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CMS Releases FY2020 Proposed Payment Rule for Inpatient Payment Prospective System (IPPS) and Long-Term Care Hospitals (LTCH)

On May 3, the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* the [proposed rule](#) updating the 2020 Medicare payment policies and rates under the Medicare hospital inpatient payment prospective system (IPPS) and the long-term care hospitals (LTCH) prospective payment system. CMS released a [fact sheet](#) and a [press release](#) on the proposed rule. Comments are due on June 24.

In general, CMS proposes to increase payment rates for acute care hospitals by approximately 3.2 percent if the hospitals successfully participate in the hospital inpatient quality reporting program and are meaningful electronic health record users. This summary discusses several proposed policies related to blood and blood products, transfusion medicine and cellular therapies.

Blood Products and Transfusion Procedure Codes

CMS proposes to delete 128 transfusion procedure codes because they identify transfusion using arterial access (see [Table 6P.1a](#) that accompanied the proposed rule). CMS reasons that transfusion procedures always use venous access rather than arterial access, and therefore these codes are clinically invalid. In addition, CMS proposes a cost-to-charge ratio for blood and blood products equal to 0.282.

Allogeneic Bone Marrow Transplant

CMS considered, but decided against proposing to split the code for allogeneic bone marrow transplants, MS-DRG 014, into two new MS-DRGs based on donor source - one MS-DRG for allogeneic related matched donor source and a different MS-DRG for allogeneic unrelated matched donor source. The requestor of this policy change highlighted that allogeneic related and allogeneic unrelated HCT cases are clinically different and have significantly different donor search and cell acquisition costs. However, CMS conducted its own analysis and concluded that the average length of stay and average costs for each subset of cases reporting a procedure code for an allogeneic HCT procedure (related, unrelated or unspecified donor source) were comparable to the average length of stay and average costs of all cases in MS-DRG 014.

In addition, the Agency noted that eight procedure codes for autologous HCT procedures are currently improperly included in MS-DRG 014, since the code is defined by cases reporting allogeneic HCT procedures. CMS proposes to delete four of these procedure codes, which the Agency determined to be clinically invalid since they describe autologous cord blood stem cell transfusion via arterial access - a transfusion procedure always uses venous access. CMS proposes to reassign the remaining four ICD-10-PCS codes for HCT procedures for autologous HCT procedures from MS-DRG 014 to MS-DRGs 016 and 017 (Autologous Bone Marrow



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Transplant with CC/MCC or T-cell Immunotherapy and Autologous Bone Marrow Transplant without CC/MCC, respectively).

CAR-T Cell Therapies

CMS considered, but decided not to propose a new MS-DRG for procedures involving CAR T-cell therapies. CMS believes that it is premature to create a new MS-DRG for cases involving CAR T-cell therapies. The Agency anticipates collecting clinical and cost data over the next few years, which may be used to evaluate the potential creation of a new MS-DRG for cases involving CAR T-cell therapies.

CMS proposes to continue providing new technology add-on payments for FY 2020 discharges reporting ICD-10-PCS codes XW033C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3) and XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3). As explained under the section below entitled, “New Technology Add-On Payments,” CMS proposes to increase the new technology add-on payment from 50 percent to 65 percent, which would increase payment for KYMRIA[®] and YESCARTA[®] from \$186,000 to \$242,450.

In addition, CMS is soliciting comments on several payment policies related to CAR T-cell therapies:

- Payment alternatives for CAR-T cell therapies, including payment policies under any potential new MS-DRG, and how these policies would affect access to care and incentives to encourage lower drug prices.
- Eliminating the use of the CCR in calculating the new technology add-on payment for KYMRIA[®] and YESCARTA[®] by making a uniform add-on payment that equals the proposed maximum add-on payment (65 percent of the cost of the technology, which in this case would be \$242,450); and/or using a higher percentage than the proposed 65 percent to calculate the maximum new technology add-on payment amount.
- Utilizing a specific CCR for ICD-10-PCS procedure codes used to report the performance of procedures involving the use of CAR T-cell therapies (for example, a CCR of 1.0).

