY2018 proposed rule.

ASBMT Concerns with Proposed Changes to Outpatient Reimbursement Policies

ASBMT appreciates the opportunity to comment on the CY2018 OPPS Proposed Rule. Our feedback to the Agency is captured below and includes the following items:

- CMS should not change the indicator for CPT 38205 from B to S, as proposed
- CMS should consider extending C-APC payment models to CPT codes 38241-38243
- CMS may need to issue specific billing guidance regarding CPT 38240 and the need to report donor acquisition charges on Revenue Code 0815
- CMS should find ways to pay separately for donor acquisition services in both the OPPS and IPPS settings

Status Indicator Change for Marrow Harvest

In the 2018 rule, CMS is proposing to change the status indicator from B to S for code 38205, *blood-derived hematopoietic progenitor cell harvesting for allogeneic transplantation, per*

[1] National Institutes of Health, National Cancer Institute Hematopoietic Cell Transplantation Summary
[2] CMS MLN Matters MM957
[3] D'Souza A, Zhu X. Current Uses and Outcomes of Hematopoietic Cell Transplantation (HCT): CIBMTR Summary Slides, 2016. Available at: http://www.cibmtr.org

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collection, in order to "promote consistency across codes" within this clinical area. While we understand the desire of the Agency to achieve consistency, we are concerned that this change in status would inadvertently cause providers to violate CMS's own billing guidance. CMS provides detailed instructions in its claims processing manual on how hospitals are required to hold charges associated with donor cell acquisition, even if the donor is a Medicare beneficiary, and to report these charges on the transplant recipient's final transplant encounter claim. This set of donor services placed on the final bill would include the service described by CPT code 38205. In the case of allogeneic harvest, even if the individual undergoing the procedure was a Medicare beneficiary, the cells would be utilized for a different beneficiary's benefit. 38205 should remain as status indicator "B" for this reason; these services are, by nature, being performed for the benefit of another individual and are donor services as CMS describes them in the billing manual.

The code CMS was trying to create alignment with, 38206 (blood-derived HPC harvesting for *autologous* transplantation), is different from 38205 (donor harvest for use in allogeneic transplant) in that 38206 is an autologous harvest – meaning that a patient's own cells are being collected for future reinfusion to that same patient after additional transplantation preparations. As the patient is a Medicare beneficiary and the cells will be used for their own future treatment, the cells and services are not considered to be within the description of donor services. CMS's billing guidance does not instruct providers to hold autologous charges until the time of transplantation and thus it appropriately has a separately payable status indicator, which should be maintained. This differentiation between the allogeneic and autologous codes holds true for 38230 and 38232 – bone marrow harvest for transplantation – as well. We would welcome engagement with the Agency on this issue if it remains unclear.

Payment for HCT and Associated Cellular Therapy Procedures

We greatly appreciate the efforts CMS is making to create more appropriate reimbursement for HCT in the beneficiary population. Instead of the proposed change to the status indicator for 38205, we would ask CMS to consider investigating the creation and use of C-APCs for CPT codes 38241, 38242 and 38243. Codes 38242 (allogeneic donor lymphocyte infusion) and 38243 (allogeneic hematopoietic cellular transplant boost) both have donor acquisition cost components well beyond the reimbursement level currently assigned to APC 5242, with a payment rate of $1,193. All three of these clinical procedures will routinely involve multiple separately payable procedures on the same day and will rarely lend themselves to reduction to single or pseudo-single claims for the purposes of rate-setting; evidence of this is found in the

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low proportion of claims used in rate-setting for CY2018. As CMS did for 38240 (Allogeneic HCT), it could create C-APCs for these services to more appropriately package and reimburse for the services consistently provided together during these patient encounters. For CPT code 38241, autologous transplant, while there are not donor services utilized during the procedure, there is a relatively standard set of separately payable clinical procedure codes that appear frequently with 38241. In the CPT Costs Statistics file, CMS shows that only 22 of the 348 claims submitted for autologous transplant were identified as single or pseudo-single claims for use in rate-setting. These are likely clinically incomplete claims and thus are creating an artificially low payment rate for the APC. Moving these services to the C-APC model would more appropriately reimburse providers for the services they are providing to beneficiaries.

Need for Provider Education in Billing Donor Acquisition Services

Despite the decrease in payment rate for C-APC 5244 in CY2018 (down $1,702 from CY2017), we support the use of the new methodology outlined in the creation of the C-APC last year, including the restriction of only using those claims which report donor acquisition charges more than $0 in revenue code 0815 for use in rate-setting. In previous years, 30-40 allogeneic HCTs were reported in the outpatient setting. As only 11 claims were utilized to set the CY2018 proposed payment rate, we assume that the other claims were correctly rejected for incomplete billing practices. We agree with the payment calculation process for C-APC 5244 used by CMS, but the reduced number of claims used for rate-setting points to a potential provider education issue. We will continue educational efforts regarding reporting of charges and encourage CMS to do the same through specific transmittals and/or billing guidance revisions that reflect the need for a non-$0 charge in revenue code 0815 for allogeneic HCT.

Separate Payment for Donor Acquisition Costs

Finally, we urge CMS to continue working with stakeholders such as the National Marrow Donor Program to find ways to create separate donor acquisition payment structures for donor search and cell acquisition cost for allogeneic transplant procedures in a site-neutral manner. Transplant programs often spend $35,000-$60,000 on donor cells for allogeneic transplant before providing any billable services to the Medicare beneficiary being treated. Even with the proposed CY2018 C-APC payment rate of $26,049, hospitals incur significant losses each time they provide HCT to a beneficiary.

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Changes to 340B

The proposed changes to 340B payment program would pose serious challenges for the hospitals currently providing HCT and other cellular therapies. Most transplant/cell therapy programs are housed within academic medical centers and other tertiary care centers that receive referrals for specialized care from surrounding hospitals. Accordingly, the patient populations of these facilities reflect a disproportionately high proportion of Medicare, Medicaid and uninsured individuals. 340B savings allow these providers to offset losses incurred through other aspects of treating these patients.

Logistically, there are challenges for the technical proposed changes as well. 340B hospitals use virtual inventories to manage their drug inventory in compliance with 340B Program rules and the resulting virtual inventory management systems will make it extremely challenging for 340B hospitals to comply with CMS's proposed requirement to report a modifier on any claims for non-340B drugs. CMS's proposal requires hospitals to identify the 340B or non-340B nature of the drugs they dispense at the time the claim is submitted; in reality, covered entities often do not know whether the drugs dispensed to any given patient were "340B drugs" until long after the claim was submitted due to the retrospective nature of these virtual inventory management systems. As a result, CMS would entirely reverse the pharmacy management model used by most covered entities; doing so would create significant disruption and administrative burden that would require an extensive investment of time and resources.

Contact Information and Resources for CMS

ASBMT greatly appreciates the opportunity to review the Agency's proposed changes regarding the CY2018 OPPS rule. ASBMT peer-elected leaders, member clinicians and policy staff are available as a resource for CMS staff when issues associated with HCT and other cellular therapies are raised internally in the future. Please do not hesitate to reach out whenever we may be of assistance.

Krishna Komanduri, MD
ASBMT President, 2017-2018

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