

Centers for Medicare & Medicaid Services FY 2022 Hospital Inpatient Prospective Payment System (IPPS) Final Rule Summary

On August 2, the Centers for Medicare & Medicaid Services (CMS) released updates to the Inpatient Prospective Payment System (IPPS) final rule for fiscal year (FY) 2022. The final rule: (1) updates payment policies and payment rates for acute care hospitals; (2) finalizes the new technology add-on payment application for pathogen-reduced cryoprecipitated fibrinogen complex (PRCFC); (3) finalizes pre-MDC Medicare Severity Diagnosis Related Group (MS-DRG) 018 for chimeric antigen receptor (CAR) T-cell services; and (4) finalizes the cost categories for blood and blood products.

Payment Rates and Add-on Payments

CMS finalized its proposal to use FY 2019 data for FY 2022 IPPS rate setting as a result of the COVID–19 public health emergency (PHE) and concerns around inpatient hospital utilization driven by the PHE. Additionally, CMS is extending the New COVID-19 Treatments Add-on Payment (NCTAP) for eligible COVID-19 products, which includes convalescent plasma, through the end of the fiscal year. CMS is also extending the New Technology Add-on Payments (NTAP) for 13 technologies for which NTAP payment would have otherwise been discontinued beginning in FY 2022.

New Technology Add-on Payments (NTAP) for Pathogen-Reduced Cryoprecipitated Fibrinogen Complex (PRCFC)

For FY 2022, Cerus Corporation applied for an NTAP for the PRCFC also known as INTERCEPT Fibrinogen Complex. The INTERCEPT Fibrinogen Complex received the Food and Drug Administration's (FDA) Breakthrough Device designation in November 2020 for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency. CMS finalized its proposal to approve the NTAP with a maximum payment of \$2,535 per case for FY 2022. Inpatient cases utilizing the blood product will be identified by the new ICD-10- PCS codes 30233D1 (Transfusion of non-autologous pathogen-reduced cryoprecipitated fibrinogen complex into peripheral vein, percutaneous approach) and 30243D1 (Transfusion of non-autologous pathogen-reduced cryoprecipitated fibrinogen complex into central vein, percutaneous approach) in combination with the ICD-10-CM codes D65 (disseminated intravascular coagulation) or D68.2 (hereditary deficiency of other clotting factors). The ICD-10-PCS codes go into effect on Oct. 1, 2021.

<u>Pre-MDC Medicare Severity Diagnosis Related Group (MS-DRG) 018 Chimeric Antigen</u> <u>Receptor (CAR) T-Cell Immunotherapy</u>

In FY 2021, CMS created Pre-MDC MS-DRG 018 for CAR T-cell therapy and reassigned cases from MS-DRG 016 (Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy) to MS-DRG 018. CMS also clarified at that time that if more cell therapies



were to be available in the future, the established process that determines MS-DRG assignment would be used. As a result of additional FDA-approved cell therapies introduced this year, CMS proposed to assign ICD-10-PCS codes for CAR T-cell, non-CAR T-cell therapies and other immunotherapies and rename pre-MDC MS-DRG 018 "Chimeric Antigen Receptor (CAR) T-cell Immunotherapy" to "Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies" to better reflect the cases reporting the administration of these therapies that would also be assigned to this MS-DRG for FY 2022.

AABB <u>requested</u> that CMS clarify the term "immunotherapies" in its proposal. Unfortunately, CMS finalized its proposal to assign the ICD-10-PCS procedure codes and revise the title for MS-DRG 018 to "Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies." However, CMS did state that the agency will continue to engage with stakeholders on other options, such as the creation of new MS-DRGs, for cell and gene therapies. CMS also finalized new procedure codes that describe the administration of CAR T-cell and non-CAR T-cell therapies and other immunotherapies and classified them as non-O.R. procedures. Finally, the agency will continue to use FY 2019 claims data to set the FY 2022 rates for MS-DRG 018.

Cost Categories - Blood and Blood Products

CMS calculates blood and blood products costs as total costs reported for the Whole Blood & Packed Red Blood Cells cost center plus the Blood Storing, Processing, & Transfusing cost center minus wages and salaries and estimated employee benefits attributable to these two cost centers for IPPS market basket calculations. CMS proposed to update the methodology used and derive costs using the 2018-based IPPS market basket from the CMS Medicare cost reports for blood and blood products rather than using the 2014-based IPPS market basket methodology. AABB supported this proposal and asked CMS to release additional information to hospitals on appropriate reporting of blood products and services in the CMS Medicare cost report. CMS thanked AABB for the support and restated the following:

...the blood and blood products cost weight is based on data reported in the Whole Blood & Packed Red Blood Cells cost center (line 62) and Blood Storing, Processing & Transfusion cost center (line 63) of the hospital Medicare cost reports. The instructions state these costs should include the direct expenses incurred: in obtaining blood directly from donors, in obtaining whole blood and packed red blood cells from suppliers and for processing, storing, and transfusing whole blood, packed red blood cells, and blood derivatives. We encourage hospitals to report these expenses consistent with the Medicare cost report instructions. We also welcome any specific suggestions that stakeholders may have on these instructions.

CMS finalized the methodology for the 2018-based IPPS market basket as proposed with the cost weight for blood and blood products set at 0.6 percent.