New Technology Add-On Payments

Current payment policy limits inpatient hospital new technology add-on payments to the full MS-DRG payment plus the lesser of (1) 50 percent of the estimated costs of the new technology or medical service or (2) 50 percent of the amount by which the costs of the case exceed the standard DRG payment. The Agency recognizes that this 50 percent cap may not provide the requisite incentive for the use of new technology. Therefore, CMS proposes to increase the amount of the maximum new technology add on payment to the lesser of: (1) 65



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percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment.

In addition, CMS is proposing an alternative inpatient new technology add-on payment pathway for “transformative medical devices,” which include medical devices that are part of FDA’s Breakthrough Devices Program and have received FDA marketing authorization (i.e., PMA, 510(k) clearance or the granting of a De Novo classification request). CMS proposes to facilitate Medicare beneficiaries’ access to these devices by considering such devices “new and not substantially similar to an existing technology for the purposes of new technology add-on payment under the IPPS.” In addition, CMS proposes that the device would not need to meet the requirement that “it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.”

CMS is also requesting information on the criteria used to evaluate whether a device qualifies for a new technology add-on payment under the IPPS and a transitional device pass-through payment under the OPSS. Specifically, CMS is considering potential revisions to the substantial clinical improvement criterion that must be satisfied under the IPPS new technology add-on payment policy and the OPSS transitional pass-through payment policy for devices.

CMS discusses several add-on payment requests in the proposed rule. Some examples relevant to the transfusion medicine and cellular therapy community include:

- JAKAFI™ (ruxolitinib), an oral kinase inhibitor that inhibits Janus-associated kinases 1 and 2 (JAK1/JAK2). According to the applicant, JAK inhibition represents a novel therapeutic approach for the treatment of acute graft-versus-host disease (GVHD) in patients who have had an inadequate response to corticosteroids.
- Defitelio® (defibrotide), a treatment for patients who have been diagnosed with hepatic veno-occlusive disease (VOD) with evidence of multi-organ dysfunction. VOD, also known as sinusoidal obstruction syndrome (SOS), is a potentially life-threatening complication of hematopoietic stem cell transplantation (HSCT).

Post-Acute Care Settings: Transfusions Data Element

CMS recognizes four post-acute care (PAC) settings, including home health agencies (HHAs), inpatient rehabilitation facilities (IRFs), skilled nursing facilities (SNFs) and long-term care hospitals (LTCHs). Medicare coverage and payment policies are different for each setting of care.

As a result of a federal law implemented in 2014, CMS requires PAC providers to report standardized patient assessment data, data on quality measures and data on resource use and other measures. In the proposed payment rule for LTCHs for 2020, as well as the 2020 skilled nursing facility (SNF) payment rule and the 2020 inpatient rehabilitation facility (IRF) payment rule, CMS proposes to include a transfusion data element as part of the standardized patient



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assessment data elements (SPADEs). CMS recognizes that “blood transfusions are based on specific protocols, with multiple safety checks and monitoring required during and after the infusion in case of adverse events. Coordination with the provider’s blood bank is necessary, as well as documentation by clinical staff to ensure compliance with regulatory requirements. In addition, the need for transfusions signifies underlying patient complexity that is likely to require care coordination and patient monitoring, and impacts planning for transitions of care, as transfusions are not performed by all PAC providers.”

CMS issued separate [“Proposed Specifications for LTCH QRP Quality Measures and SPADE,”](#) [“Proposed Specifications for SNF QRP Quality Measures and SPADE,”](#) and [“Proposed Specifications for IRF QRP Quality Measures and SPADE”](#) and highlights that transfusions may occur in each care settings. CMS notes that unpublished data illustrate that transfusions are the second most-common LTCH procedure and occurred in 18.4 percent of LTCH admissions from 2007 through 2012. One study from 2011 found that 3.5 percent of SNF residents received blood transfusions during their stay. CMS notes that while data regarding blood transfusions are not currently collected for the IRF setting of care, key populations of IRF patients may benefit from blood transfusions during their stay. CMS believes that including a transfusion data element in the standardized assessment will provide important information for care planning, clinical decision making, patient safety, care transitions and resource use in the different care settings.