

ASBMT™

American Society for Blood
and Marrow Transplantation

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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.

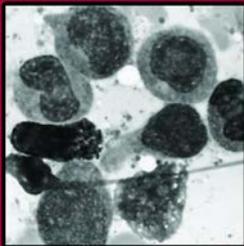
Re: File CMS-1676-P

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.

ASBMT Commentary on CY2018 Proposed Changes to Physician Fee Schedule

Bone Marrow Aspiration (CPT Codes 38220, 38221, 382X3, 2093X)

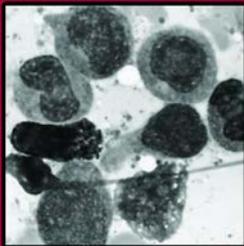
This family of codes was reviewed resultant of CPT code 38221 being identified as part of a high expenditure screen for services with Medicare allowed charges of \$10 million or more that had not been recently reviewed. Before being surveyed and reviewed by the RUC, the descriptors for CPT codes 38220 and 38221 were revised to reflect changes in practice patterns and two new CPT codes, 382X3 and 2093X, were added to the family. ASBMT supports the revisions made to this code family and the elimination of G0364, as these services are now covered by the new code 382X3. Significant clarity in the descriptions of the services provided was gained during this process and we are appreciative of the updates.

ASBMT takes issue with the RUC's recommendation to change the global period for these services from XXX to 000. Maintaining these codes as XXX global status is consistent with both medical practice and the survey methodology used to determine the RUC-recommended values. As we understand it, XXX codes are generally utilized for E/M, imaging & diagnostic

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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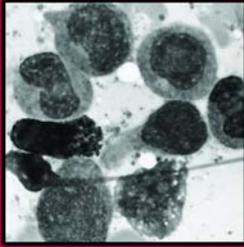
services, therapeutic services, radiation oncology and pathology. These services are part of a diagnostic service and there is no compelling reason to change them to a 0-day global.

These codes are billed less than 25 percent of the time with an E/M service. Since an E/M service being performed on the same day is not typical, this is not a compelling reason to change the global period. In the instances when an E/M service is billed on the same day, the patient has been found to have a condition like acute leukemia or aplastic anemia where there is time-sensitive decision-making which needs to take place. By changing the global designation, we are concerned that this will increase the risk of an audit.

ASBMT does not support the agency's proposal to reduce the "Lab Tech activities" practice expense allocation from 12 to 9 minutes. The technician must be present for the entire procedure. Immediately after the physician inserts the aspiration and biopsy needle, the med tech takes the aspiration and biopsy material to make slides. The physician performing the aspiration and biopsy needs to know, while still in the procedure room, that the slides show quality material was collected. If the material in the specimen is of the appropriate quality, the technician informs the physician so the bone marrow aspiration needle can be reinserted to collect a new sample. Because the most common indication for this procedure is unspecified anemia, multiple aspirations are needed to obtain marrow aspirate for studies on bone marrow material in addition to making slides. The technician at the bedside is responsible for transferring aspirate to appropriate lab tubes for this additional diagnostic testing for testing such as flow cytometry, cytogenetics and molecular diagnostics. These diagnostic samples are critical to make the correct diagnosis. 12 minutes of time is required for completion of these clinical needs and duties.

Apheresis (CPT Codes 36511-36516, 36522)

In the proposed rule, CMS requested information on whether patients need new venous access on each day of apheresis. ASBMT feels the clinical vignettes approved by CPT are appropriate in not including new venous access as many patients already have some access given the underlying condition for which apheresis is needed. Of note, however, on the initial day of apheresis a second venous access must be established, even if one is currently in place, as apheresis requires one access point for removal of blood and another for return. If more than one day of apheresis is required, venous access is not removed but maintained unless it appears to increase risk of infection. Apheresis often requires a second central venous catheter be placed, as not all central venous catheters can support apheresis. Apheresis removes and returns blood



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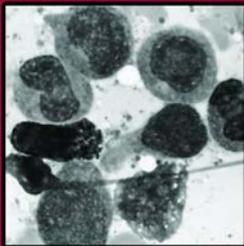
under pressure, thus requiring venous access points to have catheter walls that can tolerate this pressure without collapsing.

Chemotherapy Administration (CPT 96401, 96402, 96409, 96411) and Infusion Services

ASBMT supports the RVU values proposed in the rule. ASBMT would like to use this opportunity to note that there are no acuity adjustments for chemotherapy or infusion services. HCT patients often come into an infusion setting for a scheduled service and end up receiving additional infusions, including electrolyte replacement, dehydration fluid support, IV antibiotics and blood transfusions, due to the results of their pre-infusion laboratory analysis. AlloHCT patients are immunocompromised and (post-transplant) have hematologic compositions that cross ABO and Rh blood group barriers, so transfusions are much more complicated for cross matching. These transfusions need irradiation and require different selection parameters, as well. Due to these issues, HCT patients can rarely have their needs met in private practice associate infusion centers, yet there is no coding adjustment to reflect this added intensity and use of physician services. CMS could enact site-of-service neutrality for payment of these codes, as well as add acuity adjustment modifiers to reflect more intensive care given some patients. Finally, RVU supervision credit is only given for practice based infusion centers; not when in a facility, where many of these complicated infusions take place. RVU supervision of these chemotherapy and infusion services should be usable by both practice providers and facility providers.

Telehealth Services

ASBMT appreciates CMS's on-going interest in establishing more opportunities for compensated telehealth services. HCT providers are located at large tertiary care facilities, where patients travel to the facility for the service and then return to their local care teams. HCT patients often have long-term complications such as chronic graft versus host disease (cGVHD) and unusual infections related to their chronically immunocompromised status. Local communities rarely have a provider with HCT expertise even among the community hematologists and medical oncologists. ASBMT members frequently provide telehealth services to patients and community providers for years after the patient has been at their own centers and this care is uncompensated. CMS's support of using these codes to bill for a broader range of services is a very positive step and will assist with providers being able to devote more time to supporting their specialty patients from a distance, as well as being better partners to their distant colleagues providing direct patient care. ASBMT encourages further expansion of



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reimbursement for these services and would welcome an opportunity to share the experiences of our members with the Agency.

Biosimilars

We note CMS's request for comments regarding future potential changes to the current biosimilar payment policy. ASBMT members utilize a limited number of biosimilars currently, but understand the opposing views of the various stakeholders. Manufacturers have expressed concern that a single APC payment, based on weighted average, for multiple biosimilars tied to the same reference product will create incentive for providers to choose the lowest cost option. ASBMT members are interested in preserving their ability to utilize different products if and when varying clinical outcomes or indications are tied to them; if biosimilar products have different clinical outcomes in patient subpopulations, preserving the ability to utilize a full range of options will be important. As the biosimilar space is new, CMS may wish to establish a process by which usage of individual products and their accompanying costs are tracked and publicly reported. If the usage patterns of biosimilar products within the same APC are significantly different, CMS should consider creating unique payment codes that allow reimbursement levels to become appropriate to a specific product.

Contact Information and Resources for CMS

The ASBMT greatly appreciates the opportunity to review the Agency's proposal regarding the 2018 Physician Fee Schedule proposed 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

Krishna Komanduri, MD
ASBMT President, 2017-2018

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